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Judicial Training Project

Fundamental Rights In Courts and Regulation

CASEBOOK

JUDICIAL PROTECTION OF HEALTH AS A FUNDAMENTAL RIGHT

SSM

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Judicial Protection of Health as a Fundamental Right

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Introduction: A Brief Guide to the Casebook

The FRICoRe Casebook on *Judicial Protection of Health as a Fundamental Right* aims to provide guidance to judges in their complex task of adjudicating cases in which the right to health is at stake, as enshrined not only in most MSs' constitutions but also in Article 35 of the Charter of Fundamental Rights of the European Union (hereinafter CFR). The right to health covers a broad spectrum that includes but does not coincide with the right to health care. Hence right holders are not only patients but also consumers, migrants, and prisoners, to name a few. Its definition results from common constitutional traditions and from EU primary and secondary legislation and refers to both individual and collective interests. The collective dimension of health protection emerges in the field of prevention, but it may also have relevant implications in relation to care and treatment.

Health is a dynamic concept that evolves according to scientific and cultural developments. Governing collective health-related risks entails decision making in situations of uncertainty by both policy makers and Courts. Courts must decide cases on the basis of available scientific knowledge, medical and technical knowledge in particular. But knowledge and technology evolve rapidly and Courts must define principles and rules that can adapt to this evolution and innovation. These changes are reflected in the legal domain both at the EU and national level.

Within the framework of the FRICoRe Project, this Casebook mostly reflects the European dimension of the right to health with a main focus on the judicial dialogue between national Courts and the Court of Justice of the European Union, as well as, in specific instances, the European Court of Human Rights. Such dialogue is likely to increase with the development of litigation concerning matters related to Covid-19.

Covid-19 posed new challenges that are modifying the modes of interaction between EU institutions and MSs. Developed within the framework of Art. 168 TFEU, the EU vaccine policy and the EU Digital COVID Certificate[1] provide good examples of a much broader set of issues generated by the pandemic that are shaping a new institutional equilibrium (see Commission Communication, *Building a European Health Union*, 11 November 2020, COM (2020)724 final). National judiciaries have been guardians of the rights of citizens and have reviewed government choices in the context of the pandemic emergency. The scope of judicial review in times of a pandemic acquired further relevance, given the delegation of powers to executives by legislators. It is too soon to say whether the principles emerging from this case law are likely to remain or whether they will be associated with times of emergency. Clearly the challenges at both the national and EU levels are unprecedented and call for a conceptual legal framework different from that used for previous health crises that are also examined in this Casebook (in Chapter 3 and Chapter 7).

Based on the awareness of States' competence in the organisation of healthcare systems (see below in this Introduction), prior attention has been paid to areas in which the European Union has carried out actions to support, coordinate, or supplement the actions of Member States for the protection and improvement of human health under Article 6, TFEU, or has exercised its legislative competence in fields such as the internal market, consumer protection, cross-border healthcare, and the like, with a view to ensuring, under Article 168 TFEU, a high level of human health protection in the definition and implementation of all Union policies and activities. This choice has allowed us to consider the impact of

[1] Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification, and acceptance of interoperable COVID-19 vaccination, test, and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic.

the general principles of EU law as well as the Charter of Fundamental Rights on the right to health in national case law.

Within the Charter of Fundamental Rights special consideration is given to Art. 8 CFR (on the right to private and family life), to Art. 35 CFR (on the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices and, more generally, the high level of human health protection as an objective for Union policies), to Art. 47 CFR (on the right to an effective remedy and a fair trial), to Art. 52 CFR (on the principle of proportionality as applied to limitations introduced by law with respect to fundamental rights and freedoms). Although the Casebook shows that the explicit application of these provisions by national and EU Courts is limited (see, however, Art. 35 and 52 CFR, *Léger,* C-528/13; Art. 47 CJEU, *Abdida*, C-562/13), the substantive references to the right to health as a fundamental right and to its effective protection do represent a relevant basis for judicial dialogue in this field (*Sanofi,* C-621/15, 21 June 2017; *Boston Scientific Medizintechnik*, C 503/13 and C 504/13, 5 March 2015; *Veselības ministrija*, C-243/19, 29 October 2020).

The right to health poses relevant challenges to judges. With regard to legislation aimed at protecting health as a prior interest of individuals and of society at large (e.g. legislation on health safety standards imposed in workplaces or in food production), interpretive challenges may arise concerning the use of general principles or constitutional norms as gap fillers. With regard to other legislation that is not primarily aimed at protecting health (e.g. competition law or data protection), health may emerge as a conflicting interest that needs to be balanced together with or against other rights, including fundamental rights, and the Charter may play a role in this regard as well.

Indeed, more and more, both at the EU and national levels, health has become a cornerstone of existing litigation, imposing a new direction on judges' decisions due to the prior ranking assigned to life as an essential value to be preserved. A producer's liability is subject to stricter standards when health is involved instead of or in addition to economic interests; international protection of asylum seekers finds new grounds based on health protection; the principle of non-discrimination may be boosted when discrimination impairs a person's health, and the intersection between health and disability presents important systemic questions. At the same time, as health is not an absolute right (especially when life is not at risk), it may be balanced against other rights: measures passed to protect public health, as in the current pandemic, may not always defeat the freedom of movement, the right to run a business, to enjoy one's property, or data protection, to name a few. Here the task of law makers, firstly, and judges, secondly, is to strike a balance by taking all circumstances into account. In this regard, under Art. 52 CFR, the principle of proportionality is often the key.

Moving on from this perspective, this Casebook is by definition cross-sectoral. It does not focus specifically on health law as sector-specific legislation but as a functional area that crosses over into many other fields. Hence, balancing various fundamental rights is the main focus of the Casebook. To explore the case-law, some *intersections* have been selected here by combining health with food law, consumer protection, non-discrimination, migration, cross-border healthcare, and crisis management during a pandemic. The notion of the right to health emerging from the various balances with other constitutional rights is many-fold but it maintains an essential uniform dimension.

Within this framework, two main questions have been addressed in the Casebook:

i) Whether the need to ensure the effective protection of health-related rights based on EU law has an impact on the definition of duties imposed on States, individuals, and organisations and on the choice and the functioning of remedies available for the right holder; here the main reference is to health-related rights that either incorporate the right to health (e.g. right to healthcare access in cross-border situations), or are instrumental for health protection (e.g.

right to consumer protection with regard to product safety); Chapters 1, 2, 3, 5 and 6 will be particularly illustrative on this issue.

ii) Whether the need to balance the right to health with other rights and freedoms calls for a peculiar application of the principle of proportionality, since the interests at stake are potentially linked with the right to life and, in many instances, human dignity; Chapters 2, 3, 4 and 7 will mainly explore this question.

From the first perspective, the role of Article 47 CFR and of the principle of **effective judicial protection** has been examined. Analysis shows that the impact may consist in, depending on circumstances, reinforcing:

- the role of procedural safeguards (e.g., with regard to cross border healthcare, see Watts, C-372/04),
- the role of preventive and injunctive measures in light of the precautionary principle (e.g., with respect to food safety: *Pfizer*, T-13/99; *Monsanto*, C-236/01),
- the scope of liability rules (e.g., in the field of product liability: *Sanofi* (C-621/15),
- the extent to which non-economic losses may be claimed (e.g., in the field of State liability for infection with the HIV virus through blood transfusion, ECtHR, *Oyal v. Turkey*, Application no. 4864/05, 23 March 2010).

When protection has been claimed against States or public authorities, the caselaw of the ECtHR and the doctrine of positive obligations have played a role (*e.g.*, ECtHR, *Cyprus v. Turkey*, Application no. 25781/94, 10 May 2001; ECtHR, Nitecki v. Poland, App. No(s) 65653/01, 21 March 2002). The dialogue between the two European Courts has been relevant on this and in other regards (e.g., in a migration case, *Abdida*, C-562/13, the CJEU relied on ECtHR case law; in a consumer case, *Philip Morris* (C-547/14) the CJEU referred to the ECHR; likewise, in a data protection case: *I v. Finland*, app. no. 20511/03, of 17 July 2008).

The second perspective mentioned above concerns the application of the **principle of proportionality** to limitations imposed on fundamental rights and freedoms by measures aimed at protecting health. The balance between health and the right to run a business (Chapter 2) and between health and data protection (Chapter 4) provide clear illustrations of the function of proportionality. Looking at more recent fields of judicial intervention, the increasing litigation raised by challenges brought against government measures countering the current pandemic represent an unfortunate treasure trove in this regard, especially at the national level since, for many reasons, the role of European Courts has thus far been limited (see, part., chapter 7).

Many interpretive questions arise in judges' daily work in this area. Under Art. 52 CFR, subject to the principle of proportionality, limitations to fundamental rights and freedoms may only be upheld if they *necessarily* and *genuinely meet objectives of the general interest* recognised by the Union or the need to protect the rights and freedoms of others. A variety of issues stand before national Courts. How should the 'necessity' and 'genuine' adequacy of meeting objectives of the general interest be interpreted when there is a need to protect public health? Does the notion of health as a collective rather than an individual right make a difference in this regard? When assessing proportionality, how should judges take the costs of restrictive measures impinging on people freedoms into account? Should they distinguish between economic and non-economic burdens posed by such restrictions or between recoverable and not recoverable losses?

Science may also play a major role in the assessment of the adequacy of restrictions. Health related issues often require managing risks in conditions of uncertainty. Governing uncertainty calls for a closer interaction between scientists, policy makers, and Courts. What if scientific developments don't allow the establishment of a certain correlation between limitations and the protection of health, since a positive

impact is possible but not certain? Here the principle of proportionality is often combined with the **precautionary principle** according to which "where there is uncertainty as to the existence or extent of *risks to human health*, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent. Where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because the results of studies conducted are inconclusive, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures" (CJEU, C-616/17, *Blaise*, 1 October 2019, para 43). Is this a general principle of EU law likely to complement the principle of proportionality? To what extent can it lead judges to justify restrictions on fundamental freedoms despite the uncertain impact of measures on poorly known risks? The debate on the use of lockdowns and curfews in relation to COVID-19 was a clear example of the interpretative challenges posed by scientific uncertainty on policy makers and Courts.

Focusing on a selection of cases decided by European and national Courts, this Casebook offers an opportunity for testing the application of the Charter and of general principles of EU law in the many fields of application of the Charter in which health is at stake, guiding both judicial trainers and trainees along the path of a mutual learning process that will be definitively enriched in the near future in the framework of upcoming legislation and caselaw.

I. The Structure of the Casebook: Some Keys for Reading

The Casebook is divided into 7 chapters. ***Chapter 1*** **concerns the effective protection of health and cross-border healthcare.** The legal implications of cross-border healthcare provide some very relevant insights on the main legal issues concerning effective protection of the right to healthcare under an EU law perspective. Despite the lack of EU competence concerning the organisation of healthcare, which is a matter of national law, European Law has also begun to intersect the right to access to medical treatment and the corresponding national organisations. Indeed, the chapter focuses on the possibility of receiving healthcare in another Member State, at the expense of the competent health authority of the state of affiliation. Since the landmark *Watts* decision by the Court of Justice of the European Union in 2006, in fact, this principle has been seen as a real revolution in the rights of European patients. In 2011, the adoption of a Directive on patients' rights in cross-border healthcare finally completed this process, largely building on the outcomes of judicial dialogue in this field. In both legislation and caselaw, the principle of effective protection of individual rights plays a major role; as it does for the corresponding procedural schemes that must be followed by national authorities to make cross-border healthcare effective.

Chapter 2 addresses several issues of consumer protection that often arise in cases concerning the right to health, understood in both its individual and collective dimensions. In such cases, the CJEU has often placed an emphasis on the general principles of EU law, for example the principle of effective protection, proportionality, equivalence, and the precautionary principle. Chapter 2 examines several key cases (e.g. *S.*, C-219/15; *Sanofi*, C-621/15) from the CJEU dealing with health and consumer protection from two angles: first, looking at the complementarity between health and consumer protection in light of the principle of effective protection (Section 2.1); and second, considering the conflicts that can arise between the right to health and other fundamental rights (such as the right to conduct a business under Art. 16 CFR) in consumer law cases (Section 2.2).

The main purpose of ***Chapter 3*** is to assess the impact that the notion of effective protection of health had and has on the interpretation and application of European rules regarding food safety. In the first place, the analysis will focus on the role of the precautionary principle in ensuring effective protection of

health in the context of food policies and food legislation, in connection with the principle of proportionality as well. Particular attention is devoted to the role of risk assessment. Secondly, the chapter assesses the relationships (and possible conflicts) between effective protection of health and the freedom of movement of goods, with special attention to issues concerning restrictions to imports of foodstuffs within the internal market. Thirdly, the relation between health protection and freedom of expression is examined, inquiring as to how the proportionality and precautionary principles should be applied within the assessment of the lawfulness of measures concerning nutrition and health claims made on foods aimed at protecting consumers' health, restricting freedom of expression, and the freedom to conduct a business. The chapter, read in connection with Chapter 7, provides interesting insights into how Courts solve health issues during times of crisis.

Chapter 4 addresses some issues related to the regime of health data, in light of the need to ensure health and data protection. First, it analyses, in light of the ECtHR case law, the role of the principle of proportionality and of Art. 8 ECHR in assessing the lawfulness of sharing patients' personal data among institutions and its public disclosure. Second, it examines the influence of the right to data protection and the principle of mutual cooperation in the planning of health data processing by MSs in relation to cross-border healthcare. Thirdly, it analyses the relationship between the right to data protection and the collective dimension of the right to health in relation to data processing for scientific research (e.g., with regard to the relationship between informed consent in medicine and consent as a legal basis for processing). Lastly, the role of the principle of proportionality is considered, jointly with necessity, in the current planning of data processing within Health Data Spaces.

Chapter 5 discusses the material and personal scope of protection from discrimination based on health-related conditions, with the aim of understanding whether protection from non-discrimination has a positive impact on the protection of health, and whether and how the CJEU has dealt with complementarity (Section 5.1) and conflicts (Section 5.2) between the right to health and other fundamental rights in cases concerning non-discrimination. Key questions addressed concern whether non-discrimination extends to health-related conditions even though "health" itself is not protected ground in Article 21 CFREU (e.g. *HK* Denmark, Joined Cases C-335/11 and C-337/11), and whether individuals who do not suffer from such a condition themselves but are associated with somebody who does, may also be protected by EU non-discrimination law (e.g. *Coleman*, C-303/06).

Chapter 6 shows that the health status of a migrant or an asylum seeker can play a role even when its protection – or its relevance within the concrete area covered by EU law – is not formally requested. Migrant health needs may become a criterion which integrates the concrete enforcement of different areas of migration law, and international protection in particular, such as – among others – irregular migrants, asylum seekers under the Dublin III Regulation, residence permits on health grounds and family reunification. In many of the cases analysed reference to Article 47 – often in conjunction with Articles 4 and/or 19.2 – of the CFREU becomes essential to giving relevance to health status. Health status then becomes a condition for the concrete respect of the former, as happened in the case surrounding the need to confer suspensive effect to an appeal against a return decision or to guarantee the principle of non-refoulement. In general terms, it appears from the CJEU case-law that when a migrant's health is at stake, special procedural safeguards must be implemented when Member States assess migrant applications.

Chapter 7 **on Health and COVID** addresses the legal issues related to healthcare management within the COVID-19 crisis (*e.g.*, vaccination, therapies against COVID-19) and to the relationship between

health (mainly in its collective dimension) and other fundamental rights. As for the latter, the chapter examines the role of the principle of effectiveness and, when applicable, that of Art. 47 CFR in interpreting national procedural rules adopted to handle the COVID-19 emergency, taking into account CJEU case law and national litigation concerning modifications of procedures related to COVID-19. Moreover, the Chapter addresses, from a European perspective, the legal issues that have arisen in national case law concerning the relationship between health protection and other fundamental rights such as the freedom of information (including the right to be informed), freedom of movement, the freedom to conduct a business, the right to data protection. In the analysis particular attention is devoted to the application of general principles such as proportionality and necessity.

II. Cross-Project Methodology

The FRICoRe Casebook on *Judicial Protection of Health as a Fundamental Right* builds upon the collaborative venture developed in previous projects of judicial training and, more recently, in the Re-Jus project. The core element of its methodology concerns the active dialogue established between **academics and judges of various European countries** on the role of the Charter and that of Article 47, here particularly developed in the field of health. In continuity with previous projects, including Re-Jus, this collaboration combines rigorous scientific methodologies with judicial practices, and provides trainers with the sort of rich comparative material that should always characterize transnational trainings. We firmly believe that transnational training of judges should be based on a rigorous analysis of judicial dialogue between national and European Courts and, when it exists, among national Courts. Training includes not only the transfer of knowledge, but also the creation of a learning community composed of different professional skills. As in previous experience, this casebook is due to evolve both in content and in method over time, with additional suggestions arising from its use in training events.

As in previous projects, **judicial dialogue** is a key dimension of the approach followed in this Casebook. We investigate the full life cycle of a CJEU case, from its birth with the preliminary reference, to its impact in different Member States. We examine the ascendant phase and analyse how the preliminary reference is made and whether and how it is reframed by the Advocate General and the Court. We then analyse the judgments and distinguish them according to the chosen degree of detail when they provide guidance both to the referring Court and to other Courts that must apply the judgments in the various Member States.

Judicial dialogue develops both vertically and horizontally, at both the national and supranational levels. Preliminary references represent the main driver of this dialogue in most chapters. Linked with preliminary reference procedures, horizontal interaction among national Courts takes place when the principles identified by the CJEU are applied in pertinent cases, mostly in the same and sometimes in connected fields. Depending on the type of reference enacted, the guidance provided by the CJEU may also consist in specific rules or in general principles to be applied. Very frequently the latter may consist in the principle of effectiveness or that of equivalence, to be balanced against the principle of national procedural autonomy (see, e.g., *S.* (C-219/15); *Sanofi* (C-621/15)).

Diverging approaches may be provoked by the same CJEU judgement and a national vertical dialogue may emerge, involving constitutional Courts, higher Courts, and Courts of first instance. The example provided in Chapter 2, on the different approaches taken by French Courts after the *Sanofi* judgment by the CJEU on the use of presumptions in vaccine liability cases, is quite illustrative and may be compared with parallel applications of the same judgment by other MSs' Courts therein examined.

While CJEU judgments are formally binding on Member State Courts, their application requires a careful analysis of which substantive and procedural rules may be affected by the judgment, in particular the

application of Article 47 of the Charter, the principle of effectiveness, and that of proportionality. The Casebook examines the impact of CJEU judgments in MS legal systems to shed light on the potential different interpretations driven by contextual factors that are considered by national Courts. **Impact analysis** is very important for judges other than the referring judge. Their effort to interpret and adapt the judgment to their national legal context is often underestimated. Comparing different stories and taking national specificities into account enables national Courts other than that of referral to define the impact of EU law on the adjudication of national cases. This is why the **comparative perspective** provided by this Casebook may clarify the impact of the judgment or of a cluster of judgments addressing the same issue on the case law of Member States other than that of the referring Court. In some cases, the impact can be examined through national judgments expressly referring to the CJEU's decisions; in other cases, the Casebook suggests interpretative tools to address issues discussed in national case law through the lens of the CJEU's decision even if the CJEU judgments are not explicitly mentioned.

Based on the methodology adopted in Re-Jus and now in Fricore, the analysis does not mainly focus on single CJEU judgments but on **clusters of judgments** around common issues. Clusters of CJEU judgments are diachronic and synchronic. Diachronic clusters include judgments dealing with complementary issues. Synchronic clusters include judgments that have dealt with the same issues interpreting, refining, or revising the principle over time. Judicial dialogue is not static. It occurs over time among Courts from different MSs. The Casebook provides national judges with an interpretation of the cases in light of the complexity of judicial dialogues. Often, CJEU judgments touch on many questions depending on how the preliminary references are framed, and it might be more effective to choose a subset of complementary issues and examine them in sequence across several cases over time, rather than to focus on a single judgment. This approach may add a bit of complexity, but it reflects the problem-solving approach, rather than the conventional doctrinal perspective. The internal coordination of chapters ensures the possibility of reconstructing the judgment across different chapters.

The casebook is complemented by a **Database** (https://www.fricore.eu/content/database-index) that endorses the methodological approach of judicial dialogue, giving continuity to that established in the Re-Jus Project and integrating the whole set of materials developed therein. It is organized around EU judgments and their impact on national legal systems. Two series of national judgments are examined in the Database: those directly concerning cases brought before the CJEU within a preliminary reference procedure, and those that apply or take into consideration the CJEU case law when addressing national cases outside of a referral procedure. Hence, the database is specific, and it reflects the idea that judicial dialogue is a pillar of EU law.

In training courses organized by national judicial schools we would like to encourage both the use of the Casebook and that of the Database, which is subject to constant updates during the project, thanks to contributions from both the Schools of the Judiciary and from workshop participants.

III. Health as a Fundamental Right: a European Union Law Perspective[2]

III. 1. Health and Healthcare in the Charter of Fundamental Rights of the European Union

Health is a very wide concept, as the WHO Constitution makes clear since 1948: "health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity." Therefore, its acknowledgement and protection is not easy for contemporary legal systems. Indeed, the recognition of the right to health implies that it is the responsibility of the corresponding public power

[2] Section (I) has been drafted by Lucia Busatta, University of Trento.

to provide the necessary measures to make the right effective. Actually though, it is not always possible to properly guarantee such a right because, beyond its wide extension (not merely the absence of illness), it is really quite difficult to meet all possible health needs of all people.

Moreover, the granting of the right to health also requires addressing the issue of competence. If at a national level – especially in legal systems characterised by federalism or by asymmetric forms of regionalism – it is not always easy to distinguish between the role of the central government and the duties of local autonomies with regard to the organisation of healthcare services and to the provision of medical treatments, things seem to be even more complicated if we consider the interactions between national and EU law. The European Union has progressively intensified its involvement in legal issues related to the right to health and to healthcare, even if – formally – it does not have an explicit competence on this.

Against this complex scenario, a possible method of addressing the multi-faceted nature of the right to health is to compare its level of protection under EU law, in the interpretation of the European Court of Human Rights and in national frameworks. Moving from the analysis and interpretation of the relevant provisions of the Charter of Fundamental Rights of the European Union (CFREU), it will be possible to highlight that protection of the right to health does not only stem from a dedicated Article, but could also be related to other provisions of the Charter.

This feature also applies to Conventional rights. It is common knowledge, in fact, that the European Convention (ECHR) does not include specific provisions for the right to health nor for other "social rights." Nevertheless, the Strasbourg Court has found states in breach of the Convention's provisions several times due to their failure to protect the health of people within their territory.

As is well known, the CFREU has the same legal value as the Treaties and includes several provisions of crucial importance in the field of health and healthcare. Beyond Art. 35, on healthcare, a number of provisions of the CFREU are related to the fundamental right to health, in the fields of EU action.

In particular, **Title I,** entitled **"Human dignity"** consists of several provisions related to respecting the dignity of the human being, self-determination, and the right to life. More precisely, after the proclamation of the inviolability of human dignity (Art. 1), the Charter continues with the right to life (Art. 2) and with the right to physical and mental integrity (Art. 3), which includes informed consent and a wider respect of the human body. Other relevant provisions are Article 7 (Respect for private and family life) and Art. 8 (Protection of personal data). The first, in fact, recalls the provision of Art. 8 of the European Convention of Human Rights and may be relevant in protecting individual choices connected to the field of health, whereas the second provision represents a significant point of reference for the broadest protection possible of personal data. As we will see in the casebook, data protection, especially after the adoption of the General Regulation 2016/679/EU (GDPR), became a crucial issue in the field of healthcare in the EU.

Other relevant provisions in the field of health include Art. 25 CFREU, on the rights of the elderly, and Art. 26 CFREU on persons with disabilities. Even if these Articles are not directly connected with the right to health, they both recall the need to protect and respect the rights and dignity of such persons and to ensure their independence and participation in social life. This is obviously not possible without a due

protection of their right to health.[3] Similarly, Art. 31 and 32 protect the rights of workers and of young people at work. Protection of health and safety of workers is at the core of these provisions.

Several of these provisions have already been recalled in the case-law of the Court of Justice of the European Union (CJEU) which, from case to case, linked the concept of health to the rights of the Charter. For example, in 2019, the Court stated that the provision on the possibility to reduce or withdraw the material reception conditions for applicants for international protection shall be read in light of Art. 1 CFREU on human dignity[4]. Therefore, "respect for human dignity within the meaning of that Article requires the person concerned not finding himself or herself in a situation of extreme material poverty that does not allow that person to meet his or her most basic needs such as a place to live, food, clothing and personal hygiene, and that undermines his or her physical or mental health" (para 46). This means that a Member State cannot reduce the material reception conditions so much that the person is deprived of the possibility of meeting her most basic needs, health included.

A similar connection between the protection of the health of migrants during their application for international protection was given in other decisions, in which the CJEU was called to give an interpretation on different provisions of EU Directives on migrations. In *Jawo* in 2018, for example, the Court of Justice cited respect for human dignity (Art. 1 CFREU) and the prohibition on inhuman and degrading treatment (Art. 4 CFREU) in its interpretation of Regulation (EU) No 604/2013, establishing the criteria and mechanisms for determining the Member State responsible for examining an application for international protection. Therefore, when evaluating the transfer of a migrant to the Member States responsible for the evaluation of her applications, the possibility that she will be exposed to a substantial risk of suffering inhuman or degrading treatment must be considered. Among the elements to be assessed by state authorities, the particularly high level of severity of deficiencies the migrant might face if transferred to another Member State is of crucial importance. These deficiencies should also include a "situation of extreme material poverty that does not allow him to meet his most basic needs" that would ultimately undermine their physical or mental health (para 92).[5]

Above all, the most relevant provision of the CFREU is **Art. 35, "Health care"** which provides that: "Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities."

It should be immediately underlined that this Article does not fund an autonomous right to health care in the European Union. In fact, the EU does not have competence over the organisation of the healthcare system, which is a matter of national competence (see *infra*). Moreover, the Charter provisions are addressed to EU institutions, bodies, and offices and to the Member States "only when they are implementing Union law."[6]

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[3] On these implications see T.K. Hervey, We Don't See a Connection: The 'Right to Health' in the EU Charter and European Social Charter, in G. De Búrca, B. De Witte (eds.), Social Rights in Europe, Oxford University Press 2005, 315.

[4] C-233/18, Haqbin, 12 November 2019, ECLI:EU:C:2019:956.

[5] C-163/17, Jawo, 19 March 2019, EU:C:2019:218.

[6] Art. 51 CFREU. See T. Hervey, J. McHale, Art. 35 – Health Care, in S. Peer, T. Hervey, J. Kenner, A. Ward (eds.), The EU Charter of Fundamental Rights, Hart, Oxford, 2014, 951.

Therefore, on the one hand, the field of application of Art. 35 might seem very limited, if we consider that EU institutions do not have competence over medical treatments, preventive health care or in the organization of health services. These activities rest within Member States' purview, as we will see in the following paragraphs.

On the other hand, however, the Charter also applies to Member States when implementing EU law. In this sense, the field of application of Art. 35 expands, because there are several provisions of EU law that might affect the national organisation of health care systems and they include the regulation on the coordination of social security systems (Reg 883/2004/EC), the patients' rights directive (Directive 2011/24/EU), but also EU principles on free movement of services, goods and persons, public procurement law, competition law and so on.

Moreover, it must be considered that the second sentence of Art. 35 CFREU goes far beyond the mere regulation of healthcare systems and is a sort of literal repetition of Art. 168.1 TFEU. In this sense, it recalls the mainstream of health in all policies; it also means that EU institutions must ensure a high level of health protection almost in *any* policy and activity that is carried out. This is an aspect that should be given due relevance, because several EU policies and activities do involve an improvement in the level of health of persons in the EU. Even without mentioning Art. 35 CFREU, this aspect was recently highlighted by the CJEU in one of several decisions concerning the persistent exceedance of the limit values in ambient air set by EU Directives (in particular, Directive 2008/50, on Air quality plans).[7] In *Commission v. Italy*, decided in November 2020, the Court reiterated that "the need to ensure clean air serves the fundamental interest of *protecting human health* and that the *discretion of the competent authorities* should be consistent with that imperative" (para 124). In other words, independently of their national or EU nature, competent authorities shall in any case pursue the fundamental interest of protecting human health.

Thus far, Art. 35 CFREU has been frequently cited in proceedings before the Court of Justice, especially in the last few years. Interestingly enough, the most significant decisions concern the second phrase of Art. 35 CFREU ("A high level of human health protection shall be ensured…"), whereas the acknowledgement of the individual right to access preventive care and medical treatment has been less effective in CJEU case-law, due to the scheme of sharing competences between the EU and Member States, which we will discuss *infra*. A brief presentation of some of the most relevant CJEU decisions in which Art. 35 CFREU was cited and played a significant role in the ruling is functional for underlining this aspect.

A recent decision on the freedom of establishment and on the freedom to provide services offers a good example of the judicial use of Art. 35 CFREU.[8] The case concerned the immediate closure of a massage salon managed by a Bulgarian woman in Innsbruck (Austria) because police believed sexual services were being offered within the establishment. Even though the core of the decision concerned the criminal proceedings and the principles of legality and proportionality of criminal offences and penalties (Art. 49 CFREU), the Court of Justice also had the opportunity to focus on the nature of the provision of health

[7] The Commission began infringement procedures on several Member States that did not respect EU discipline on Air quality and environmental protection. Some of these procedures have already ended with a decision by the Court of Justice. See C-336/16, Commission v Poland, 22 February 2018, EU:C:2018:94; C-638/18, Commission v Romania, 30 April 2020, EU:C:2020:334; C-488/15, Commission v Bulgaria, 5 April 2017, EU:C:2017:267; C-644/18, Commission v Italy, 10 November 2020, ECLI:EU:C:2020:895.

[8] C-230/18, PI, 8 May 2019, ECLI:EU:C:2019:383.

protection under Art. 35 CFREU. This Article recalls the individual right to have access to preventive care and medical treatments under the conditions established by national law. In the concrete case, the supply of services in an unregistered commercial activity not only breached national laws, but excluded the possibility of ensuring proper control. Therefore, persons offering such services are "not subject to specific health requirements and regular checks to detect sexually transmitted diseases likely to increase risks for the health of both persons who engage in prostitution and to their customers" (para 74). Therefore, the immediate closure of a commercial activity for these reasons represents a restriction on the freedom of establishment, provided by national legislation, which is objectively justified by overriding reasons of public interest, namely the prevention of criminal offences and the protection of public health (para 75).

Under a different perspective, the CJEU recently had the opportunity to clarify the meaning of Art. 35 CFREU as the source of a general objective for the EU legislature, in functional connection with the **precautionary principle**. Health protection, in other words, is the final scope of the precautionary principle, according to which, "where there is uncertainty as to the existence or extent of risks to human health, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent. Where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because the results of studies conducted are inconclusive, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures."[9]

Beyond the precautionary principle, Art. 35 CFREU has also been cited to evaluate the proportionality of a restrictive measure adopted by a Member State in connection with the EU Directives on blood products, which were clearly designed to ensure a high level of protection of human health.[10] The issue concerned the permanent deferral of blood donation by persons of same-sex sexual relationships because of the need to minimise the risk of transmitting infectious diseases to blood recipients. Even though the Court recognised that the aim of the national provision was to ensure a high level of human health protection, in accordance with Art. 168 TFEU and with Art. 35 CFREU, the Court stated that the measure adopted must be assessed under the **principle of proportionality**.[11] In the case itself, the Court evaluated whether permanent deferral of blood donation was the least onerous measure possible, or whether there was the possibility of selecting other more appropriate measures; such an evaluation pertained to the national judge.

Other types of decisions of the Court of Justice in which Art. 35 has been applied concern other areas of intervention of EU institutions, such as migration and asylum, tobacco and alcohol (which also falls under the umbrella of consumer protection in relation to the precautionary principle once more).

As we have already seen, the Charter provisions are frequently cited in CJEU case law concerning migration and asylum and the protection of the fundamental rights of migrants, especially in situations of deprivation and vulnerability. Health protection, in these cases, works either as the scope of activities performed by national institutions towards migrants or as a ground to fund exceptions to restrictive measures. As already noted, in cases concerning the interpretation of EU migration laws, health

[9] C-616/17, Blaise, 1 October 2019, ECLI:EU:C:2019:800, paras 42 and 43 (the case concerned the placing of plant protection products on the market as well as glyphosate).
[10] Directive 2004/33, implementing Directive 2002/98 of the European Parliament and of the Council with regardto certain technical requirements for blood and blood components.
[11] C-528/13, Léger, 29 April 2015, ECLI:EU:C:2015:288, paras 57-58.

protection is frequently cited together with other CFREU provisions, such as human dignity, the prohibition on inhuman and degrading treatment, respect for private and family life (Art. 7), the right to work, etc. For example, when interpreting the provision concerning a refusal to grant or revoke refugee status in the event of danger to the security or the community of a host Member State (Art. 14 of Directive 2011/95/EU, the so-called qualification directive) the CJEU reiterated that the application of such provisions does not prejudice "the obligation of the Member State concerned to comply with the relevant provisions of the Charter" such as those set out in Articles 7, 15, 34 and 35 (para 109).[12] It is not by coincidence that Art. 35 CFREU, intended as the right to access a dignified level of health protection, assumed a decisive role in cases concerning migration law because of the tight connection with individual fundamental rights protection that migration laws and policies have.

As for tobacco products, the *Philip Morris Brands* decision should be mentioned because it cited Art. 35 CFREU in connection with Art. 114 TFEU, stating that the objective of granting a high level of human health protection was correctly pursued by prohibiting the placement of tobacco products on the market with a characteristic flavour, which was thus not considered manifestly disproportionate.[13] Similarly, in a case concerning electronic smoking, the CJEU defined the aim of obtaining a high level of human health protection not only as a general objective of the EU legislature but as an obligation. In the words of the Court of Justice: "The fact that tobacco products have been able to benefit for many years from advertising campaigns cannot under any circumstances constitute a reason requiring the EU legislature to allow such campaigns also for electronic cigarettes. On the contrary, as soon as it became aware of serious scientific information alleging the existence of potential risks to human health to which a relatively new product on the market might give rise, the EU legislature was required to act in accordance with the precautionary principle in the second sentence of Article 35 of the Charter, Article 9 TFEU and Articles 114(3) TFEU and 168(1) TFEU which require it to ensure a high level of protection of human health in the definition and implementation of all Union policies and activities."

A very important decision in which Art. 35 CFREU proved central to the Court of Justice concerned alcohol and EU rules on labelling and the presentation of foodstuffs. In *Deutsches Weintor*, decided in 2012, the CJEU stated that the right to engage in work and the freedom to conduct a business (Articles 15 and 16 CFREU respectively) must be balanced with Art. 35 CFREU.[14] Therefore, the prohibition of health claims with respect to wine must be evaluated in light of both the freedom to conduct a business and the protection of health. At this point, European judges stated that "measures restricting the advertising of alcoholic beverages in order to combat alcohol abuse reflect public health concerns and that the protection of public health constitutes, as follows also from Article 9 TFEU, an objective of general interest justifying, where appropriate, a restriction of a fundamental freedom" (para 49). The Court pointed out that nutrition and health claims on food and beverages must not be false or ambiguous and this is far more important with regard to alcohol: it is essential that labels on these products are clear, so that consumers can adapt their behaviours by also taking dangers into account and thereby "protect their health effectively" (para 50). This is necessary in order to respect Art. 35 CFREU.

III. 2. The Right to Healthcare and the European Court of Human Rights

[12] Joined Cases C-391/16, C-77/17 and C-78/17, M, 14 May 2019, ECLI:EU:C:2019:403.
[13] C-547/14, Philip Morris Brands, 4 May 2016, ECLI:EU:C:2016:325, paras 187 ff.
[14] C-544/10, Deutsches Weintor, 6 September 2012, ECLI:EU:C:2012:526.

As the interpretation of the CFREU given by the Court of Justice clearly pointed out, the right to health could be understood from several different perspectives. This includes, for example, the right to access medical treatments and prevention, but also embraces the promotion of a healthy lifestyle, the protection of mental health, and has also been understood as a portion of the right to physical integrity and been linked to the prohibition on inhuman and degrading treatments.

This perspective is crucial when dealing with the nature of the right to healthcare and the meaning of health as the content of a right. In fact, issues related to health might overlap several fundamental rights and are also connected with the commitment of public institutions to adopt means and invest resources to making the right effective. This represents a bridge between health intended as a human right and healthcare as a social right.

The most effective example of this feature of the right to healthcare is outlined by the European Court of Human Rights (ECtHR) approach to issues related to healthcare obligations. Strasbourg judges, in fact, never refer to a right to healthcare, which is not included in the Convention, and which depends on the national choices of States in granting social rights within their territories. Nevertheless, the ECtHR has often been involved in cases connected to health, intended as access to medical treatments, to states' choices concerning healthcare, to protection of persons in situations of vulnerability because of their physical or mental health status, and so on. Obviously, the motivations for the Court's intervention lay in an alleged breach of the fundamental rights of the Convention, especially in connection with the right to life (Art. 2 ECHR), the prohibition on inhuman and degrading treatments (Art. 3 ECHR), the respect of private life (Art. 8 ECHR), or the prohibition on discrimination (Art. 14 ECHR).

In these cases, the ECtHR developed a **"positive obligations" doctrine** which means that contracting States have the duty to take measures to safeguard the health of an individual. This is necessary to avoid a breach of Conventional obligations.[15]

Even if the Convention and its interpretation do not guarantee the right to any particular standard of medical service (which strictly belongs to national decisions) or the right to access medical treatment in any particular country, the Court has several times been involved in issues connected with access to medical care from different perspectives. The latter included the health of detainees or migrants, but also ethical issues (in which case the doctrine of the margin of appreciation proved to be central for any judicial evaluation of the State's responsibility under the Convention[16]), the problem of informed consent, medical negligence, and access to medicines. In all of these circumstances, while confirming that the Convention does not include a right to healthcare intended as a provision that required Contracting States to organise healthcare services or to provide specific treatments, the ECtHR found that respect of Conventional duties might include a positive obligation on state authorities to also take steps in the field of healthcare that are necessary for guaranteeing conventional rights.

To give some examples, **Art. 2 ECHR** requires States to refrain from life-threating acts that could put the life or health of individuals at risk. The positive obligation doctrine implies States' duty to adopt measures to protect the health of persons in particular circumstances that may put the individual's life at risk. This is the case in *Oyal v. Turkey*, where the ECtHR found a violation of Art. 2 by state authorities who failed to adopt all necessary measures to protect the life of a patient who was infected with the HIV

[15] Thematic Report, Health-related issues in the case-law of the European Court of Human Rights, Council of Europe, June 2015, available at https://www.echr.coe.int/Documents/Research_report_health.pdf, 5
[16] See among all decisions, A, B and C v. Ireland, app. no. 25579/05, 16 December 2010, on abortion.

virus by blood transfusions given to him at birth, by providing full and free medical coverage for life.[17] In *Panaitescu v. Romania*, the Court found a violation of Art. 2 because state authorities had abusively failed to provide the applicant's father with the specific anti-cancer medication he needed for free, in accordance with the domestic Courts' judgment which recognised his right to free access to those drugs.[18]

It is also worth mentioning a case on medical negligence related to pregnancy and birth, in which the Court declined to consider a claim under Art. 2 ECHR because it would have involved deciding whether the unborn was a person for the purposes of the conventional right to life.[19]

Art. 3 ECHR on the prohibition of torture has also been frequently cited in connection with access to medical treatments and health protection. Here, the Court found both a negative and a positive obligation for state authorities in connection with the prohibition on degrading treatment. More specifically, States must refrain from actions that cause damage to an individual's physical or mental health, that attain a minimum level of severity assessed by the Court for declaring a breach of Art. 3.[20]

A violation of Article 3 has also been found with reference to the conditions of detention of persons suffering from mental-health problems[21] and in some issues concerning the force-feeding of detainees on hunger strike.[22] Moreover, with regard to the possibility of contracting a disease while in jail, there is significant case law by the Court. Very briefly, the Court tended to recognise a breach of Art. 3 if a detainee is deprived of necessary medical assistance, including psychiatric care,[23] but did not recognise a violation of Convention provisions when the allegation concerned a failure in health prevention: in a case concerning a detainee who contracted tuberculosis while in jail, the Court excluded that it could satisfy the threshold of severity to be considered a violation of Art. 3.[24]

A partially different perspective was recently adopted in *Feilazoo v. Malta*, decided in March 2021,[25] in which the Court found, *inter alia*, a violation of Art. 3 in connection to the conditions of an applicant's immigration detention. Of relevance to the topics we are dealing with, the Court was concerned by the unrebutted allegations that the applicant had been housed with people in Covid-19 quarantine where

[17] Oyal v. Turkey, app. no. 4864/05, 23 March 2010.
[18] Panaitescu v. Romania, app. no. 30909/06, 10 April 2012.
[19] Vo v. France, app. no. 53924/00, 8 July 2004.
[20] Kaçiu and Kotorri v. Albania, app. nos. 33192/07 and 33194/07, 25 June 2013; Gäfgen v. Germany, app. no. 22978/05, 1 June 2010. For more details on this see Thematic Report, Health-related issues in the case-law of the European Court of Human Rights, cited above, 5.
[21] M.S. v. the United Kingdom, app. no. 24527/08, 3 May 2012.
[22] Rappaz v. Switzerland, app. no. 73175/10, 26 March 2013; Nevmerzhitsky v. Ukraine, app. no. 54825/00, 5 April 2005; Ciorap v. Moldova, app. no. 12066/02, 19 June 2007.
[23] Mouisel V. France, app. no. 67263/01, 14 November 2002, concerning the State's failure to provide adequate medical care for a detainee with leukaemia; Kudla v. Poland, app. no. 30210/96, 26 October 2000, concerning the violation of the Convention for lack of adequate psychiatric treatment during detention. Similarly, and more recently, see also Strazimiri v. Albania, appl. no. 34602/16, 21 January 2020, concerning the lack of a special medical institution for the mentally ill deprived of their liberty on the basis of Court-ordered compulsory treatment. See also Venken and Others v. Belgium, appl. no. 46130/14, 9 April 2021, in which the Court found a violation of Art. 3 ECHR in relation to the long-term imprisonment in psychiatric wings of persons placed in compulsory confinement.

[24] Khokhlich v. Ukraine, app. No. 41707/98, 29 April 2003; Alver v. Estonia, app. no. 64812/01, 8 November 2005.
[25] Feilazoo v. Malta, application no. 6865/19, 11 March 2021.

there appeared to have been no medical reason for doing so. This was considered an avoidable exposition of the person to an unjustified risk, that of contracting an infection, and we could therefore conclude that as a result of the pandemic, the Court also began considering prevention and sanitary measures to be part of the state obligation to prevent a breach of Convention rights. As to the **positive obligations** deriving from Art. 3, states must also take positive measures to protect the physical and mental health of individuals, for whom state authorities assume special responsibility, such as detainees or persons in particular situations of vulnerability. For example, if national law provides for access to prenatal information and testing when there is the suspicion of a genetic or developmental disorder, a positive obligation of state authorities to adopt all means to make such a right effective arises. In *R.R. v. Poland*, the Court found a violation of Art. 3 by the Polish government which, due to a delay in granting access to such testing to a pregnant woman, breached her right to information about her health status; when she finally received the results of medical tests confirming that her foetus was suffering from a severe syndrome, it was too late to make an informed choice about abortion.[26]

On another occasion, the ECtHR found a violation of Art. 3 with reference to a seriously ill migrant. The requested deportation to his country of origin would, given the specific and concrete circumstances of the case, amount to a breach of Art. 3 because the man was affected by AIDS at a terminal level and in his country of origin he would not have had access to necessary treatments.[27] It must be underlined, however, that this decision was grounded on the very exceptional circumstances of the concrete case. The Court made it clear that it was not in the position to deal with disparities in access to medical treatments in States that are not parties to the Convention, by providing free and unlimited medical treatment to all aliens without a right to stay within their jurisdiction.[28]

The case-law connected with health matters in which the ECtHR found a violation of **Art. 8** (the right to respect private and family life), is far more articulated and includes several different issues. Central to the matter of medical law is free and informed consent, which was connected to the right to respect private and family life, as a matter of self-determination of the individual.

Together with informed consent, cases related to end of life choices are also part of this reasoning. In fact, there are several cases in which a breach of Art. 8 was invoked.[29] Nevertheless, the Court often cited a lack of consensus among the High Contracting Parties on legislative choices concerning end of life decisions and, thus, the margin of appreciation doctrine applies.

Art. 8 ECtHR was also successfully invoked with regard to medically assisted reproduction, in *Costa and Pavan v. Italy* in 2012, where the ECtHR found Italian legislation to be inconsistent: whereas it prohibited preimplantation genetic testing, it permitted the abortion of a foetus with a genetic disease. The Court stated that interference with the applicants' right to respect for their private and family life was

[26] R.R. v. Poland, app. no. 27617/04, 26 May 2011.
[27] D. v. the United Kingdom, app. no. 30240/96, 2 May 1997.
[28] N. v. the United Kingdom, app. no. 26565/05, 27 May 2008.
[29] Pretty v. the United Kingdom, app. no. 2346/0229 April 2002; Haas v. Switzerland, app. no. 31322/0720, January 2011, Koch v. Germany, app. no. 497/09, 19 July 2012, Gross v. Switzerland, app. no. 67810/1030, September 2014, Lambert and others v. France, app. no. 46043/145 June 2015.

disproportionate.[30] Art. 8 was also successfully invoked in some claims regarding abortion.[31] The right to respect for private and family life is then relevant in cases concerning assisted reproduction technologies. In this field the ECtHR is more likely to adopt a cautious position, giving prevalence to the margin of appreciation doctrine, in consideration of the complex ethical and political choices subtended to this discipline.[32]

It is worth pointing out that very recently, the Court had the opportunity to give its first relevant judgement on vaccines. In *Vavricka*, the Strasbourg judge excluded a violation of Art. 8 ECHR by the Czech Republic in connection with the consequences provided by national law for parents who refused to vaccinate their children. The Court held that the measures applicants complained about were in a reasonable relationship of proportionality to the legitimate aims pursued by the Czech authorities through the vaccination duty and the State did not exceed its margin of appreciation.[33]

Finally, the Court also decided cases concerning health matters on the grounds of **Art. 14 ECHR** (non-discrimination), often in connection with Art. 8. For example, in *Kyutin v. Russia*[34], the refusal of Russian authorities to grant the applicant a residence permit because he tested positive for HIV was judged to be disproportionate to the legitimate aims of the protection of public health, in breach of Article 14 and in conjunction with Article 8.[35]

In the near future, moreover, the ECtHR will also be called to give its judgements on issues related to the pandemic emergency. It is very likely that this case-law will add some extremely interesting materials to the ECtHR's approach to health matters, in particular to those linked to the balancing between health protection and the enjoyment of other fundamental rights. There are currently some cases already pending before the Court on health measures adopted by national authorities.[36] In March 2022 the Court handed down one of its first decisions on the merits, in *Communauté genevoise d'action syndicale (CGAS) v. Switzerland*, the ECtHR found Switzerland in violation of Art. 11 of the Convention: an absolute ban on public protest was found in breach of the right to freedom of peaceful assembly because it was disproportionate.[37] Despite a specific provision on the right to healthcare, the ECtHR has a wide and dense case-law on issues related to health, which often represent a milestone for the guarantee of fundamental rights and that either proved to be significant for granting the effectiveness of rights connected to healthcare at a national level[38] or to improve internal procedures in order to make individual rights more effective. As provided by Art. 52(3) of the CFREU, the scope and interpretation of the rights of the Charter shall be (at least) the same as those laid down by the ECHR. Therefore, an appropriate

[30] Costa and Pavan v. Italy, app. no. 54270/10, 12 June 2014. See also S.H. v. Austria, appl. no. 57813/00, 3 November 2011.

[31] Tysiąc v. Poland, app. no. 5410/03, 20 March 2007; P. and S. v. Poland, app. no. 57375/08, 30 October 2010; A., B. and C. v. Ireland, app. no. 25579/05, 16 December 2010.

[32] S.H. v. Austria, app. no. 57813/00, 3 November 2011; Evans v. the United Kingdom, app. no. 6339/05, 10 April 2007; Dickson v. the United Kingdom, app. no. 44362/04, 4 December 2007.

[33] Vavřička and Others v. the Czech Republic, Applications no. 47621/13 and five others, 8 April 2021.

[34] Kiyutin v. Russia, app. no. 2700/10, 15 March 2011.

[35] A similar decision was adopted a few years later in Novruk and Others v. Russia, app. no. 31039/11, 16 March 2016.

[36] For some preliminary hints see the dedicated Factsheet – COVID-19 health crisis, available on the website of the Court: https://www.echr.coe.int/Documents/FS_Covid_ENG.pdf.

[37] Communauté genevoise d'action syndicale (CGAS) v. Switzerland, appl. no. 21881/20, 15 March 2022.

[38] For example, see the effects of Costa and Pavan v. Italy at a national level: after the ECtHR decision, the Italian Constitutional Court declared the prohibition of preimplantation genetic diagnosis void (decision n. 96 of 2015).

focus on the interpretation of conventional rights serves to better understand the various implications of the protection of fundamental rights in the field of health.

III. 3. The Right to Health, Rights to Healthcare, and Common Constitutional Traditions of Member States

As already noted, tackling the essence of the right to health within the EU legal framework underscores that the right to health entails several dimensions, not only under EU law, but also in its interface with national levels. In particular, we can distinguish between an individual right to healthcare and public institutions' intervention in the field of health, for example to make preventive medicine available, to guarantee medical treatments, and so on. Additionally, the individual right to healthcare can be understood from several perspectives that include a negative dimension (often connected with the right to physical integrity) and a positive one, i.e. health as a social right (which entails the problem of limited health resources and the problems of priority setting). Furthermore, the right to healthcare corresponds to a positive obligation on the part of public institutions to take appropriate steps to guaranteeing this right. In this regard, the right to healthcare opens some of the most problematic challenges of our time because even the richest state is unable to grant every form of healthcare possible to every individual. Thus, political choices surrounding available treatments, national healthcare investments, and priorities are the main tools for making this right as effective as possible.

Against this background, and beyond the already discussed connection between the CFREU and the ECHR (as provided by Art. 52(3) of the Charter), it is worth mentioning that the Charter also provides for a very useful and important connection between the Charter's rights and Member States' common constitutional traditions (Art. 52(4) CFREU). This provision is based on Art. 6(3) of the Treaty that places **fundamental rights – as guaranteed by the ECHR and as they result from common constitutional traditions** – at the core of EU law, by making them **general principles of EU law**. Thus, under this provision, Charter rights must be interpreted to offer a high standard of protection which is adequate for EU law and in harmony with the common constitutional traditions. For this reason, when dealing with the complex nature of health rights, it is also important to give due consideration to common constitutional traditions of Member States concerning this right.

On these premises, the starting point for any reflection upon the meaning of the right to healthcare and the public duty to intervene in the field of health is the WHO definition of health, as "a complete physical, mental and social well-being and not merely the absence of disease and infirmity." In addition, the WHO also affirmed that "the attainment of the highest possible level of health is a most important worldwide social goal whose realisation requires the action of many other social and economic sectors in addition to the health sector."[39]

This broad concept, on the one hand, recalls the mainstream of health in all policies that is found both in Art. 35 CFREU and in Art. 168 TFEU. These Articles represent the legal basis for the wide intervention of EU institutions in matters that do have an impact upon the health of individuals that are not directly connected to healthcare systems and rights. These are, for example, all those interventions connected to lifestyles, to the improvement of well-being of the population through public policies, and

[39] WHO, Declaration of Alma-Ata, 1978.

to incentives for a change in some behaviours or habits that might have a negative impact upon human health, including pollution and environmental promotion.

On the other hand, the broad definition of health promoted by the WHO requires discussion of the various meanings of the rights to healthcare. Lexical clarification therefore becomes necessary. Particularly in the English-speaking context, it has already been noted that dealing with the "right to health" might lead to some confusion, because it is quite difficult, or even impossible, to clearly identify the corresponding public obligation in granting "health" or in determining the practical content of the right. Thus, it has been observed that "a broad definition of 'health' may, in practice, lead to considerable problems in both the definition and the conceptualisation of the discipline of 'health law'."[40] Therefore, under this perspective, it is preferable to talk about a right to healthcare, rather than a right to health, if only because the latter seems too vague and broad to describe institutional responsibilities and individual rights.

Indeed, the right to healthcare is expected to fund a corresponding obligation in the public powers' duty to organise healthcare systems and to make them accessible to the population. This is quite evident from an overview of the constitutions of European Countries and their Articles on healthcare: the great majority of them refer to an individual right to social security, health insurance or health protection under the conditions established by law.[41]

Providing healthcare as a social right and, in particular, as a portion of social security does not exclude that health is also promoted as a wider goal and as a value. In fact, some Constitutions recall health, well-being, or welfare of people as a general objective of all State actions, in line with the WHO definition of health cited above. Of utmost relevance are Art. 32 of the Italian Constitution ("The Republic safeguards health as a fundamental right of the individual and as a collective interest…") and Art. 9 of the Portuguese Constitution that, among the basic tasks of the State, includes promotion of "the people's welfare and quality of life, real equality among the Portuguese." The first approach addresses healthcare as the object of a pure and classic social right: the individual position is granted by a state duty to organise an insurance or a public healthcare system. Therefore, individual demands strongly depend on the legislative realisation of the constitutional provision. The second approach has a more programmatic nature: health, wellbeing, and welfare of the population are considered as general objectives that all state actions shall pursue. This implies that health has a wider scope but at the same time the individual position is less enforceable.

Another possible way to define the difference between a right to health and right(s) to healthcare is to use the latter to refer to the legislative /regulatory competence concerning the structuring and the organisation of healthcare services, which means dealing with structures responsible for the granting of medical treatments, access to care, eligibility criteria, setting the list of treatments available, etc. On the other hand, "health" refers to a broader concept that includes healthcare but also goes beyond it (i.e. health in all policies approach), even if it is more difficult to properly refer to a "right to health" because it is difficult to define exactly which are the subjects responsible for its guarantee and how to ensure its

[40] T. Hervey, J. McHale, European Union Health Law, Cambridge, 2015, 11.

[41] L. Tonini Alabisio, The protection of the right to Social Security in European Constitutions, © International Labour Organization 2012, available at http://www.ilo.org/wcmsp5/groups/public/---ed_norm/---normes/documents/publication/wcms_191459.pdf. Some relevant examples of the right to healthcare intended as a purely social right. Polish Constitution (Art. 68): "Everyone shall have the right to have his health protected;" Constitution of Portugal (Art. 64) talks about a right to health protection; Slovakia (Art. 40), "right to health protection."

effectiveness. Therefore, **for the purposes of this work, we refer to "right(s) to healthcare" when dealing with medical treatments and medical services and to "health" when dealing with policies and actions intended to improve the well-being of the population but that are not necessarily limited to healthcare delivery**.

Against this background, we can distinguish between **a negative dimension of the right to healthcare and a positive one**. As discussed above, this distinction is quite familiar to the case-law of the European Court of Human Rights. The first (negative dimension) must be intended as freedom from unwanted interference in the personal sphere concerning health. It entails the right to choose or refuse medical treatments without undue interposition by public powers or private subjects; it is strictly and definitively related to the right to physical and psychological integrity.[42] When matched with EU law, this negative dimension of the right to healthcare intersects EU fundamental freedoms and can be understood as the possibility to choose medical services and to move for healthcare reasons. Intending the right to healthcare as a negative right implies that it is a freedom; as a freedom, it can clash with other individuals' freedom and therefore requires the intervention of public powers to regulate this clash of rights.[43] In other words, it is connected with the EU freedom of movement.

By contrast, the positive dimension of the right to healthcare poses the individual in relation to public powers. In this sense, it has been stated that "positive rights embrace rights against the state, […] positive rights are referred to as social and economic rights, not to freedom from interference."[44] Positive rights basically confer some tangible benefits to the individual which depend on the economic capacity of the state to pay for it.

These are those rights usually referred to in terms of "social rights" and are related to the obligation of public powers to grant health treatments and healthcare structures and set up a healthcare service that satisfies the needs of the population. It encompasses choices concerning treatments to be granted within the healthcare service; it also requires healthcare bodies to set priorities and to foresee legal, economic, and medical conditions in order to efficiently allocate scarce resources and to treat the widest possible number of patients.[45] From this viewpoint, the reason Member States are responsible for granting healthcare services is clear: they detain this competence because choices about the type of healthcare system and healthcare delivery depends on national states and on the concept of the right to healthcare they embrace at a legal and constitutional level (universal coverage; benefit in kind system; mutualistic system, …). Therefore, states identify institutions responsible for the organisation of healthcare delivery, for the regulation of both individual access to medical services and of professional requirements, for the setting of priorities and for making those ethical decisions which are frequently necessary to define the list of medical treatments available within a healthcare service.

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[42] A. Goldworth, Human Rights and the Right to Health Care, in D.N. Weisstub, G. Díaz Pintos (eds.), Autonomy and human rights in health care, an international perspective, Dordrecht: Springer. 2008, 54.
[43] See T. Hervey, J. McHale, cited above at 22.
[44] C. Newdick, Health care rights and NHS rationing: turning theory into practice, in Revista Portuguesa de Saúde Pública, 32(2), 2014, 153.
[45] M. Cappelletti, Healthcare Right and Principle of "Minimum Standards": The interpretation of the Judiciary in a Comparative Perspective. In L. Pineschi (ed.), General Principles of Law - The Role of the Judiciary. Cham: Springer2015. p. 243-261.

Another aspect that must be considered is the **relative nature of healthcare**. The positive/public/social right to healthcare can never be considered in isolation from the corresponding rights of others.[46] Nor can the right to healthcare intended as freedom be considered in absolute isolation from third parties' legal positions. In this respect, of seminal importance are the considerations laid down by the CJEU in the landmark *Watts* decision of 2006. Even though the CFREU is not cited in the reasoning of the Court, EU judges make clear that when dealing with the guarantee of the right to healthcare, national authorities are entitled to set a "system of waiting lists in order to manage the supply of that treatment and to set priorities on the basis of the available resources and capacities" (para 67).[47] This proves that the individual right to have access to medical treatments, especially in a publicly funded healthcare system, must always be balanced with the corresponding rights of others.

From this perspective, we can further observe that, first, the distinction between positive and negative right is not as intense as it might seem at first glance; second, that in any case, public intervention and regulation is necessary when dealing with complex decisions such as those affecting the health of the population (especially when including large resources); third, that the granting of the right to healthcare requires several degrees and levels of intervention that are carried out at a state level but that could also involve, within the sharing of competences designed by the Treaties, also EU institutions.

The right of healthcare has multiple dimensions: in fact, beyond its positive and negative meaning, we can also distinguish other facets of this right which include its substantial guarantee and its **procedural implications**. This latter dimension is particularly important when dealing with Court rulings on the right to healthcare, because it often happens that judges exercise a sort of substantial self-restraint considering that jurisdictional function cannot enter the merits of clinical decisions. In such cases, judicial scrutiny is limited to an evaluation of respect for procedural rules to ensure individual access to healthcare, rather than substantial scrutiny, which is normally limited to arbitrariness of the decision.[48] In this respect, the decision adopted by the Court of Justice in the aforementioned *Léger* case[49] serves as an example of judicial self-restraint on substantial issues, connected with the need for respect of procedural safeguards: the CJEU did not consider whether the permanent prohibition of blood donation from men who have had sexual intercourse with other men was legitimate or not under EU law, but required the national judge to assess all relevant circumstances, including current medical, scientific, and epidemiological knowledge.

Procedural rights to healthcare may also have a wider understanding, not necessarily related only to healthcare access, but recalling the need to ensure effective access to administrative and judicial remedies when health issues are at stake. In a recent decision of the Austrian Constitutional Court, for example, a breach of the constitutional right to an oral examination in judicial proceedings, as protected by Art. 47 CFREU, was found in a case concerning an asylum seeker with mental health problems. Here, the fact that medical examination was not duly considered during the evaluation of the applicant's asylum request represented the reason for the violation of the right to be heard and to an effective remedy.[50] Similarly,

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[46] C. Newdick, The positive side of healthcare rights, in S.A.M. McLean (ed.), First do not harm, Ashgate, 2006, 579.

[47] C-372/04, Watts, 16 May 2006, ECLI:EU:C:2006:325.

[48] C. Newdick, The positive side of healthcare rights, cited above at C. Newdick, Healthcare rights and NHS rationing, cited above.

[49] See Léger, cited above.

[50] Austrian Constitutional Court, E137 / 2019, 6 November 2019.

in *Abdida*, in 2014, the CJEU found that Art. 47 CFREU had been breached by the national legislation that did not provide for the possibility of a suspension of an appeal against a decision ordering a third country national suffering from a serious illness to leave the territory of the Member State, where the enforcement of that decision may expose that person to a serious risk of grave and irreversible deterioration to his state of health.[51] Here, the problem raised before the Court was not access to healthcare per se; health was relevant in order to assess the violation of another fundamental right protected in the Charter.

In conclusion, dealing with health and healthcare requires a careful approach in distinguishing the different understandings of health that are relevant in the concrete case at stake. When adopting the viewpoint of EU law, moreover, consideration must always be given both to the interpretation of the ECHR provisions and to the constitutional traditions of Member States. The analysis developed shows, on the one hand, the strong connection between dignity and health: in this sense, health must be regarded as a general objective of all actions (both at a EU and national level) because it is related to the natural and inherent human aspiration to happiness and wellbeing. On the other hand, though, health is not just a general goal, but also the object of protection by state and EU actions. In this regard, health protection includes the right to healthcare, intended as the individual right to medical treatments and care. This right is the source of the obligation of public institutions to make all efforts to make such a right effective. It follows that the individuation of the public institution responsible for the satisfaction of individual rights depends on the sharing of competences between the EU and Member States.

III. 4. Health Law and the European Union, a Matter of Competences

In the last couple decades, the European Union has progressively gained influence in the field of health law and health policy. This was the effect of several combined factors dealt with in this casebook and does not necessarily or exclusively depend on the EU legislative competences which might be relevant in this field. In this sense, the Treaty of Lisbon, entered into force in 2009, represents a significant step towards a wider recognition of the role of EU institutions in the field of healthcare (especially with regard to legislative competences, in comparison with the previous versions of the Treaties). Nevertheless, health issues "still constitute an important derogation within the framework of free movement."[52] Before focusing on the different areas of EU intervention in the field of health, it is necessary to briefly clarify the complex interweaving of legal sources that affect EU competences in this broad area.

First of all, it should be mentioned that, under the Treaties, EU competencies in the field of healthcare are quite limited. Indeed, as provided by Article 6 TFEU, the EU does not have exclusive competence in the field of health, but can "support, coordinate or supplement the actions of the Member States" concerning the protection and improvement of human health. At the same time, however, under Art. 4 TFEU, there are some areas in which the EU shares its competence with Member States and which could be relevant both in the limited field of healthcare and in the wider perspective of health policies. As we will see in the following paragraphs, these are mainly related to the "Internal market" (Art. 4.2.a), even if some other matters may, from time to time, be relevant when dealing with health policies such as, for example, the environment, consumer protection, as well as common safety that concerns public health

[51] C 562/13, Abdida, 18 Dember 2014, ECLI:EU:C:2014:2453.

[52] U. Neergaard, EU Health Care Law in a Constitutional Light: Distribution of Competences, Notions of 'Solidarity', and 'Social Europe', in van de Gronden, J.W., Szyszczak, E., Neergaard, U., Krajewski, M. (Eds.), Health Care and EU Law, Springer, 2011, 22.

matters. In other words, the sharing of competences illustrated by Art. 6 TFEU shows that Member States are responsible for the organisation of healthcare within their territories, but that such competence is not exclusive as far as health is concerned within the areas of shared competence.[53]

Title XIV of the TFEU concerns "public health" and consists of only one provision, that designs the shape of EU policies and interventions in the field of health. Art. 168 TFEU is the relevant provision for any kind of EU action that concerns health, as provided by par. 1: "A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities," which means that the mainstream in all EU activities and policies shall be health protection and promotion. As already noted, the EU does not have competence over the organisation of healthcare systems, which remains the responsibility of member States. Therefore, when related to healthcare delivery and the organisation of medical treatments and healthcare services, EU intervention is quite limited. Instead, the power of EU institutions expands when dealing with health rights beyond the organisation of healthcare services and includes the free movement of persons, services, and goods around the EU territory.

Art. 168 TFEU brought a significant development in the definition of EU and Member State competences in the field of healthcare by fostering their cooperation. In particular, the role of the EU consists in boosting **cross-border cooperation** between Member States for the complementarity of health services in cross-border areas. Beyond a strong encouragement to facilitate the cooperation between member States and the achievement of standards of quality and the safety of medical products, including medicines and devices, the TFEU makes clear that the EU shall respect "the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care" (Art. 168.7).

The respect of Member States' responsibilities in the organization of domestic healthcare services is an important principle guiding all EU activities in the field of healthcare. Indeed, it is relevant in the regulation of cross-border healthcare and in the case-law of the Court of Justice of the EU on the matter.[54] In the past few decades, the EU approach to healthcare matters has progressively changed and developed: if in the past it was more focused on disease prevention and on public safety concerns, now a broader understanding of human health pervades the whole provision of EU Treaties. From this perspective, under EU law, health protection focuses more on the promotion of healthy lifestyles, determinants of good health, and health surveillance. We should also consider that the EU has been increasingly empowered to adopt law focused more on individuals, in addition to law that adopts a collective or "public health" approach.[55] This framework becomes effective in the so-called "health in all policies" approach and the patients' rights directive (2011/24/EU).

Another relevant provision, when dealing with the issue of healthcare at the EU level, is Art. 114 TFEU, which provides for the general legal basis of the Internal Market. Paragraph 3 of Art. 114 provides that harmonisation measures in this field shall guarantee a high level of protection of human health. In this

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[53] U. Neergaard, EU Health Care Law, cited above at 23.

[54] M. Guy, W. Sauter, The History and scope of EU health law and policy, TILEC Discussion Paper, 18 January 2016, 6. For CJEU caselaw that acknowledges the respect of Member States responsibilities in organising healthcare services see: C-157/99, Smits and Peerbooms, 12 July 2001, EU:C:2001:404, paragraphs 76 to 79; C-372/04, Watts, 16 May 2006, EU:C:2006:325, paragraphs 108 and 109; C-173/09, E., 5 October 2010, EU:C:2010:581, paragraph 43; C-243/19, Veselības ministrija, 29 October 2020, ECLI:EU:C:2020:872.

[55] T. Hervey, J. McHale, European Union Health Law Cited above, 42.

regard, Art. 114 TFEU proved to be a "wide-ranging provision,"[56] representing the legal basis for several EU interventions in the field of health, from the cross-border healthcare directive to tobacco regulation.[57] This provision is also important because it is the legal basis for the adoption of measures for the approximation of national laws concerning the internal market. Very significant, from this perspective, was the adoption of Directive 2011/24/EU on patients' rights in cross-border healthcare. The 2011 Directive represented a seminal example of several issues concerning the complex interweaving between member States and EU competences and intervention in the field of health and is relevant to the analysis of the sharing of competences under the Treaties because it is adopted both on the basis of Art. 168 TFEU and as a harmonisation instrument under Art. 114 TFEU. The patients' rights directive, both for its content and for the impact that it would presumably have on national healthcare organisation and legislation, "considerably extended the scope of the EU's involvement in healthcare."[58] It is worth mentioning that, after the Watts decision, the fear of an uncontrolled flow of patients travelling from one Member State to another to obtain the best and quickest treatment possible[59] was one of the most common criticisms to the CJEU's interventionism that slowed down the approval of the Directive.[60]

III. 5. The Mainstream: Health in All Policies (HiAP)

As discussed above, the right to healthcare covers several facets and health could also be considered, as EU Treaties make clear, a general goal that shall guide *any* public intervention. In this regard, Art. 9 TFEU provides that "In defining and implementing its policies and activities, the Union shall take into account requirements linked to […] protection of human health" and, as pointed out above, Art. 168.1 TFEU echoes this statement, thereby creating a sort of "mainstreaming provision," which can be interpreted as the general objective to protect and promote health that all EU interventions are to pursue.

The interesting aspect of this mainstream provision is its cross-cutting nature, that potentially involves all areas of regulation and competences. The approach of promoting health in all policies adheres quite well to the WHO comprehensive definitions of health. Indeed, according to the definition of HiAP elaborated by the WHO in the Helsinki Statement in 2013, "Health in All Policies is an approach to public policies across sectors that systematically takes into account the health implications of decisions, seeks synergies, and avoids harmful health impacts in order to improve population health and health equity. It improves accountability of policymakers for health impacts at all levels of policy-making. It includes an emphasis on the consequences of public policies on health systems, determinants of health and well-being."[61]

At the EU level, a HiAP approach is the most natural way to work on the promotion of health without infringing upon Member States' competences and responsibilities in the organisation of healthcare

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[56] M. Guy, W. Sauter, The History and scope of EU health law and policy, cited above, 8.
[57] A. Alemanno, A. Garde, The emergence of an EU lifestyle policy: the case of alcohol, tobacco and unhealthy diets, Common Market Law Review, 50, 2013, 1745.
[58] M. Guy, W. Sauter, The History and scope of EU health law and policy, cited above, 11.
[59] L. Busatta, T. Hervey, Cross-border healthcare and the social market economy, in D. Ferri, F. Cortese (eds.), The EU Social Market Economy and the Law, Routledge, 2018, 196.
[60] C. Newdick, Disrupting the community: saving public health ethics from the EU internal market, in J. van de Gronden, E. Szyszczak, U. Neergaard, M. Krajewski (eds.), Health Care and EU Law. Legal Issues of Services of General Interest. Asser Press, The Hague, 2011, 211.
[61] WHO, Health in all policies: Helsinki statement. Framework for country action, 23 April 2014, available at https://www.who.int/publications/i/item/9789241506908.

systems and in the granting of the right to healthcare, in term of access to medical treatments. Nevertheless, HiAP does suffer from a significant problem of effectiveness, as the protection and promotion of health is not the object of the legislative intervention, but is rather a general goal of the action. Therefore, we can assume that an EU policy, act, or action would improbably be found in violation of the general rule on competencies. It is rather more likely that, due to a failure in ensuring the objectives it is enacted for, it indirectly does not succeed in reaching its goal of health protection and promotion.[62]

There are several examples of the EU commitment in HiAP. One of those is the effort in working on social determinants of health which, according to Wilkinson and Marmot, are concerned with key aspects of people's living, working circumstances, and lifestyles.[63] In their view, health policy must be considered as a comprehensive matter that goes far beyond the provision of medical care. Indeed, while medicines prolong the life of people, the main concern of a public health policy based on social determinants of health is to prevent the insurgence of diseases and to tackle social and economic conditions that make people sick, from their lifestyle, to the environment. In this respect, a strong political commitment of EU institutions dealing with the social determinants of health is to remove health inequalities, by promoting strategies analysing and assessing health inequalities in the EU, finding ways to reduce them, and providing information for public institutions to tackle inequalities.[64]

In this field, for example, EU institutions found that access to healthcare for migrants is still very different across EU countries which is a significant health inequality that must be removed. Even if the EU does not have competence over the organisation of healthcare services, through its competence over immigration it has begun to work for a more migrant-friendly healthcare in the EU. The recent adoption of the 2020 New Pact on Migration and Asylum,[65] for example, provides for the introduction of health checks that will allow the early identification of a migrant's potential needs. At the moment, this is only a proposal for a Regulation in the European Parliament and Council introducing a screening of third country nationals at the external borders.

Connected with lifestyles, an important area of EU intervention in the field of social determinants of health is alcohol and tobacco regulation. In both cases, EU interventions pass through consumer and product regulations but the general aim they pursue is to discourage behaviour that is proven to be detrimental to human health.[66]

This goes beyond product and consumer regulations, though these interventions can also be read under the wide umbrella of health in all policies. Instead, health is regarded as a general objective that these legal interventions shall pursue. At the same time, they also satisfy the so-called behavioural approach: by creating a series of incentives and disincentives, the law-maker succeeds in the scope of promoting health and deterring habits prejudicial to health care. From a public policy viewpoint, moreover, this can contribute to the prevention of ill-health.

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[62] E. Ollila, Health in All Policies: from rhetoric to action, in Scand J Public Health. Mar;39(6 Suppl), 2011 11-8.
[63] R. Wilkinson, M. Marmot, Social Determinants of Health. The Solid Facts, World Health Organisation 2003, available at https://www.euro.who.int/__data/assets/pdf_file/0005/98438/e81384.pdf.
[64] Commission Communication - Solidarity in Health: Reducing Health Inequalities in the EU, COM/2009/0567 final, available at https://ec.europa.eu/health/social_determinants/policy/commission_communication_en.
[65] New Pact on Migration and Asylum https://ec.europa.eu/home-affairs/what-we-do/policies/european-agenda-migration_en.
[66] The Tobacco Products Directive (2014/40/EU).

III. 6. The EU in the Fight Against the Pandemic Emergency

Finally, a few short considerations should address the role of the European Union's institutions in the fight against the Covid-19 pandemic.

The first important point to bear in mind is that EU institutions initially seemed rather distant and let Member States adopt interventions during the first phase of the outbreak. Actually, from a strict healthcare legal perspective it was quite easy to understand that this depended upon the limited EU competence over the organisation of healthcare systems.

Nevertheless, the wideness and gravity of the situation quickly underlined the need for several significant European interventions, which also included lifting financial constraints. This yearning finally found recognition in April 2020 when the Council of the European Union's finance ministers unanimously decided that in face of the pandemic "*We are committed to do everything necessary to meet this challenge in a spirit of solidarity.*"[67]

The need to provide for severe restrictions on freedoms and on economic activities, of course, required public powers to intervene with important subsidies in order to contain the economic crisis generated by the pandemic. The European Union, in this field, confirmed its strong commitment to helping Member States.

A field in which the EU significantly intervened was in support for medical research and vaccine production. Moreover, as is well-known, the EU directly negotiated with pharmaceutical firms to supply vaccines to the EU population.

Finally, in light of a "return to normalcy" in daily habits in the pandemic context, the Commission recently adopted a legislative proposal for a Digital Green Pass to restore freedom of movement in Europe. As is well known, the digital document serves the purpose of attesting to the fact that a person has been vaccinated against the coronavirus, has received a negative PCR test result, or has recovered from COVID-19. This document was free of charge, was issued by national authorities and has permitted (and continues to permit) persons to freely move across the EU territory. National authorities, moreover, have provided that the Digital Green Pass is necessary to access some specific places, offices, or activities.

Overall, the pandemic emergency has shown that it is necessary to invest in preparedness, pandemic response, and to serious health threats at the European level. Cross-border cooperation towards this end and common planning are essential to granting health security across Europe.

The role of the European Medicines Agency (EMA), moreover, proved to be central for an energetic reaction to the pandemic, both in terms of the availability of medicines and vaccines and for the complex process subtended to clinical trials.

Finally, as strongly recommended by the Commission's communication "Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats," an effective European commitment to the strengthening of the EU and national response to health threats cannot be

[67] See Report on the comprehensive economic policy response to the COVID-19 pandemic, press release, 9 April 2020, available here https://www.consilium.europa.eu/it/press/press-releases/2020/04/09/report-on-the-comprehensive-economic-policy-response-to-the-covid-19-pandemic/?fbclid=IwAR0ONBLmUJhY7CRZkkDODJEI6_PmyxxKr4_hc2xhjy7KvEJGuUEmygvsuGE.

postponed.[68] This approach has brought the EU institution to a new phase of the pandemic, which could also be read in a communication by the EU Commission, released on April 2022, entitled "COVID-19 - Sustaining EU Preparedness and Response: Looking ahead." The document is aimed at reminding Member States to remain vigilant and responsive by promoting the uptake of vaccines, by continuing surveillance through testing and sequencing, and by adopting preparedness measures.[69]

[68] Communication from the commission to the European parliament, the Council, the European economic and social committee and the committee of the regions, Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats, Brussels, 11.11.2020, COM(2020) 724 final.

[69] See Communication from the Commission, Brussels, 26.04.2022, COVID-19 - Sustaining EU Preparedness and Response: Looking ahead, COM(2022) 190 final, available at https://ec.europa.eu/health/publications/covid-19-sustaining-eu-preparedness-and-response_en.

1 Cross-Border Healthcare

1.1 Cross-Border Healthcare: Its Definition and Importance in EU Health Law

The phenomenon of cross-border healthcare involves patients who travel from their home State to another country to receive medical treatment. Reasons that force patients to move for healthcare might be very different in nature, which has quite a significant impact on the variability of the phenomenon. Depending on the kind of healthcare required and on state legal frameworks, the rules under which patients can access treatments abroad and the possibility of obtaining a reimbursement of medical expenses can considerably differ from case to case. Therefore, a brief definition of the main legal concepts that are relevant in this matter might help to better draw the boundaries of the issue and to highlight the most salient legal points regarding the effectiveness of EU intervention in the field of health and its impact on national healthcare services and individual rights.

First of all, it is worth underlining that cross-border healthcare is a portion of a wider phenomenon known as "patient mobility" or "medical tourism." This latter expression has a wider meaning, and it is actually used to describe the phenomenon of patient worldwide mobility, but is not appropriate to describe the phenomenon of cross-border healthcare which is far more specific. In fact, by medical tourism, we usually refer to the possibility of traveling abroad to obtain medical services, but it frequently happens that the related expenses are directly paid by the patient. In other words, the person exercises his/her freedom of circulation, obtains healthcare by private providers, and pays for the services received. There is no link with either the hosting or the home healthcare institution. This can be possible both within the EU territory or in third countries.

On a different note, cross-border healthcare is a purely EU phenomenon, with its own regulation: a patient obtains medical treatment in another member State, following the rules provided by EU legislation. Therefore, individual mobility is limited to the EU territory, which means that medical care can be obtained only in another Member State. Moreover, treatments that could be covered are only those that are already included in the list of treatments available within the home healthcare institution. Thus, to obtain reimbursement of medical expenses, a patient cannot get a treatment that is not already provided by her healthcare service of affiliation. This is due to the fact that the travelling patient relies on the healthcare institutions of both the affiliation state (which economically fund the treatments) and of the hosting state (which provides the medical care needed).

In this respect, we should also note that, depending on the legal scheme applicable, the treatment concerned could be paid by the healthcare institution of affiliation (i.e. from the State where the individual patient is a resident or registered), either directly[70] or by reimbursement of medical expenses to the patient.[71] In order to fulfil the requirements that permit the home health institution to assume medical expenses incurred abroad, the individual patient must meet some features provided for by EU law.

The EU legal framework applicable is based upon the principles of the free movement of persons and services and does not concern the freedom of establishment (with the exception of healthcare professionals) or residence permits. In this respect, a further distinction is necessary: cross-border

[70] As provided for by the Regulation on social security systems (Reg. 883/2004).
[71] As it is currently provided by the Directive on patients' rights in cross border healthcare.

healthcare includes only those treatments available and permitted both in the affiliation healthcare system and in the hosting institution. In this case, the Regulation or the Directive provisions (especially those on prior authorisation and on reimbursement eligibility of medical expenses) are applicable[72].

In cases where a patient travels to another Member State to obtain medical treatment that is strictly limited or prohibited by the home healthcare institution (for example, for ethical or moral reasons, i.e. assisted suicide or abortion), only freedom of movement applies. This means that Member States cannot prevent their citizens or residents from travelling to another country for treatment banned within the territory of the State, but that patients can not claim reimbursement for medical expenses incurred abroad, as the treatment sought is not included within the list of benefits that the home healthcare institution grants to its patients.[73]

This brief explanation is useful to show how, under EU law, the same phenomenon could assume different facets and can intersect with different EU competences. Moreover, when dealing with EU health law, this description shows that under the same phenomenon, different dimensions of the right could take precedence and influence the legal discipline, the interpretation of the relevant legal positions and, finally, the effectiveness of the right. In fact, it is relevant to bear in mind that the EU discipline on cross-border healthcare borrows a strong commitment from the case-law of the CJEU.

Relevant CJEU cases

- C-158/96 Kohll [1998] ECR I-01931. ECLI:EU:C:1998:171
- C-120/95 Decker [1998] ECR I-01831. ECLI:EU:C:1998:167
- C-368/98 Vanbraekel [2001] ECR I-05363. ECLI:EU:C:2001:400
- C-157/99 Smits e Peerbooms [2001] ECR I-05473. ECLI:EU:C:2001:404
- C-385/99 Müller-Fauré e van Riet [2003] ECR I-04509. ECLI:EU:C:2003:270
- C-56/01 Inizan [2003] ECR I-12403. ECLI:EU:C:2003:578
- C-145/03 Keller [2005] ECR I-02529. ECLI:EU:C:2005:211
- C-372/04 Watts [2006] ECR I-04325. ECLI:EU:C:2006:325
- C-444/05, Stamatelaki [2007] ECR I-03185. ECLI:EU:C:2007:231
- C-466/04 Herrera [2006] ECR I-05341. EU:C:2006:405
- C-211/08 Commission v Spain (Major Medical Equipment) [2010] ECR I-05267. ECLI:EU:C:2010:340
- C-173/09 E. [2010] ECR I-08889. ECLI:EU:C:2010:581
- C-268/13 Petru [2014] ECLI:EU:C:2014:2271

[72] Council Regulation (EEC) 1408/71 of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community [1971] OJ L 149/2. The 1971 Regulation has now been replaced by the European Parliament and Council Regulation (EC) 883/2004 of 29 April 2004 on the coordination of social security systems [2004] OJ L 166/1. Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, OJ L 88, 4.4.2011.

[73] On this matter see, for example the so-called abortion information case: C-159/90, Grogan, 4 October 1991, ECLI:EU:C:1991:378.

- C-777/18, Vas Megyei Kormányhivatal (cross-border healthcare), 23 September 2020, ECLI:EU:C:2020:745
- C-243/19, Veselības ministrija, 29 October 2020, ECLI:EU:C:2020:872
- C-538/19, Casa Națională de Asigurări de Sănătate e Casa de Asigurări de Sănătate Constanţa, 6 October 2021, ECLI:EU:C:2021:809

Main questions addressed

Question 1 How should a judge assess the reciprocity of national provisions on medical services, in light of the Regulation and Directive provision and in light of the fundamental freedoms of the Treaty? Is Art. 35 CFREU somehow relevant? Is there any remedy for the patient in case a state institution does not consider the treatment within the list of treatments provided by the health institution?

Question 2 What is the meaning of undue delay in access to medical treatments? Are waiting lists a possible cause of undue delay? In light of the principle of non-discrimination in access to medical treatments, could the provision of waiting lists be a possible cause of inequality in access to medical treatments? Can an individual obtain a medical treatment abroad, paid for by the home healthcare institution, if undue delay is caused by waiting lists? Which remedies are available for the individual in case the waiting list is irrational? Are they effective?

Question 3 Could a structural lack of medication and basic medical supplies be claimed as "undue delay"?

Question 4 Shall an authorisation to get medical treatment in another Member State be granted, when a treatment is available in the State of residence, but the method of treatment used is contrary to that person's religious beliefs?

Question 1 – List of Reimbursable Medical Treatments

How should a judge assess the reciprocity of national provisions on medical services, in light of the Regulation and Directive provision and in light of the fundamental freedoms of the Treaty? Is Art. 35 CFREU somehow relevant? Is there any remedy for the patient in case a state institution does not consider the treatment within the list of treatments provided by the health institution?

The analysis is based on the *E.* case (C-173/2009)

The case

Mr. E. was a Bulgarian citizen, affiliated with Bulgarian health insurance (NZOK), and suffered from a serious illness. In 2007 he asked NZOK to cover the expenses for an advanced treatment in a specialist clinic in Berlin (Germany), since such treatment was not available in Bulgaria. He was admitted to hospital in Germany and treated before receiving a reply from NZOK, due to the state of his health.

ZNOK refused to give Mr. E. the authorisation requested, because the requirements for granting such authorisation, as laid down in Art. 22 of Regulation No 1408/71, were not met: the treatment required was not included in the list of treatments reimbursed by NZOK.

E. challenged this refusal. The administrative tribunal in Sofia (Bulgaria) annulled the decision, stating that the conditions for granting authorisation laid down by Article 22(2) of Regulation No 1408/71 were met. In fact, the treatment in question did not exist in Bulgaria, but corresponded to the services enumerated in the list of clinical treatments.

NZOK appealed the judgment before the Supreme Administrative Court, which referred the case back to a different chamber of the lower Court. This Court found that the treatments received by Mr. E. were not included in the list of Bulgarian clinical treatments. Moreover, if those treatments were reimbursable, they would have been available in a Bulgarian healthcare institution. Therefore, it decided that the lower Court should have ruled on whether such treatment could be given in such an institution within a period which would not endanger the state of health of the person concerned. As the treatment was not available in Bulgaria, the administrative judge referred the question for a preliminary ruling to the Court of Justice.

Preliminary questions referred to the Court

After asking whether the lower Court was bound to the higher Court's decision, even if there was reason to assume that these directions were inconsistent with EU law, the main preliminary question concerned the interpretation of the concept of a reimbursable list of treatments.

For prior authorisation disciplined by Art. 22(1)c of regulation 1408/71, if the treatment cannot be given in the territory of the Member State of affiliation, is it sufficient that the treatment is included within the benefits provided for under the legislation of the first mentioned Member State even if that legislation does not expressly stipulate the specific method of treatment?

Are the provisions of the regulation (Art. 49 and 22) in conflict with a national provision that provides that an insured person has the right to receive, in part or in full, reimbursement for the value of medical expenses abroad only if that person has received prior authorisation?

Reasoning of the Court

The Court observed that, in principle, it is not incompatible with EU law for a Member State to draw up limited lists of reimbursable medical services for its social security system. It is solely up to the national bodies to determine whether such treatments fall within the provisions of the list of benefits. In this case, the national Court had to decide whether the treatment received by Mr. E. in Germany fell under clinical care protocols (par. 61).

If the list of medical treatments available at a national level did not expressly specify the method applied in the concrete case, but only defined types of treatments, it was for the competent home institution to assess by applying the usual principles of interpretation and on the basis of objective and non-discriminatory criteria and taking into consideration all the relevant medical factors and available scientific data, whether that treatment method corresponded to benefits provided for by the legislation of that Member State. If such was the case, prior authorisation cannot be refused.

In order to assess whether a treatment with the same degree of effectiveness for the patient can be obtained in good time within the Member State of residence, the competent institution is required to take into consideration all the circumstances which characterize each specific case, taking into account not only the clinical picture of the patient when authorization is requested but, if necessary, the degree of pain or the nature of the infirmity of the latter, which could, for example, make it impossible or excessively difficult to exercise a professional activity, but also its antecedents (par. 63).

Conclusion of the Court

With regard to medical treatment which cannot be given in the Member State in whose territory the insured person resides, prior authorisation required under the Regulation on coordination of social security systems cannot be refused if the following conditions are met.

Where the **list of treatments** provided at the national level does not expressly and precisely specify the treatment method applied but defines **types of treatment** reimbursed by the competent institution, then the treatment can be reimbursed if it satisfies the following requirements. Firstly, the treatment method in question corresponds to types of treatment included in that list, applying the usual principles of interpretation and on the basis of objective and non-discriminatory criteria, taking into consideration all the relevant medical factors and the available scientific data. Moreover, the treatment may be reimbursed if no alternative treatment which is equally effective can be given without undue delay in the Member State on whose territory the insured person resides

Where it is established that a refusal to issue the authorisation required under Article 22(1)(c)(i) of Regulation No 1408/71, and following amendments, was unjustified, when the hospital treatment has been completed and the related expenses incurred by the insured person, the national Court must oblige the competent institution, in accordance with national procedural rules, to reimburse that insured person in the amount which it would ordinarily have paid if authorisation had been properly granted.

That amount is equal to that determined in accordance with the provisions of the legislation to which the institution of the Member State on whose territory the hospital treatment was given is subject. If that amount is less than that which would have resulted from application of the legislation in force in the Member State of residence if hospital treatment had been provided there, complementary reimbursement corresponding to the difference between those two amounts must in addition be made by the competent institution.

Elements of judicial dialogue

The reason to focus so deeply on cross-border healthcare in a casebook which deals with the effective protection of the right to healthcare in the European Union rests on the importance that the case-law of the CJEU had on the development of this area of law and, furthermore, on the indirect influence that this new discipline had on national systems and on the effective guarantee of the right to healthcare within state healthcare services.

The starting point for any consideration of the CJEU's case law on healthcare rights is the 1984 Luisi and Carbone decision.[74] It actually paved the way for all subsequent case law of the CJEU in the field of healthcare (not only for those decisions related to patients' mobility). On that occasion, the Court stated that not only providers of services, but also recipients of those services are included within the scope of the protection of the freedom of movement. This means that the freedom to provide services, as depicted in the Treaties, includes a freedom, for those who want to use these services, to go to another Member State in order to receive a service there, without undue restrictions. The innovative content of the decision is that healthcare shall be considered as a service under the provisions of the Treaties.[75] This statement opened the box for the subsequent interpretation of the CJEU on freedom to provide services in healthcare matters.[76]

The decision in E. represents a further consequence of the cross-border healthcare saga, whose leading case is represented by the 2006 Watts decision (see *infra*). As we will see in the following paragraphs, after Luisi and Carbone, the Court of Justice was required to intervene on issues concerning cross-border healthcare on several occasions. Since the 1998 Kohll decision, interpretation of the Regulation on the coordination of social security systems was oriented towards promoting free movement of EU patients to receive healthcare abroad.[77]

E. added that, even if treatment is not expressly included in the list of treatments reimbursable, it is enough that it is of the same type of treatments provided. This decision adds a new element because it was therefore possible to obtain a treatment abroad which is more advanced than those available in the home health system. This is possible only if the list of treatments available in the state of residence comprehends the typology of treatments and if within those typologies more advanced treatments are included, even if they are not expressly specified.

Impact on national case law in Member States other than that of the Court referring the preliminary question to the CJEU

Spain

Judgement of the Superior Court, Cantabria, Social jurisdiction, 5 October 2006: an insured person, authorized by the Spanish competent institution to go to France to receive treatment appropriate to his condition, is not entitled to a reimbursement of travel, accommodation, and subsistence costs related to that medical treatment, because the insured person would not be entitled to the reimbursement of those costs where the treatment would have been provided in a hospital covered by the Spanish national system. Note that the case was decided five years before the E. case and the Directive's approval.

[74] Joined cases 286/82 and 26/83, Graziana Luisi and Giuseppe Carbone v Ministero del Tesoro, 31 January 1984, ECLI: ECLI:EU:C:1984:35.

[75] Luisi and Carbone, para 16: "It follows that the freedom to provide services includes the freedom, for the recipients of services, to go to another member state in order to receive a service there, without being obstructed by restrictions, even in relation to payments and that tourists, persons receiving medical treatment, and persons travelling for the purpose of education or business are to be regarded as recipients of services."

[76] See Case 131/85, Gül, 1986 ECR 1573; Grogan (the so-called abortion information case).

[77] Council Regulation (EEC) 1408/71 of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community, now replaced by the European Parliament and Council Regulation (EC) 883/2004 of 29 April 2004 on the coordination of social security systems.

In the proceedings, the Spanish Court referred a **preliminary ruling** to the ECJ on the interpretation of Article 22, section 1, letter c) and Article 22, section 2 of the Council Regulation (ECC) No 1408/71. The ECJ Decision was June 15, 2006, Manuel Acereda c. Servicio Cántabro de Salud, C-466/04.

Judgement of the Superior Court, Galicia, Social Jurisdiction, 29 May 2014:

The Spanish Court decided that an insured person, authorized by the Spanish competent institution to go to France to receive treatment appropriate to his condition, was entitled to the reimbursement of travel and medical costs related to that medical treatment, because, according to the Spanish rules applicable at the time of the events, the insured person would be entitled to the reimbursement of those costs where the treatment would have been provided in a hospital covered by the Spanish national system. The Spanish Court based its decision on the interpretation of Article 49 EC established in the ECJ case C-372/04 Watts [2006].

1.2 Procedural Requirements

In the landmark *Watts* case in 2006,[78] the CJEU went further in specifying its previous case-law, to the point that it stated that the refusal of prior authorisation cannot be justified on the mere existence of waiting lists in the health service of affiliation.

The case concerned an English woman that went to France for a hip replacement without prior authorisation of the competent English health institution. The woman's position was that the English NHS could not grant her the medical intervention within a time limit that was compatible with her clinical condition, whereas the NHS argued that the system of waiting lists is built in a non-discriminatory way based on evaluation of the clinical needs of patients.

To solve the case, the Court of Justice analysed the organisation of the English health service in depth, which is completely publicly funded and universal in nature (i.e. individuals affiliated with the service are all equal with regard to point of access to healthcare treatments and clinical priorities are dealt with through waiting lists). As a result, EU judges provided a strong contribution to the definition of undue delay in access to medical treatment, as a reason for cross-border healthcare, by stating that it must be considered with reference to an individual patient's clinical needs.

As an aftermath of the decision, the EU legislature began working on a Directive to harmonise national rules and to give legislative shape to the principles progressively established by the Court of Justice. At the same time, the decision raised harsh criticism because it was considered to be unbalanced towards a mere consumeristic approach to healthcare services.[79] For example, it was argued that "EU institutions have misconceived the relationship between the economics of free market individualism and the politics of social welfare in the EU."[80] More precisely, the peak of criticism towards CJEU activism dealt with

[78] C-372/04 Watts [2006] ECR I-04325. ECLI:EU:C:2006:325

[79] Dougan M, Stalford H. The Impact of Migration on Healthcare in the European Union. *Maastricht Journal of European and Comparative Law*. 2007;14(3):209-212.

[80] Newdick, C. (2011) *Disrupting the community: saving public health ethics from the EU internal market.* In: van de Gronden, J., Szyszczak , E., Neergaard , U. and Krajewski, M. (eds.) Health Care and EU Law. Legal Issues of Services of General Interest. Asser Press, The Hague, pp. 211-239, 211.

the individualistic and libertarian approach to healthcare, without due consideration to the difficult needs of balancing national healthcare services.

From this viewpoint, CJEU case-law was summarised in these terms: "firstly, patients have cross-border rights to hospital care which cannot be modified solely by reference to economic constraints, secondly, the right may become enforceable once the patient has a health need generally recognised by international medical science which cannot be treated at home without undue delay. If these conditions are satisfied, then the patient may obtain treatment in a "host" state and return to present the bill to his "home" health authority. Clearly, this promotes an individualistic approach to healthcare resource allocation."[81]

Question 2 – Undue Delay

What is the meaning of undue delay in access to medical treatments? Are waiting lists a possible cause of undue delay? In light of the principle of non-discrimination in access to medical treatments, could the provision of waiting lists be a possible cause of inequality in access to medical treatments? Can an individual obtain medical treatment abroad, paid for by the home healthcare institution, if undue delay is caused by waiting lists? Which remedies are available for the individual in case the waiting list is irrational? Are they effective?

The analysis is based on the *W.* case (C-372/04)

The case

Ms. W. suffered from hip arthritis and had inquired at her referral healthcare facility in England about the possibility of having surgery abroad using an E 112 form (within the framework of Regulation 1408/1971 and following amendments, which have now been replaced by Regulation 883/2004).

The local health authority classified her clinical case as "habitual," a category to which a waiting time of about one year is attributed. In the meantime, the health administration refused her authorization for surgery abroad, without taking the second requirement provided for by Art. 22 of Reg. 1408 (the health service could be obtained "without undue delay") into account. After filing an appeal against this denial, Ms. W.'s clinical condition was re-examined and her case was reconsidered with a four-month waiting period, but the prior authorisation to obtain the medical treatment abroad was refused again.

Faced with a new refusal of authorization, the woman still underwent surgery in France and continued the judicial procedure in order to obtain reimbursement for the medical expenses incurred. The Court of Appeal (England & Wales), Civil Division, invested with the appeal, decided to suspend the proceedings and to submit a request for a preliminary ruling before the Court of Justice of the EU.

Preliminary questions referred to the Court

The national judge elaborated several questions for the Court of Justice, ranging from the features of a universal healthcare service vis-à-vis EU law, to the legitimacy of the provision of waiting lists. These questions were raised in light of the freedom of circulation of EU citizens, restrictions that could

[81] Newdick, C. (2011) *Disrupting the community: saving public health ethics from the EU internal market*, cit., 219.

eventually be provided at a national level and freedom to provide (and receive) services in the territory of the EU.

With regard to "undue delay" and "procedural requirements," the national judge asked:

In determining whether treatment is available "without undue delay" for the purposes of Article 49 EC, to what extent is it necessary or permissible to give regard to waiting times; the clinical priority accorded to the treatment by the relevant NHS body; the management of the provision of hospital care in accordance with priorities aimed at giving best effect to finite resources; the fact that treatment under the NHS is provided free at the point of delivery; finally, the individual medical condition of the patient, and the history and probable course of the disease in respect of which that patient seeks treatment.

Then, the Court of Appeals also asked the CJEU how to correctly interpret the words "within the time normally necessary for obtaining the treatment in question" as provided by Art. 22(1)(c) of Regulation No 1408/71. The Court asked whether this expression made reference to the same criteria applicable in determining the concept of "undue delay" for the purposes of Art. 49 EC.

Other issues raised concerned the amount of reimbursable costs.

Reasoning of the Court

Referring to previous judgments (*Initan, Smits and Peerbooms, Müller Fauré and Van Riet*), the Court stated that, in order to assess whether a treatment presenting the same degree of effectiveness for the patient can be promptly obtained in the Member State of residence, the competent institution is required to take into consideration the set of circumstances that characterize each specific case, taking due account not only of the patient's clinical situation at the time the authorization is requested and, if necessary, the degree of pain or the nature of the illness. This has to be evaluated with reference to his/her professional activity and his/her medical history.

However, "where the demand for hospital treatment is constantly rising, primarily as a consequence of medical progress and increased life expectancy, and the supply is necessarily limited by budgetary constraints, it cannot be denied that the national authorities responsible for managing the supply of such treatment are entitled, if they consider it necessary, to institute a system of waiting lists in order to manage the supply of that treatment and to set priorities on the basis of the available resources and capacities."

Waiting lists, therefore, arise from objectives relating to the planning and management of the supply of hospital care pursued by the national authorities on the basis of generally predetermined clinical priorities. In this context, when the patient cannot receive the treatment in question without undue delay, it means that the waiting time exceeds the period which is acceptable for an objective medical assessment of the clinical needs of the person concerned, in light of their medical condition and the history and probable course of their illness, the degree of pain they are in and/or the nature of their disability at the time when the authorisation is sought (par. 68).

In light of the abovementioned conditions, the CJEU set a system of **procedural requirements** that the scheme of prior authorisation must fulfil in order to be considered objectively justifiable under EU law. This system must be strictly fulfilled because it derogates from a fundamental freedom of the Treaty. Therefore, the system of prior authorisation that the patient must follow to be entitled to obtaining medical treatment (hospital care) abroad at the expense of the home healthcare institution must in any

event be based on objective, non-discriminatory criteria which are known in advance, in such a way as to circumscribe the exercise of the national authorities' discretion, so that it is not used arbitrarily (par. 116).

Such a system must furthermore be based on a procedural system which is easily accessible and capable of ensuring that a request for authorisation will be dealt with objectively and impartially within a reasonable time and refusals to grant authorisation must also be capable of being challenged in judicial or quasi-judicial proceedings (par. 116).

Conclusion of the Court

Article 49 EC applies where a person whose state of health necessitates hospital treatment goes to another Member State and there receives such treatment for consideration. It does not preclude reimbursement of the cost of hospital treatment to be provided in another Member State from being made subject to the granting of prior authorisation by the competent institution.

A refusal to grant prior authorisation cannot be based merely on the existence of waiting lists (even if they are based on the need to safeguard the general equilibrium of the healthcare service involved), without carrying out an objective medical assessment of the patient's medical condition. This assessment must involve the history and probable course of their illness, the degree of pain they are in and/or the nature of their disability at the time when the request for authorisation was made or renewed. Where the delay arising from such waiting lists appears to exceed an acceptable time with regard to an objective medical assessment of the abovementioned circumstances, the competent institution may not refuse the authorisation sought on the grounds of the existence of those waiting lists.

The refusal of prior authorisation must be challengeable in judicial or quasi-judicial proceedings.

Elements of judicial dialogue

As already noted, the discipline progressively drawn by the CJEU is based upon free movement provisions and on the EU Regulation on the coordination of social security systems. Indeed, the Regulation provision on free movement of workers represents the starting point that gave origin to the Court of Justice's saga on cross-border healthcare.

The 1998 Kohll decision originated from a question surrounding a preliminary ruling raised by the Luxembourg Cour de Cassation. The CJEU was required to verify whether the Treaty Articles on free movement of services (now Arts. 52 and 62 TFEU) precluded reimbursement of the costs of benefits obtained in another Member State subject to prior authorisation of the home healthcare institution and if the compatibility of the authorisation regime somehow changed if the reason for such a rule was to maintain a balanced medical and hospital service.[82]

To summarize: is the system of prior authorisation a restriction on the freedom to provide (and receive) services in the territory of the EU? If this is the case, could this restriction be justifiable under the Treaty provision? If yes, could the need to maintain a balanced medical service be regarded as a valid justification?

The CJEU held that the provision of **prior authorisation** established by the national healthcare institution for the reimbursement of costs for medical care incurred abroad does not preclude EU citizens from travelling to another Member State to obtain medical service, but nevertheless represents a

[82] C-158/96 Kohll [1998] ECR I-01931. ECLI:EU:C:1998:171.

restriction on the freedom to provide services. In fact, a similar authorisation is not required for costs incurred within the State of affiliation. This principle was confirmed in Watts.

The CJEU examined whether this barrier on the freedom to provide services (to obtain services) was **objectively justified** (Kohll, para 35). In the words of the Court: "aims of a purely economic nature cannot justify a barrier to the fundamental principle of freedom to provide services," but "it cannot be excluded that the risk of seriously undermining the financial balance of the social security system may constitute an overriding reason in the general interest capable of justifying a barrier of that kind" (Kohll, para 41).

Treatment in the concrete case was quite limited (dentist care for the daughter of the appellant). Thus, the Court found that the need to safeguard the internal financial balance of the healthcare service was not relevant to the case. It also examined whether there were any justifications on grounds of public health that could make the restriction legitimate, but found that the protection of the quality of medical services provided in the Member State and the objective of maintaining the general balance of the medical service could abstractly fall within the general justification of the grounds of public health, but they were not met in the concrete case.

This decision generated opposite reactions: on the one hand, it was read as the starting point for the new EU freedom of medical services and was intended as the launch of a consumer oriented health Union. On the other hand, Member States, under the fear of being forced to pay for medical treatment received abroad by their patients, started to limit the impact of the decision. For example, some States argued that "hospital services did not constitute an economic activity within the meaning of Article 57 of the TFEU, particularly when they are provided in-kind and free of charge under the relevant sickness insurance scheme."[83]

Inevitably, the tension between EU institutions' willingness to open healthcare services to mobility and intra-European exchange and a not-irrelevant trend towards a consumer-oriented approach to healthcare treatments, on the one hand, and the strong reaction of Member States seriously concerned about the maintenance of the internal balance of healthcare services, on the other, soon brought intense litigation before the CJEU.

To summarize, the CJEU progressively specified whether **national restrictions** on the freedom to travel for medical services (such as a regime of prior authorisation or the exclusion of some treatments) could be **objectively justifiable** under the Treaty, by verifying whether the risk of distortion of economic equilibrium of the national healthcare system was real, with respect to the specific medical treatment sought by the patient.

In this respect, the CJEU confirmed that **hospital care** also fell under the meaning of services and, therefore, Articles 56 e 57 TFEU should apply. For the purposes of the right to reimbursement of medical expenses incurred abroad, in other words, there was no need to distinguish between hospital and non-hospital care.[84]

In any case, considering the need to safeguard the internal balance of healthcare services both as a financial necessity of Member States and as a way to ensure healthcare service open to all that contributes

[83] H.J. Meyer, Current legislation on cross-border health care in the European Union, in I.G. Cohen, The Globalization of Health Care: Legal and Ethical Issues, Oxford 2013, 91.
[84] C-157/99 Smits e Peerbooms [2001] ECR I-05473. ECLI:EU:C:2001:404.

to attaining a high level of health protection, the CJEU stated that, in general terms, prior authorisation for hospital care abroad could be acceptable under EU law, only if some conditions were met. In particular, the treatment required must be included in the list of benefits of the healthcare system of affiliation and must be considered "normal in the professional circles concerned"[85] and that the individual patients' medical situation must require that treatment.[86]

Subsequent decisions went on to further specify these assumptions. For example, in Vanbraekel the reimbursable amount was clarified, considering the different nature of national healthcare systems, whereas Herrera excluded the reimbursement of complementary expenses, in addition to the cost of the treatment obtained, such as travel, accommodation, and subsistence costs that the patient or any person accompanying her incurred.[87]

Interestingly enough, the CJEU gradually developed some **procedural requirements** that must be followed by State authorities during the evaluation of patient authorisation. The conditions for granting authorisation must be justified under imperative criteria – which were set out since Smits and Peerbooms and later specified further – and must not exceed what is objectively necessary and proportionate. The issue of authorisation must be funded on objective and non-discriminatory parameters known in advance, so that the exercise of discretionary power by State authorities is limited.[88] Furthermore, refusals to grant authorisation shall be challengeable in judicial or quasi-judicial proceedings.[89]

Impact on national case law in Member States other than that of the Court referring the preliminary question to the CJEU

Spain

Tribunal Superior de Justicia, Madrid, Resolucion 405/2018, of 12/06/2018: a woman was refused reimbursement for medical expenses incurred during a staying abroad in the context of the Erasmus programme. The Court stated that the health authority should have informed her that she could have had access to the reimbursement procedure provided by the cross-border healthcare framework, instead of opposing a mere refusal based on the fact that the woman did not satisfy the requirements for reimbursement she had applied for.

Judgment of the Superior Court, Islas Canarias, Social Jurisdiction, 22 October 2008:

The Court decided that a person insured in Spain was entitled to the reimbursement of costs (35.000 euros) related to medical treatment provided in an emergency in a hospital covered by the German national system. Moreover, the medical assessment of the emergency didn't have to be approved by the Spanish competent institution (Article 22.1.a), i) Council Regulation (ECC) No 1408/71). The decision referred to ECJ case C-120/95 Decker [1998].

Judgments of the Superior Courts, Extremadura, Social Jurisdiction, 15 February 2018; Castilla y León, 31 October 2016. The issue here was whether a person insured in Spain was entitled to the reimbursement of medical costs when the service was provided by a private Spanish hospital. The Court interpreted the national law according to ECJ case C-385/99 Müller-Fauré e van Riet [2003] and Article 22.2 of the

[85] C-157/99 Smits e Peerbooms, para 43
[86] It is worth pointing out that a further distinction between hospital and non-hospital care was later introduced by the Müller-Fauré decision in 2003. See C-385/99 Müller-Fauré e van Riet [2003] ECR I-04509. ECLI:EU:C:2003:270.
[87] Case C-466/04 *Acereda Herrera* ECLI:EU:C:2006:405, para. 39.
[88] *Smits e Peerbooms*, para. 90; *Müller-Fauré e van Riet*, para. 85; *Watts*, para. 116; *E.*, para 44.
[89] *Watts*, para. 116.

Council Regulation (ECC) No 1408/71: "authorisation may be refused (…) only if treatment which is the same or equally effective for the patient can be obtained without undue delay in an establishment which has concluded an agreement with the fund."

1.3 The Impact of CJEU Caselaw on the Directive on Patient's Rights in Cross-Border Healthcare

After such intense litigation, a clarification of the principles progressively affirmed by the CJEU was felt to be necessary both by EU institutions and Member States.

Moreover, the need for a Directive on patient mobility also arose during the legislative process that led to the Services Directive 2006/123/EC, from which healthcare, because of its particular nature, was finally excluded.[90] The patients' Rights Directive was finally approved in 2011, after a very long drafting process which attests to how many issues were at stake.[91] It has three fundamental objectives, which are: the setting of **rules on procedures** and **reimbursement of costs** for cross-border healthcare; the definition of Member States' responsibilities in cross-border healthcare and correlatively the establishment of measures to ensure patients' safety and, finally, the setting of a broad framework of cooperation for Member States in the field of healthcare, from reference networks for highly specialised care and rare diseases, to the exchange of good practices. A central part of the act concerns the **procedures for cross-border healthcare** and reimbursement of costs, which is also related to the problem of **effective protection** of fundamental rights.

First of all, the Directive clarifies that access to medical care in a Member State other than that of affiliation runs on two parallel tracks under EU law. In fact, the Regulation on the coordination of social security systems shall be the main framework for regulating access to healthcare abroad. The Directive provisions are basically residual: "Patients should not be deprived of the more beneficial rights guaranteed by the Union Regulations on the coordination of social security systems when the conditions are met." (recital 31). The application of the Directive is therefore limited to those cases that do not fall under the Regulation provisions.

The Directive outlines the limited circumstances in which Member States may lawfully restrict freedom of movement for medical treatment. The Directive provides for a detailed procedural framework that today regulates cross-border healthcare provisions across the entire EU territory.[92] These rules have been defined first by case law.

Briefly, patients can obtain medical treatments in another MS and be reimbursed mainly freely afterwards, unless they need **highly specialised or hospital care**. In this case, they need to obtain **prior authorisation** from the healthcare institution of affiliation. More specifically, the Member State of affiliation shall reimburse the costs for medical care received in another State, if this treatment is among the benefits to which the insured person is entitled in the Member State of affiliation (Art. 7.1). Member States shall determine the competent institution that must deal with the reimbursement request of the patient and the costs to be reimbursed are up to the level that the affiliation institution would have paid if that treatment had been provided within the territory, without exceeding the actual costs of the

[90] M. Peeters, Free Movement of Patients: Directive 2011/24 on the Application of Patients' Rights in Cross-Border healthcare, in European Journal of Health Law, 19, 2012, 29-60, 30.
[91] S. De la Rosa, The Directive on Cross-Border Healthcare or the art of Codifying Complex Case Law, in Common Market Law Review, 49, 2012, 15-46, 26
[92] Articles 7, 8, and 9.

treatment received (Art. 7.4). To make these rights effective, Member States shall also define internal procedures for prior authorisation, including the individual right to challenge a refusal within a judicial or quasi-judicial mechanism.

Prior authorisation may be requested only in the circumstances described in Art. 8, which basically involve hospital care and highly specialised care. The reason for this provision must obviously be found in the principles already stated by the CJEU and in the need to maintain a financial balance of national healthcare services. Prior authorisations might also be requested if the care concerned could be risky for the patient. Art. 8 also clarifies that in some given circumstances the home institution may refuse the prior authorisation, namely for safety reasons. Finally, there is also **a clinical condition that may lead to a refusal** of prior authorisation that echoes both the Regulation provisions and the principles set by the CJEU in its case-law, especially in Watts: "this healthcare can be provided on its territory **within a time limit which is medically justifiable**, taking into account the current state of health and the probable course of the illness of each patient concerned" (Art. 8.6.d).

The last provision concerning cross-border healthcare (Art. 9) is dedicated to the procedures that have to be followed by patients in order to obtain reimbursement. These rules have found slightly different national implementation, due to the different schemes of administrative proceedings. Art. 9 provides for a detailed set of procedural rights which contribute to the definition of the substantial right to cross-border healthcare. In this field, characterised by decisions of a highly technical nature, the **proceduralisation of rights** is the only way to ensure their effectiveness.

This was a precise and conscious choice of both the CJEU and of the EU law-maker: developing concrete standards of healthcare access or treatment and the sharing of competences discussed above would not have been possible under EU law. Instead, a detailed "framework of intertwining principles" was developed first by the CJEU to evaluate Member State rules in the area of patient mobility and, then, it was similarly adopted in the Directive to influence the setting of national rules both in this area and indirectly in the field of access to healthcare.[93] In other words, **procedural rights** force individual behaviour but also national choices: for example, as a consequence of the Directive, national healthcare systems should be more careful in the organisation of waiting lists and in the evaluation of the clinical situation of the individual patient included in a waiting list.

As for the other objectives, the Directive also instituted National Contact Points, to provide information on cross-border healthcare which boosts the cooperation among MSs in key areas such as the treatment of rare diseases, telemedicine through European Reference Networks, and encourages the exchange of good practices among Member States. Above all, the main scope of the Directive was to stop litigation before the CJEU and to definitively clarify the rules concerning healthcare abroad.

Question 3 – A Wide Interpretation of Undue Delay

Could a structural lack of medication and basic medical supplies be claimed as "undue delay?"

The analysis is based on *Petru* (C-268/13).

The case

[93] S.L. Greer, T. Sokol, Rules for rights: European Law, Health Care and Social Citizenship, in European Law Journal, 20(1), 2014, 66-87, 79.

Ms. Petru suffered from serious cardiovascular disease and had undergone surgery following a heart attack. Following the worsening of her health condition, during another hospitalization, the medical examinations to which the lady was subjected led to the decision to proceed with an open-heart operation to replace the mitral valve and introduce two stents.

The applicant therefore decided to go to Germany to undergo this surgery, the cost of which amounted to a total of € 17,714.70.

The choice of a German hospital was determined for Ms. Petru by the lack of material conditions in the Institute of Cardiovascular Diseases of Timişoara (Romania). Before the trip, the applicant requested her enrollment in the sickness fund to pay for the costs of the surgery, but her application (based on form E112) was rejected because, according to the health facility, the requested medical service was available within a reasonable amount of time in Romania.

The case before the Court of Justice of the EU concerned the interpretation, under EU law, of the concept of undue delay in access to medical treatment. Ms. Petru claimed that the enduring and structural lack of medication and basic medical commodities should be interpreted as a reason that forbid the patient to obtain the care she needed in due time.

Preliminary questions referred to by the Court

In the second subparagraph of Article 22(2) of Regulation No 1408/71, is the requirement that the person concerned be unable to obtain treatment in the country of residence which is to be construed as categorical or reasonable. In other words: if the required surgery could, in technical terms, be carried out in due time in the country of residence (i.e. specialists are present there and have the same level of specialist skills as those abroad), does a ***lack of medicines and basic medical supplies and infrastructure*** *mean that such a situation can be equated with a situation in which the necessary medical treatment cannot be provided?*

Reasoning of the Court

In assessing the patients' request for prior authorisation to obtain medical treatment abroad, the competent health institution must take **the lack of medication and basic medical supplies and infrastructure** into account as well. The relevant provision of the Regulation on the coordination of social security systems (Art. 22.2) does not distinguish between the different reasons for which a particular treatment cannot be provided in good time. Clearly however, such a lack of medication and of medical supplies and infrastructure can, in the same way as a lack of specific equipment or particular expertise, make it impossible for the same or equally effective treatment to be provided in good time in the Member State of residence (par. 33).

However, to determine whether it is actually impossible to obtain care in due time, it is necessary to take **all the hospital establishments in the Member State of residence** into account. The applicant, in fact, had the right to approach any other medical establishment in Romania. Therefore, it was for the referring Court to determine whether that treatment could have been carried out within three months in another hospital establishment in Romania.

Conclusion of the Court

The relevant provision of the EU Regulation must be interpreted as meaning that the authorisation necessary cannot be refused due to a lack of medication and basic medical supplies and infrastructure

that the hospital treatment concerned cannot be provided in good time in the insured person's Member State of residence. The question whether it is possible or not must be determined with reference to all the hospital establishments in that Member State capable of providing the treatment in question and with reference to the period within which the treatment can be obtained in good time.

Elements of judicial dialogue

In this case, it is very important to underline that the Court linked a lack of medical supplies to the issue of undue delay, as provided by Art. 22.2 of the Regulation. To do so, the Court cited its previous decision in which it dealt with the concept of undue delay in access to medical treatments. See in particular: Inizan, C 56/01, paragraphs 45 and 60; Watts, paragraph 61; E., paragraph 65.

In order to determine whether the treatment can be obtained in due time in the Member State of residence, the competent institution must consider the circumstances of the specific case and the individual situation of the patient. As provided by previous case law, this consideration must include the degree of pain or the nature of the patient's disability (also in relation to their professional activity), and the patient's medical history (Inizan, paragraph 46; Watts, paragraph 62, E., paragraph 66).

It is relevant to point out that, in accordance with arguments made by the national government, the patient has the right to obtain treatment in any other medical establishment in the Member State of residence. Therefore, evaluation of the availability of medical supplies must be done with reference to the entire home health system, not only in the location in which authorisation is sought. This was an important specification made by the CJEU in the Petru decision.

Impact on national case law in Member States other than that of the Court referring the preliminary question to the CJEU

Italy

Council of State, sez III, decision 05861/2018, concerning refusal of access to an Italian couple seeking assisted reproduction with gamete donation abroad. The Council of State annulled the health authority's denial because it did not indicate in which Italian structures the treatment sought by the applicants was available.

1.4 Effectiveness of Remedies in Recent Times and New Issues

After the Directive was adopted, litigation before the Court of Justice has been substantially reduced, with the only exception being requests for preliminary references based on pre-existing cases (which led for example to the *Petru* decision in 2013) and to secondary issues concerning the mutual acknowledgement of medical prescriptions.

This should be considered proof of success of the Directive. Indeed, its main aim was to provide for a clear and effective procedural set of rules to clarify patients' rights in cross-border healthcare and the circumstances under which a state institution can legitimately refuse to pay for healthcare abroad.

To summarize, the phenomenon of cross-border healthcare and its complex regulation at the EU level serves as a good example of several interactions between State and EU roles and competences in the effective guarantee of fundamental rights.

First, cross-border healthcare demonstrates that, even though the EU does not have direct competence over the organisation of healthcare services, it can significantly influence state provisions on treatments

and services. Second, it touches upon the delicate chords of enduring tensions between EU and state legal discipline on social rights: enforcing EU Treaties and giving shape to its principles requires state action more and more on social rights and, therefore, a strong public economic commitment to the granting of services. Third, it is strictly linked to realizing the principle of solidarity that, in several fields, has been challenged and questioned by states forced to enact policies and regulations to fulfil EU obligations. Finally, the ongoing pandemic emergency that has impacted most European countries has demonstrated to all of us the essential need for a strong and structured cooperation among MSs in the field of healthcare, which is the only concrete solution to prepare for and seriously face global health challenges.

Question 4 - Cross-Border Healthcare and Non-Discrimination

Shall an authorisation for medical treatment in another Member State be granted, when treatment is available in the State of residence, but the method of treatment used is contrary to that person's religious beliefs?

The analysis is based on *Veselības ministrija*, (C-243/19)

The case

The case arose in Latvia. The applicant's son, a minor who suffered from a congenital heart defect, had to have open-heart surgery. The applicant refused to consent to the use of blood transfusion during the operation, on the ground that he was a Jehovah's Witness.

As the operation in question was not available in Latvia without the use of blood transfusion, the applicant requested that the Latvian National Health Service issue authorisation for his son to receive such surgery abroad in Poland. The Latvian health service refused to give prior authorisation. The Ministry of Health upheld the health service's decision, on the grounds that the surgery at issue could be carried out in Latvia and that a person's medical situation and physical limitations alone must be taken into consideration for issuing the form.

The applicant then initiated an action before the administrative Court in order to obtain a favourable measure for his son, recognising the right to receive scheduled healthcare abroad. His action was again dismissed both in the first instance and in appeals. The latter Court found that the medical procedure at issue (blood transfusion) in the main proceedings, treatment which is publicly funded in Latvia, was indeed necessary to avoid the irreversible deterioration of the vital functions or health of the applicant's son during the surgery. However, at the time the request for authorisation was under consideration the hospital confirmed that that procedure could be carried out in Latvia. Furthermore, the Court found that it was not possible to infer from the applicant's refusal of such a transfusion that the hospital was unable to provide the medical procedure in question.

The applicant in the main proceedings brought an appeal on a point of law before the referring Court, arguing, specifically, that he was a victim of discrimination since the vast majority of those affiliated to the health system were able to receive the healthcare at issue without having to give up their religious beliefs. In the meantime, the son had heart surgery in Poland. The referring Court was uncertain whether the Latvian health authorities were entitled to refuse authorisation for treatment solely on the basis of medical criteria or whether they were also required to take the applicant's religious beliefs into account.

Preliminary questions referred to the Court

The preliminary question concerns the interpretation of Art. 20(2) of Regulation No. 883/2004 (which replaced Art. 22.2 of Regulation No. 1408/71), in conjunction with Art. 21.1 of the EU Charter of Fundamental Rights. On these bases, can a Member State refuse to grant authorisation to receive medical care abroad if the treatment required is available in the Member State of residence, but the method used is contrary to the person's religious beliefs?

The same preliminary question also applies to Art. 56 TFEU and Art. 8(5) of Directive 2011/24, read in conjunction with Art. 21.1 of the EU Charter of Fundamental Rights. Under the Directive's provisions, hospital care is subject to prior authorisation; the care required is available in the Member State of residence, but the method of treatment used is contrary to that person's religious beliefs.

Reasoning of the Court

1. In the case, the operation at issue was necessary in order to avoid irreversible deterioration in the vital functions or state of health of the applicant's son, taking the examination of his condition and the foreseeable course of his illness into account. Furthermore, said operation could be carried out in Latvia using blood transfusion and there was no medical justification for employing another method of treatment. The applicant opposed such a transfusion on the sole ground that it conflicted with his religious beliefs and he expressed a wish for the operation to be carried out without a transfusion, which was not possible in Latvia.

In light of Regulation provisions, the assessment consisted exclusively in examining the patient's medical condition and medical history, the probable course of his or her illness, the degree of his or her pain and/or the nature of his or her disability, and **did not involve taking the patient's personal choice into account** with regard to treatment. Thus, the decision by the Latvian authorities to refuse the authorisation cannot be considered incompatible with that provision.

Nevertheless, the applicant invoked a **violation of Art. 21 of the CFREU**, because of **religious discrimination**. Since the issue was within the field of application of EU law and as the principle of non-discrimination is mandatory as a general principle of EU law, the Court stated that it was for the referring Court to ascertain whether the refusal to grant the applicant prior authorisation established a difference in treatment based on religion. If that were the case, the national judge must ascertain whether that difference in treatment was based on an objective and reasonable criterion.

However, in the case in question, it appeared that the national legislation at issue in the main proceedings was formulated in a neutral way and did not give rise to direct discrimination based on religion. It was also important to examine whether such refusal brought about a difference in treatment which was indirectly based on religious beliefs. In the concrete case, there was no medical justification for the applicant's son not to receive treatment in Latvia.

Thus, on the one hand, a difference in treatment was effectively made on the grounds of religion. On the other hand, however, the context was one of public health, which also found protection within the UE Treaty. In these circumstances, the need to maintain a **balanced healthcare service is an objective justification for a refusal of prior authorisation**. In a situation where benefits in kind provided in the Member State of stay give rise to higher costs than those relating to benefits which would have been provided in the insured person's Member State of residence, the obligation to refund in full may give rise to additional costs for the Member State of residence. If the competent institution were obliged to take account of the insured person's religious beliefs, such additional costs could, given their unpredictability

and potential scale, be capable of entailing a risk in relation to the need to protect the financial stability of the health insurance system, which is a legitimate objective recognised by EU law.

2. The second preliminary question concerned the interpretation of the Directive's provisions. In particular, the reimbursement provided for by Article 7 of Directive 2011/24 may, therefore, be subject to a twofold limit. First, it is calculated on the basis of the fees for healthcare in the Member State of affiliation. Second, if the cost of healthcare provided in the host Member State is lower than that of the healthcare provided in the Member State of affiliation, that reimbursement does not exceed the actual costs of the treatment received.

Since reimbursement of healthcare under Directive 2011/24 is subject to that twofold limit, the healthcare system of the Member State of affiliation is not liable to be faced with a risk of additional costs linked to the assumption of cross-border healthcare costs. Accordingly, in the context of Directive 2011/24, and by contrast with situations governed by Regulation No 883/2004, the Member State of affiliation will not, as a rule, be exposed to any additional financial costs with respect to cross-border healthcare (par. 77).

Conclusion of the Court

1. Article 20(2) of Regulation No 883/2004, read in light of Article 21(1) of the Charter, must be interpreted as not precluding the insured person's Member State of residence from refusing the authorisation provided for in Article 20(1) of that regulation, where hospital care, the medical effectiveness of which is not contested, is available in that Member State, although the method of treatment used is contrary to that person's religious beliefs. (par. 55)

2. Article 8(5) and (6)(d) of Directive 2011/24, read in light of Article 21(1) of the Charter, must be interpreted as precluding a patient's Member State of affiliation from refusing to grant that patient the authorisation provided for in Article 8(1) of that directive, where hospital care, the medical effectiveness of which is not contested, is available in that Member State, although the method of treatment used is contrary to that patient's religious beliefs, unless that refusal is objectively justified by a legitimate aim relating to maintaining treatment capacity or medical competence, and is an appropriate and necessary means of achieving that aim, which it is for the referring Court to determine. (par. 85)

Elements of judicial dialogue

This is the first decision of the CJEU where the Directive found application. Nevertheless, the preliminary questions raised before the Court concerned both the Regulation provisions and that Directive. As to the first question, the Court cited previous case law, particularly in order to determine the extent of the reasons for a denial of authorisation.

In previous judgements, the CJEU already held that the authorisation required cannot be refused if the same or equally effective treatment cannot be given in good time in the Member State of residence of the person concerned (see in particular Watts and Petru). To this end, the Court stated that the home health institution was required to take all the circumstances of each specific case into account, not only of the patient's medical condition at the time when authorisation is sought and, where appropriate, the degree of pain or the nature of the patient's disability, but also of his or her medical history (par. 29).

At the same time, though, in the field of public health, the need to maintain financial balance of the healthcare system is considered an objective justification for a restriction on the freedom to provide

services (see Watts). Therefore, in this case, the amount paid by the applicant's son for healthcare abroad could be reimbursed under the Directive's legal framework, up until the amount the Latvian healthcare system would have paid if the healthcare were provided in the Member State of residence. A refusal of prior authorisation, in this case, was justifiable under the objective need to maintain the internal balance of the healthcare system.

Impact on national case law in Member States other than that of the Court referring the preliminary question to the CJEU

Prior to the judgement, there were other cases in which national Courts had to deal with the reimbursement of elective medical treatments.

Spain

Judgement of the Superior Court, Basque Country, Social Jurisdiction, 18 January 2011:

The main issue was whether an insured person, authorized by the Spanish competent institution to travel to Switzerland to receive treatment appropriate to his condition, was entitled to reimbursement of the extraordinary costs based on the patient's election of surgeon. The Court rejected the claim because the insured person would not have been entitled to the reimbursement of such costs were the treatment provided in a hospital covered by the Spanish national system, because such costs were not necessary for the patient to receive adequate medical service

1.5 Guidelines Emerging from the Analysis

The case law of the CJEU is coherent in stating that medical treatments must be considered as services in light of EU law. Therefore, the fundamental freedom to provide services applies and Member States can only impose those restrictions that are objectively justified under the exceptions provided by treaty norms.

In the case in which a person who is ensured in one Member State obtains medical treatment in another, the provisions of Regulation 883/2004 or those of the Directive 2011/24/EU apply. Therefore, the person is entitled either to have the treatment paid for by the healthcare insurance of affiliation, or to have the costs reimbursed. To this end, some requirements must be satisfied. A very controversial point concerns those cases in which prior authorisation is lacking. The CJEU gave some clarification on the cases in which prior authorisation was not necessary or in which the institution of affiliation must reimburse the costs of medical treatment.

In a recent decision (Case C-777/18 WO v Vas Megyei Kormányhivatal, 23 September 2020), the Court stated that a person without prior authorisation is also entitled to reimbursement for a scheduled treatment in an amount equivalent to that which would ordinarily have been reimbursed by the institution if the insured person had been granted such authorisation.

This principle applies in connection with some specific reasons, linked to the interpretation of EU law and namely for reasons relating to his or her state of health or to the need to receive urgent treatment. It is also relevant if the insured person was prevented from applying for such authorisation or was not able to wait for the decision of the home institution in his or her application ('individual circumstances').

Stemming from the need to assess the relationship between the requirement of prior authorisation and legitimate justifications to restrictions on the freedom to provide services, the CJEU progressively refined its interpretation on individual rights in cross-border healthcare. Among those, the Court specified that the list of medical treatments available in one Member States must be updated, otherwise the patient is entitled to the reimbursement of the more technologically advanced treatment even without prior authorisation. Similarly, the structural lack of medical material and medications is also a reason to recognise reimbursement without prior authorisation. The CJEU provided its contribution in interpreting the notion of undue delay as well, as a reason to be entitled to reimbursement.

More generally, it is possible to observe that the Court worked to carefully define a framework for a set of procedural rights that must be respected by national health authorities and by national Courts when evaluating a request for prior authorisation or when judging a refusal or denial of reimbursement. These are inspired by the principle of good administration and of effectiveness of judicial remedies.

2 Health and Consumer Protection

Issues of consumer protection often arise in cases concerning health, understood in both its individual and collective dimensions. In such cases, the CJEU has often placed an emphasis on general principles of EU law, for example the principle of effective protection, proportionality, equivalence and the precautionary principle. This chapter examines key cases from the CJEU dealing with health and consumer protection from two angles: first, looking at the complementarity between health and consumer protection in light of the principle of effective protection (Section 2.1); and second, considering the conflicts that can arise between the right to health and other fundamental rights in consumer law cases (Section 2.2). This chapter also provides general guidelines emerging from analysis of the case law (Section 2.3).

2.1 The Principle of Effectiveness and Complementarity between Health and Consumer Protection

This section focuses on the principle of effective (consumer) protection and how this relates to the right to health as found in Article 35 CFREU. Questions addressed concern, for example, the relationship between the individual and collective dimensions of the right to health in cases concerning consumer protection, the locus standi of individuals in cases regarding the protection of consumer health, and various issues related to liability in light of the principles of effective consumer protection, dissuasiveness, proportionality, and equivalence.

Relevant CJEU cases in this cluster

➢ Judgment of the Court (Second Chamber) of 25 July 2008, *Dieter Janecek v Freistaat Bayern*, (Case C-237/07) ("**Janecek**")

➢ Judgment of the Court (Fourth Chamber) of 5 March 2015, *Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt – Die Gesundheitskasse and Betriebskrankenkasse RWE,* Joined Cases C-503/13 and C-504/13 ("**Boston Scientific Medizintechnik**") (reference case, Question 4)

➢ Judgment of the Court (First Chamber) of 16 February 2017, *Elisabeth S. v TÜV Rheinland LGA Products GmbH*, Case C-219/15 ("**S.**") (reference case, Question 2)

➢ Judgment of the Court (Second Chamber) of 21 June 2017, *N.W, L.W., C.W v. Sanofi Pasteur MSD SNC, Caisse primaire d'assurance maladie des Hauts-de-Seine, Carpimko.*, Case C-621/15 ("**Sanofi**") (reference case, Question 3)

➢ Judgment of the Court (First Chamber) of 26 June 2019, *Lies Craeynest and Others v Brussels Hoofdstedelijk Gewest and Brussels Instituut voor Milieubeheer*, Case C-723/17 ("**Craeynest and Others**")

➢ Judgment of the Court (First Chamber) of 3 October 2019, *Wasserleitungsverband Nördliches Burgenland and Others*, Case C-197/18 ("**Wasserleitungsverband Nördliches Burgenland and Others**") (reference case, Question 1)

Main questions addressed

Question 1 In light of Article 47 CFR, can a consumer seek positive action from the authority in charge of public interest services that have an impact on public health? In light of Article 47 CFREU, can a consumer, authorised by law to use the water from his own domestic well, require the competent national authorities to amend an existing action programme or adopt additional measures or reinforced actions, provided for by EU law, in order to attain a nitrate level suitable for drinking water?

Question 2 How do the principles of effectiveness and equivalence impact the liability of conformity assurance bodies? In light of the principles of equivalence and effectiveness, in cases of damages derived by lack of conformity of medical devices, under which conditions should the body in charge of the control of the manufacturer's quality systems be considered liable vis-à-vis end-users of medical devices?

Question 3 What is the impact of the Charter of Fundamental Rights and related general principles of EU law on the application of the Product Liability Directive? How does the principle of effective judicial protection impact the burden of proof of consumers in cases in which scientific development has not clarified the specific impact of certain medical treatments on health?

Question 4 In light of the principle of effective consumer protection and of the fundamental right to health, in assessing liability, is the existence of a mere risk of damage a sufficient element to establish that a product is defective? In light of the principle of effective consumer protection and of the fundamental right to health, is the Product Liability Directive (85/374) to be interpreted so as to enable the recovery of damages consisting of those caused by the need for replacement of the product, when replacement is needed, to prevent the risk of future damages to health?

Relevant legal sources

EU level

Recitals 1, 2, 6, 7, 9 and 18, and Articles 1, 4, and 6(1) of Directive 85/374

Recitals 1, 3, 5, 6 and 10 to 13 of Directive 91/676

Articles 1, 2, 3, 4, and 5 of Directive 91/676, and Annex II and III to that Directive

Article 1 of Commission Directive 2003/12/EC

Recitals 1 and 5, and Articles 2, 11(1)(a), 11(9), 11(10) and 16(6) of Directive 93/42, and Sections 3.2, 3,3, 4.2, 4.3, 5.1, 5.2 and 5.3 of Annex II to that Directive, and Annex XI to that Directive

Article 3(3) TEU

Articles 191(2) and 288 TFEU

Articles 47 and 37 of the Charter of Fundamental Rights of the European Union

Question 1 – Relationship between the Individual and Collective Dimensions of the Right to Health

In light of Article 47 CFR, can a consumer seek positive action from the authority in charge of public interest services that have an impact on public health? In light of Article 47 CFREU, can a consumer, authorised by law to use the water from his own domestic well, require the competent national authorities to amend an existing action programme or adopt additional measures or reinforced actions, provided for by EU law, in order to attain a nitrate level suitable for drinking water?

This question was dealt with in *Wasserleitungsverband Nördliches Burgenland and Others* (C-197/18).

National legal sources (Austria)

Paragraph 55p of the Wasserrechtsgesetz (1959) (Law on Water Rights), transposing Article 5 of Directive 91/676:

This provision authorises the Federal Minister to adopt, by means of a regulation, programmes with a view to gradually reducing and preventing further water pollution from the discharge, directly or indirectly, of nitrogen compounds from agricultural sources.

Paragraph 10(1) of the 2012 Nitrate Action Programme Regulation (adopted on the basis of Paragraph 55p of the Law on Water Rights 1959):

This provision governs the use of groundwater by landowners, who may use groundwater for domestic and commercial needs without requesting authorisation, provided that water is extracted only by hand-operated pumps or the intake is proportionate to the size of the individual's land.

The case

The Water Association, Mr. Prandl, and the Municipality of Zillingdorf contested the Ministry's decision of May 30, 2016 that rejected as inadmissible their requests to have the 2012 Nitrate Action Programme Regulation amended. All the applicants had measured nitrate levels in different measuring points from groundwater used for drinking water that exceeded the value permitted in the Programme. For the water to be used as drinking water, nitrate levels must be below 50 mg/l.

The Ministry's decision to dismiss the request was based on a principle of Austrian law according to which a legal or natural person has *locus standi* in administrative or judicial proceedings only in so far as that person has individual substantive rights which he claims have been infringed. The Administrative Court of Vienna (Verwaltungsgericht Wien) noted that in the dispute before it, the relevant provisions of Austrian administrative law, namely the Law on Water Rights 1959 and the Allgemeines Verwaltungsverfahrensgesetz (Law on General Administrative Procedure), do not confer any individual substantive rights to the applicants in the main proceedings.

The Administrative Court introduced several factors that prevented an individual from relying on their rights before a national authority but nevertheless referred questions to the CJEU and wished to know whether the applicants in the main proceedings could rely on EU law and, in particular, on Directive 91/676 in order to have the 2012 Nitrate Action Programme Regulation amended.

Preliminary questions referred to the Court

Is Article 288 TFEU, in conjunction with Article 5(4) [of Directive 91/676] or with Article 5(5), in conjunction with Annex I A, point 2 to [that directive], to be interpreted as meaning that:

(a) a public water supplier, … in so far as it is concerned by what are claimed to be inadequate action plans (as the value of 50 mg/l nitrate concentration in the water was exceeded) must, for that reason, take measures to treat the water

(b) a consumer … authorised by law to use the water from his own domestic well … in so far as he is concerned by what are claimed to be inadequate action plans and a value in excess of 50 mg/l nitrate concentration from his water intake (domestic well), is unable to exercise his legal right to make limited use of the groundwaters on his property

…

(c) a municipality, which … uses or makes available a communal well … only for non-drinking water …, in so far as [due to what are claimed to be inadequate action plans] the value of 50 mg/l of nitrate concentration in the water source is exceeded, may not use it for drinking water,

[all are] directly concerned within the meaning of the case-law of the Court of Justice of the European Union, in this case possibly by a failure to implement Directive 91/676 and are therefore granted subjective rights under that directive:

– to amend an action programme already adopted nationally to implement Directive [91/676] (pursuant to Article 5(4) of [that directive]) in such a way that stricter measures with the aim of attaining the objectives of Article 1 of [that directive], specifically attaining a value of up to a maximum of 50 mg/l nitrate concentration in the groundwater at individual intake points?

– to adopt additional measures or reinforced actions (pursuant to Article 5(5) of Directive [91/676] with the aim of achieving the objectives laid down in Article 1(1) of [that directive] and specifically, to attain a value of up to a maximum of 50 mg/l nitrate concentration in groundwater at individual intake points?

In all three cases the protection of consumer health is safeguarded in any event either – in cases (b) and (c) – by taking the water from water suppliers that provide it (with compulsory connection and a right to connection) or – in case (a) – by corresponding treatment measures.

Reasoning of the Court

The Court established that the referring Court essentially sought to ascertain, first, **whether and under what conditions EU law confers *locus standi* to individuals in such proceedings** before the national authorities and Courts and; second, what the specific obligations deriving from Directive 91/676 are and; third, whether those obligations may be invoked by an individual directly against the competent national authorities.

The Court established where the EU legislature has, by directive, **imposed the obligation on Member States to pursue a particular course of action; the effectiveness of such action would be weakened if individuals were prevented from relying on it before their national Courts**. This is supported by the case-law of the Court together with the Opinion of the Advocate General (point 41). The Aarhus Convention in conjunction with Article 47 of the CFREU imposes an obligation on Member States to

ensure effective judicial protection of the rights conferred by EU law, in particular the provisions of environmental law (paragraph 33).

In the Court's view, in order to determine whether natural and legal persons such as the applicants in the main proceedings were directly concerned by an infringement of the obligations provided for in Directive 91/676, it was necessary to examine the purpose and the relevant provisions of that directive, the proper application of which was asserted before the referring Court (paragraph 35).

The purpose of Article 1 of Directive 91/676 was to reduce water pollution caused or induced by nitrates from agricultural sources and to prevent further such pollution. Pollution is defined as "the discharge, directly or indirectly, of nitrogen compounds from agricultural sources into the aquatic environment, the results of which are such as to **cause hazards to human health** …" in Article 20 (j).[94]

To that end, Article 5 of that directive provided that, in accordance with the conditions set forth, Member States are to establish action programmes and, if necessary, adopt additional measures or reinforced actions (paragraph 36). The Court concluded that it followed from Article 2(j) and Article 3(1) of Directive 91/676 that nitrate levels in groundwater that exceed or could exceed 50 mg/l must be considered to be such as to interfere with the legitimate use of water.

It follows from the above that **a natural or legal person with the option of withdrawing and using groundwater** is directly concerned by that threshold being exceeded or the risk of it being exceeded, which is capable of limiting that person's option by interfering with the legitimate use of that water. It follows that natural and legal persons, such as the applicants in the main proceedings, **must be in a position to require national authorities to observe those obligations, if necessary, by bringing an action before the competent Courts** (paragraphs 40 and 46). Regarding the extent of the obligation to reduce and prevent pollution, the Court established that Member States are, in all circumstances, obliged to ensure that the objectives of the directive, and consequently the objectives of European Union policy in the area of the environment, are achieved in accordance with the requirements of Article 191(1) and (2) TFEU. Court case-law establishes that Member States must take such additional measures or reinforced actions to the point at which it first becomes clear they are necessary. As the Advocate General observed in paragraph 105 of her Opinion, a surplus of nitrogen in the soil is also a relevant factor in order to establish the inadequacy of an action programme.

Conclusion of the Court

"Article 288 TFEU and Article 5(4) and (5) of, and Annex I A, point 2 to, Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources must be interpreted as meaning that, provided that the discharge of nitrogen compounds of agricultural origin significantly contributes to the pollution of the groundwaters in question, natural and legal persons, such as the applicants in the main proceedings, should be in a position to require the competent national authorities to amend an existing action programme or adopt additional measures or reinforced actions, provided for in Article 5(5) of that directive, as long as the nitrate levels in the groundwaters exceed or could exceed, in the absence of such measures, 50 mg/l at one or more measuring points within the meaning of Article 5(6) of that directive."

Elements of judicial dialogue

[94] Emphasis added.

In terms of horizontal dialogue, in defining the *locus standi* of individuals and the obligations of reducing and preventing pollution, the Court repeatedly referred back to its case law on asserting individual rights, on the imposition of EU law, and the Union objectives of environmental policy. For example, the Court referred to *Janecek* (C-237/07) and *ClientEarth* (C-404/13) and stated that while certain persons can assert their rights with respect to a direct danger to their health in respect to air quality such as in these cases, in the case of water quality this is incertain.

Referring to *Becker* (C-8/81, ECLI:EU:C:1982:7, paragraph 22), *Waddenvereniging and Vogelbeschermingsvereniging* (C-127/02, ECLI:EU:C:2004:482, paragraph 66), *Protect Natur-, Arten- und Landschaftsschutz Umweltorganisation* (C-664/15, ECLI:EU:C:2017:987, paragraph 34), the Court established that it is incompatible with the binding effect conferred by Article 288 TFEU on a directive to exclude, in principle, the possibility that the obligations which it imposes may be relied on by the persons concerned.

Moreover, the Court established that when the EU has imposed obligations on Member States via directives, the **effectiveness of such action would be weakened if individuals cannot rely on it before national Courts**, as in *Kraaijeveld and Others* (C-72/95, ECLI:EU:C:1996:404, paragraph 56) and *Craeynest and Others* (paragraph 34). Also, as stated in *American Express* (C-304/16, ECLI:EU:C:2018:66, paragraph 54), in interpreting EU law, the context in which it occurs and the objectives pursued by the rules of which it is part must be considered.

By analogy to *Craeynest and Others* (pararaph 42), the Court established that the obligations provided for in Article 5(4) and (5) of Directive 91/676 were clear, precise and unconditional, which means that they can be invoked by individuals against the State. By referring to *Kraaijeveld and Others* (paragraph 59), the Court added that **the competent authorities' decisions must be subject to judicial review**, in particular, to verify that they have not exceeded the limits set for the exercise of those powers, as seen in *Janecek* and *Craeynest and Others*.

Impact on national case law in Member States other than that of the Court referring the preliminary question to the CJEU

United Kingdom

Although the case did not refer to *Wasserleitungsverband Nördliches Burgenland and Others* directly, a similar question was dealt with by the UK Supreme Court in *R (on the application of Association of Independent Meat Suppliers and another) (Appellants) v Food Standards Agency (Respondent)* [2021] UKSC 54.

The case concerned the right to effective judicial protection and the question of whether an appeal procedure for the decision of an Official Veterinarian (an administrative authority) concerning meat from a bull bought at auction was fit for human consumption extended to judicial review on the full factual merits or whether the more limited scope of challenge involved in judicial review of the authority's decision and of a disposal notice on conventional public law grounds was all that was required. The Supreme Court referred the question to the CJEU, which was answered in Case C-578/19. In its follow-up judgment, the Supreme Court noted that these grounds would allow the authority's decision to be quashed if, for example, he or she acted for an improper purpose, did not apply the correct legal test, reached an irrational decision or one with no sufficient evidential basis. The Supreme Court then referred to the CJEU's ruling where it explained that to determine the rigour required in relation to judicial review

of national decisions adopted pursuant to EU law, "it is necessary to take into account the purpose of the act and to ensure that its effectiveness is not undermined" (para. 74 of the CJEU's ruling). Although the CJEU explained that this corresponded with Article 47 CFREU, the Supreme Court did not mention the provision, or indeed the Charter as a whole, in its judgment.

The Supreme Court did continue to follow the CJEU's reasoning that, bearing Article 52(3) CFREU in mind and the necessary consistency between rights protected in the Charter and the ECHR respectively, examining whether there is effective judicial protection in relation to legal rights involves taking into account "such factors as, first, the subject matter of the decision appealed against, and in particular, whether or not it concerned a specialised issue requiring professional knowledge or experience and whether it involved the exercise of administrative discretion and, if so, to what extent; second, the manner in which that decision was arrived at, in particular the procedural guarantees available in the proceedings before the administrative body; and third, the content of the dispute, including the desired and actual grounds of appeal" (para. 79 of the CJEU's judgment).

Applying this approach to the case at hand, the Supreme Court noted the CJEU's discussion in paras. 83-98 of its judgment in which it considered that in deciding whether or not a health mark should be affixed to a carcass the Official Veterinarian "must carry out a complex technical assessment requiring appropriate professional qualifications and expertise in the field" (para. 88) and that Official Veterinarians are obliged to give written notification of their decisions which "puts their addressees in a position to defend their rights under the best possible conditions and decide in full knowledge of the circumstances whether it is worthwhile to bring an action against those decisions" and also assists Courts to review the lawfulness of those decisions (para. 89).

Paraphrasing the CJEU, the Supreme Court then noted that "the responsibility of the [Official Veterinarian] in relation to securing the objective pursued by Regulations (EC) Nos 854/2004 and 882/2004 of achieving a **high level of protection of public health** means that EU law does not require a member state to establish a procedure which allows for judicial review of all of the [Official Veterinarian]'s assessments of the specific facts found during inspections relating to health marking." It then concluded, as did the CJEU, that judicial review of an Official Veterinarian decision on conventional public law grounds can satisfy the right under EU law of a slaughterhouse operator to effective judicial protection, in accordance with the applicable Regulations, and that this was not undermined by the effect of the Official Veterinarian's decision on the property rights of the meat company that had bought the bull. The Supreme Court then emphasised, as the CJEU had done, that "'[t]he **importance of the objective of consumer protection may justify even substantial negative economic consequences** for certain economic operators,' including food business operators" like the meat company.

The Supreme Court dismissed the appeal on the grounds that: "the section 9 procedure is not compatible with the requirements of Regulations (EC) Nos 854/2004 and 882/2004, whereas judicial review of a decision of an Official Veterinarian such as that at issue in these proceedings is compatible with those requirements."

Question 2 – Declaration of conformity of medical products with quality systems

How do the principle of effectiveness and equivalence impact the liability of conformity assurance bodies? In light of the principles of equivalence and effectiveness, in case of damages derived by a lack of conformity of medical devices, under which conditions should the body in charge of the control of the manufacturer's quality systems be considered liable vis-à-vis end-users of medical devices?

This question was dealt with in *S.* (C-219/15).

National legal sources (Germany)

"It is apparent from the order for reference that Directive 93/42 was transposed into German law by the Medizinproduktegesetz (Law on medical devices) ("the MPG") and the Medizinprodukt-Verordnung (the Order on medical devices).

In accordance with the first sentence of Paragraph 6(2) and Paragraph 37(1) of the MPG and point 1 of Paragraph 7(1) of the Order on medical devices, Class III medical devices may be placed on the market only if the requirements of the conformity assessment procedure laid down in Annex II to Directive 93/42 are met.

It is clear from various provisions of the Bürgerliches Gesetzbuch (German Civil Code), as interpreted in German case-law, first, that civil liability may be incurred for breach of a rule conferring legal protection and, second, that the scope of the duty to exercise due diligence and take all due care under a contract may, in certain cases, extend to third parties."

The case

In December 2008, Mrs. S. had breast implants which were manufactured in France and implanted in Germany. The manufacturer of the implants, which became insolvent after that date, appointed TÜV Rheinland to assess its quality system.

In 2010, the competent French authority established that the manufacturer in question had produced breast implants using industrial silicone which did not comply with quality standards. Accordingly, Mrs. S. had the implants removed in 2012. She claimed EUR 40,000 by way of compensation for non-material damage from TÜV Rheinland before the German Courts.

Those claims were rejected in the Court of first instance and also by the appeals Court. Mrs. S. then brought an appeal on a point of law before the referring Court.

In the view of the referring Court, how the dispute would be resolved under German law depended, essentially, on the purpose of the involvement of a notified body in the conformity assessment procedure and on that body's obligations under that procedure.

Preliminary questions referred to the Court

1. Is it the purpose and intention of Directive 93/42 that, in the case of Class III medical devices, the notified body responsible for auditing the quality system, examining the design of the product and surveillance acts in order to protect all potential patients and may therefore, in the event of a culpable infringement of an obligation, have direct and unrestricted liability towards the patients concerned?

2. Does it follow from Sections [3.3, 4.3, 5.3 and 5.4] of Annex II to Directive 93/42 that, in the case of Class III medical devices, the notified body responsible for auditing the quality system, examining the design of the product, and surveillance is subject to a general obligation to examine devices, or at least to examine them where there is due cause?

3. Does it follow from the aforementioned sections of Annex II to Directive 93/42 that, in the case of Class III medical devices, the notified body responsible for auditing the quality system, examining the design of the product, and surveillance is subject to a general obligation to examine the manufacturer's business records and/or to carry out unannounced inspections, or at least to do so where there is due cause?

Reasoning of the Court

On the questions concerning the general obligation in the Directive to carry out unannounced inspection and to examine business records, the Court held that there is no such obligation in the Directive. The body must, however, take every necessary step to ensure its surveillance obligations laid down in the directive are met.

On the first question related to the role of the surveillance body's involvement in the procedure of EC declaration of conformity, and its liability in case of failure to protect, the Court held that the purpose of its involvement is to protect the end users of medical devices. It also held that **in case of failure to protect end users, it could be held liable under the conditions defined in national law**. This is only an option open to Member States and **must not go against the effective implementation of the directive** (principle of effectiveness). Besides, **the claim must be open to end-users under the same procedural conditions as rights derived from domestic law** (principle of equivalence). However, it is not an obligation enshrined in the Directive as surveillance obligations can be provided in the Directive without conferring any rights to protected injured parties.

The Court did not further elaborate on the implication of the principles of effectiveness and equivalence in this particular case but relied on them to constrain the possible implementation of a procedure to bring a claim against the surveillance body – States have considerable discretion in this context as long as the protection provided by the Directive is ensured.

Conclusion of the Court

"The provisions of Annex II to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003, read in light of Article 11(1) and (10) and Article 16(6) of the directive, are to be interpreted as meaning that the notified body is not under a general obligation to carry out unannounced inspections, to examine devices, and/or to examine the manufacturer's business records. However, in the **face of evidence indicating that a medical device may not comply with requirement**s laid down in Directive 93/42, as amended by Regulation No 1882/2003, the **notified body must take all the steps necessary to ensure that it fulfils its obligation**s under Article 16(6) of the directive and Sections 3.2, 3.3, 4.1 to 4.3 and 5.1 of Annex II to the directive."

"Directive 93/42, as amended by Regulation No 1882/2003, is to be interpreted as meaning that, in the procedure relating to the EC declaration of conformity, **the purpose of the notified body's involvement is to protect the end users of medical devices**. The conditions under which culpable

failure by that body to fulfil its obligations under the directive in connection with that procedure may give rise to liability on its part vis-à-vis those end users are governed by national law, subject to the **principles of equivalence and effectiveness**."

Elements of judicial dialogue

In this case, judicial dialogue was used to support the argument and maintain coherent jurisprudence. The Court quoted its previous judgment in *Lohmann & Rauscher International* (C-662/15, EU:C:2016:903) to recall the goals of protection of the health and safety of persons. ("surveillance obligations, the combination of surveillance obligations of Member States in connection with the procedures for safeguarding, vigilance, and health surveillance, all of which are laid down by the directive, ensures protection for the health and safety of persons.").

It also used *Nordiska Dental* (C-288/08, EU:C:2009:718, paragraph 29) to support a broad interpretation of the scope of the Directive that is not limited to health but also ensures the safety of users ("**the aim of the directive is not only the protection of health stricto sensu, but also the safety of persons** and that it does not concern only patients and users of medical devices but, more generally, 'third parties' or 'other persons'.").

To support the statement related to the first question that the protection obligation of a third party does not mean there is a right to engage liability of the same third party, the Court quoted its judgment in *Paul and Others* (C-222/02, EU:C:2004:606). It also recalled the case of *Skov and Bilka* (C-402/03, EU:C:2006:6), in which it held that provisions of Member States concerning liability for defective products does not preclude the application of other systems of contractual or non-contractual liability, like fault, to recognise a potential action by end users against the surveillance body.

Impact on national case law in Member States other than that of the Court referring the preliminary question to the CJEU

France

S. has had an impact on French case law. On October 10, 2018 the French Court of Cassation relied on *S.* concerning the liability of notified bodies for damage caused by medical devices. The Court of Cassation imposed an obligation of vigilance on notified bodies responsible for the certification of implantable medical devices within the meaning of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (No. 15-26.093). During the monitoring mission, if there are indices which suggest that a medical device does not comply with the requirements of Directive 93/42, the notified body must take all necessary measures and, in this case, check the documents identifying the raw materials or proceed with unscheduled visits to the manufacturer. If such failures are observed, the notified authority is liable.

Question 3 – Defective Products that Could Be Dangerous for Health

What is the impact of the Charter of Fundamental Rights and related general principles of EU law on the application of the Product Liability Directive? How does the principle of effective judicial protection impact the burden of proof of consumers in cases in which scientific development has not clarified the specific impact of certain medical treatments on health?

This question was dealt with in *Sanofi* (C-621/15).[95]

National legal sources (France)

Article 1386-1, French Civil Code:

The producer shall be liable for the damage caused by a defect in his product, whether or not he is bound to the victim by contract.

Article 1386-9, French Civil Code:

The plaintiff is required to prove the damage, the defect, and the causal relationship between defect and damage.

Furthermore, case-law from the *Cour de cassation* holds that in relation to extra-contractual liability of pharmaceutical laboratories resulting from vaccinations produced by them, proof of a causal relationship between the defect in the product and the damage suffered by the injured person can be derived from "serious, specific, and consistent presumptions" (see two judgments dated 22 May 2008 (Cass. Civ. 1ère, Bull. Civ. I, No 148 and No 149).

The case

Mr. W was vaccinated against hepatitis B through three injections, executed between December 1998 and July 1999. The vaccine was produced by Sanofi Pasteur. From August 1999, Mr. W began to have various troubles, which led to a diagnosis of multiple sclerosis in November 2000. From January 2001 he was no longer fit to work. Mr. W's state of health continued to decline progressively until he reached a functional disability of 90%. He died in October 2011.

In 2006, Mr. W, his wife, and two daughters brought proceedings on the basis of Article 1386-1 et. seq. of the Civil Code, seeking to have Sanofi Pasteur ordered to pay compensation for the damage they claimed to have suffered. They argued that the short period between the vaccination and the appearance of the first symptoms of the disease, in conjunction with a lack of any personal or family history of the disease, were such as to give rise to serious, specific, and consistent presumptions of a defect in the vaccine, and a causal link between the defect and Mr. W's illness.

They relied in this regard on the case-law of the Cour de Cassation, according to which, in the area of liability of pharmaceutical laboratories for the vaccines they produce, proof of a causal link between the defect in the product and the damage suffered by the person injured can be derived from "serious, specific, and consistent presumptions."

In particular, the case law is very clear on the point that the Court, ruling on the merits, in the exercise of its exclusive jurisdiction to appraise the facts, may consider that the short period between the injection of the hepatitis B vaccine and the appearance of the first symptoms of multiple sclerosis, in conjunction with the lack of any personal or family antecedent of the disease, constituted such serious, specific, and consistent presumptions of a defect in the vaccine and the existence of a causal relationship between it

[95] This summary is based on text from Chapter 9 of the FRICoRe Casebook on Effective Consumer Protection and Fundamental Rights.

and the disease in question. This can be the case even if medical research does not, in general, confirm the existence of such a link.

The action was upheld in the Court of first instance by the Tribunal de Grande Instance de Nanterre, in a judgment on September 4, 2009. It was subsequently overturned on appeal by the Cour d'Appel de Versailles in a judgment of February 10, 2011. The latter Court held that the evidence relied on by the claimants was sufficient to establish a presumption of a causal link but were insufficient to establish a defect in the vaccine. An appeal against that judgment was then brought before the Cour de Cassation, which quashed it in a judgment of September 26, 2012, holding that the latter had not given a legal basis for its decision in relation to the absence of the defect of the vaccines.

The case was sent before the Cour d'Appel de Paris, which again overturned the first instance judgment of the Tribunal de Grande Instance de Nanterre in its judgment of March 7, 2014. The Court held that there was no scientific consensus to support a causal relationship between the vaccination against hepatitis B and multiple sclerosis. It considered, second, that according to multiple medical studies the aetiology of multiple sclerosis is currently unknown. Third, a recent medical publication concluded that, at the time when the first symptoms of the disease appear, the pathophysiological process probably commenced many months, or many years, earlier. Fourth and lastly, the Court noted that epidemiological studies showed that 92 to 95% of individuals with multiple sclerosis had no antecedent of the disease in their family. In light of these elements, the Court concluded that the criteria relating to temporal proximity between the vaccination and the first symptoms and the lack of personal and family antecedents could not establish serious, specific, and consistent presumptions supporting the conclusion that there was a causal link between the vaccination and the disease in question.

A new appeal on a point of law was finally brought by W and Others against the judgment of the Cour de Cassation, which requested a preliminary ruling regarding the legitimacy and the eventual parameters of application of the "serious, specific, and consistent presumptions" method of proof.

Preliminary questions referred to the Court

The Cour de cassation referred the following three questions to the Court of Justice for a preliminary ruling:

1. Must Article 4 of [Directive 85/374] be interpreted as precluding, in the area of liability of pharmaceutical laboratories for the vaccines that they manufacture, a method of proof by which the Court ruling on the merits, in the exercise of its exclusive jurisdiction to appraise the facts, may consider that the facts relied on by the applicant constitute serious, specific, and consistent presumptions capable of proving a defect in the vaccine and the existence of a causal relationship between it and the disease, notwithstanding the finding that medical research does not establish a relationship between the vaccine and the occurrence of the disease?

2. If the answer to Question 1 is in the negative, does Article 4 of Directive 85/374 […] preclude a system of presumptions by which the existence of a causal relationship between the defect attributed to a vaccine and the damage suffered by the injured person will always be considered to be established where certain indications of causation are found?

3. If the answer to Question 1 is in the affirmative, must Article 4 of Directive 85/374 … be interpreted as meaning that proof, the burden of which rests on the person injured, of the existence of a causal

relationship between the defect attributed to a vaccine and the damage suffered by that person cannot be considered to have been adduced unless the causal relationship is established scientifically?

Reasoning of the Court

In the present case, the national Court's first question was whether Article 4 of Directive 85/374 precluded a method of proof whereby certain facts can give rise to a factual presumption that a vaccine is defective and caused a disease, even if medical research does not establish a relationship between the vaccine and the occurrence of the disease. The term "factual presumption" is used to refer to a situation where the possibility exists for the judge to infer B from A, but only as part of her free assessment of evidence.

The Court emphasised that Article 4 of Directive 85/374 imposes on the injured party the burden of proving defect, damage, and a causal link between those two. However, the Directive does not harmonise rules of proof and evidence to determine how the injured party can discharge its burden of proof. It is therefore for the national legal order of each Member State, in accordance with the principle of procedural autonomy, to establish the ways in which evidence is to be elicited, what evidence is to be admissible before the appropriate national Court, or the principles governing the Courts assessment of the probative value of the evidence adduced before it and also the level of proof required. However, **national rules of proof and evidence must respect the principles of equivalence and effectiveness.**

The Court especially stressed the importance of the **principle of effectiveness** which requires, in terms of the detailed procedural rules governing actions for safeguarding rights which individuals derive directly from EU law, that those rules do not render practically impossible or excessively difficult the exercise of rights conferred by EU law.

The Court concluded that Article 4 in itself does not preclude national evidentiary rules under which a national Court may consider certain factual presumptions to constitute serious, specific, and consistent evidence of the defect of a product and to constitute the causal link with the damage, even if there is no conclusive scientific evidence. National evidentiary rules must, however, not be applied by national Courts in such a way that in practice they introduce, to the detriment of the producer, unjustified presumptions liable to infringe Article 4 of the Directive 85/374 or even undermine the effectiveness of the system of liability introduced by Article 1 of the Directive. That could arise:

- First, in a situation where national Courts apply those evidentiary rules in an overly rigorous manner by accepting irrelevant or insufficient evidence.

- Second, if national Courts were to apply such evidentiary rules in such a way that, where one or more types of factual evidence were presented together, an immediate and automatic presumption would operate of there being a defect in the product and/or a causal link between the defect and the damage.

Therefore, national Courts must first ensure that the evidence adduced is **sufficiently serious, specific, and consistent** to warrant the conclusion that, notwithstanding the evidence produced and the arguments put forward by the producer, **a defect in the product appears to be the most plausible explanation for the occurrence of the damage**, with the result that the defect and the causal link may reasonably be considered to be established**.**

The **principle of effectiveness and the fundamental right to health** and safety played an important role in the Court's reasoning when banning a stricter approach to causality that could exclude the use of

presumptions. Indeed, as the Court stated in paragraphs 31 and 32, "such a high evidentiary standard, which amounts to excluding any method of proof other than certain proof based on medical research, could make it excessively difficult in many situations or, as in the present case, where it is common ground that medical research neither confirms nor rules out the existence of such a causal link, impossible to establish producer liability, thereby undermining the effectiveness of Article 1 of Directive 85/374 (…). Such a limitation as to the types of admissible evidence would also be inconsistent with the objectives pursued by Directive 85/374, seeking to ensure, in particular, as is apparent from the second and seventh recitals thereof, a fair apportionment of the risks inherent in modern technological production between the injured person and the producer (see, to that effect, the judgment of March 5, 2015, Boston Scientific Medizintechnik, C-503/13 and C-504/13, EU:C:2015:148, paragraph 42) and, as evidenced by the first and sixth recitals thereof, that of protecting consumer health and safety (see, to that effect, the judgment of March 5, 2015, Boston Scientific Medizintechnik, C-503/13 and C-504/13, EU:C:2015:148, paragraph 47)."

The Court then addressed whether these findings would change if the presumption were legal as opposed to factual. The term "legal presumption" is used to refer to a presumption that a judge is legally obliged to follow. The Court recalled once again the **importance of the correct allocation of the burden of proof as well as the principle of legal certainty and effectiveness** of the system of liability.

The conclusion reached by the Court was that the use by the national legislature or, as the case may be, the supreme judicial body, of a method of proof such as that referred to in the second question, would *inter alia* have the consequence of undermining the burden of proof provided for in Article 4 of Directive 85/374. If the presumption were irrefutable, such a presumption would have the consequence that the producer would be deprived of all opportunity to adduce facts or put forward arguments in order to rebut that presumption, and the Court would thus not have any opportunity to assess the facts in light of the evidence or arguments. Even if the presumption were to be refutable, the fact remains that, since the facts pre-identified would be proven, the existence of a causal link would be automatically presumed, with the result that the producer could then find itself in the position of having to rebut that presumption in order to defend itself successfully against the claim.

Regarding whether the causal link between vaccine and disease must be established using scientific evidence, the Court indicated that excluding any method of proof other than certain proof based on medical research could make it excessively difficult in many situations or, as in the present case – where medical research neither confirms nor rules out the existence of such a causal link – impossible to establish producer liability, which would undermine the effectiveness of Article 1 of the Directive 85/374. Such a limitation would also be inconsistent with the objectives pursued by the Directive, seeking to ensure a fair apportionment of the risks inherent in modern technological production between the injured person and the producer (2nd and 7th recitals, Directive 85/374).

Conclusion of the Court

"On those grounds, the Court (Second Chamber) hereby rules:

1. Article 4 of Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products must be interpreted as not precluding national evidentiary rules such as those at issue in the main proceedings under which, when a Court ruling on the merits of an action involving the liability of the producer of a vaccine due to an alleged defect in that vaccine, in the exercise of its exclusive jurisdiction

to appraise the facts, may consider that, notwithstanding the finding that medical research neither establishes nor rules out the existence of a link between the administering of the vaccine and the occurrence of the victim's disease, certain factual evidence relied on by the applicant constitutes serious, specific, and consistent evidence enabling it to conclude that there is a defect in the vaccine and that there is a causal link between that defect and that disease. National Courts must, however, ensure that their specific application of those evidentiary rules does not result in the burden of proof introduced by Article 4 being disregarded or the effectiveness of the system of liability introduced by that directive being undermined.

2. Article 4 of Directive 85/374 must be interpreted as precluding evidentiary rules based on presumptions according to which, where medical research neither establishes nor rules out the existence of a link between the administering of the vaccine and the occurrence of the victim's disease, the existence of a causal link between the defect attributed to the vaccine and the damage suffered by the victim will always be considered to be established when certain predetermined causation-related factual evidence is presented."

Impact on the follow-up case

Although not follow-up cases *per se*, the CJEU's decision in Sanofi has had an effect on subsequent decisions by the French Court of Cassation.

First, in January 2018, the *Sanofi* case was referred to by the Court of Appeals of Bordeaux in support of its reasoning regarding a similar case (Cour d'appel de Bordeaux 1e civ., 23 January 2018, 17-01816). The facts were very similar to the *Sanofi* case because the applicant also claimed that three injections of a Sanofi vaccine against hepatitis B caused him to contract multiple sclerosis. To establish Sanofi's liability, the applicant had to prove the damage, the defect, and the causal relationship between defect and damage. The Court held that the damage was established since it was not disputed that the applicant suffered from multiple sclerosis. Similarly, it was not disputed that the vaccine was defective because multiple sclerosis had been identified as one of the unintended side effects of the vaccine.

However, the Cour d'Appel de Bordeaux had different conclusions regarding the causal link between the defect and the damage compared to the Cour de Cassation in the *Sanofi* case. Just like the Cour de Cassation, the appellate Court used the CJEU's decision in *Sanofi* to hold that the lack of established scientific evidence to prove the existence of a causal link could not affect the effectiveness of the liability regime in place. However, the appellate Court found a causal link between the vaccine and the damage based on the following elements which it considered "serious, specific, and consistent presumptions":

- The expert report neither established nor ruled out the existence of a link between the administration of the vaccine and the occurrence of the victim's disease;
- The applicant had no personal or family history of neurological conditions;
- The rarity of the causal link between the vaccine and the sclerosis did not bar the existence of such a causal link;
- The fact that the applicant suffered another disease (thanks to which he noticed that he had sclerosis) six months after the last injection of the vaccine did not bar the existence of a causal link because, although the expert report mentioned a period of two months between the injection and the onset of sclerosis, that period was only an average;

- The fact that the sclerosis was only detected six months after the vaccination did not exclude the possibility that the disease was already present during that six-month period;
- A study showed that the risk of contracting sclerosis was multiplied by three if the patient was vaccinated against hepatitis B within three years before the onset of the sclerosis.

Consequently, the Cour d'Appel found that Sanofi was liable for the disease that the applicant suffered as a result of the company's defective vaccine. Although the facts were very similar to the *Sanofi* case examined by the Court of Justice and then by the Cour de Sassation, the Cour d'Appel de Bordeaux had a different conclusion from the latter. While the Cour de Cassation in *Sanofi* held that the short period between the vaccination and the appearance of the first symptoms of sclerosis was irrelevant, the appellate Court here found the contrary: the fact that the sclerosis was not detected sooner did not exclude the possibility that the applicant had already contracted the disease during those six months. Additionally, while the Cour de Cassation in *Sanofi* found that the ignorance about the aetiology of sclerosis and the lack of history of the disease could not be interpreted in the applicant's favour, the Cour d'Appel did just that in the present case. Therefore, although both cases had very similar facts, the two Courts ruled rather differently and interpreted the indications of the CJEU differently. It is interesting to note that the Cour d'Appel de Bordeaux, contrary to the Cour de Cassation in the *Sanofi* case, did expressly mention that the lack of scientific certainty could not be an obstacle to the effectiveness of the liability regime as indicated by the CJEU.

Second, on November 27, 2019, the Court of Cassation heard a case concerning defective medicine that failed to include risk information in the package instructions (No. 18-16.537). The Court found that a product is defective when it does not offer information about the safety that can legitimately be expected when taking the medication. In assessing this, all circumstances must be taken into account, in particular the presentation of the product, the use for which it may reasonably be expected, and the time at which it is put into circulation. In characterising the defectiveness of the medicinal product, the judges focused on the content of the package instructions of the product brought to the attention of the user and its completeness with regard to the known risks of adverse effects.

Finally, on October 21, 2020, the Court of Cassation ruled on the liability of a producer on the basis of the special regime of liability for defective products (No 19-18.689, Monsanto). Although the judgment did not refer explicitly to *Sanofi*, it constituted a good illustration of the application of the directive on liability for defective products. In this case, the Court of Cassation confirmed that under Article 1245-10, 4° of the Civil Code, transposing Article 7 of the aforementioned Directive, and a decision of the Court of Justice of the European Union (*Commission v. United Kingdom*, C-300/95) that "in order to be released from liability (...), the producer of a defective product must establish that the objective state of technical and scientific knowledge, including its most advanced level, at the time the product in question was put into circulation, did not make it possible to detect the defect in it." The producer was therefore automatically liable unless he proved that the state of scientific and technical knowledge, at the time he put the product into circulation, did not allow the existence of the defect to be detected.

Elements of judicial dialogue

In the *Sanofi* case there was vertical judicial dialogue. The Cour de Cassation (France) requested a preliminary ruling to determine potential incompatibility between Articles 1 and 4 of Directive 85/374 and Articles 1386-1 and 1386-9 of the French Civil Code (specifically, the Cour de Cassation case law regarding the application of those Articles in cases of extra-contractual liability of pharmaceutical

laboratories resulting from vaccines produced by them). The Court of Justice provided guidelines for the interpretation of these provisions in light of the principle of effective consumer protection and the fundamental right to health; indeed, these principles should influence the balance between scientific uncertainty and evidentiary rules in liability cases. Apparently, the impact was limited since the French Court has adopted a relatively strict approach to presumptions without specific consideration of the fundamental rights involved.

In terms of horizontal dialogue, *Sanofi* has been relied on in subsequent cases (see e.g. *Avon Cosmetics*, C-305/16, ECLI:EU:C:2017:970; *AFEP and others*, C-365/16, ECLI:EU:C:2017:378; and *Grupa Lotos*, C-225/18, ECLI:EU:C:2019:349). However, given the subject matter and context of the references, which do not concern the issue of effective consumer protection and health, they will not be discussed here.

The CJEU did refer to several of its own previous cases in its judgment in *Sanofi*, including that of *Boston Scientific Medizintechnik* (Joined Cases C-503/13 and C-504/13), which is discussed in Section 2.1.4 of this Casebook.

Impact on national case law in Member States other than that of the Court referring the preliminary question to the CJEU

United Kingdom

Sanofi has had an impact on UK case law, as evidenced in several cases.

For example, in *John Hastings v Finsbury Orthopaedics Limited and Stryker UK Limited* [2021] CSIH 6, the Scottish Court of Session relied on the CJEU's warning in *Sanofi* against evidentiary burdens that make it "excessively difficult to establish product liability, thereby **undermining the effectiveness**" of a provision, not only through the evidentiary rules themselves, but also how they are applied (paragraph 39). Sanofi was then further relied on as evidence that the product liability directive "sought a fair apportionment of risks inherent in modern technology between the injured person and the producer and that of **protecting consumer health** and safety" (paragraph 40).

In the earlier case of *Gee & Ors v Depuy International Ltd* [2018] EWHC 1208, heard by the UK High Court of Justice, the CJEU's judgment in *Sanofi* was referred to on a number of occasions. For example, when stating that under the product liability directive Member States are free "to establish detailed **rules of proof and evidence** for practical implementation of the Directive, which might vary depending on the type of product involved, national rules governing how evidence is to be adduced and appraised must not be such as to undermine either the apportionment of the **burden of proof** provided for under Article 4 or, more generally, the **effectiveness of the system of liability** provided for under the Directive, or the objectives pursued by the EU legislature by means of that system" (paragraph 79). The Court believed this to provide evidence of the CJEU's vigilance in ensuring that the rights conferred in the Directive are **effective**, whether they are for the benefit of consumers or producers. Furthermore, when discussing the matter of causation, the High Court opined that *Sanofi* "made it clear that this is a matter for the national Courts, subject only to ensuring that the rules adopted do not undermine the scheme of no-fault liability and create a different **balance between the competing interests** from the one that is set by the Directive" (paragraph 179).

Finally, *Sanofi* was referred to in *NHS Lothian Health Board v HMRC* [2020] CSIH 14. Although the subject matter of this case is quite different (the case concerned historical claims for the recovery of overpaid tax), the Scottish Court of Session referred to the CJEU judgment when discussing the treatment of evidence in proceedings, in particular to support the view that "a national Court or tribunal, in giving

effect to EU-derived legal rights, must not apply national rules of evidence that prevent reliance on any evidence that has, in practical terms, a bearing on the claim that is made" (paragraph 41).

Question 4 – Risk of Defective Products and Damage to Health

> In light of the principle of effective consumer protection and of the fundamental right to health, in assessing liability, is the existence of a mere risk of damage a sufficient element to establish that a product is defective? In light of the principle of effective consumer protection and of the fundamental right to health, is the Product Liability Directive to be interpreted so to enable recovery of damages consisting in those caused by the need for replacement of the product, when replacement is needed to prevent the risk of future damages to health?

This question was dealt with in *Boston Scientific Medizintechnik* (Joined Cases C-503/13 and C-504/13).[96]

National legal sources (Germany)

Article 1 of the German Law on liability for defective products, of 15 December 1989:

"If, due to a defect in a product, a person dies, is injured, or his health is impaired or there is damage to an item of property, the producer of the product shall compensate the injured person for the damage which arises as a result thereof. In the case of damage to an item of property, this shall apply only if an item of property other than the defective product is damaged and this other item of property is of a type ordinarily intended for private use or consumption and was used by the injured person mainly for private use or consumption."

Article 3 of the German Law on liability for defective products, of 15 December 1989:

"A product has a defect when it does not provide the safety which may reasonably be expected, taking all circumstances into account, including:

(a) its presentation,

(b) the use to which it could reasonably be expected to be put,

(c) the time when it was put into circulation."

Article 8 of the German Law on liability for defective products, of 15 December 1989:

"Where a person has been injured or his health impaired, compensation shall be made in respect of the costs incurred in restoring the injured person's health and also the pecuniary loss which the injured person suffers because, as a result of the injury, his earning capacity is permanently or temporarily brought to an end or reduced or his needs are increased on a temporary or permanent basis."

The case

[96] This summary is based on text from Chapter 9 of the FRICoRe Casebook on Effective Consumer Protection and Fundamental Rights.

G. Corporation, now B. S. Corporation, a company established in Saint Paul (United States), manufactures and sells pacemakers and implantable cardioverter defibrillators.

G. imported and marketed in Germany "Guidant Pulsar 470" and "Guidant Meridian 976" pacemakers, which were manufactured in the United States by G. Corporation, and "G. Contak Renewal 4 AVT 6" implantable cardioverter defibrillators, manufactured by the latter in Europe …

In a letter of July 22, 2005 sent, inter alia, to treating physicians, G. indicated that its quality control system had established that a component utilised to hermetically seal the pacemakers which it marketed may experience a gradual degradation. That defect could lead to premature battery depletion, resulting in loss of telemetry and/or loss of pacing output without warning.

As a consequence, G. recommended physicians to consider, inter alia, replacing such pacemakers for the patients affected. Notwithstanding the fact that the warranty for the pacemakers may have expired, G. undertook to make replacement devices available free of charge for pacemaker-dependent patients and those deemed by their physicians to be best served by replacement.

Following that recommendation, the pacemakers previously implanted in B and W, who both had medical insurance coverage with AOK, were replaced in September and November 2005, respectively, by other pacemakers provided free of charge by the manufacturer. The pacemakers that had been removed were destroyed without any expert opinion being obtained on their functioning.

AOK, on the basis of the devolved rights of B and W, brought proceedings before the Amtsgericht Stendal (Local Court, Stendal) seeking an order that Boston Scientific Medizintechnik pay compensation in respect of the costs relating to the implantation of the original pacemakers, updated to the dates on which those pacemakers were replaced. Those costs were EUR 2,655.38 with respect to B and EUR 5,914.07 with respect to W.

The Amstgericht Stendal upheld that claim in its judgment of May 25, 2011. As Boston Scientific Medizintechnik's appeal against that decision was dismissed by the Landgericht Stendal (Regional Court, Stendal), that company lodged an appeal on a point of law before the referring Court [Case C-503/13] (...)

By letter of June 2005, G. informed treating physicians that its quality control system had established that the functioning of implantable "G. Contak Renewal 4 AVT 6" defibrillators might be affected by a defect in one of its components which could limit the device's therapeutic efficacy. It was apparent from the scientific analysis carried out that a magnetic switch in those defibrillators might remain stuck in the closed position.

As is apparent from the order for reference in Case C-503/13, if the "enable magnet use" mode was activated and the magnetic switch became stuck in the closed position, treatment of ventricular or atrial arrhythmias would be inhibited. As a consequence, any cardiac dysrhythmia that could be fatal would not be recognised by the defibrillators and no life-saving shock would be given to the patient. In those circumstances, G. recommended that treating physicians deactivate the magnetic switch in the defibrillators concerned.

On March 2, 2006, the implantable cardioverter defibrillator implanted in F, who was covered for insurance purposes by Betriebskrankenkasse RWE, was replaced prematurely. By letter of August 31, 2009, Betriebskrankenkasse RWE requested Boston Scientific Medizintechnik to reimburse the costs

incurred in respect of F's treatment, amounting to EUR 20,315.01 and EUR 122.50, in connection with the operation to replace the defibrillator.

An action was brought by Betriebskrankenkasse RWE for an order that Boston Scientific Medizintechnik reimburse the sums in question before the Landgericht Düsseldorf (Regional Court, Düsseldorf), which upheld that claim by judgment of February 3, 2011. After Boston Scientific Medizintechnik appealed that judgment, the Oberlandesgericht Düsseldorf (Higher Regional Court, Düsseldorf) varied that decision in part, ordering that company to pay the sum of EUR 5,952.80, together with interest. Boston Scientific Medizintechnik lodged an appeal on a point of law before the referring Court, contending that Betriebskrankenkasse RWE's claim should be dismissed in its entirety" (C-504/13).

Preliminary questions referred to the Court

1. Is Article 6(1) of Directive 85/374 to be interpreted as meaning that a product in the form of a medical device implanted in the human body (in this case, a pacemaker [and an implantable cardioverter defibrillator]) is already defective if [pacemakers] in the same product group have a significantly increased risk of failure [or where a malfunction has occurred in a significant number of defibrillators in the same series], but a defect has not been detected in the device which has been implanted in the specific case in point?

2. If the answer to the first question is in the affirmative:

   (a) Do the costs of the operation to remove the product and to implant another pacemaker [or another defibrillator] constitute damage caused by personal injury for the purposes of Article 1 and section (a) of the first paragraph of Article 9 of Directive 85/374?

Reasoning of the Court

In relation to whether a risk of defect also violates the reasonable expectations of safety of consumers, the Court based its reasoning on three main considerations:

First, according to the Directive, the safety which the public at large is entitled to expect must be based on the objective characteristics and properties of the product and on the specific requirements of the group of users for whom the product is intended. In cases of pacemakers and defibrillators, the safety requirements expected by the consumers are particularly high in light of its function and the particularly vulnerable situation of patients using such devices.

Secondly, the potential unsafe condition of such products stems from the abnormal potential for damage which those products might cause to the person concerned in case of failure, as observed by the Advocate General. So, "**where it is found that such products belonging to the same group or forming part of the same production series have a potential defect, it is possible to classify as defective all the products in that group or series, without there being any need to show that the product in question is defective**" (paragraph 41).

This interpretation is consistent with the aims of the Directive, seeking to ensure **a fair apportionment of the risks inherent in modern technological production between the injured person and the producer**.

The CJEU assumed the conclusion of the Advocate General. However, the Court did not show the reasoning of the Advocate General regarding the human health protection concern in European Union policy:

The Advocate General pointed out that "the defect for the purposes of Article 6(1) of Directive 85/374 is a risk of damage of such a degree of seriousness that it affects the public's legitimate expectations in so far as concerns safety." The Advocate General gave three arguments to support this: (1) the concept of product defect can exist irrespective of any internal fault in the product concerned; (2) this definition of defect is also dictated by consumer protection requirements and the protection which Directive 85/374 seeks to grant consumers would be seriously undermined if, in the event that a number of products of the same model were placed on the market and a safety defect occurred in only some of those products, the probability that the defect was present in other products could not be taken into consideration; and (3) this approach is corroborated by the need for the integration of health concerns in European Union policy: "account must be taken of Article 168(1) TFEU and the second sentence of Article 35 of the Charter of Fundamental Rights of the European Union, which require a high level of human health protection in the definition and implementation of all Union policies and activities …, such protection must be regarded as an objective that also forms part of the policy calling for the harmonisation of the Member States' rules on liability for damage caused by defective products."

In relation to the second question, the Court gave a broad interpretation to the concept of "damage caused by death or personal injuries," with regard to the **objective of protecting consumer health and safety pursued by the Directive.** Again, the nature of fundamental rights affected (health and safety) influenced judicial interpretation so as to ensure effective consumer protection. Thus, according to the Court, compensation for damage relates to all that is necessary to eliminate harmful consequences and to restore the level of safety which a person is entitled to expect. Consequently, in the case of implantable medical devices which are defective according to Article 6 of the Directive, compensation for damage must cover the costs relating to the replacement of the defective product.

According to paragraph 63 of the opinion of the Advocate General, "the exclusion of loss or injury caused by a surgical operation to remove a defective medical device would be entirely contrary to the general objective of protecting consumer health and safety pursued by Directive 85/374." In conclusion, all material loss or damage resulting from personal injury must be compensated for in full (paragraph 66). The Court introduced a final distinction between pacemakers and implantable defibrillators because in the case of implantable defibrillators the manufacturer only recommended deactivating the magnetic switch of those medical devices. Therefore, the Court concluded that it is for the national Court to determine whether the deactivation of the product is sufficient to eliminate the defect and the risk of damage or whether the surgery of product replacement was also necessary. By clarifying the notion of damages, the Court actually enlarged the function of liability, which is aimed at providing consumers with redress in kind rather than simply providing for monetary compensation. Indeed, one could observe that only enabling replacement of a defective pacemaker would ensure **effective protection of a consumer's health**.

One can observe that whereas in the *Sanofi* case above the notion of proof concerning the causal link was interpreted broadly by taking the high level of *uncertainty* related to scientific research outcomes into consideration, in this case the notion of defective product was interpreted broadly by taking the **high level of *risk* of damages to a patient's health** into consideration. In both cases, the need for effective protection of consumers whose health is put in danger led the Court to a broader interpretation of EU law.

Conclusion of the Court

"1. Article 6(1) of Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products must be interpreted as meaning that, where it is found that products belonging to the same group or forming part of the same production series, such as pacemakers and implantable cardioverter defibrillators, have a potential defect, such a product may be classified as defective without there being any need to establish that that product has such a defect.

2. Article 1 and section (a) of the first paragraph of Article 9 of Directive 85/374 are to be interpreted as meaning that the damage caused by a surgical operation for the replacement of a defective product, such as a pacemaker or an implantable cardioverter defibrillator, constitutes 'damage caused by death or personal injuries' for which the producer is liable, if such an operation is necessary to overcome the defect in the product in question. It is for the national Court to verify whether that condition is satisfied in the main proceedings."

Impact on the follow-up case

The Supreme Court accepted the reasoning of the CJEU and referred the assessment of the causation of any damage to the Court of Appeals. There is presently no further information about the history of the case available.

Elements of judicial dialogue

Boston Scientific Medizintechnik has been referred to by several subsequent cases before the CJEU. Most of the references do not concern the aspects of the case emphasised in this Casebook, and instead relate to issues of patents that are purely procedural in nature. However, the case was referred to on several occasions in *Sanofi* (C-621/15, discussed in Section 2.1.3 above), which also concerned the protection of consumer health. Here, the Court relied on the judgment when stating the definition of a defective product under Article 6(1) of Directive 85/374, as well as when discussing the burden of proof for victims in cases such as the present one, and limitations to admissible evidence. In this respect, the Court noted that certain limitations on the types of admissible evidence would be inconsistent with the objectives of the Directive, which include **protecting consumer health and safety.**

Within the judgment of *Boston Scientific Medizintechnik* itself, the CJEU refers only to one other case: *Veedfald* (C-203/99, EU:C:2001:258). It does so in reiterating its previous findings that "**full and proper compensation for persons injured by a defective product must be available**" in relation to **damage caused by death or personal injuries** which are the result of a producer's product being defective.

Impact on national case law in Member States other than that of the Court referring the preliminary question to the CJEU

United Kingdom

Boston Scientific Medizintechnik was referred to by the Scottish Court of Session (Scotland's supreme civil Court) in the case of *John Hastings v Finsbury Orthopaedics Limited and Stryker UK Limited* [2021] CSIH 6. In this case, the Court of Session relied on the CJEU's judgment to hold that whether or not a product is defective must "be approached on the basis of the reasonable expectation of the public at large, taking into account the intended purpose, the objective characteristics and properties of the product and the specific requirements of the patients" (paragraph 24), and that such a determination must be fact-specific (paragraph 59). The *John Hastings* case also mentioned *Boston Scientific Medizintechnik* together with *Sanofi* (as mentioned in Section 2.1.3 above) in support of the Court of Session's statement that "the [product

liability] Directive sought a fair apportionment of risks inherent in modern technology between the injured person and the producer and that of protecting consumer health and safety" (paragraph 40).

The UK High Court of Justice also discussed *Boston Scientific Medizintechnik* in the case of *Gee & Ors v Depuy International Ltd* [2018] EWHC 1208. Here, the claimants relied on the CJEU's judgment to make several arguments concerning the meaning of "defect." This was discussed by the High Court, which found the claimants to have misinterpreted the CJEU's judgment, finding, for example, that *Boston Scientific Medizintechnik* did not support a claim that "the normal risks inherent in the use of a product can constitute a 'defect,'" and that the liability of the producer in the CJEU case "arose from '*the abnormal potential for damage which those products might cause to the person concerned*'."[97]

2.2 Conflicts between Freedom to Conduct a Business, Freedom of Expression and the Protection of Health in its Collective Dimension with Consumer Law

In the protection of fundamental rights, conflicts can arise between the protection of different rights and interests. In the context of consumer protection and the right to health (which often requires safeguarding consumers' health), conflicts have arisen in particular with the right to conduct a business (Article 16 CFREU) and the right to freedom of expression (Article 11 CFREU). This section explores the CJEU's case law in such situations, which have arisen particularly often in relation to the marketing, advertisement, and sale of tobacco products. This section examines the role of the precautionary principle (Section 2.2.1) and the proportionality principle (Section 2.2.2) in finding the correct balance of protection between conflicting rights.

2.2.1 The Role of the Precautionary Principle

Relevant CJEU cases in this cluster:

➢ Judgment of the Court (First Chamber) of 22 November 2018, *Swedish Match AB v Secretary of State for Health*, Case C-151/17 ("**Swedish Match AB**")

Relevant legal sources

EU level

Recital 32 and Articles 1, 17, 19(1) and 24(3) Directive 2014/40/EU

Articles 34, 35 and 296 TFEU

Articles 1, 7, and 35 Charter of Fundamentals Right of the European Union

National level (United Kingdom)

Regulation 17 of the Tobacco and Related Products Regulations 2016, transposing the directive 2014/40 into UK laws.

[97] Italics in original.

Question 5 – The precautionary principle and risks to consumer health

Is the prohibition in EU law of placing tobacco products for oral use on the market valid, with regard to the principles of non-discrimination, proportionality, and subsidiarity, and Articles 1, 7, and 35 of the Charter of Fundamental Rights of the EU? Is the prohibition an effective way to protect public health?

This question was dealt with in *Swedish Match AB*.

The case

When joining the EU, Sweden negotiated a derogation, for its territory only, to the European prohibition of tobacco products for oral use (snus) because of established local practice (Article 151 of the Act of Accession, mentioned in the Article 17 of the Directive). A Swedish private company challenged the legality of the prohibition of these products in the UK, which transposed the EU secondary legislation. Even though this was not the first time the Court had to pronounce itself on the issue (*Swedish Match*, C-210/03), the company invoked new scientific evidence and a change of circumstances to support its claim.

Preliminary question referred

"Are [Article 1(c) and Article 17] of Directive [2014/40] invalid by reason of:

i. breach of the EU general principle of non-discrimination;

ii. breach of the EU general principle of proportionality (precaution);

iii. breach of Article 5(3) TEU and the EU principle of subsidiarity;

iv. breach of [the second paragraph of Article 296 TFEU];

v. breach of Articles 34 and 35 TFEU; and

vi. breach of Articles 1, 7 and 35 of [the Charter]?"

Reasoning of the Court

First, the Court stated that the general **principle of non-discrimination** requires that comparable situations are treated in the same way and that different situations are treated differently.[98] Tobacco products for oral use were in a different situation than cigarettes as they were new to Member States' markets. Their introduction could be attractive to young people. As already judged (*Swedish Match*, C-210/03), there was no discrimination – the fact that tobacco products for oral use could have a mass market expansion put them in a different situation than other smokeless products that cannot be produced at industrial scale.

Electronic cigarettes did not have the same objective characteristics and constituted another product category (*Pillbox 38,* C-477/14), as such there was no discrimination against tobacco products for oral use as they were not in a comparable situation with other tobacco products.

Addressing the **principle of proportionality and the precautionary principle**, the CJEU noted that a restriction of a right or freedom must have a legitimate goal and must not go beyond what is necessary to meet the desired objectives (*American Express*, C-304/16). Even if the mentioned products were less dangerous than cigarettes, they still posed risks to health. The precautionary principle was discussed in the context of the proportionality of the restriction. The Court defined the principle as meaning that "where there is uncertainty as to the existence or extent of risks to human health, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent. Where it proves to be impossible to determine with certainty the existence or extent of the alleged risk

[98] See Chapter 5 of this Casebook for a discussion of the right to non-discrimination in health-related cases.

because the results of studies conducted are inconclusive, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures." The Court noted that these considerations should guide an evaluation of the proportionality of the restriction in question and went on to discuss the scientific evidence concerning the health risks of snus. Specifically, it noted that although studies indicated that smokeless tobacco products were less dangerous to health than traditional smoking products, they still contained carcinogens and it had not been proven that the levels in snus would reduce the risk of cancer. In fact, there were even indications that they increased some other health risks. In addition, there was no conclusive evidence that tobacco products for oral use provided help to stop smoking. However, there was an obvious risk that they would encourage young people who were not yet consumers to start smoking (i.e. the "gateway effect"). Indeed, those products could hardly be detected when used by minors, and could be consumed in smoke-free areas. Ultimately, "in the exercise of the broad discretion available to it in that regard and in conformity with the precautionary principle," the scientific studies entitled the EU legislature to conclude "that the effectiveness of tobacco products for oral use as an aid to the cessation of smoking, if the prohibition on placing such products on the market were to be lifted, was uncertain and that there were public health risks, such as the risk of a gateway effect, due, in particular, to those products being attractive to young people."

When discussing the appropriateness of the measure, the Court found that it did not manifestly exceed what was necessary to attain the objective of ensuring a high level of public health, given that the positive effects of lifting the prohibition were uncertain, there would be risks to consumers' health, and less restrictive measures would not be equally appropriate to achieving the objective. The Court also referred to its previous ruling that **the protection of health takes precedence over economic considerations** (*Artegodan v Commission*, C-221/10) and found that the economic consequences for the development of the market for such products in the UK was uncertain. Therefore, there was no breach of equal treatment and the restrictions did not breach the principle of proportionality.

In relation to the **principle of subsidiarity**, the Court found that regarding shared competences, an act must only be taken by the EU institutions if the goal would be better achieved by the EU rather than by a Member State. Improving the internal market is a shared competence. Giving discretion to Member States on whether or not to prohibit the concerned products would counter the objective of improving the internal market enshrined in Article 1 of the Directive. The interdependence of the two objectives contained in the prohibition (internal market improvement and health protection) prevented the Member State from being able to achieve it adequately. Therefore, there was no breach of the principle of subsidiarity.

Concerning the breach of the obligation in Article 296(2) TFEU to state reasons, the Court found that the obligation must be appropriate to the measure and disclose the reasoning of the authority. There was no need to go into all relevant facts and points of law and the context can provide reasons. Having considered the previous Directive, the comments and preambles, there was enough information to explain why such a prohibition was introduced.

Regarding the breach of Articles 1, 7, and 35 of the Charter, the Court assessed it in light of Article 52(1) of the Charter, according to which "any limitation on the exercise of the rights and freedoms recognised by the Charter must be provided for by law and must respect the essence of those rights and freedoms" (paragraph 87). These conditions were met here (see above). The Court went on to state that rather than

restricting the right to health, the prohibition in question was intended "to give expression to that right and, consequently, to ensure a high level of health protection with respect to all consumers, by not entirely depriving people who want to stop smoking of a choice of products which could help them achieve that goal." Therefore, the Directive was not invalid with regard to Articles 1, 7, and 35 of the Charter.

Conclusion of the Court

"It follows from all the foregoing that consideration of the question referred has disclosed nothing capable of affecting the validity of Article 1(c) and Article 17 of Directive 2014/40."

The prohibition of tobacco products for oral use on the European market, except in Sweden, is valid under EU law as these products are very popular among young people and could increase the number of EU citizens consuming tobacco products.

Judicial dialogue

Interestingly, the same case was brought years earlier by the same company before the Court in order to challenge, on the same grounds, the prohibition of tobacco products for oral use enshrined at the time in Directive 2001/37/EC (*Swedish Match*, C-210/03). The decision mainly discussed the legal basis of the prohibition (Article 114 TFEU, former Article 95 EC) while being very brief on the non-discrimination principle. In the earlier case there was no mention of the precautionary principle. The Court declared that when a national measure transposed the prohibition in the directive, there was no need to ascertain separately whether that national measure complied with Articles 28 EC and 29 EC (Art. 34 and 35 TFEU). It rejected the claim of the company.

Similar questions to those in *Swedish Match* were referred to the Court in an earlier, pre-Charter case regarding the prohibition of certain food supplements by Directive 2002/46/EC by two associations of companies distributing food supplements and dietary products (*Alliance for Natural Health*, Joined Cases C-154/04 and C-155/04). The legal basis of the Directive, the restriction on the free movement of goods and respect for the principles of subsidiarity, proportionality, and equality were challenged. The Court stated that Article 95 EC (Article 114 TFEU) was the only appropriate legal basis for the prohibition. On the principle of subsidiarity, the Court similarly invoked the achievement of a high level of human health protection and the harmonisation of the internal market to justify the need for a European measure. The proportionality assessment was very brief. The Court identified a difference in situation to justify different treatment. The longest development was to assess conformity with Articles 28 and 30 EC (Articles 34 and 36 TFEU) with a proportionality test. Referencing *Swedish Match AB*, the reasoning of the judge was very similar to that used in this summarised case.

Concerning the definition of the precautionary principle, the CJEU relied on its previous case of *Pesce and Others* (Joined Cases C-78/16 and C-79/16, paragraph 47), building on a string of previous cases in which the definition was reiterated (including, for example, *Neptune Distribution*, C-157/14, discussed in Section 2.2.2.1 above).

The Court also referred to previous cases related to tobacco products and public health protection. For example, it relied on *Philip Morris* (C-547/14), in which the European regulation on cigarettes was challenged. The Court balanced the economic consequences of the prohibition of some products (flavoured cigarettes) against its effect on public health and found that the latter outweighed the former. It used this analysis to assess the proportionality of the prohibition of snus with its impact on the economy and trade. The Court also referred to its previous ruling in *Pillbox 38* (handed down on the same

day as *Philip Morris*) in order to respond to the company's argument that e-cigarettes were allowed in the EU. The case highlighted the difference between e-cigarettes and other tobacco products, preventing any analogy.

2.2.2 The Role of the Proportionality Principle

Relevant CJEU cases in this cluster:

➢ Judgment of the Court of 10 December 2002, *The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd*, Case C-491/01 ("**British American Tobacco (Investments) and Imperial Tobacco**")

➢ Judgment of the Court (Grand Chamber) of 12 July 2005, *Alliance for Natural Health and Others v Secretary of State for Health*, Cases C-154/04 and C-155/04 (**"Alliance for Natural Health"**)

➢ Judgment of the Court (Grand Chamber) of 8 December 2009, *Liga Portuguesa de Futebol Profissional and Bwin International*, Case C-42/07 ("**Liga Portuguesa de Futebol Profissional and Bwin International**")

➢ Judgment of the Court (Fourth Chamber) of 9 September 2010, *Criminal proceedings against Ernst Engelmann*, Case C-64/08 ("**Engelmann**")

➢ Judgment of the Court (Third Chamber), 6 September 2012, *Deutsches Weintor eG v Land Rheinland-Pfalz*, Case C-544/10 ("**Deutsches Weintor**")

➢ Judgment of the Court (Fourth Chamber), 10 April 2014, *Ehrmann AG v Zentrale zur Bekämpfung unlauteren Wettbewerbs eV*, Case C-609/12 ("**Ehrmann**")

➢ Judgment of the Court (First Chamber) of 11 June 2015, *Berlington Hungary and Others*, Case C-98/14 ("**Berlington Hungary and Others**")

➢ Judgment of the Court (Fourth Chamber) of 17 December 2015, *Neptune Distribution SNC v Ministre de l'Economie et des Finances (Minister for Economic Affairs and Finance)*, Case C-157-14 **("Neptune Distribution")**

➢ Judgment of the Court (Second Chamber) of 4 May 2016, *Philip Morris Brands SARL and Others v Secretary of State for Health*, Case C-547/14 ("**Philip Morris**") (reference case, Question 2)

➢ Judgment of the Court (Second Chamber) of 4 May 2016, *Pillbox 38 (UK) Limited, trading as Totally Wicked v Secretary of State for Health*, Case C-477/14 ("**Pillbox 38**") (reference case, Question 1)

➢ Judgment of the Court (Second Chamber) of 14 June 2017, *Online Games and Others*, Case C-685/15 ("**Online Games and Others**")

➢ Judgment of the Court (First Chamber) of 22 June 2017, *Unibet International*, Case C-49/16 ("**Unibet International**")

➢ Judgment of the Court (Sixth Chamber) of 28 February 2018, *Sporting Odds Limited v Nemzeti Adó- és Vámhivatal Központi Irányítása*, Case C-3/17 ("**Sporting Odds**") (reference case, Question 3)

➢ Judgment of the Court (Second Chamber) of 19 December 2018, *Stanley International Betting Ltd*, Case C-375/17 ("**Stanley International Betting Ltd**")

Relevant legal sources

EU level

Recitals 7, 33, 36, 38 to 41, 43, to 45, 47 and 48, and Articles 1, 2(4), (16) and (17), 8, 9, 10, 13(1), 14,18, 20, 24, 28 of Directive 2014/40/EU of the European Parliament and of the Council of April 3, 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products

Article 56 TFEU

Articles 16 and 17, 41, 47 and 48 Charter of Fundamental Rights of the European Union

Main questions addressed

Question 1 Do harsher rules on the placing of E-cigarettes on the market, compared to regular cigarettes, breach the EU legal principles of equal treatment and free competition, proportionality and legal certainty, and Articles 16 and 17 of the Charter?

Question 2 Are EU restrictions on the advertising and labelling of products compatible with the Charter of Fundamental Rights, bearing in mind the rationale of the protection of public health?

Question 3 Can reasons of public health, public policy, and public security justify restrictions on gaming and betting activities both with regard to the State monopoly system for certain types of such games and with regard to the concessions and licence system for the organisation of games of chance? What is the role of the principle of proportionality in this respect?

Question 6 – Restrictive rules for E-cigarettes and freedom to conduct a business

Is the imposition of harsher rules concerning the placing of E-cigarettes on the market, compared to regular cigarettes, contrary to EU legal principles of equal treatment and free competition, proportionality, and legal certainty, and Articles 16 and 17 of the Charter? What is the role of the protection of consumer health in this respect?

This question was dealt with in *Pillbox 38* (C-477/14).

National legal sources (United Kingdom)

Article R. 112-7 of the Consumer Code (intended to transpose Article 2 of Directive 2000/13):

"The labels and labelling methods used must not be such as to give rise to confusion in the mind of the purchaser or the consumer, particularly as to the characteristics of the foodstuff and, specifically, as to

its nature, identity, properties, composition, quantity, durability, method of conservation, origin or provenance, method of manufacture or production"

...

"The prohibitions or restrictions referred to above...shall also apply to the presentations of foodstuffs and... advertising"

Articles R. 1322-44-13 and R. 1322-44-14 of the Public Health Code (intended to transpose Article 9 of Directive 2009/54/EC):

"The misleading labelling of water suggesting characteristics that the water does not possess is prohibited."

The case

Pillbox 38 (UK) Ltd, trading as "Totally Wicked" brought a claim before the British national Courts seeking judicial review of the "intention and/or obligation" of the British government in the implementation of Directive 2014/40 on the approximation of tobacco products. According to the claimant, Article 20 of Directive 2014/40/EU was in violation of: (a) the principles of equal treatment and free competition; (b) the principles of proportionality and legal certainty; and (c) Articles 16 and 17 of the Charter, which concern freedom to conduct a business and the right to property, respectively. The national Court, being of the opinion that the arguments brought forward by the claimant were at least "reasonably arguable," referred the case to the CJEU for a preliminary ruling procedure. The Court ruled in favour of the British government, stating that none of the arguments and claims brought by Pillbox constituted a valid basis for the invalidity of the Directive, therefore allowing its implementation into British national law.

Preliminary questions referred to the Court

"Is Article 20 of Directive 2014/40 invalid, either in whole or in a relevant part, for one or more of the following reasons:

– it imposes either as a whole or in a relevant part a series of obligations on electronic cigarette manufacturers and/or retailers

which infringe the principle of proportionality, read in conjunction with the principle of legal certainty?

– for equivalent or similar reasons, it fails to comply with the principle of equality and/or unlawfully distorts competition?

– it fails to comply with the principle of subsidiarity?

– it infringes the rights of electronic cigarette manufacturers or retailers under Articles 16 and 17 of the Charter?"

Reasoning of the Court

The Court stated that the question being asked was essentially whether Article 20 of Directive 2014/40 is invalid on the ground that it infringes the principles of proportionality, legal certainty, equal treatment, free competition and subsidiarity and also Articles 16 and 17 of the Charter.

The Court first examined the principles of equal treatment and free competition. Pillbox claimed that the harsher treatment of E-cigarettes in comparison to tobacco cigarettes is inconsistent with the principle of equal treatment. The Court stressed that in order to find a violation of these principles, it must be shown that **comparable situations were treated differently, or different situations were treated in the same way, without objective justification** for doing so. The Court saw a clear differentiation between the two products with regard to: (1) their composition; (2) their consumption patterns; and (3) the scientific standpoint in regard to health risks, which could justify differential treatment of the products. The Court then found that the arguments concerning the infringement of free competition had no independent elements from those concerning the principle of equal treatment, and referred back to its reasoning on the latter point. Therefore, there was no infringement of either the principle of equal treatment or free competition.

Addressing the principles of proportionality and legal certainty, the Court first reiterated the definition of **proportionality**, which "requires that acts of EU institutions be appropriate for attaining the legitimate objectives pursued by the legislation at issue and do not exceed the limits of what is necessary in order to achieve those objectives" (paragraph 48); essentially, **when several appropriate measures are available, the least onerous must be chosen**, and the **disadvantages caused must not be disproportionate to the aims pursued**. In circumstances such as those of the present case, dealing with the economic, social, and political choices of the EU legislature, which must conduct complex assessments, it must be given broad discretion. Accordingly, a measure in this area would only be disproportionate if it were "manifestly inappropriate with regard to the objective" of the legislation (paragraph 49).

Pillbox claimed that Article 20 of Directive 2014/40 violated the principle of proportionality because the fact that E-cigarettes were "less harmful than tobacco products, or even beneficial for public health" meant that electronic cigarettes should not be subject to specific rules. In this respect, the Court pointed to the controversy surrounding the question of the health risks posed by E-cigarettes (compared with tobacco cigarettes as well). EU institutions, for instance, consider that E-cigarettes could facilitate a nicotine addiction and/or poisoning. Moreover, they could serve as a gateway to tobacco cigarettes for non-smokers. The Court further mentioned the ENDS report, which identified certain risks of E-cigarette usage, and pointed to the **precautionary principle** in arguing that, in cases of scientific uncertainty, protective/restrictive measures may be justified. Ultimately, in light of the EU legislature's intention to (i) "ensure the smooth functioning of the internal market with regard to those products, taking as a base a **high level of protection of human health**, especially for young people, and (ii) to meet the obligations of the Union under the FCTC" (concerning the possible prohibition or regulation of electronic nicotine), no violation of the principle of proportionality was found on this first ground.

Pillbox also claimed that the harsher treatment of E-cigarettes in comparison to cigarettes was inconsistent with the **principle of proportionality**, given the fact that E-cigarettes were less harmful. Discussing this claim, the Court referenced its discussion of the principle of equal treatment, stating that tobacco cigarettes and E-cigarettes could be distinguished for one another and the application of specific rules to them was justified.

Finally, the Court found that the fact that the EU legislature adopted a different measure in its impact assessment than that envisaged by the Commission (on the approximation of the laws, regulations, and administrative provisions of Member States concerning the manufacture, presentation, and sale of tobacco and related products) did not demonstrate that the measure adopted manifestly exceeded the

limits of what was necessary to achieve the relevant objective. Furthermore, Union institutions had taken all appropriate steps in educating themselves on the scientific evidence and opinions during the legislative process. There was therefore no infringement of either the principle of proportionality or legal certainty.

Finally, Pillbox's claim in relation to the CFREU provisions concerned Article 20(5) of the Directive in particular. According to Pillbox, this provision hindered its business activity. First, in regard to Article 16 of the Charter (the freedom to conduct a business in accordance with Union law and national laws and practices), the Court pointed out that this was not an absolute right but must be "examined in light of its function in society," in accordance with Article 52(1) of the Charter. The limitation was appropriate and necessary to achieve the legitimate objectives of the Directive. Second, concerning Article 17 of the Charter (the right to property), the Court held that paragraph 2 of the provision on intellectual property had not been violated. It found that the Directive did not hinder "the use of its intellectual property in connection with the marketing of its products, with the result that the essence of its property right essentially remains intact." Thus Article 20 of the Directive did not violate either Article 16 or 17 of the Charter.

Conclusion of the Court

The Court did not find any factor that would affect the validity of Article 20 of Directive 2014/40/EU on the approximation of the laws, regulations, and administrative provisions of Member States concerning the manufacture, presentation, and sale of tobacco and related products and repealing Directive 2001/37/EC.

Impact on the follow-up case

A very similar question to that raised in *Pillbox 38* was also raised in the national case of *Philip Morris Brands SARL, Philip Morris Ltd, British American Tobacco UK Ltd v The Secretary of State for Health* [2014] EWHC 3669, in which questions regarding the manufacture, presentation and sale of tobacco products were also referred to the CJEU. Due to the referral of the question in *Pillbox 38*, the Court chose to refer to the impending ruling of the CJEU on this matter rather than referring a very similar question itself, but requested that the CJEU consider the remaining questions referred at the same time as those in *Pillbox 38*. The CJEU did so, and the rulings have both been referred to in subsequent case law in the United Kingdom.

In *British American Tobacco v Secretary of State for Health* EWCA [2016] civ 1182, the judgment in *Pillbox 38* was also relied upon during discussions on the limitations of rights contained in the CFREU and the **precautionary principle** (paragraph 220 onwards). Concerning limitations of the rights in the Charter, the Court discussed Article 17 CFREU in conjunction with Article 52(1) CFREU. The argument by the applicants was that the Regulations in question were a limitation of the rights protected by the Charter, and that any limitation must be both proportionate and "respect 'the essence of the rights and freedoms'" (paragraph 119). The Tobacco Appellants claimed that these were two separate conditions for a limitation to meet, relying predominantly on the fact that in *Pillbox 38* the CJEU dealt with these two aspects separately. The Supreme Court was not convinced by this argument for three reasons: (1) the essence of the right created by registration of a trade mark is a series of negative rights; and those remain; (2) the right to property in Article 17 Charter "includes the provision that the use of property may be regulated by law in so far as is necessary for the general interest"; and (3) "rights guaranteed by the Charter may conflict with one another." Ultimately, the Court held that determining **whether or not a restriction complies with the Charter** requires an "**assessment of proportionality in the context of the**

objectives pursued by the impugned measure, **the importance of the rights** that they affect, and the **extent of the interference**" (paragraph 124).

Regarding the **precautionary principle**, the Supreme Court referred to the judgment (as well as those of *Phillip Morris*, C-547/14 and *Poland v Parliament and Council*, C-358/14, ECLI:EU:C:2016:323, handed down on the same day) in finding that "[t]he mere existence of a public health objective is not sufficient to bring [the principle] into play" (paragraph 221). The Court specifically noted that the principle was only invoked in *Pillbox 38* because of the "significant difference in scientific opinion" concerning the risks of the product, and was not invoked in the other cases cited. Ultimately, the Supreme Court held that even where the principle does apply, "it does not fundamentally alter the proportionality analysis" but rather allows the legislature to continue as though the product does constitute a risk.

Elements of judicial dialogue

In terms of horizontal dialogue, in defining the principle of proportionality and what it requires, the Court repeatedly referred back to its own case law on the validity of a directive concerning the manufacture, presentation, and sale of tobacco products, in the judgment of *British American Tobacco (Investments) and Imperial Tobacco* (C-491/01, ECLI:EU:C:2002:741). The Court also made reference to its previous decision in *Neptune Distribution* (C-157/14) in finding that "[w]here it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness, or imprecision of the results of studies conducted, but the **likelihood of real harm to public health persists should the risk materialise**, the **precautionary principle justifies** the adoption of **restrictive measures**." These cases build on the earlier, pre-Charter case of *Natural Health Alliance* (Joined Cases C-154/04 and C-155/04). This case concerned the free movement of substances that had not yet been formally evaluated and with regard to which there were "serious doubts, in the absence of adequate and appropriate scientific data, regarding their safety and/or their bioavailability." The Court held that in light of the need in such cases for the Community to take the **precautionary principle** into account when adopting measures intended to protect public health in the context of policy on the internal market, it was reasonable that entitlement to free movement could be restricted and reserved for a list of food supplements regarding which the necessary scientific data was available, whilst allowing for new substances to be added to the list according to scientific and technological developments (paragraph 68).

The Court's definition in *Pillbox 38* of the principle of proportionality and the requirements that must be met for the principle to be respected have been followed in several subsequent cases. This includes *Client Earth v Commission* (T-108/17, ECLI:EU:T:2019:215) and *Vanda Pharmaceuticals Ltd* (Case T-211/18, ECLI:EU:T:2019:892). Similarly, the Court's definition of the principle of equal treatment in Pillbox 38 was cited in the cases of *Rzecznik Praw Obywatelskich (RPO)* (C-390/15, ECLI:EU:C:2017:174) and *Vanda Pharmaceuticals Ltd.*

The CJEU's discussion in *Pillbox 38* of the limitations of rights and freedoms protected by the CFREU were also followed in *SC Star Storage SA* (Case 439/13, ECLI:EU:C:2016:688), where the Court agreed with the Opinion of the Advocate General, who noted that the measure in question thereby constituted a limitation on the **right to an effective remedy** before a tribunal within the meaning of Article 47 of the Charter. This right can, in accordance with Article 52(1) of the Charter only be justified "if it is provided for by law, if it respects the essence of that right and, subject to the principle of proportionality, if it is necessary and genuinely meets objectives of general interest recognised by the EU or the need to

protect the rights and freedoms of others (see judgment of 4 May 2016, *Pillbox 38*, C-477/14, EU:C:2016:324, paragraph 160)."

The Court's finding in *Pillbox 38* concerning the principle of equal treatment and the application of different rules for tobacco vs. E-cigarettes was reiterated in *Swedish Match AB* (C-151/17, ECLI:EU:C:2018:938). Here, the Court found that it followed from the ruling in *Pillbox 38* (that the different objective characteristics of the types of cigarettes involved in the case did not violate the principle of equal treatment), that "the principle of equal treatment cannot be infringed by reason of the fact that the particular category consisting of tobacco products for oral use is subject to different treatment from that of the other category that consists of electronic cigarettes" (paragraph 30). The Court's reasoning in these cases follows its application of the principle of equal treatment given expression in Article 20 CFREU, as well as the right to non-discrimination under Article 21 CFREU (see Chapter 5 below on Health and Non-Discrimination).

Impact on national case law in Member States other than that of the Court referring the preliminary question to the CJEU

France

In August 2019, the French Council of State relied on *Pillbox 38* in a case concerning whether the transposition of European Directive 2015/2302 on package travel and related travel services had been correctly carried out by Ordinance No. 2017-1717 of 20 December 2017.[99] *Pillbox 38* was relied upon in the Council of State's discussion of whether the Ordinance or the directive which it transposed, breached the freedom to conduct a business, as protected in Article 16 of the CFREU. Specifically, the Court followed the CJEU's findings that Article 16 CFREU "covers the freedom to exercise an economic or commercial activity, the freedom of contract and free competition" (*Pillbox* 38, paragraph 155) but that this "does not constitute an unfettered prerogative, but must be examined in light of its function in society" and may therefore be subject to a wide range of public authority interventions "which may limit the exercise of economic activity in the public interest." Without mentioning the provision explicitly, the Council of State then followed the CJEU's discussion of Article 52(1) CFREU, in which it reiterated that limitations placed on rights and freedoms in the Charter must be (1) provided for by law; (2) respect the essence of those rights and freedoms; and (3) in compliance with the principle of proportionality, "be necessary and actually meet objectives of general interest recognised by the European Union or the need to protect the rights and freedoms of others" (*Pillbox 38* paragraphs 157-160, referring to *Sky Österreich*, C-283/11). The Council of State found that there was no violation of the freedom to conduct business.

Question 7 – Limits on the labelling and advertising of products

In light of health protection and of Article 11 CFR, how must the proportionality of EU law restrictions on the labelling and advertising of products, in particular tobacco and food products, be assessed?

This question was addressed in *Philip Morris* (C-547/14).

The case

[99] French Council of State, Judgment 418394 of 12 August 2019, ECLI:FR: CECHR :2019:418394.20190712. This summary is based on a summary on the European e-Justice portal, available at <https://e-justice.europa.eu/caseDetails.do?plang=en&clang=fr&idTaxonomy=37194&idCountry=10> accessed 24 March 2021.

Philip Morris and British American Tobacco (BAT) initiated a case of judicial review against the Secretary of State for Health of the United Kingdom concerning the "intention and obligation" to implement Directive 2014/40/EU on the approximation of the laws, regulations, and administrative provisions of the Member States concerning the manufacture, presentation, and sale of tobacco and related products; also known as the Tobacco Products Directive (TPD). During the judicial review procedure, concerns regarding the Directive's general validity arose, leading the High Court of Justice of England and Wales to refer to the CJEU for a preliminary ruling on various provisions of the Directive and their compatibility with various TFEU provisions and the Charter of Fundamental Rights of the EU.

One of the main questions referred concerned Article 13(1) of Directive 2014/40/EU which basically prohibited any labelling that would encourage the consumption of tobacco. The UK Court, in essence, asked whether this provision should be interpreted to also prohibit information which was "factually accurate" and if it were to be interpreted that way, would the provision itself be valid in light of Article 11 of the Charter of Fundamental Rights and the principle of proportionality. The Court upheld Article 13(1) through justifications largely based on the grounds of consumer/public health.

In essence, the tobacco companies claimed numerous parts of the TPD were incompatible with EU treaties, did not adhere to the principle of subsidiarity nor proportionality and infringed fundamental Charter rights in its imposition of requirements on the packaging, manufacturing, and sale of tobacco products. The Court used health care and the aim of a high level of health as a basis for much of its reasoning, which led it to eventually uphold the challenged provisions of the Directive.

Preliminary questions referred to the Court

Seven questions were referred to the CJEU, two of which are relevant to our analysis.

1. In relation to Article 13 [of Directive 2014/40]:
    a) in its true interpretation, does it prohibit true and non-misleading statements about tobacco products on the product packaging; and,
    b) if so, is it invalid because it violates the principle of proportionality and/or Article 11 of the [Charter]?
2. Are any or all of the following provisions of [Directive 2014/40] invalid because they infringe the principle of proportionality:
    a) Article 7(1) and (7), in so far as [it] prohibit[s] the placing on the market of tobacco products with menthol as a characterising flavour and the placing on the market of tobacco products containing flavourings in any of their components;
    b) Articles 8(3), 9(3), 10(1)(g) and 14, in so far as they impose various pack standardisation requirements; and,
    c) Article 10(1)(a) and (c), in so far as [it] require[s] health warnings to cover 65% of the external front and back surface of the unit packaging and any outside packaging?

Reasoning of the Court

The legal reasoning of the Court in answering the question concerning Article 13(1) of Directive 2014/40/EU primarily focused on the overall aim of the (TPD) Directive which sought to ensure the

smooth functioning of the internal market and ensure/promote a high level of protection of human health. The Court first noted that information placed on the exterior packaging of tobacco products may be factually "accurate" and still have the effect of encouraging or promoting consumption; consequently, Article 13(1), which requires that "labels shall not include any information about the nicotine, tar, or carbon monoxide content of the tobacco product," attributes no importance to whether the information is factually accurate or not. The Court then explained that Article 13 has the aim of preventing consumers from being misled, in other words, to prevent companies from making them believe that certain types of tobacco are better for them, their health, or the environment than others. The Court, again, referred to the aim of the Directive enshrined in Article 1, which assumes a **high level of protection for human health as a basis**. The Court placed an emphasis on ensuring a high level of health for young people, stressing that in order to ensure the protection of public health, consumers should not be encouraged to consume these products through the provision of any information which they may interpret as meaning that the risks to their health may be lower when consuming certain tobaccos over others. Consequently, the Court held that the Directive excludes the display of information on the packets of any information considered in the Directive, regardless of how factually accurate it may be.

Second, the Court examined the validity of Article 13(1) in light of the **principle of proportionality** and Article 11 of the CFREU. The Court indicated that freedom of expression may also be used by businesses in the form of advertising and dissemination of commercial information. Consequently, the Court stated that the prohibitions on labelling provided by Article 13(1) were an interference with the tobacco companies' freedom of expression. However, with reference to Article 52(1) of the Charter and in light of Article 35 thereof, the Court held that human health protection outweighs the entitlement of a business' right to freedom of expression. Moreover, the Court did not accept the argument that Article 13 was not necessary as consumer health was ensured with the mandatory health warnings on tobacco, nor the argument that less stringent measures could be taken. Conversely, the Court reasoned that less restrictive measures would not have been effective in ensuring the protection of consumers' health.

The applicants then challenged Article 7 of the Directive leading to the prohibition of menthol cigarettes on grounds that this was neither necessary nor appropriate to achieve the Directive's aim. Consequently, they believed this prohibition to be disproportionate. The Court stressed the dual effects of the Directive, one of which concerned the functioning of the internal market and the other the protection of public health. The Court held that the prohibition was **appropriate for ensuring a high level of human health protection**, especially regarding younger people who may be persuaded by the flavourings, and held it to be completely proportionate when weighing the economic consequences of prohibition against Article 35 of the Charter for ensuring a high level of protection of human health.

Conclusion of the Court

Article 13(1) of Directive 2014/40 prohibits the display of any information covered by the Directive on tobacco packaging, regardless of whether the information is factually accurate or not.

Article 7(1) of Directive 2014/40 is proportionate to the aim of ensuring a high level of protection of human health and, consequently, remains valid.

Impact on the follow-up case

United Kingdom

Although not a follow up case to *Philip Morris* per se, the CJEU's judgment was implemented in *British American Tobacco (UK Limited) v Secretary of State for Health* [2016] ECA Civ 1182. In recognition that fundamental rights may conflict with one another the UK Civil Court of Appeal relied on *Philip Morris* to justify its finding that the economic interests of tobacco companies are secondary to the protection of human health consistent with Articles 9, 114 (3), and 168 (1) of the TFEU and Article 35 of the Charter.

Concerning issues of competence, the national Court concluded that Article 24(1) and (2) of the Tobacco Products Directive are partial harmonising measures, confirmed by Philip Morris. In this context, the UK Court held that "the provisions in the Regulations relating to plain packaging fall squarely within Article 24(2) and therefore within the competence of the UK." British American Tobacco appealed the case to the Supreme Court, which declined to hear the case.

The Netherlands

The Dutch case of *Stichting Rookpreventie Jeugd v the Staatssecretaris van Volksgezondheid, Welzijn en Sport* ECLI:NL:RBROT:2020:2382 of 20 March 2020 did not mention the CJEU's judgment in *Philip Morris*. However, it did refer to the earlier case of *British American Tobacco (Investments) and Imperial Tobacco* (C-491/01) mentioned in the judicial dialogue section below and which was relied on in *Philip Morris*. The Dutch case is now pending at the CJEU where, amongst others, the question of "Does Article 4(1) of [Directive 2014/40/EU] conflict with the principles of the Directive, with Article 114(3) TFEU, with the purpose of the WHO Framework Convention on Tobacco Control and with **Articles 24 and 35 of the Charter** because the method of measurement prescribed therein does not measure emissions from filter cigarettes in intended use, since that method does not take into account the effect of ventilation holes in the filter, which are largely closed by the lips and fingers of the smoker?."

Elements of judicial dialogue

In terms of horizontal judicial dialogue, the Court relied on its previous case law to determine the relationship between Charter rights and those of the ECHR. It referred to the judgment *Neptune Distribution* (C-157/14) in finding that Article 11 CFREU also grants freedom of expression to businesses, as well as their ability to impart/advertise information. In this respect, the CJEU explicitly stated that in line with Article 52(3) CFREU, Article 11 of the Charter has the same meaning and scope as Article 10 ECHR allowing for the freedom relied upon by businesses.

In delineating the principle of proportionality and the precautionary principle, the Court relied on its reasoning in *Neptune Distribution* (C-157/14) to employ a balancing exercise in establishing the validity of contested provisions in Directive 2009/54/EC regulating the rules on natural mineral water. The Court referred to its prior finding that "[w]here it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness, or imprecision of the results of studies conducted, but the likelihood of real harm to public health persists should the risk materialise, the **precautionary principle justifies the adoption of restrictive measures**." This was also reiterated by the CJEU in the more recent case of *Blaise* (C-616/17, ECLI:EU:C:2019:800) in the context of placing plant protection products on the market. Here, the Court referred back to both *Swedish Match* and *Neptune Distribution* after stating that '[w]here it proves to be impossible to determine with certainty the existence or extent of the alleged risk because the results of studies conducted are inconclusive, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures" (paragraph 43).

In Neptune Distribution, the CJEU found that given that it is undisputed that tobacco consumption and exposure to tobacco smoke are causes of death, disease, and disability, the prohibition laid down in Article 13(1) of Directive 2014/40 contributes to the achievement of the objective (of the provision) of preventing the promotion of tobacco products and incitements to use them. Thus, the Court found that human health protection outweighed the freedom of expression of businesses under Article 11 CFREU, thus upholding the fundamental right to health over freedom of expression.

Further, in relation to harmonisation and the principle of proportionality, the Court referred to its 2002 judgment *British American Tobacco (Investments) and Imperial Tobacco* (C-491/01) finding that merely regulating descriptions on tobacco packaging, instead of prohibiting them all together, would lead to uncertain effects and thus would not ensure that consumers received objective information. Furthermore, in relation to the **precautionary principle**, it ruled that some descriptions may, contrarily, encourage smoking and thus achieve the opposite of what Directive 2014/40 sought – ensuring a **high protection of human health**.

The Court also mentioned *Swedish Match* (C-210/03) and *Arnold André* (C-434/02) on several occasions in relation to the protection of public health and harmonisation of legislation. In this context, the CJEU considered that the first subparagraph of Article 168(1) TFEU provides that a high level of human health protection is to be ensured in the definition and implementation of all EU policies and activities, and that Article 114(3) TFEU explicitly requires that, in achieving harmonisation, a high level of protection of human health should be guaranteed. Moreover, concerning the **principle of proportionality**, the Court followed its reasoning in the *Swedish Match* (C-210/03) and *Arnold André* (C-434/02, ECLI:EU:C:2004:800), ruling that the measures referred to in Article 114(1) TFEU may require all Member States to authorise the marketing of the products concerned, may subject such an obligation of authorisation to certain conditions, or may even provisionally or definitively prohibit the marketing of a certain product, depending on the particular circumstances. These cases were also relied upon in *Alliance for Natural Health* (Joined cases C-154/04 and C-155/04, ECLI:EU:C:2005:449), where the CJEU stated that "Articles 3, 4(1), and 15(b) of Directive 2002/46, which give rise to a prohibition […] on marketing food supplements which do not comply with the directive, could be adopted on the basis of Article 95 EC" and that the fact that the protection of health was considered in the formulation of the provisions could not invalidate that finding.

Question 8 - The role of proportionality in justifying restrictions on the licensing of gaming and betting activities

Can reasons of public health, public policy, and public security justify restrictions on gaming and betting activities both with regard to the State monopoly system for certain types of such games and with regard to the concessions and licence system for the organisation of games of chance? What is the role of the principle of proportionality in this respect?

This question was addressed in *Sporting Odds* (Case C-3/17).

The case

The Hungarian Court asked sixteen questions, much of which the Court grouped together. The Administrative and Labour Court was uncertain how to proceed when "Sporting Odds," a British company which organises online games of chance, was investigated by the Hungarian Tax Authority due to a website "hu.sportingbeteuro.com" resulting in the imposition of a fine of HUF 3,500,000. Sporting

Odds brought action before the Fővárosi Közigazgatási és Munkaügyi Bíróság (Administrative and Labour Court, Budapest, Hungary) as they believed that Hungarian law on games of chance was contrary to EU law.

The Administrative and Labour Court was unsure how to proceed as a result of several issues. One such issue was linked to the Court's uncertainty as to the rules on which the examination of the consistency and systematic nature of the measures restricting the freedom to provide services was to be based. An issue which also raised considerable doubt was related to the "dual system" imposed by the Hungarian government. Namely, that the national authorities had a State monopoly over online and offline sports betting and horse racing in order **to combat compulsive gambling and to protect consumers**; and at the same time, since their reorganisation of the market, allowed private operators of casinos online and offline situated in Hungary to function under a concession and provide other games of chance which also entailed a **considerable risk of addiction** (i.e. casino and card games (online and offline) and slot machines).

Another area of uncertainty was that of issues surrounding the provision of evidence, **burden of proof,** and matters pertaining to **effective judicial remedy**. The Hungarian Court inquired about the examination and gathering of evidence by national Courts *proprio motu* in discerning Member State authorities' compliance with EU law. Further, it asked about interpretations surrounding the burden of proof to show compatibility with EU law, necessity, and proportionality. Of note is that the Hungarian Court inquired as to whether a failure of national authorities to demonstrate compliance with EU law and show necessity and proportionality would prove, in and of itself, that said national law breached EU law.

In terms of concerns raised about effective judicial remedy and the right to good administration, the referring Court sought clarity on the scope of opportunities available for service providers to question the compatibility of national legislation with EU law. In particular, it questioned whether the right to an effective remedy, defence rights, and rights of good administration are met if there is no opportunity to allow service providers to question the compatibility of national measures with EU law before going before the Courts.

Preliminary questions referred to the Court

Sixteen questions were referred by the national Court, five of which are relevant to our analysis:

1. Must Article 56 TFEU, the prohibition of discrimination and the requirement that the restriction of gambling activities by Member States be carried out consistently and systematically, be interpreted as meaning that that Article is infringed and that requirement is not fulfilled if it is established that the reorganisation of the market, on the grounds of combating compulsive gambling and pursuing the statutory objective of protecting consumers, has, since the market reorganisation carried out by the Member State, effectively had as its consequence, or given rise to, a continuous increase in: the number of casinos, the annual tax on games of chance, the national budget forecast of revenue from casino concession fees, the amount of gambling chips bought by players and the amount of money needed to be entitled to play slot machines?

2. Must Article 56 TFEU and the prohibition of discrimination be interpreted as precluding a situation in which only service providers with casinos (and a concession) in Hungary may obtain a licence to offer online casino games, since service providers which do not have a casino in

Hungary (including service providers with a casino in another Member State) cannot access the licence to offer online casino games?

3. May Article 56 TFEU and the obligation for the Member States to justify and state reasons for the restriction of the free movement of services be interpreted as meaning that the Member State has not fulfilled that obligation if the relevant impact assessment on which the public policy objectives of the restriction are based was not available at either the time it adopted the restriction or at the time of the examination?

4. Must Article 56 TFEU, the sincere cooperation clause in Article 4(3) TEU, and the institutional and procedural autonomy of the Member States, in conjunction with Articles 47 and 48 of the Charter, as well as the right to effective judicial review mechanisms and the rights of defence laid down in those provisions, be interpreted as meaning that, in examining the requirements of EU law deriving from the case-law of the Court of Justice, and the necessity and proportionality of the restriction adopted by the Member State in question, the national Court ruling on the dispute may order and carry out of its own motion to examine and gather evidence, even if this is not provided for under the national procedural legislation of the Member State?

5. Must Article 56 TFEU, in conjunction with Articles 47 and 48 of the Charter, as well as the right to effective judicial review mechanisms and the rights of defence laid down in those provisions, be interpreted as meaning that in examining the requirements of EU law deriving from the case-law of the Court of Justice, and the necessity and proportionality of the restriction adopted by the Member State in question, the national Court ruling on the dispute cannot place the burden of proof on the service providers affected by the restriction, but that rather it is for the Member State — and, in particular, for the State authority that adopts the contested decision in question — to justify and demonstrate its compliance with EU law, as well as the necessity and proportionality of the national legislation, and that failure to do so has, by itself, the consequence that the national legislation breaches EU law?

Reasoning of the Court

Regarding Article 56 TFEU, the prohibition of discrimination and the requirement that the restriction of gambling activities by Member States be carried out consistently and systematically, the Court recalled that legislation on games of chance is one of the areas with significant moral, religious, and cultural differences between Member States. Thus, in the absence of EU harmonisation within a particular area it is for each Member State to determine, in line with its own values, what is necessary to ensure the interests in question are protected. Furthermore, the national authorities have a **margin of discretion** in doing so. The Court assessed whether the restriction imposed by Hungary was suitable for achieving the objective(s) they invoked. The Hungarian Government relied on reasons of **public order, public health, overriding reasons of consumer protection and prevention of addiction to gambling** in order to **justify the dual system of regulation of games of chance**. The Court noted, in reference to its prior case law, that simply because some games of chance resulted from a public monopoly while others fell under a system of authorisation for private operators was not in and of itself enough to affect the suitability of measures imposed in order to curb people's addiction to gambling. However, should the national authorities be found to be encouraging participation in games other than those falling under the State monopoly, rather than limiting the activities in a non-discriminatory manner, the entire rationale behind having a monopoly – to curb addiction to gambling – would be rendered inefficient.

Sporting Odds claimed that the real aim of the dual system was to increase revenue from the taxes levied on the privately operating casinos and that the liberalisation of certain games of chance had produced an effect that ran counter to the Government's alleged objective of preventing addiction to gambling and protecting consumers. The Court acknowledged that as such the goal of expanding public revenue cannot, alone, permit restricting freedom to provide services but an incidental increase in revenue is permissible so long as the restriction is appropriate for achieving legitimate objectives of an overriding public interest. The policy of controlled expansion could therefore only be regarded as consistent if criminal and fraudulent activities linked to gambling and addiction to gambling were a problem in Hungary at the moment in question and if the expansion of authorised and regulated activities helped solve the problem. The Court held that Article 56 TFEU must be interpreted as meaning that it does not preclude a dual system of organising games of chance in the market so long as the referring Court can establish that the measures in fact pursue the objectives of consumer protection and prevention of addiction to gambling, relied on by Hungary, in a consistent and systematic manner.

Concerning the issue of possible discrimination, the Court noted that **the freedom to provide services entails *inter alia* the abolition of discrimination on the basis of nationality** and allowing a person to provide services in another Member State other than the one in which he is established. In the present case, the national measures restricted the organisation of online games of chance to operators managing a casino within the national territory and which had a concession and a licence for that purpose. The Court recalled that systems of concessions/licencing must be based on objective, non-discriminatory criteria and must not entail an arbitrary abuse of a national authorities' discretion. The Hungarian government relied on the **protection of public order and health**, claiming that by allowing only trustworthy operators running a casino within the national territory which satisfied consumer protection requirements to provide services, it allowed for greater control of online gaming. The Court found that the restriction of reserving access to the market for online games of chance to casino operators situated within the national territory was **disproportionate and unnecessary as there were less restrictive measures available** for achieving the objectives.

Next, the Court considered the obligation of Member States to justify and state reasons for the restriction on the free movement of services. It noted that while a Member State relying on a particular objective in order to justify a restriction under Article 56 TFEU must supply the Court with evidence to enable the Court to be satisfied that the measure does comply with requirements of proportionality; this cannot be taken to mean that a Member State is prevented from imposing restrictive measures solely because they cannot produce studies which serve as a basis to adopt the restrictive measure. It is instead for the national Courts to carry out a global assessment of the circumstances surrounding the adoption and implementation of the restrictive legislation.

The Court then turned to the question of national Courts collecting and **assessing evidence *ex officio***, absent national legislation. The CJEU first established that it was for the national Courts to carry out a global assessment of the circumstances in which restrictive legislation was adopted and implemented on the basis of the evidence provided by the competent authorities of the Member State. It continued that while national procedural rules may sometimes require Courts to take measures in order to encourage parties to produce evidence, they cannot be required to substitute themselves for those authorities in setting out the justifications which it is the duty of the latter to provide. The Court concluded that as long as the national rules do not have the effect of substituting the position of the national authorities – whose task is to provide the evidence to the Court in order to determine whether a restriction is justified – with

the national Courts, the national legal system may require the Courts to examine of its own motion the facts of the case before it. National legislation which does not provide for *ex officio* examination of the proportionality of measures restricting the freedom to provide services within the meaning of Article 56 TFEU and which puts the burden of proof on the parties to the proceedings is not precluded by Article 56 TFEU and Article 4(3) TEU, read in conjunction with Articles 47 and 48 of the Charter.

In relation to the **burden of proof**, the Court noted that it is for the competent authorities of a Member State which have implemented such legislation to produce evidence establishing the existence of objectives capable of justifying a restriction on fundamental freedoms and its proportionality. However, the Court continued that in the absence or passivity of national authorities providing for such justifications, national Courts must be able to draw all inferences which result from such a failure. In sum, Article 56 TFEU, read in conjunction with Articles 47 and 48 of the Charter, must be interpreted as meaning that it is not for the service providers but for a Member State, which has put in place restrictive legislation, to provide evidence proving the existence of objectives capable of justifying a restriction on a fundamental freedom, in the absence of which the national Court must draw all the inferences which result from such a failure.

Conclusion of the Court

"Article 56 TFEU must be interpreted as meaning that it does not, in principle, preclude a dual system of organisation of the market for games of chance under which certain types of those games fall within the State monopoly system, while others fall within the system of concessions and licences for the organisation of games of chance, if the referring Court establishes that the rules restricting the freedom to provide services in fact pursues in a consistent and systematic manner the objectives relied on by the Member State concerned."

"Article 56 TFEU must be interpreted as meaning that it precludes a national measure, such as that at issue in the main proceedings, according to which the grant of a licence to organise online games of chance is reserved exclusively to operators of games of chance holding a concession for a casino situated on national territory, since that rule does not constitute a condition indispensable to the achievement of the desired objectives, and that there are less restrictive measures which are capable of attaining them."

"Article 56 TFEU must be interpreted as meaning that it cannot be held that a Member State has failed to satisfy its obligation to justify a restrictive measure because it has failed to provide an analysis of the effects of that measure on the date on which that measure was introduced into national law or the date of the examination of such a measure by the national Court."

"Article 56 TFEU and Article 4(3) TEU, read in conjunction with Articles 47 and 48 of the Charter, must be interpreted as meaning that they do not preclude national legislation, such as that at issue in the main proceedings, which does not provide for the *ex officio* examination of the proportionality of measures restricting the freedom to provide services within the meaning of Article 56 TFEU and which puts the burden of proof on the parties to the proceedings."

"Article 56 TFEU, read in conjunction with Articles 47 and 48 of the Charter, must be interpreted as meaning that it is for a Member State which has put in place restrictive legislation to provide evidence to prove the existence of objectives capable of justifying a restriction on a fundamental freedom guaranteed by the FEU Treaty and its proportionality, in the absence of which the national Court must draw all the inferences which result from such a failure."

Elements of judicial dialogue

In terms of horizontal judicial dialogue of prior CJEU cases regarding the same referring country, in applying the **principle of proportionality** the Court relied on its reasoning from *Berlington Hungary and Others* (C-98/14). The CJEU found that in order to rule that a policy of controlled expansion of gambling activities may be consistent both with the objective of preventing the use of gambling activities for criminal or fraudulent purposes and with that of preventing incitement to squander money on gambling and of combating addiction to gambling, by directing consumers towards the offer emanating from authorised operators, that offer is deemed to be protected from criminal elements and also designed to safeguard consumers more effectively against squandering money and an addiction to gambling. However, a policy of controlled expansion of gambling activities can only be regarded as being consistent if, first, criminal and fraudulent activities linked to gambling and, secondly, addiction to gambling, were a problem in Hungary at the material time, and if the expansion of authorised and regulated activities was likely to solve the problem. In this context, the CJEU carried out a global assessment of the circumstances in which the restrictive legislation at issue was adopted and implemented, examining the justification in

light of fundamental rights. Thus, the CJEU held that Article 56 TFEU must be interpreted as meaning that it does not, in principle, preclude a dual system of organisation of the market for games of chance under which certain types of those games fall within the State monopoly system, while others fall within the system of concessions and licences for the organisation of games of chance, if the referring Court establishes that the rules restricting the freedom to provide services in fact pursues in a consistent and systematic manner the objectives relied on by the Member State concerned.

With regard to the principle of non-discrimination, the Court referred to its previous case *Unibet International* (C-49/16) in finding that a system of concessions and licences for the organisation of games of chance must be based on objective, non-discriminatory criteria which are known in advance, in such a way as to circumscribe the exercise of the national authorities' discretion so that it is not used arbitrarily.

In terms of horizontal judicial dialogue, when assessing ex officio examination of circumstances in which restrictive legislation was adopted the CJEU extensively referred to its own case law. The Court made reference to its previous decision *Online Games and Others* (C-685/15) in finding that, with regard to the principle of proportionality, it is for the national Courts to carry out a global assessment of the circumstances in which restrictive legislation was adopted and implemented on the basis of the evidence provided by the competent authorities of the Member State, seeking to demonstrate the existence of objectives capable of justifying a restriction of a fundamental freedom guaranteed by the FEU Treaty and its proportionality. Furthermore, in *Online Games and Others* (C-685/15) the CJEU considered that if such justifications are not provided through absence or passivity of those authorities, the national Courts must be able to draw all inferences which result from such a failure. Thus, the Court followed its ruling in *Online Games and Others* (C-685/15) that Article 56 TFEU, read in light of **Article 47 of the Charter,** does not preclude a national procedural system according to which, in administrative offence proceedings, the Court called upon to rule on the compliance with EU legislation restricting the exercise of a fundamental freedom of the European Union, is required to examine of its own motion the facts of the case before it in the context of examining whether administrative offences arise, provided that such a system does not have the consequence that that Court is required to substitute itself for the competent authorities of the Member State concerned, whose task it is to provide the evidence necessary to enable that Court to determine whether that restriction is justified.

In relation to harmonisation, the CJEU relied on its prior reasoning in *Liga Portuguesa de Futebol Profissional and Bwin International* (C-42/07) to find that in the absence of EU harmonisation in a particular field, it is for each Member State to determine in those areas, in accordance with its own scale of values, what is required in order to ensure that the interests in question are protected. With regard to Article 56 TFEU, in *Liga Portuguesa de Futebol Profissional and Bwin International* (C-42/07) the CJEU held that it does not preclude national legislation which prohibits operators established in other Member States where they legally provide similar services from offering online casino games within the territory of a Member State. Furthermore, with regard to the principle of proportionality, in *Liga Portuguesa de Futebol Profissional and Bwin International* (C-42/07) the CJEU considered that it is common ground that, because of the lack of direct contact between consumer and operator, games of chance accessible via the internet involve different and more substantial risks of fraud by operators against consumers compared with the traditional markets for such games.

The findings of the Court in *Sporting Odds,* with regard to the duty of administrative authorities to give a reasoned decision when imposing restrictions on the freedom of establishment, was relied on in subsequent cases. Furthermore, the obligation for national Courts to conduct a global assessment of the

circumstances in which restrictive legislation was implemented on the basis of the evidence provided by the competent authorities of the Member State, in order to demonstrate the existence of proportional objectives capable of justifying a restriction of a fundamental freedom guaranteed by the FEU Treaty was also relied on. In *PI* (C-230/18) the Court ruled that, in line with the conclusion of *Sporting Odds*, the authorities must justify their decisions, and that national legislation which allows administrative authorities to close a commercial establishment with immediate effect without requiring reasons to be given in fact or in law nor requiring the decision to be in writing, nor requiring the decision to be communicated to the addressee, is prohibited. Furthermore, the CJEU ruled in *PI* that any application brought by that addressee seeking annulment of that decision must be reasoned in line with Article 49 TFEU, Article 15(2) and Articles 16, 47, and 52 of the Charter and the general principle of the right to good administration.

The CJEU's discussion in *Sporting Odds* with regard to the **principle of proportionality** was also followed in *Stanley International Betting Ltd* (C-375/17), where the CJEU decided that Articles 49 and 56 TFEU must be interpreted as not precluding national rules which provide for a sole concessionaire model for the concession of management of a lottery, unlike other games, prediction games, and betting, to which a multiple concessionaire model applies, provided that the national Court establishes that the national rules actually pursue, in a consistent and systematic manner, the objectives relied on by the Member State concerned, in this case combating addiction to gambling.

2.3. Guidelines emerging from the analysis

Several guidelines emerge from the analysis of consumer protection in health-related cases:

Effective judicial protection of consumers' health and the right to an effective remedy

As expressed by the CJEU in *S.* (C-219/15):

- Directive 93/42 on medical devices does not create rights for end-users to bring a claim against a surveillance body if it fails in its duty of surveillance, but authorises such rights to be implemented in national law.
- The responsibility of surveillance bodies must be invoked under the same conditions as the other national responsibility regimes (principle of equivalence) and it must not go against the effective transposition of the directive (principle of effectiveness).

As expressed by the CJEU in *Wasserleitungsverband Nördliches Burgenland and Others* (C-197/18):

- A natural or legal person with the option of drawing and using groundwater and who is directly concerned by a level of nitrate that is capable of limiting that person's option by interfering with the legitimate use of that water, must be in a position to require national authorities to observe those obligations, if necessary, by bringing an action before the competent Courts.
- The Aarhus Convention in conjunction with Article 47 of the CFREU imposes an obligation on Member States to ensure effective judicial protection of the rights conferred by EU law. Where the EU legislature has, by directive, imposed on Member States the obligation to pursue a particular course of action, the effectiveness of such action would be weakened if individuals were prevented from relying on it before their national Courts.

The principle of proportionality and the right to an effective remedy

As expressed by the CJEU in *Sporting Odds* (C-3/17):

- Article 56 TFEU and Article 4(3) TEU, read in conjunction with Articles 47 and 48 of the Charter, do not preclude national legislation that does not provide for the *ex officio* examination of the proportionality of measures restricting the freedom to provide services within the meaning of Article 56 TFEU and which puts the burden of proof on the parties to the proceedings.
- Article 56 TFEU, read in conjunction with Articles 47 and 48 of the Charter provides that it is for a Member State which has put in place restrictive legislation to provide evidence to prove the existence of objectives capable of justifying a restriction on a fundamental freedom guaranteed by the FEU Treaty and its proportionality, in the absence of which the national Court must draw all the inferences which result from such a failure.
- Pursuant to Article 56 TFEU, it cannot be said that a Member State has failed to satisfy its obligation to justify a restrictive measure because it has failed to provide an analysis of the effects of that measure on the date on which that measure was introduced into national law or on the date of the examination of such a measure by the national Court.
- Article 56 TFEU does not preclude a system under which certain types of games of chance fall within the State monopoly system, while others fall within a system of concessions and licences, if the national Courts establish that the rules restricting the freedom to provide services in fact pursues, in a consistent and systematic manner, the objectives (i.e. public health, overriding reasons of consumer protection and prevention of addiction to gambling) relied on by the Member States concerned.
- Article 56 TFEU precludes a national measure according to which the granting of a licence to organise online games of chance is reserved exclusively to operators of games of chance holding a concession for a casino situated within the national territory, as that rule does not constitute a vital condition for the achievement of the desired objectives (i.e. public health, overriding reasons of consumer protection and prevention of addiction to gambling), and considering that there are less restrictive measures capable of attaining such objectives.

As expressed by the CJEU in *Philip Morris* (C-547/14):

- A ban on menthol cigarettes is appropriate and proportionate when weighing the economic consequences of this prohibition against Article 35 of the Charter for ensuring a high level of protection to human health.
- By virtue of Article 52(1) of the Charter and in light of Article 35 thereof, the protection of human health outweighs the entitlement of the businesses' right to freedom of expression.
- Interference with a business' freedom of expression, which in turn has implications for various economic interests, is proportional if it meets the objective of the protection of human health.

The precautionary principle in health-related cases

As expressed by the CJEU in *Swedish Match AB* (C-151/17):

- Where there is uncertainty as to the existence or extent of risks to human health, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent. Where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because the results of studies conducted are inconclusive, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures.
- Considerations relevant to the precautionary principle should guide an evaluation of the proportionality of a restrictive measure.

Defective products and the protection of consumers' health

As expressed by the CJEU in *Sanofi* (C-621/15):

- Article 4 of Directive 85/374 must be interpreted, in light of the general **principle of effectiveness**, as not precluding national Courts from establishing a causal link between a vaccination and the damages arising from it insofar as the scientific evidence can neither confirm nor rule out such a link and insofar as the evidence brought by the plaintiff can be regarded as serious, specific, and consistent by the national Courts.
- In cases of scientific uncertainty as to whether a vaccination can be linked to a medical condition suffered by the plaintiff, Article 4 of Directive 85/374 must be interpreted as precluding national Courts from automatically deriving a causal link in favour of the plaintiff.

As expressed by the CJEU in *Boston Scientific Medizintechnik* (Joined Cases C-503/13 and C-504/13):

- In assessing medical products, Courts should take product functions into account as well as the vulnerable situations of patients that make use of such products. In the Court's view, therefore, patients are entitled to expect particularly high safety requirements from devices such as pacemakers and defibrillators.
- Article 6(1) of Directive 85/374 must be interpreted as meaning that where it is found that products belonging to the same group or forming part of the same production series, such as pacemakers and implantable cardioverter defibrillators, suffer from a potential defect, national Courts may classify as defective all the products in that group or production series without having to establish that the product at hand has such a defect.
- Articles 1 and 9(1)(a) of Directive 85/734 must be interpreted as meaning that the damage caused by a surgical operation that is necessary to replace a defective product, constitutes damage caused by death or personal injuries. The producer of such defective products is liable insofar as the surgical operation is deemed to be necessary to overcome the defect of the underlying product. However, it is for national Courts to determine whether that is, or is not, the case.

3 Food Safety and Effective Protection of Health

3.1 Introduction

The purpose of this chapter is to assess the impact that the notion of effective protection of health has had and continues to have on the interpretation and application of European rules regarding food safety. In particular, the focus of the analysis is on the legal relation between effectiveness, precaution, and proportionality as built up by European and national case law concerning the marketization of foodstuffs and food-related products such as additives.

The European policy concerning food safety revolves around health protection and consumer protection, as laid out in the Commission's White Paper on Food Safety (COM (1999) 719 final) – Chapter 2. This combination reflects the interaction between health protection and market efficiency which, in a concrete way, Courts are in charge of assessing through a complex balance of different interests. Such integration implies that the EU policy on food safety is governed, at the broadest level, by the Treaty provisions on health (Art. 168 TFEU) and consumer protection (Art. 169 TFEU).

At the same time, the protection of health is framed within a double dimension which comprises both individual and public health, corresponding as such to the general notion of public interest that justifies the actions taken by the EU and national institutions especially when prohibiting the marketization of foodstuffs, agricultural products, and chemical products that may be potentially dangerous to human health. In this regard, even if consumer protection represents one of the main goals of legislation on food safety, the scope of application of the Regulations mentioned in this chapter goes beyond consumer protection as it is also applicable to business-to-business relations.

The effectiveness of the protection, in this context, cannot be separated from a scientific assessment of the risks connected to the usage of certain products. Therefore, the approach of European regulators has always emphasized the relevance of scientific risk analysis (provided by specific institutions) as the foundation for food safety policy, on the basis of three different "dimensions": risk assessment, risk management, and risk communication. If, in one or more of these dimension, there are elements which are potentially connected to a danger to human health, then EU law empowers public authorities to act on the basis of the precautionary principle.

The precautionary principle is inherently linked to the application of a proportionality test, which must guide the specific precautionary measures taken to ensure health protection. The test, shaped around the classic tripartite structure well-known to European law, inevitably touches upon the different interests (especially economic interests) related to the commercialization of food-related products and chemicals. At the same time, both proportionality and precaution are criteria for assessing the legitimacy of measures which regulate nutrition and health claims made about foods, thus restricting both the freedom of business and the freedom of expression in order to ensure the protection of consumers and human health.

3.2 Right to Health and Food Safety: the Role of the Precautionary Principle

Relevant CJEU cases

- Judgment of the Court of First Instance of 11 September 2002, Pfizer Animal Health SA v. Council of the European Union, Case T-13/99 ("**Pfizer**")
- Judgment of the Court of Justice of the European Union of 9 September 2003, Monsanto Agricoltura Italia Spa and Others, Case C-236/01 ("**Monsanto**")

Main question addressed

Question 1 Which role does the precautionary principle play in order to ensure an effective protection of health in the context of the application of the legislation concerning agriculture and food policies? How does the precautionary principle relate to the principle of effectiveness and the principle of proportionality within the risk assessment procedure?

Question 2 In situations concerning the application of the precautionary principle for health protection purposes how should the burden of proof regarding risks to human health or the environment arising from new products be allocated?

Question 3 Could a Member State contest the proportionality of a decision made by EU institutions that imposes restrictions on imports of foods products which aims at health protection? Which is the role of arguments based on scientific knowledge in evaluating the proportionality of such a measure?

Question 4 How should the proportionality and precautionary principles be applied within the assessment of the lawfulness of measures concerning nutrition and health claims made about foods which aims at protecting consumer health, restricting freedom of expression, and freedom to conduct a business?

Relevant legal sources

EU level

Art. 191 of the TFEU (previously Art. 174(2) of the EC Treaty) (Pfizer)

Council Regulation EC/2821/98 (Pfizer)

Directive 70/524/EEC; Directive 84/587/EEC; Directive 96/51/EC (Pfizer)

Directive 90/220/EEC; Regulation 258/97; Recommendation 97/618/EC (Monsanto)

National legal sources

Decree of the President of the Council of Ministers of 4 August 2000 (Monsanto)

Question 1 – Effective protection of health and the precautionary principle

Which role does the precautionary principle play in order to ensure an effective protection of health in the context of the application of the legislation concerning agriculture and food policies? How does the precautionary principle relate to the principle of effectiveness and the principle of proportionality within the risk assessment procedure?

The case

Pfizer Animal Health SA was the only world producer of virginiamycin, a feedstuffs additive for poultry and pigs. The additive had been originally authorized by the EEC on the basis of Dir. 70/524 and the authorizations were confirmed even after Dir. 96/51.

The Kingdom of Denmark decided to ban the use of virginiamycin, acting pursuant to Art. 11 of Dir. 70/524 as amended by Dir. 84/587 and Dir. 96/51, which empowered MSs to "temporarily suspend or restrict application of the provisions" due to "*new information or of a reassessment of existing information (…) has detailed grounds for establishing that the use of one of the additives authorised (…) constitutes a danger to animal or human health or the environment*."

Denmark based its decision on a report from the National Veterinary Laboratory which pointed out how virginiamycin, when used as a growth promoter in animals, could stimulate the development of virginiamycin-resistant bacteria, transmissible to humans through meat consumption, which could hinder the efficacy of certain products to treat infections in humans (e.g. streptogramins). Even if there was not an immediate threat to public health, since streptogramins were not in use at that moment for treatment of human infections, they could be needed in the future.

In the months that followed, both the Danish government and Pfizer submitted several documents to the Commission. Pfizer argued that the scientific evidence produced by Denmark was inadequate to prove the risks connected with the use of virginiamycin.

In July 1998 the Scientific Committee for Animal Nutrition (SCAN), at the Commission's request, published a scientific opinion concluding that "No new evidence has been provided to (…) compromise the future use of therapeutics in human medicine." The SCAN's opinions therefore did not regard the usage of virginiamycin to be an immediate risk to public health.

However, the Council, in light of the aforementioned debate, decided on December 17, 1998 to adopt the contested regulation (no. 2821/98) revoking the authorization of virginiamycin. Pfizer challenged the regulation before the Court seeking its annulment.

Issues assessed by the Court

Pfizer claimed that the Court should: a) annul the contested regulation in its entirety or with regard to virginiamycin; b) take other measures as it deemed appropriate; c) order the council to pay costs.

In particular, Pfizer put forward eight pleas concerning, among others, i) infringement of Art. 11 of Dir. 70/524; ii) manifest error of assessment; iii) breach of the precautionary principle; iv) breach of the proportionality principle.

The Council claimed that the Court should: a) dismiss the action as inadmissible; b) in alternative, dismiss the action as unfounded; order Pfizer to pay costs.

Reasoning of the Court

I. Admissibility

The Court observes that the contested regulation directly affected Pfizer insofar as "**it withdraws the authorisation of virginiamycin as an additive in feedstuffs." Being the sole producer of virginiamycin at the time when the authorization was conferred,** "Pfizer had obtained a position in respect of which Directive 70/524 offered legal safeguards." Therefore, the Court deemed the action admissible.

II. Substance

Pfizer argued that the Community institutions "have made errors in their analysis, by which is meant the assessment and management, of any risks to human health associated with the use of virginiamycin as a growth promoter, as well as in their application of the precautionary principle."

III. Risk Assessment and Precautionary Principle

The Council relied on the precautionary principle to adopt the contested regulation (Rec. 26) since, at the time of the enactment, neither the reality nor the seriousness of the risk connected to the usage of virginiamycin had been scientifically proven. Therefore, the Council decided in light of the potential risks. The Court pointed out that neither the EC Treaty nor the secondary legislation contained a definition of the precautionary principle.

Pfizer argued that the Council had violated the Guidelines on the Application of the Precautionary Principle of October 17, 1998 as well as the Communication from the Commission on the Precautionary Principle of February 2, 2000 (COM(2000)1. The Court pointed out, however, that the first document (the Guidelines) was meant to be a working document for the Commission which was neither adopted nor published, whereas the Communication on the Precautionary Principle was published more than a year after the adoption of the contested regulation, thus it could not limit the Community institutions' discretion.

A) General application of the precautionary principle

With regard to the application of the precautionary principle, the Court pointed out that Dir. 70/524 referred to "dangers to human health" as the criterion for withdrawing authorisations. The notion of danger was connected to that of risk assessment. **According to the Court, the European institutions, when there is scientific uncertainty concerning the risks connected to a product, may, in light of the precautionary principle, take measure without having to wait for the reality of such risks to become fully apparent**. Indeed, **if the precautionary principle is applied, it means that there is scientific uncertainty and therefore a full risk assessment cannot be regarded as a requisite** for the application of such a principle.

This does not mean that the principle is based on purely hypothetical allegations. There must be some data suggesting a risk, even if they are not definitive or certain. **The institutions, when carrying out the risk assessment, must determine the level of protection appropriate for society and, secondly, determine the level of risk** (i.e. critical probability threshold for adverse effects) **which they deem unacceptable and above which it is necessary to take preventive measures in spite of scientific uncertainty**. The authority must therefore "*weigh up its obligations and decide either to wait until the results of more detailed scientific research become available or to act on the basis of the scientific information available. Where measures*

for the protection of human health are concerned, the outcome of that balancing exercise will depend, account being taken of the particular circumstances of each individual case, on the level of risk which the authority deems unacceptable for society."

With regard to the burden of proof, the Court pointed out that the community institutions must demonstrate that, even in absence of conclusive scientific evidence, they carried out a thorough risk analysis to determine the existence of a risk in light of the aforementioned criteria.

With regard to the scientific assessments of both the Danish authorities and the SCAN, the Court pointed out that the Community institutions were not bound by either of those documents. The incompleteness of the national assessment cannot affect the Council assessment, since they are independent from each other. In the second place, the Council may decide not to follow the SCAN opinion, provided that it lays out a proper reasoning based on a thorough and impartial examination. In this case, the Council, acting on the Commission's proposal, decided to disregard the SCAN opinion but provided reasons justifying its choice.

The Court also assessed the alleged obligation, for community institutions, to consult the SCAN for a second opinion, after having obtained new scientific evidence. Given the specific purpose of SCAN (i.e. ensuring that Community legislation is founded on objective and sound scientific findings), the Court pointed out that the institutions could avoid asking for the SCAN's opinion only when they may rely on an adequate scientific basis to assess particularly complex facts of a scientific nature. In this case, the Court considered that such bases were indeed present and that the institutions were under no obligation to consult the SCAN a second time.

Indeed, the institutions also took, in addition to new scientific evidence produced, the reports and communications of international scientific bodies and organizations (e.g. the WHO) into account. This fact, contrary to what was argued by the plaintiff, indeed reinforced the legitimacy of the institutions' action in light of the precautionary principle, since it ensured that final decisions were made on the basis of a comprehensive analysis of world-wide research.

B) The specific assessment on the risks of virginiamycin.

The plaintiff argued that the scientific basis of the Regulation was not adequate to infer a connection between the usage of virginiamycin as a feedstuffs additive and risks to human health.

The Court argued, in the first place, that "*contrary to the view held by the SCAN, which had ruled out any 'immediate' risk, the Community institutions could properly adopt a cautious approach and pursue the objective of preserving the effectiveness of products used in human medicine even though, at the time when the contested regulation was adopted, they were little used in that sphere.*" Indeed "*The objective of ensuring that patients with a reduced immune system (…) are effectively treated is consonant with the objective laid down in the Treaty, namely ensuring a high level of human health protection.*" Even if a medicinal product is important only in the treatment of a specific patient, community institutions must take every measure to ensure its maximum effectiveness.

With regard to the adequacy of the scientific basis, the Court stated that since partial evidence on the potential risks of virginiamycin was available, the precautionary principle could then be activated. The Court also noted that if the institutions were unable to take protective measures until the whole research process of possible risks was completed, then the precautionary principle itself would be rendered devoid of purpose.

In light of such considerations, the Court considered that the community institutions did not exceed the boundaries of their discretion.

IV. Risk Management and the Principle of Proportionality

The plaintiff argued that the instrument chosen by the Council to implement the precautionary principle (i.e. the withdrawal of authorization to virginiamycin) violated the principle of proportionality, since, from the perspective of a cost/benefits analysis, there were other less onerous means to achieve the same purpose.

A) The cost/benefit analysis

The Court pointed out that the cost/benefit analysis is an expression of the principle of proportionality as founded on three different steps (necessity, appropriateness, strict proportionality). However, in the context of agricultural policy, the European legislature has discretionary powers corresponding to the political objectives laid out in the Treaty. As a consequence, **the legality of a measure may be contested only when it is manifestly inappropriate to reach the objective pursued. Given the proper assessment carried out by Community institutions, the decision to take protective measures cannot be criticized**. Furthermore, as the potential risk discussed was a link between the usage of a product and the development of human resistance to medicinal products used in treatments, the ban on the use of the product represented an appropriate means for ensuring the effectiveness of the medicinal products.

With regard to the negative outcomes of the ban on virginiamycin, the Courts pointed out that they may be easily offset by corresponding "positive trends." In the first place, alternative products for growth promotion in animals are available and even if some consider them to be less effective, changes in farming methods could easily overcome the problem. In the second place, an increase in the use of antibiotics for treatment in animals (made weaker by the non-usage of virginiamycin) would balance a reduction in their use as growth promoters. With regard to the possible use of unauthorized additives as substitutes, the Court stated that such a danger does not affect the lawfulness of the contested regulation, but merely confirms the need to take further regulatory measures. In conclusion, the Court stated that, even in light of a cost/benefit analysis, the ban on virginiamycin was an appropriate measure in line with the objectives of the agricultural policy.

B) No action against imports from third countries

According to the Court, the fact that Community institutions have not adopted measures at the international level against imports of meat produced using virginiamycin as a growth promoter cannot affect the legitimacy of the ban within the Community. Furthermore, the plaintiff did not prove that the absence of actions against imports would render the contested regulation an inappropriate means for reaching the objectives pursued by the Community.

C) Duty to take other, less onerous measures

The plaintiff argued, first, that Community institutions could have, as happened in other countries, waited for the scientific assessments to be complete before banning virginiamycin. The Court responded that such a ban was in line with the precautionary principle which empowers institutions to take protective measures even before a full scientific assessment is completed.

Second, the plaintiff argued "*that it would have been possible to provide for veterinary scrutiny of the amount of virginiamycin consumed by different animals or to lower the maximum age limits up to which virginiamycin could be used.*" However, the Court stated, the plaintiff did not prove how such alternative measures would achieve the objective pursued by the contested regulation, i.e. protection of human health.

D) Disproportionate nature of the disadvantages caused

The Court highlighted that the importance of the objective pursued by the regulation (protection of human health) justifies adverse consequences, even substantial, for some traders. Public health must take precedence over economic considerations. Economic rights and freedoms, as established in the case-law of European Courts, must also be viewed in light of their social function. Furthermore, the use of antibiotics in animal husbandry is not strictly necessary, since there are alternative methods of husbandry, even if at a greater cost to both farmers and consumers. This set of considerations must therefore be considered when weighing the different interests at stake and when assessing the disadvantages caused by the contested regulation.

V. Breach of the Principle of Non-Discrimination

The plaintiff argued that "*the contested regulation is vitiated by breach of the principle of non-discrimination since other antibiotics, some of which may be used in veterinary or perhaps even human medicine, were not banned.*" The Court considered that "*the lack of any action against the use of other substances, even if assumed to be unlawful, could not in itself affect the lawfulness of the ban on virginiamycin.*" In the second place, the plaintiff did not prove that the position of virginiamycin was comparable to that of other products in order to justify equal treatment for all of them.

VI. The Role of the Principles of Precaution and Proportionality

The Court examined the precautionary principle in connection with the assessment of the risks related to the use of virginiamycin. The core issue addressed by the Court was the assessment of the objective scientific basis needed to "activate" the precautionary principle. The Court stated that full, comprehensive, and definitive scientific evidence concerning a risk is not necessary in order to issue protective and preventive measures. Indeed, the precautionary principle's logic is a preventive one. It would be unreasonable to require definitive scientific evidence for a principle designed to empower Community institutions to act to prevent risk. Therefore, the Court emphasized the importance of a sort of standard setting, meaning that Community institutions must determine both an appropriate level of protection for society (in this case, in terms of human health) and a level of risk which is deemed unacceptable. If this risk, on the basis of the available scientific evidence, albeit incomplete or non-definitive, is present, then institutions may act pursuant to the precautionary principle even is the scientific assessments are still not complete.

With regard to proportionality, the Court emphasized that, due to the objectives of agricultural policy and the discretion enjoyed by community institutions, the judicial review must be limited to the appropriateness of the measure chosen to prevent risks. The Court embraced the cost/benefit analysis but also pointed out that, in light of the precautionary principles, preventive measures are legitimate. Furthermore, economic interests cannot prevail over public health interests, given the social function of economic rights and freedoms in European law.

VII. The Role of Effectiveness

The Court did not refer to the principle of effectiveness. The notion of effectiveness is indeed employed when referring to the insurance of the "effectiveness" of the medicinal product which could be hindered by virginiamycin. However, when interpreting the precautionary principle in light of its preventive function (in connection with the scientific evidence available at the time of its "activation") the Court implicitly evoked a concept of effectiveness, since it pointed out how the entire logic of the precautionary principle would be deprived of reason and practical effect if definitive scientific evidence were required in order to take protective measures.

Conclusion of the Court

The Court rejected all the plaintiff's claims and upheld the legitimacy of the contested regulation.

Elements of judicial dialogue

The connection between the precautionary principle and risk assessment was further explored in case C-236/01 (*Monsanto*) which directly referred to the reasoning of *Pfizer*. The CJEU, in *Monsanto*, states that "*protective measures may be taken (…) in light of the precautionary principle even if it proves impossible to carry out as full a risk assessment as possible in the particular circumstances of a given case because of the inadequate nature of the available scientific data*" (see for reference § 1.1.2).

The *Pfizer* reasoning was referred to by several decisions of both the Court of First Instance and the Court of Justice in order to interpret the precautionary principle, especially in relation to the state of scientific evidence. European case law has gradually strengthened the interpretation of such principles pointing out that it requires, first, detection of potentially negative consequences connected to the use of a certain product and, second, a comprehensive evaluation of health risks based on the scientific evidence available, even if incomplete. See in this regard, CJEU, C-77/09, *Gowan*; C-323/15, *Polynt SpA*.

A further specification of the precautionary principle was also developed by decision C-616/17, *Blaise et al.*, concerning compliance with the principle of Regulation (EC) No 1107/2009 of the European Parliament and of the Council of October 21, 2009 concerning the placing of plant protection products on the market. A French tribunal asked the CJEU whether or not the Regulation complied with the precautionary principle given that: i) it did not provide a specific definition of "active substance" in a phytosanitary product, leaving it to the applicant (for authorisation) to determine it; ii) it provided that the test and analysis concerning the application of the product are conducted by the applicant alone without any independent counter-analysis; iii) it took no account of the cumulative use of multiple active substances; iv) it exempted pesticide products from toxicity tests in the commercial formulations in which they are placed on the market, requiring only summary testing.

The Court, in defining the precautionary principle, referred to *Gowan* and, albeit implicitly, to *Pfizer*, so that "*where there is uncertainty as to the existence or extent of risks to human health, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent. Where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because the results of studies conducted are inconclusive, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures*" (§ 43). With regard to Reg. 1107/2009, however, the CJEU noted that, first, notwithstanding the absence of a specific definition of active substances, Commission Reg. 283/2013, taken in accordance with Reg. 1107/2009, sets out the data requirements for active substances, so that the applicant is concretely bound to identify such substances when submitting the application. Second, the Court stated that "*the procedures leading to the authorisation of a plant protection product must necessarily include*

an assessment not only of the specific effects of the active substances contained in that product, but also of the cumulative effects of those substances and their effects combined with other constituents of that product." Such assessment is indeed also inherent in the examination of the products in light of the possible harmful effects on human health. Third, the Court denied that the test produced by the applicant may be biased, given the specific requirements and control to which the tests were subjected.

Impact on national case law in Member States other than that of the Court referring the preliminary question to the CJEU

Italy

Italian local Courts referred to the Pfizer decision in order to justify, in light of the precautionary principle, safeguard measures taken by authorities in order to limit the use of medicinal products (Decision of the Trento Regional Administrative Tribunal of 8 July 2010, no. 171) and polluting substances (Decision of the Trento Regional Administrative Tribunal of 25 March 2010, no. 93) in presence of potential risks for human health and the environment. In particular, in both decisions the Courts pointed out how a lack of definitive scientific evidence regarding risks does not mean that authorities may overlook potential negative consequences arising from the use of certain products. Indeed, the high level of protection for both human health and the environment laid out in the treaties, means that the precautionary principle must be activated even without definitive scientific evidence.

Question 2 – The allocation of the burden of proof

In situations concerning the application of the precautionary principle for health protection purposes how should the burden of proof regarding risks to human health or the environment arising from new products be allocated?

The case

In response to a series of decisions from the Commission, concerning the marketing of genetically modified maize (Commission Decision 98/292/EC; Commission Decision 98/294/EC), French and British authorities authorized the marketing of genetically modified maize grains that were more resistant to insects and herbicides. On behalf of several companies, notifications were made to the Commission according to the simplified procedure laid out in Art. 5 of Reg. 258/97, accompanied by opinions from the Advisory Committee on Novel Foods and Processes which regarded the aforementioned novel foods as substantially equivalent to products derived from conventional maize and safe for use in food.

The Italian ministry of health argued before the Commission that the use of the simplified procedure for such products was improper and argued that the genetically modified maize was not substantially equivalent to conventional food. The Italian ministry concluded that "preventive measures had to be taken to ensure that the novel foods were safe and that their potential health risks were rigorously assessed before they were placed on the market." In spite of the Commission's confirmation about the substantial equivalence, the Italian ministry maintained its objections. Therefore, the Italian government adopted the Decree of 4 August 2000 pursuant to Art. 12 of Reg. 258/97, suspending trade of the aforementioned novel foods.

The producers of these novel foods brought an action before the Regional Administrative Tribunal of Lazio seeking to annul the Decree of August 4, 2000 and full compensation for damages suffered. The national Court considered both the use of the simplified procedure and the safeguard clause contained

in Art. 12 of Reg. 258/97, on the basis of the precautionary principle and empowering authorities to take preventive measures, and raised doubts concerning their correct interpretation. There, the Court decided to raise several preliminary questions.

Preliminary questions referred to the Court

1) Is the first subparagraph of Article 3(4) of Regulation No 258/97 to be interpreted as meaning that foods and food ingredients covered by Article 1(2)(b) of the Regulation may be considered substantially equivalent to existing foods or food ingredients and may therefore be placed on the market by means of the simplified procedure (…)?
2) If the answer to the first question is negative (…) what are the consequences, in particular for the power of Member States to adopt measures such as the Decree of August 4, 2000 on the basis of the precautionary principle, which is given specific expression in Article 12 of Regulation No 258/97, and for the allocation of the burden of proof with regard to risks to human health or the environment arising from the new product?
3) Does it affect the answer to the second question if the simplified procedure is found to entail tacit consent by the Commission to place the products concerned on the market in that the Member State concerned must first challenge the lawfulness of that tacit consent?
4) If the answer to the first question is affirmative, is Article 5 of Regulation No 258/97 compatible with Articles 153 EC and 174 EC and with the precautionary principle and the principles of proportionality and 'reasonableness,' in so far as:
    - it does not provide for a full assessment of the safety of the foods and food ingredients with regard to the risks they pose to human health and the environment and does not ensure the informed participation of the Member States and of their scientific bodies, although such involvement is necessary in light of the requirement for protection of those values, as shown by the normal procedure provided for in Article 6 et seq. of the Regulation, and
    - such a simplified procedure can be used, solely in order to speed up and simplify administrative action, for the placing of foods and food ingredients on the market in respect of which (…) information is not available concerning all the implications of placing them on the market for the health of consumers, human consumption, and the environment, as can be generally deduced from Recommendation 97/618?

Reasoning of the Court

I. The Notion of Substantial Equivalence

In the first place, the Court assessed the notion of substantial equivalence with regard to novel foods containing transgenic proteins. The Court stated that "*For the purpose of the simplified procedure, the condition of substantial equivalence (…) is assessed either on the basis of the available and generally recognised scientific evidence or (…) by scientific bodies which specialise in assessment of the risks generated by novel foods, namely the competent bodies of the Member States referred to in Article 4(3) of the Regulation (…).*" In light of the principle of equality, a uniform interpretation must be given to the notion throughout the Community, complying with the Regulation's objectives and purposes. The Court ruled that the presence of transgenic proteins does not prevent a novel food from being deemed as substantially equivalent to conventional food and thus from acceding to the simplified procedure. However, "*that is not the case where the existence of a risk of potentially*

dangerous effects on human health can be identified on the basis of the scientific knowledge available at the time of the initial assessment. It is for the national Court to determine whether that condition is satisfied."

II. The Precautionary Principle and the Burden of Proof

The Court stated that the applicability of Art. 12 of the Regulation was not affected by the type of procedure (ordinary or simplified) followed prior to the placing on the market of novel foods. However, the Court also pointed out that in a case where the simplified procedure was wrongly applied "*given that differences between the composition of a novel food and that of an existing food did not warrant the conclusion that those products are substantially equivalent*," in light of public health risks, the adoption of safeguard measures was justified.

Safeguard measures must be founded on a risk assessment which is as complete as possible, taking the two main objectives of the regulation into account, i.e. the functioning of the internal market and the protection of public health.

With regard to the burden of proof, the Court reiterated that **the regulation requires Member States to have "*detailed grounds*" for considering that the use of a novel food endangers human health or the environment. In light of the temporary nature of safeguard measures, and the limited nature of the risk analysis under the simplified procedure, a Member State may satisfy "*the burden of proof on it if it relies on evidence which indicates the existence of a specific risk which those novel foods could involve.*"**

Protective measures can be taken even if it is impossible to carry out a full risk assessment. It is important, however, that the evidence available "*makes it possible reasonably to conclude (…) that the implementation of those measures is necessary in order to avoid novel foods which pose potential risks to human health being offered on the market.*"

Lastly, the Court assessed the simplified procedure from the perspective of the insurance of a high level of protection for health and the environment pursuant to the EC Treaty. The Court pointed out that the simplified procedure is connected to the notion of substantial equivalence, which is a specific method to identify potential dangers, whose identification prevents the use of the simplified procedure. In the second place, health protection is also ensured by Art. 12 and by the precautionary principle which may lead to the application of safeguard measures.

With regard to the principle of proportionality, the Court pointed out that the simplified procedure constituted an appropriate instrument for dealing with complex assessments, for the objectives of ensuring the functioning of the internal market and protecting the human health and the environment.

Conclusion of the Court

The Court stated that:

i) "*the mere presence in novel foods of residues of transgenic protein at certain levels does not preclude those foods from being considered substantially equivalent to existing foods and, consequently, use of the simplified procedure for placing those foods on the market. However, that is not the case where the existence of a risk of potentially dangerous effects on human health can be identified on the basis of the scientific knowledge available at the time of the initial assessment. It is for the national Court to determine whether that condition is satisfied.*"

ii) "*In principle, the issue of the validity of the use of the simplified procedure laid down in Article 5 of Regulation No 258/97 (…) does not affect the power of the Member States to adopt measures falling under Article 12 of the Regulation (…) Nevertheless, those measures can be adopted only if the Member State has first carried out a risk assessment which is as complete as possible given the particular circumstances of the individual case, from which it is apparent that, in light of the precautionary principle, the implementation of such measures is necessary in order to ensure that novel foods do not present a danger for the consumer, in accordance with the first indent of Article 3(1) of Regulation No 258/97.*"

Impact on the follow-up case

The Lazio Regional Administrative Tribunal (decision no. 2028 of 3 March 2004) confirmed in the first place the legitimacy of the simplified procedure for transgenic products. In the second place, it pointed out that the decisive issue to be resolved regarded the state of scientific evidence at the time of the marketization of the products. In particular, the Court had to assess whether or not such evidence could indicate the presence of potential risks. Since, according to the CJEU, the precautionary principle justifies the adoption of protective measures even in presence of mere "specific indications" concerning risks, it is necessary to ascertain the presence of such indications. The Court therefore required the President of the Italian Superior Institute of Health to carry out a technical assessment regarding the state of scientific knowledge at the time of the marketization of the products.

With decision no. 14477 of 29 November 2004, the Lazio Regional Administrative Tribunal annulled the Decree of 4 August 2000. In the first place, the Tribunal reiterated that the CJEU declared the simplified procedure could very well be used for transgenic products as well; in the second place, in light of the interpretation of the precautionary principle given by the CJEU, the Tribunal pointed out that the administration did not prove the existence of a potential risk to human health. In particular, the further technical assessment carried out by the Superior Institute of Health did not show that indications about possible risks were present at the time of the marketization of the products and the Italian government did not prove otherwise. The adoption of safeguard measures was therefore not justified by an adequate scientific basis.

Elements of judicial dialogue

The interpretation of the precautionary principle was further specific by the CJEU in case C-111/16, *Fidenato*, also concerning the marketing of genetically modified maize grains. In this case, the Italian government requested the Commission to adopt safeguard measures in order to prohibit the cultivation of modified maize, pursuant to Art. 34 of Reg. 1829/2003. The Article, however, provided that "*where it is evident that products authorised by or in accordance with this Regulation are likely to constitute a serious risk to human health, animal health, or the environment … measures shall be taken under the procedures provided for in Articles 53 and 54 of Regulation [No 178/2002].*"

The Court pointed out that this Article must be interpreted as meaning that the Commission was not obliged to act "*as long as it is not evident that products authorised by Regulation No 1829/2003 or in accordance with that regulation are likely to constitute a serious risk to human health, animal health, or the environment.*" The Court also pointed out that, when the condition of Art. 34 of the regulation (i.e. evidence of serious risk) was not fulfilled, Member States cannot act solely on the base of the precautionary principle and adopt safeguard measures.

In the *Fidenato* case the CJEU confirmed the general view, already adopted in *Monsanto*, but highlighted that the precautionary principle cannot be the sole basis of protective measures m by the authorities. There must instead be the "evidence" of serious risks. In light of the *Monsanto* reasoning, the evidence does not have to amount to a definitive scientific assessment. However, if such scientifically-backed evidence is absent, then protective measured cannot be adopted.

Impact on national case law in Member States other than that of the Court referring the preliminary question to the CJEU

Italy

The Italian administrative Courts referred to *Monsanto* when assessing and interpreting the precautionary principle as laid out in European treaties. In particular, the Courts highlighted that, according to the CJEU, the precautionary principle cannot be based on purely hypothetical conclusions and must have a scientific foundation, even if incomplete. It is for the party invoking the application of the principle to offer proof that such a foundation exists. Such a line of reasoning led the Italian administrative Courts to reject claims from private parties which argued that public authorities had violated the precautionary principle by authorizing certain activities (allegedly dangerous for the environment) or by following special procedures in authorizing them. See, in this regard, the Lombardy Regional Administrative Tribunal decision of 11 March 2011 no. 398; the Council of State decisions of 14 July 2020 no. 4544 and 4545.

France

Albeit not referring explicitly to the CJEU decision, the French Council of State embraced the *Monsanto* reasoning in decision no. 329249 of 7 March 2012, concerning the marketization of phytopharmaceutical products. The Council of State pointed out that the precautionary principle requires at least partial objective scientific evidence and it is for the party invoking the application of the principle to prove that public authorities could rely on such evidence.

Question 3 - Health Protection and Restrictions to the Free Movement of Goods

Relevant CJEU case

- Judgement of the Court of 5 May 1998, C-180/96, *United Kingdom of Great Britain and Northern Ireland v Commission of the European Communities supported by Council of the European Union*

Could a Member State contest the proportionality of a decision made by EU institutions imposing restrictions on imports of foods products aiming at health protection? What is the role of arguments based on scientific knowledge in evaluating the proportionality of such a measure?

Relevant legal sources

EU level

Directive 90/425/EEC, Art. 10

1. Each Member State shall immediately notify the other Member States and the Commission of any outbreak in its territory […] of any zoonoses, diseases, or other cause likely to constitute a serious hazard to animals or to human health […]

4. The Commission shall in all cases review the situation in the Standing Veterinary Committee at the earliest opportunity. It shall adopt the necessary measures for animals and products referred to in Article 1 [live animals and products as identified in the Annexes A and B of the Directive] and, if the situation so requires, for the products derived from those animals.

Directive 89/662/EEC, Art. 9

1. Each Member State shall immediately notify the other Member States and the Commission of any outbreak in its territory […] of any zoonoses, diseases, or other cause likely to constitute a serious hazard to animals or to human health […]

[…]

4. The Commission shall in all cases review the situation in the Standing Veterinary Committee at the earliest opportunity. It shall adopt the necessary measures for the animals and the products referred to in Article 1 [products of animal origin as identified in Annexes A and B of the Directive] and, if the situation so requires, for the originating products or products derived from those products.

Commission Decision 96/239/EC Art. 1

Pending an overall examination of the situation and Community provisions adopted to protect against bovine spongiform encephalopathy notwithstanding, the United Kingdom shall not export from its territory to the other Member States or third countries:

- live bovine animals, their semen, and embryos,

- meat of bovine animals slaughtered in the United Kingdom,

- products obtained from bovine animals slaughtered in the United Kingdom which are liable to enter the animal feed or human food chain, and materials destined for use in medicinal products, cosmetics, or pharmaceutical products,

- mammalian-derived meal and bone-meal.

The case

The UK government sought annulment of Decision 96/239/EC that introduced a series of export restrictions on the UK to other Member States and third countries concerning live bovine animals, bovine meat, and other products of bovine origin.

The Decision was justified in light of new information concerning Bovine Spongiform Encephalopathy (BSE). In particular, in 1996 an independent scientific body advising the UK government on BSE-related issues released a statement in which it affirmed that BSE could be transmissible to humans in the form of the so-called variant Creutzfeldt-Jakob disease, highlighting that strict enforcement of existing measures was imperative. The Scientific Veterinary Committee of the European Union recommended adopting new measures to protect public health, even if it was not in a position to prove that BSE was transmissible to humans.

The basis for Decision 96/239/EC was identified in Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical inspections applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market and in Directive 89/662/EEC of 11 December 1989 concerning veterinary inspections in intra-Community trade with a view to the completion of the internal market.

Preliminary questions referred to the Court

The UK government sought annulment of Decision 96/239/EC based on a number of different pleas: 1. lack of compliance with the conditions posed in Directives 90/425 and 89/662; 2. lack of powers by the Commission to ban exports (both intra-Community exports and exports to third countries); 3. misuse of powers by the Commission; 4. failure to state reasons justifying the ban on exports; 5. breach of the principle of proportionality; 6. breach of the principle of non-discrimination; 7. failure to justify the decision based on the objectives of the common agricultural policy [eighth and ninth pleas omitted].

Reasoning of the Court

The Court began by considering the first three pleas advanced by the UK government. Both the directives of 1989 and 1990 provide that the Commission can adopt safeguard measures if a zoonosis, disease, or other cause is likely to represent a serious hazard. In the present case, new information related to the possible link between BSE and the variant Creutzfeldt-Jakob disease had moved the Commission to adopt additional measures coherent with the objective of Directives 90/425 and 89/662, namely allowing the Commission to intervene rapidly to prevent the spread of a disease that can represent a threat to human health. Therefore, Decision 96/239/EC was compliant with the goals set in the two abovementioned directives. Furthermore, in adopting the new measures the Commission did not go beyond its powers. Directives 90/425 and 89/662 conferred wide powers to the Commission since they provided that the latter can adopt 'necessary measures.' In the case of a disease that can give rise to a serious hazard to animals or humans, the Commission is therefore legitimised to take measures that completely ban the export of animals and products, as Decision 96/239 did. This ban can extend to the

exports to third countries since both the directives of 1989 and 1990 do not preclude the Commission from taking this course of action. With regard to the plea concerning the misuse of powers by the Commission, the Court began by noting that the Commission enjoys a wide measure of discretion with regard to the measures it adopts and that Courts must limit themselves to assessing whether the Commission did not clearly exceed the limits of discretion it enjoys. The situation of uncertainty as to the adequacy of the measures adopted, raised by the new information posing a link between BSE and the variant Creutzfeldt-Jakob disease, as well as the risks for public health that such a link implies, led the Court to state that "the Commission clearly did not exceed the bounds of its discretion in seeking to contain the disease within the territory of the United Kingdom by banning the export from that territory to other Member States and to third countries of bovine animals, meat of bovine animals, and derived products" (par. 62). The restriction to the free movement of goods that derived from such bans was legitimate insofar as it respected the principle of proportionality, an issue the Court dealt with later in the decision.

The Court moved to the analysis of the fourth plea, namely the failure of the Decision of 1996 to state the reasons that justified the ban on exports. The preamble to the Decision clearly identified the reasons justifying the measures adopted by the Commission which can be summed up in the need to protect the public health in a context of scientific uncertainty, thus making the UK aware of the rationale behind Decision 96/239.

A more thorough analysis was devoted to the alleged breach of the principle of proportionality. The UK government complained that Decision 96/239 was inappropriate in protecting animal and human health since adequate measures were already being taken and that the new measures were disproportionate. The Court highlighted that the principle of proportionality required that measures do not exceed the limits of what is appropriate and necessary to achieve given goals (in the present case: the protection of animal and human health) and that when there is a choice between different measures the least onerous should be preferred. Nonetheless, the legislature has wide discretionary powers in the context of the common agricultural policy; consequently, only those measures that are manifestly inappropriate can be considered illegitimate because they are in breach of the principle of proportionality. In the present case, it is clear that the Commission had to operate in a situation of scientific uncertainty with regard to the existence and magnitude of risks to animals and humans. In such a context, "the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent" (par. 99). More specifically, the protection of human health justifies the adoption of emergency measures that temporarily ban exports. The provisional nature of the measures is due to the emergence of new information that highlighted the possible presence of risks that were not considered before and that required additional scientific study. The reasoning of the Court was clearly inspired by the precautionary principle even if the latter was never mentioned explicitly.

The sixth plea concerned the alleged discrimination that Decision 96/239 introduced against UK producers. The Court stated that there was no discrimination since almost all cases of BSE occurred in the UK and that the principle of non-discrimination requires that comparable situations are not to be treated differently and, vice versa, that different situations are not to be treated alike.

The final plea to be considered centered around the failure to identify the objectives of the common agricultural policy that would justify the adoption of the Decision of 1996. The Court agreed with the Commission finding that "the protection of health contributes to the achievement of the objectives of the common agricultural policy […], particularly where agricultural production is directly dependent on

demand amongst consumers who are increasingly concerned to protect their health" (par. 121). Furthermore, the Court stated that "health protection requirements are to form a constituent part of the Community's other policies and that […] efforts to achieve objectives of the common agricultural policy cannot disregard requirements relating to the public interest such as the protection of consumers or the protection of the health and life of humans" (par. 120).

Conclusion of the Court

The Court confirmed the legitimacy of Decision 96/239/EC, highlighting that in situations of scientific uncertainty where new risks emerge for the life and health of humans, the European institutions can take provisional measures banning the export of live animals and products in order to protect public health.

Elements of judicial dialogue

In case C-180/96 the ECJ affirmed that situations of scientific uncertainty and the presence of new risks for humans justified the adoption of provisional measures functional to the protection of public health. The decision paved the way to the adoption of the precautionary principle in the food domain: in 2002, Art. 7 of reg. 178 formally introduced the precautionary principle into European food safety legislation. The principle has become a leitmotif in many decisions in the food safety context, such as for example in the European General Court, 9 September 2011, T-257/07 (concerning the alleged breach of the precautionary principle due to the relaxation of eradication measures taken to fight against BSE) and in the Pfizer case, mentioned above.

Impact on national case law in Member States other than that of the Court referring the preliminary question to the CJEU

Italy

The *Tribunale Amministrativo Regionale* of Naples, 10 April 2019, affirmed that, based on the precautionary principle, public health authorities can adopt measures imposing the seizure of products that might pose risks for human health (the case concerned the seizure of eggs coming from chickens fed with feed contaminated with dioxin). In the case such measures are later revoked because the risk is deemed not to exist or acceptable, public health authorities cannot be held liable.

Question 4 – Health Protection and Restrictions on the Freedom of Expression and Freedom to Conduct a Business

Relevant CJEU case

- Judgement of the Court (Fourth Chamber) of 17 December 2015, C-157/14, *Neptune Distribution SNC v Ministre de l'Économie et des Finances* ("**Neptune**")

How should the proportionality and precautionary principles be applied within the assessment of the lawfulness of measures concerning nutrition and health claims made on foods aimed at protecting consumers' health, restricting freedom of expression, and freedom to conduct a business?

Relevant legal sources

Supranational level

Art. 10, ECHR, Freedom of expression

1. Everyone has the right to freedom of expression. The right shall include freedom to hold opinions and to receive and impart information and ideas without interference by the public authority and regardless of frontiers […]. 2. The exercise of these freedoms, since it carries with it duties and responsibilities, may be subject to such formalities, conditions, restrictions or penalties as are prescribed by law and are necessary in a democratic society, for the protection of health.

EU level

Art. 11, CFREU, Freedom of Expression and Information

Everyone has the right to freedom of expression. This right shall include freedom to hold opinions and to receive and impart information and ideas without interference by the public authority and regardless of frontiers.

Art. 16, CFREU, Freedom to Conduct a Business

The freedom to conduct a business in accordance with Union law and national laws and practices is recognised.

Art. 52, CFREU, The Scope and Interpretation of Rights and Principles

Any limitation on the exercise of the rights and freedoms recognised by this Charter must be provided for by law and respect the essence of those rights and freedoms. Subject to the principle of proportionality, limitations may be made only if they are necessary and genuinely meet objectives of general interest recognised by the Union or the need to protect the rights and freedoms of others.

Art. 8(1), Reg. 1924/2006, Specific Conditions

Nutrition claims shall only be permitted if they are listed in the Annex and are in conformity with the conditions set out in this Regulation.

Art. 9(2), Dir. 2009/54

All indications attributing properties relating to the prevention, treatment, or cure of a human illness to a natural mineral water shall be prohibited. However, the indications listed in Annex III shall be authorised if they meet the relevant criteria laid down in that Annex […].

National Legal Sources

Art. R. 112-7, French Consumer Code

The labels and labelling methods used must not be such as to give rise to confusion in the mind of the purchaser or the consumer, particularly as to the characteristics of the foodstuff and, specifically, as to its nature, identity, properties, composition, quantity, durability, method of conservation, origin or provenance, method of manufacture or production.

The case

Neptune was selling and distributing natural sparkling mineral waters denominated 'Saint-Yorre' and 'Vichy Célestins.' The French Regional Directorate for Competition, Consumption, and Suppression of Fraud asked Neptune to remove from the label some statements claiming that the sodium in those mineral waters was sodium bicarbonate that has a different chemical composition from salt; the latter was present in very low quantity, less than the quantity existing in one liter of milk. According to the French authority, European regulations provided that claims such as 'low in sodium' or similar claims can be employed only insofar as the total amount of sodium present in the water complies with given limits; this was not the case for the mineral waters distributed by Neptune.

Neptune appealed the decision claiming that Art. R. 112-7 of the French Consumer Code was erroneously interpreted. The first instance Court and the appellate Court rejected the appeal brought by Neptune. The latter further appealed before the Conseil d'Ètat that, in its turn, referred to the European Court of Justice with two preliminary questions.

Preliminary questions referred to the Court

The Conseil d'Ètat identified two issues to be dealt with in order to handle the case: first, if in calculating the amount of sodium to be taken into account, should reference be made either to the total amount of sodium or only to the quantity of sodium chloride (salt) present in the water; second, whether restrictions to the freedom of expression and freedom to conduct a business imposed on Neptune were necessary and proportionate, in particular, in light of the requirement to ensure a high level of protection for the health of consumers:

1. Is the basis for calculating the "equivalent value for salt" of the quantity of sodium present in a foodstuff, for the purposes of the annex to [Regulation No 1924/2006], constituted only by the quantity of sodium which, when associated with chloride ions, forms sodium chloride or table salt, or does it include the total quantity of sodium in all its forms contained in the foodstuff?

2. In the latter case, do Article 2(1) of [Directive 2000/13] and Article 9(1) and (2) of [Directive 2009/54], together with Annex III to the latter directive, read in light of the equivalence established between sodium and salt in the annex to [Regulation No 1924/2006], infringe the first subparagraph of Article 6(1) [TEU], read with Article 11(1) (freedom of expression and information) and Article 16 (freedom to conduct a business) of the Charter and Article 10 of the ECHR, by prohibiting a distributor of mineral water from displaying on his labels and advertising slogans any indication as to the low salt content or sodium chloride content, which could be that of his product that is high in sodium bicarbonate, inasmuch as that indication would be likely to mislead the purchaser in regard to the total sodium content of the water?'

Reasoning of the Court

Starting from the first question, the Court moved from the coordination of reg. 1924/2006 with dir. 2009/54, noting that while the first regulates nutrition and health claims related to foodstuffs in a general manner, the second provides for specific rules concerning natural mineral waters. Both the pieces of legislation permit nutrition claims related to the content of sodium only insofar as the claims are listed in the annex and comply with the conditions set out in the same document. Since, in the case of natural mineral waters, the directive represents lex specialis with respect to reg. 1924/2006, for those waters the latter prohibits the use of the nutrition claims listed in the annex and related to sodium content. Moving to the directive, it provides for one single claim ('suitable for a low-medium diet') to be used if the sodium

content is less than 20 mg/l. The Court further noted that "By specifying, in Directive 2009/54, the maximum amount of sodium in cases in which the packaging, labels, or advertising for natural mineral waters contain an indication referring to low sodium content, the EU legislature does not differentiate according to the chemical compounds of which sodium is a component, or from which it originates" (Neptune, para 48). The Court concludes that since sodium can be a component of different chemical formulas, the quantity of sodium present in natural mineral waters must be determined with reference to its total quantity, whatever its chemical form.

The second question centered around the validity of those norms, provided for in dir. 2009/54 and reg. 1924/2006, that "prohibit the display on packaging, labels, and in advertising for natural mineral waters of any claim or indication that those waters are low in sodium chloride or table salt which is likely to mislead the consumer as to the total sodium content of the waters in question" (*Neptune*, par. 57). The validity of these norms must be assessed against Arts. 11(1) and 16 of the CFREU and Art. 10 of the ECHR providing for the freedom of expression, information, and to conduct a business. The Court began by recognizing that the prohibitions set both in the directive and in the regulation indeed represented a limit on the freedom of expression, information, and to conduct a business for the person carrying out that business. The Court is nonetheless aware that the freedom under consideration can be limited; at the same time such limitations must be in conformity with Art. 52 of the CFREU, meaning that they must be provided by law and respect the essence of those freedoms, be subject to the principle of proportionality, meet goals of the general interest recognised by the EU, or the need to protect the rights and freedoms of others. All these conditions were met in the instant case. First, the limitations were posed by law, namely by Art. 8(1) of reg. 1924/2006 and Art. 9(2) of dir. 2009/54, read together with the related annexes. Second, these same provisions made the information to be communicated to consumers subject to certain conditions, thus not affecting the freedom of expression and information. In addition, the legislation does not prohibit the product and marketing of natural mineral waters, since they simple regulate some claims that can be used in association with such waters; therefore, the freedom to conduct a business is not affected as well. The consequence is that both the freedom of information and expression and the freedom to conduct a business are respected in their essence. Third, the regulation on health claims met objectives of the general interest among which the protection of human health is of paramount importance in the present case. The Court added that "The need to ensure that the consumer has the most accurate and transparent information possible concerning the characteristics of goods is closely related to the protection of human health and is a question of general interest […] which may justify limitations on the freedom of expression and information of a person carrying on a business or his freedom to conduct a business" (*Neptune*, par. 74). As for the principle of proportionality, the Court noted that the legislature must be allowed broad discretion. In the case at stake, the legislature must take the need to protect human health into account as well as the precautionary principle. Since the EFSA, in an opinion published in April 2005, did not exclude that sodium, whatever its chemical form, can pose a risk to human health, the legislature was entitled to adopt restrictive regulatory measures such as those under consideration.

Conclusion of the Court

The Court concluded that:

- reg. 1924/2006 is not applicable in the present case since in the case of natural mineral waters only dir. 2009/54 is applicable;

- dir. 2009/54 mandates taking the overall quantity of sodium present in natural mineral waters into account regardless of its chemical form;

- the limitations posed by the legislature prohibiting business operators from displaying claims related to the low salt content on labels and advertising materials are legitimate since they are proportionate, appropriate, and necessary to ensuring the protection of human health in light also of the precautionary principle.

Impact on the follow-up case

Conseil d'Ètat, 15 February 2016, n. 351618

Following the EUCJ's decision, the Conseil d'Ètat affirmed the decision by the Cour administrative d'appel de Lyon confirming the injunction issued against Neptune, imposing on the latter the removal of any claim related to the contents of sodium in its natural mineral waters.

Elements of judicial dialogue

Preliminarily, it should be noted that while Regulation 1924/2006 poses consumer protection as one of its main goals, its scope of application goes beyond business-to-consumer relations, being applicable also in the business-to-business context.

In the Neptune case, the EUCJ provided national Courts with some guidelines on how to balance the freedom of expression and the freedom to conduct a business on the one hand, with the protection of public health on the other. In this balancing process the precautionary principle plays an important role since it permits taking cases into account "where there is uncertainty as to the existence or extent of risks to human health," thus justifying the adoption of measures "without having to wait until the reality and seriousness of those risks becomes fully apparent" (Neptune, par. 81). In addition to the precautionary principle, Courts should assess the validity of restrictions to fundamental freedoms considering whether such limitations respect the essence of those freedoms, are subject to the principle of proportionality, meet goals of the general interest recognised by the EU, and are needed to protect the rights and freedoms of others.

In another case decided a few years earlier, the EUCJ held that the prohibition to use health claims on labels, advertisements, and other accompanying materials of beverages containing more than 1.2% alcohol did not infringe upon the freedom to conduct a business established by Art. 16 of the CFREU since such a prohibition was justified to ensure a high level of health protection for consumers (Judgement of the Court, Third Chamber, of September 6, 2012, *Deutsches Weintor eG v Land Rheinland-Pfalz*).

Impact on national case law in Member States other than the one of the Court referring the preliminary question to the CJEU

Italy

The Tribunale di Milano, sez. specializzata impresa, 19 June 2017 held that the refusal of Facebook to accept ads promoting e-cigarettes without nicotine is legitimate since the precautionary principle justified restrictive measures in cases of scientific uncertainty. The scientific community debated whether the use of e-cigarettes, with or without nicotine, can pose a risk to human health, for example, by acting as a 'bridge' between non-nicotine products to those that contain nicotine. In such cases, also taking the

decision by the EUCJ in the case C-157/14 into account, Facebook had the right to refuse to display advertisement materials on its platform concerning e-cigarettes and products akin to tobacco products.

3.3 Guidelines Emerging from the Analysis

Precautionary principle, risk assessment and scientific evidence

Given its specific purpose, the precautionary principle does not require scientific certainty on possible risks to health and the environment connected to the use of a product, nor does it require a comprehensive and definitive scientific assessment. If such a certainty were required, the very logic of the precautionary principle (i.e. that of a preventive action) would be rendered devoid of sense. On the other hand, however, the precautionary principle cannot be based on purely hypothetical considerations. A risk assessment must always be carried out or, alternatively, scientific evidence, even if it is incomplete, must be available.

The institutions, when carrying out risk assessment, must therefore determine the level of protection appropriate for society and, secondly, determine the level of risk (i.e. critical probability threshold for adverse effects) which they deem unacceptable and above which it is necessary to take preventive measures despite any scientific uncertainty.

The burden of proof

The party that invokes the application of the precautionary principle must demonstrate that there is an adequate scientific basis for doing so. In particular, when public authorities enact protective measures which are then challenged, they must demonstrate that they have carried out a thorough risk assessment on the basis of the aforementioned criteria before taking action. If other parties (e.g. private parties) oppose the fact that the public authorities did not take any protective measure, they must prove that scientific evidence justifying the use of the precautionary principle was available or that the public authorities did not carry out a proper risk assessment.

The principle of proportionality

When evaluating the principle of proportionality in cases where safeguard measures were enacted, the Courts may also use a cost/benefit analysis in order to determine whether or not the harm suffered by economic operators targeted by safeguard measures are acceptable. However, they must take into account certain points:

i) In the context of agricultural policy, European institutions enjoy a wide degree of political discretion in determining the strategies and actions pursuant to the objectives laid out in the treaties. The proportionality test is therefore mostly focused on the appropriateness of safeguard measures with regard to the risk they want to prevent, since the "necessity" of the intervention may depend on the specific policy objectives pursued by EU institutions.

ii) When assessing the proportionality of the intervention as well as the cost/benefit analysis, Courts must consider that, in principle, the protection of human health takes precedence over economic considerations, also in light of the fact that the economic rights and freedoms laid out in the treaties must also be viewed in relation with their specific social function.

Limitations to the freedom of expression, of information, and to conduct a business

The protection of human health, especially in situations of scientific uncertainty, represents a goal of the general interest that can justify, together with the other conditions established in Art. 52 of CFREU, limitations to the freedom of expression, of information, and to conduct a business.

4 Health and Data Protection[100]

Disclaimer: data protection issues related to COVID-19 are addressed in the data protection section of Chapter 7

4.1. Health Data and their Regime under the GDPR

4.1.1. The Notion of Health Data and their Regime

Under EU law, the GDPR defines the notion of Health data and sketches their legal regime.

Art. 4 (15) Reg. EU 2016/679 defines 'data concerning health' as:

> "personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status."

In this respect, the CJEU stated that the expression "data concerning health" must be interpreted widely, "so as to include information concerning all aspects, both physical and mental, of the health of an individual" (*Lindqvist,* C-101/01, 6 November 2003). In the same vein, the European Data Protection Board (hereinafter: EDPB) considered that data concerning health can be derived from different sources (*e.g.*, information collected by a health care provider in a patient record, information that becomes health data by cross-referencing with other data thus revealing the state of health or health risks; information from a "self-check" survey, where data subjects answer questions related to their health; information that becomes health data because of its usage in a specific context, such as information regarding a recent trip to or presence in a region affected with COVID-19 processed by a medical professional to make a diagnosis).

Moreover, Art. 4(13) GDPR also defines **genetic data** as:

"personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question."

Genetic data fall into the special category of personal data provided for by Art. 9 GDPR, and the peculiarity of such data is that it concerns **multiple data subjects**, as the ECtHR recognized in *Marper v. United Kingdom*, 4 December 2008, ric. n. 30562/04 e 30566/04. In this respect, the Working Party Art. 29 (now repealed by the EDPB) in its *Working Document on Genetic Data*, adopted on March 17, 2004 recalled that:

"while genetic information is unique and distinguishes an individual from other individuals, it may also at the same time reveal information about and have implications for that individual's blood relatives (biological family) including those in succeeding and preceding generations. Furthermore, genetic data can characterize a group of persons (*e.g.*, ethnic communities)."

Genetic data are a category of data that shows **the complexity of the individual and collective dimensions of data and health protection: the same data may concern several persons and the processing of such data may be necessary for protecting the health of one among the**

[100] This Chapter has been drafted by C. Angiolini.

data subjects or may be used in order to make decisions concerning collective health (*e.g.,* for defining a better therapy for patients with the same genetic characteristics).

The interactions between the individual and collective dimensions of health and data protection go beyond genetic data: health data may concern multiple individuals (*e.g.*, the tumor rate of residents in an identified polluted area), and their processing may be conducted for collective health purposes (*e.g.*, measures to be taken in order to face an epidemic or to minimize health risks in a polluted area).

As to their regime, **health data are qualified by Art. 9 GDPR as special categories of personal data**, which are subject to specific rules for processing set forth in the same Art. 9 (in the European context with regard to the special regime of health data, see also the Council of Europe, Recommendation CM/Rec(2019)2, *Protection of Health-Related Data*).

According to Art. 9 Reg. UE 2016/679, the processing of such data is prohibited, except where the conditions provided for by the second paragraph of that Article are met (*e.g.*, explicit consent; personal data were manifestly made public by the data subject). It should be recalled that in order to legally process special categories of applicable data, both an exception to the prohibition in Art. 9 and a legal basis for its processing, among those provided for in Art. 6 EU Reg. 2016/679, must be applied. In other words, **the processing of special categories of personal data that falls under Art. 9 GDPR should only be done if i) an exception to the prohibition of processing provided for by Art. 9 GDPR is applicable and ii) a legal basis provided for by Art. 6 GDPR applies** (in that regard see: the EDPB, *Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection Regulation (GDPR) (Art. 70.1.b)* of 23 January 2019, § 28, p. 8; EDPB; *Document in response to a request from the European Commission for clarifications on the consistent application of the GDPR focusing on health research*, 2 February 2021, § 13; European Data Protection Supervisor, *Preliminary Opinion 8/2020 on the European Health Data Space,* 17 November 2020, §§ 15-16).

Moreover, according to Art. 35 GDPR, a data protection impact assessment should be conducted in case of processing of special categories of data on a large scale referred to in Article 9(1), including data concerning health.

4.1.2. Data Processing for Health-Related Purposes

Personal data may be processed for health-related purposes. Generally speaking, in these cases, a legal basis among those provided for by Art. 6 GDPR must be applied. Among the exceptions provided for by Art. 9 GDPR the following are of particular interest:

- processing is necessary to protect the vital interests of the data subject or of another natural person where the data subject is physically or legally incapable of giving consent (Art. 9(2)(c));

- **processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnoses, the provision of health or social care or treatment or the management of health or social care systems and services on the basis of Union or Member State law or pursuant to contract with a health professional and subject to conditions and safeguards** (Art. 9(2)(h));

- **processing is necessary for reasons of public interest in the area of public health**, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices, on the basis of Union or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy (Art. 9(2)(i));

- processing is necessary for archiving purposes in the **public interest, for scientific** or historical **research purposes, or statistical purposes** in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection, and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject. (Art. 9(2)(j)).

An example of application of Art. 6 and 9 is provided for by the EDPB in its *Guidelines 03/2020 on the processing of health data for the purpose of scientific research in the context of the COVID-19 outbreak*, adopted on April 21, 2020. The Board referred to consent (Art. 6, lett. a) and affirmed that Article 6 (1) e)[101] or 6 (1) f)[102] GDPR in combination with the derogations under Article 9 (2) (j) or Article 9 (2) (i) GDPR can provide a legal basis for the processing of personal (health) data for scientific research (for more on scientific research see Question 3 in this chapter).

In this respect, in the pending case ***ZQ v. Medizinischer Dienst der Krankenversicherung Nordrhein, Körperschaft des öffentlichen Rechts*** (C-667/2021) the referring judge asked the CJEU some questions concerning the interpretation of the exception to the prohibition on the processing of health data provided for in Article 9(2)(h) of Regulation (EU) 2016/679, according to which data processing is possible when it is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnoses, the provision of health or social care or treatment, or the management of health or social care systems and services, on the basis of Union or Member State law or pursuant to contract with a health professional and subject to the conditions and safeguards referred to in Art. 9(3). In particular, the referring judge asked whether Article 9(2)(h) of Regulation (EU) 2016/679 is to be interpreted as prohibiting a medical service of a health insurance fund from processing its employee's health data which are a prerequisite for the assessment of that employee's working capacity.

Moreover, the referring judge asked whether in case Art. 9 lett. h) applies, i) the lawfulness of the processing of health data depends on fulfilment of at least one of the conditions set out in Article 6(1) GDPR; ii) if there are data protection requirements beyond the conditions set out in Article 9(3) GDPR, that must be complied with and, if so, which are such requirements.

[101] Processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller.

[102] Processing is necessary for the purposes of the legitimate interests pursued by the controller or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child.

Main question addressed

Question 1 What is the role of the principles of effectiveness and proportionality and Art. 8 ECHR in assessing the lawfulness of the sharing of patients' personal data and of their public disclosure?

Question 2 How do the principle of mutual cooperation and the right to data protection (Art. 8 CFR) influence the processing of health data carried out or to be carried out by MSs in cross-border healthcare?

Question 3 What is the relationship between the right to data protection and the collective dimension of the right to health related to scientific research? In particular: i) What is the relationship between informed consent for participating in medical research and consent as a legal basis for processing? ii) what is the impact of the principles of proportionality and Art. 8 CFR in relation to health and the "compatibility presumption" concerning the processing purpose of scientific research (Article 5 (1) (b) GDPR)? iii) what is the role of proportionality in interpreting Art. 89 GDPR, with regard to safeguards and derogations relating to processing for scientific research purposes or statistical purposes?

Question 4 How health and data protection, in light of the principles of effectiveness, proportionality, and the right to data protection (Art. 8 CFR) may influence the definition of the processing of personal health data to be carried out within Health Data Spaces?

Question 5 What is the role of the principles of effectiveness, proportionality, and necessity with respect to personal data processing within the framework of the EU Digital COVID Certificate?

4.2. Health Data Processing between Individual and Collective Interests.

Question 1 - Access to health data by health professionals, public institutions and the public in light of effective data protection

What is the role of the principles of effectiveness and proportionality and Art. 8 ECHR in the legal assessment of the sharing of patients' personal data among institutions and of their public disclosure?

The following decisions of the European Court of Human Rights (hereinafter: ECtHR) are considered:

- ECtHR, *J.M. and A.T. v. North Macedonia*, App. no. 79783/13, of 22 October 2020.
- ECtHR *S. and Marper v. the United Kingdom*, App. nos. 30562/04 and 30566/04, 4 December 2008
- ECtHR *Avilkina and Others v. Russia*, no. 1585/09, 6 June 2013
- ECtHR, *Radu v. the Republic of Moldova*, 50073/07, 15 April 2014
- ECtHR, *Mockutė v. Lithuania*, app. no. 66490/09, 27 February 2018
- ECtHR, *I v. Finland,* app. no. 20511/03, 17 July 2008

- ECtHR, *Z. v. Finland*, App. No. 22009/93, 25 February 1997
- ECtHR *M.S. v. Sweden,* app. No. 74/1996/693/885, 27 August 1997

The analysis is mainly based on the **ECtHR case *J.M. and A.T. v. North Macedonia*, App. no. 79783/13, of 22 October 2020.**

The case

After a public health center for drug addiction reported to the police that an unspecified quantity of methadone was missing, the police visited the hospital and seized the original copies of lists used to identify daily methadone patients. The national DPA conducted an onsite inspection of the hospital, and stated, in its report, that the police had seized the two original lists, which contained the applicants' names, surnames, and the methadone they had received during treatment. The police were also allowed to examine a "methadone-reporting book" and individual patient files in order to verify the quantities of methadone that they had been prescribed. The DPA concluded that the police had acted lawfully, and in accordance with the Criminal Procedure Act. After some time, the police stated that there had been no elements of a crime with regard to the missing methadone and returned the seized lists to the hospital.

Afterwards, the applicants, together with four other patients of the hospital, submitted a request to the DPA for the protection of personal data against the hospital and the police. They argued that the hospital had disclosed sensitive medical data to the police without a Court order. The DPA rejected their claim, stating that data processed by the police were anonymized. The Administrative Courts before which the applicants contested the DPA's decision upheld the DPA decision. Meanwhile, a civil action for compensation of non-pecuniary damages was brought. The applicants argued that the hospital had unlawfully given access to their medical data to the police. The Court dismissed the claim stating that data processed by the police were anonymized, and the decision was confirmed in the appeal judgment.

Fundamental rights violation addressed by the Court

The applicants complained that the hospital had unlawfully disclosed their medical data to the police, thereby violating their right to a private life as protected under Article 8 ECHR, according to which:

> "1. Everyone has the right to respect for his private and family life, his home, and his correspondence.
>
> 2. There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety, or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others."

Reasoning of the Court

As to the facts, the Court considered that the hospital had disclosed patients' personal data to the police.

With regard to legal reasoning, first, the Court, relying on previous case law, stated that **the disclosure by a state hospital of applicants' medical data to the police constituted an interference with the applicants' right to respect for their private life as secured by Article 8 § 1 ECHR**.

Second, the Court examined whether that interference was justified in terms of Article 8 § 2 of the Convention, that is, whether it was in accordance with the law, pursued a legitimate aim, or was "necessary in a democratic society."

In this respect, the Court stated that the disclosure at issue i) **had a basis in domestic law** (§§ 44-45); and ii) **pursued a legitimate aim** of detection and prevention of crime.

The Court then addressed the question whether the disclosure of the applicants' data was **"necessary in a democratic society."** In this respect, the Court stated that the Government did not prove why it was **necessary** for the police to obtain full access to medical data regarding the applicants, taking into account that: i) the police took no investigative measures on the basis of the medical data; ii) the police had other options for following up on the complaint with regard to the missing methadone, (*i.e.*, they could have interviewed hospital staff before examining applicants' medical data). In that regard, the Court noted that it was an interview with one of the doctors at the hospital that was relied upon by the police in their decision to terminate the investigation into the alleged offence; iii) the domestic Courts failed to balance the protection of patients' rights against the right of the police to access sensitive medical data without a Court order.

Conclusion of the Court

The Court concluded that the collection by the police of the applicants' confidential medical data was not accompanied by sufficient safeguards to prevent disclosure which was inconsistent with the respect for the applicants' private life guaranteed under Article 8 ECHR. Accordingly, **the Court stated that there was therefore a violation of Article 8 ECHR.**

Elements of judicial dialogue - ECtHR

On the basis of Art. 8 (2) ECHR, the Court assessed the justification of interference by evaluating whether it was "**in accordance with the law**," **pursued one or more of the legitimate aims** specified therein, and to that end it was "**necessary in a democratic society**." As to **States' obligations,** in ***I v. Finland,* app. no. 20511/03, of 17 July 2008** the Court reiterated that Art. 8 ECHR is applicable in case of processing of personal data relating to a patient as this information belongs to his or her private life. Furthermore, the Court considered that this Article does not merely compel the State to abstain from arbitrary interference, but that **there may be positive obligations inherent in the effective respect for private or family life.**

In several instances the ECtHR applied this provision in cases concerning health data. The following aspects, considered within case law, are of particular interest with regard to the application of Art. 8 ECHR:

i) Assessment concerning the existence of interference with Art. 8 ECHR

In *J.M. and A.T. v. North Macedonia* the Court relied on previous judgements, recalling, with regard to the general principles applicable to the case, *S. and Marper v. the United Kingdom* App. nos. 30562/04 and 30566/04, 4 December 2008, and *Avilkina and Others v. Russia* (no. 1585/09, §§ 43-46, 6 June 2013; *Radu v. the Republic of Moldova*, 50073/07, § 27, 15 April 2014).

In ***S. and Marper v. the United Kingdom*** the Court, in determining whether the personal information retained by authorities involved any aspects of private-life, took the specific context in which the

information at issue was recorded and retained into account such as the nature of the records, the way in which such records were used and processed, and the results that could be obtained.

In ***I v. Finland,*** app. no. 20511/03, of 17 July 2008, with regard to the importance of confidentiality of health data, the Court stated that:

> "respecting the confidentiality of health data is a vital principle in the legal systems of all the Contracting Parties to the Convention. It is crucial not only to respect the sense of privacy of a patient but also to preserve his or her confidence in the medical profession and in the health services in general" (see also, in the same vein, *M.S. v. Sweden,* app. No. 74/1996/693/885, of 27 August 1997; *Z. v. Finland*, App. No. 22009/93, of 25 February 1997; *Avilkina and Others v. Russia* no. 1585/09, 6 June 2013).

In the same vein, in ***Mockutė v. Lithuania***, app. no. 66490/09, of 27 February 2018, the Court affirmed that in case of a lack of health data confidentiality, those in need of medical assistance may be deterred from revealing such information of a personal and intimate nature as may be necessary in order to receive appropriate treatment and, even, from seeking such assistance, thereby **endangering their own health and, in the case of transmissible diseases, that of the community** (In the same vein see also, *Z. v. Finland*, App. No. 22009/93, of 25 February 1997).

As for examples of cases where the Court stated that there was an interference with Art. 8 ECHR:

- In ***Radu v. the Republic of Moldova,*** (50073/07, 15 April 2014) the Court stated that disclosure of sensitive details about the applicant's pregnancy and her state of health by a Center for family doctors to the applicant's employer constituted interference with her right to private life;

- In ***M.S. v. Sweden,*** (app. No. 74/1996/693/885, of 27 August 1997) the Court stated that the Hospital's disclosure of medical records containing highly personal and sensitive data about the applicant, including information relating to an abortion, to another public authority and therefore to a wider circle of public servants constituted an interference with Art. 8 ECHR.

- In ***Z. v. Finland,*** (App. No. 22009/93, of 25 February 1997) the Court stated that there was an interference with Art. 8 ECHR with respect to the following processing of health data consisting in the applicant's condition as a carrier of HIV: 1) the orders requiring her doctors to give evidence in the criminal proceedings against her husband, (2) the seizure of her medical records and their inclusion in the investigation file, (3) the decision to make the material in question accessible to the public from the year 2002 and (4) the disclosure of her identity and medical condition in a judgment by the Court of Appeals.

- in ***Mockutė v. Lithuania***, app. no. 66490/09, of 27 February 2018, the Court pointed out that the disclosure to journalists of highly personal and sensitive confidential information about the applicant, obtained during her involuntary hospitalisation and treatment, by a psychiatrist doctor of the Vilnius Psychiatric Hospital entailed an interference with the applicant's right to respect for her private life guaranteed by Article 8 (1) ECHR. The Court affirmed that the disclosure of medical data by medical institutions to a newspaper, to a prosecutor's office, and to a patient's employer, as well as the collection of a patient's medical data by an institution responsible for monitoring the quality of medical care constituted an interference with the right to respect for private life.

ii) In accordance with the law

In *Mockutė v. Lithuania*, app. no. 66490/09, of 27 February 2018, the Court found that, as the disclosure of the data at stake was prohibited under national law, and exceptions to that prohibition were not applicable to the case, the processing was not in accordance with the law.

iii) Existence of a legitimate aim

As for examples of a "legitimate aim" which could justify the processing, the Court considered: i) the needs of processing within a trial (*Z. v. Finland*, App. No. 22009/93, of 25 February 1997); ii) the detection and prevention of crimes (*S. and Marper v. the United Kingdom*, App. nos. 30562/04 and 30566/04, 4 December 2008); iii) protecting the economic well-being of the country in deciding on the allocation of public funds (*Mockutė v. Lithuania*, app. no. 66490/09, of 27 February 2018).

iv) Necessity in a democratic society

The ECtHR's judgment ***Z. v. Finland*,** (App. No. 22009/93, of 25 February 1997) is of particular interest for our analysis, as it shows **the importance of collective and individual interests in the Court's application of proportionality**. In such a case, concerning the disclosure of health data relating to the fact that the applicant was an HIV carrier, the Court considered both the **collective and individual dimension of the impact on fundamental rights of the disclosure regime**. As to the position of the data subject, from an individual point of view, the Court considered that the disclosure of such data may dramatically affect the applicant's private and family life, as well as social and employment situation, by exposing her to opprobrium and the risk of ostracism. As for the **collective point of view**, the ECtHR pointed out that the individual risks of disclosure also discourage persons from seeking diagnosis or treatment and thus undermine any preventive efforts by the community to contain the pandemic. With regard to the public interest that could override the interests of confidentiality, the Court considered that i) **any State measures providing the disclosure of such information without the consent of the patient call for the most careful judicial scrutiny, as do the safeguards designed to secure effective protection;** ii) the confidentiality of medical data may be outweighed by the interest in **investigation and prosecution of crime** and in the publicity of Court proceedings, where such interests are shown to be of even greater importance; iii) as to the data disclosure to the public, the Court recognized the national authorities' **margin of appreciation in striking a fair balance** between the interest of publicity of Court proceedings, on the one hand, and the interests of a party or a third person in maintaining the confidentiality of such data, on the other. Moreover, the Court stated that the scope of this margin depends on such factors as the nature and seriousness of the interests at stake and the gravity of the interference.

In ***Avilkina and Others v. Russia*** (no. 1585/09, 6 June 2013) the Court pointed out that **the interests of a patient and the community as a whole in protecting the confidentiality of medical data may be outweighed by the interest of investigating and prosecuting crime and in the publicity of Court proceedings, where such interests are shown to be of even greater importance.** Moreover, the Court stated that in determining whether the impugned measures were "necessary in a democratic society," the Court considered whether, in light of the case as a whole, the reasons adduced to justify them were relevant and sufficient and the **measures were proportionate to the legitimate aims pursued**. Furthermore, the Court stated that in cases concerning the disclosure of personal data, the competent national authorities have a **margin of appreciation** in striking a fair balance between the relevant conflicting public and private interests. However, the Court stated that this margin goes hand in

hand with European supervision and the scope of this margin depends on such factors as the nature and seriousness of the interests at stake and the gravity of the interference.

In ***M.S. v. Sweden*** (app. No. 74/1996/693/885, of 27 August 1997) the Court assessed the **proportionality of the interference** (the disclosure of health data, including data concerning an abortion, to the Social Services office) and stated that there was no violation of Art. 8 ECHR. The Court took into account that the data were communicated to the office to assess whether the applicant satisfied the legal conditions for obtaining a benefit which she had requested and that in deciding whether to accept the applicant's compensation claim, the Office had a legitimate need to check information received from her against data in the possession of the clinic. Furthermore, the Court considered that in the absence of objective information from an independent source, it would have been difficult for the Office to determine whether the claim was well-founded. Moreover, the Court took into account that the processing was subject to important limitations and was accompanied by effective and adequate safeguards against abuse (*e.g.*, the duty of confidentiality of public authorities processing data; civil and/or criminal liability had they failed to observe the provided safeguards).

Another important aspect is that of remedies the data subject can rely on in case of violations. In this respect, in ***I v. Finland,*** **app. no. 20511/03, of 17 July 2008** the Court stated that:

> "the mere fact that the domestic legislation provided the applicant with an opportunity to claim compensation for damages caused by an alleged unlawful disclosure of personal data was not sufficient to protect her private life. **What is required in this connection is practical and effective protection to exclude any possibility of unauthorised access occurring in the first place.** Such protection was not given here."

Elements of judicial dialogue – national

France

With regard to the access regime to health data, French Council of State judgment no. 428451, of 25 November 2020 is of particular interest. In that decision the Council of State quashed the Decree No. 2018-1254 of December 26, 2018, on medical information departments insofar as it did not provide: i) technical and organizational safeguards suitable for ensuring pseudonymization and the absence of processing of identifying data during the access of auditors to personal health data collected during the analysis of healthcare activity; ii) technical and organizational measures to ensure that only the identifying data necessary for the purposes of the processing are processed with sufficient guarantees when external service providers have access to these data, and provisions to ensure that they actually perform their activities under the authority responsible for medical information.

Italy

With regard to the balancing of the collective interest with that of the data subject, the judgment of the Italian Court of Cassation no. 9382 of 4 April 2019 is of particular interest. In that decision, the Court stated that the protection of sensitive data prevailed over a generic need for administrative transparency. Furthermore, as to the collective dimension of health data protection, the Italian Court of Cassation's decision no. 16816 of 26 June 2018 must be considered. The case concerned the sensitivity of data relating to the health of a child with respect to their parents. The Court stated that the state of health of a family member (in the present case, of a minor daughter and a cohabiting sister), considered as the basis of a competitive privilege concerning admission to school courses for minors (as such potentially capable of being translated into information that immediately relates to the sphere of family life), was characterized by the same intrinsic sensitivity that identifies vulnerability and a consequent need for confidentiality, similar to those referring to a sick person when she exposes her illness to a third party, or to a Public Administration. According to the Court, therefore, the sensitive data related to the health condition of the child, as it characterizes the overall status of rights, as well as personal and social conditions which belong to the parents and, in general, to family members linked by ties of the community of family life or the home, is also sensitive data referable to the latter.

Spain

With regard to the notion of "health data" Tribunal Supremo **judgment No 129/2019** (ECLI:ES:TS:2019:3739), of 26 November 2019, concerning penal evidence constating in health data, used in a proceeding against a soldier who affirmed that he was at hospital on a specific day is of particular interest. The Tribunal stated that everyone has the right to respect the confidential nature of the data concerning their health and that no one can access them without prior authorization protected by law, as part of their right to privacy (Art. 7.1 of Law 41/2002 of November 14, 2002, on patient autonomy). Furthermore, the Court considered that clinical history, defined in Art. 3 of this law as the set of documents containing the data, assessments, and information of any kind on the situation and clinical evolution of a patient throughout the care process, would be included in this right to privacy and would also form part of the sensitive data, the core of privacy. Nevertheless, the tribunal pointed out that what is certainly not subject to legal protection are the data that could be considered "innocuous" and that would therefore be outside legally protected privacy, which is what happened in the present case. Considering that the information provided by the employee of a Medical Center, who was obliged to provide the information about the attendance of the defendant at the said center, turned out to be a completely innocuous piece of information within the patient's history that in no way affected his privacy, nor was it part of the content of his medical history as set forth in Article 15 of the Law on Patient Autonomy. Furthermore, the Court considered that the defendant himself provided this information, which in the end turned out to be false. Therefore, according to the Court, in the absence of any unlawfulness in the evidence incorporated into the proceedings, it would be redundant to rule on any type of connection of unlawfulness with the rest of the proceedings, provided that the information provided to the commanders of the then appellant did not constitute, from any point of view, a piece of information concerning his health, so it can hardly be argued that the right to privacy enshrined in Article 18 of the Law was undermined. The fact that he did not go to the private health center and that, therefore, he was not assisted on a certain day, and this without providing any details of a strictly sanitary or clinical nature, were circumstances that did not support the appellant's thesis.

With regard to the balance between the protection of health data and the right to be informed, in **the judgment of the Audiencia Nacional, of 29 November 2019** (ECLI:ES:AN:2019:4627) the Court

stated that the right to privacy of the people who were victims of the terrorist attack of March 11, 2004, in Madrid must prevail over the right to information.

Sweden
In December 2020 the EDPB communicated the news that the Swedish Data Protection Authority had audited eight health care providers in how they governed and restricted access by personnel to the main systems for electronic health records. The DPA discovered insufficiencies that in seven of the eight cases led to administrative fines of up to SEK 30 million (see https://edpb.europa.eu/news/national-news/2020/deficiencies-how-healthcare-providers-control-staff-access-patient-journal_en).

The Swedish Data Protection Authority primarily examined whether the health care providers had conducted the needs and risk analysis required in order to assign adequate access authorization for personal data in electronic health records. The DPA stated that i) Health care providers must carry out an assessment of personnel's need to access information in health records and the risks of accessing patient data; ii) if such an assessment is not carried out, health care providers cannot assign the personnel a correct level of authorization, with the consequence that the organizations cannot guarantee patients' right to privacy. As seven of the health care providers had not carried out a needs and risk analysis, the authority concluded that such providers did not limit user access authorization to the respective patient journal system to what is strictly necessary for the performance of their tasks.

The deficiencies of these providers resulted in administrative fines between SEK 2.5 to 30 million. The Swedish Data Protection Authority developed guidelines summarizing the conclusions from the audits with regard to the obligation to conduct needs and risk analyses.

Question 2 – Cross border health care and MSs' role with regard to health data: the eHealth Network

How do the principle of mutual cooperation and the right to data protection (Art. 8 CFR) influence the processing of health data carried out or to be carried out by MSs in cross-border healthcare?

EU legislation: Art. 14 of the EU directive on patients' rights: the eHealth network and the related data processing

Art. 14 'eHealth' of dir. 2011/24 on the application of patients' rights in cross-border healthcare reads as follows:

> "1. The **Union shall support and facilitate cooperation and the exchange of information among Member States** working within a voluntary network connecting national authorities responsible for eHealth designated by the Member States.
>
> 2. The objectives of the eHealth network shall be to: (a) work towards delivering sustainable economic and social benefits of European eHealth systems and services and interoperable applications, with a view to achieving a high level of trust and security, enhancing continuity of care, and ensuring access to safe and high-quality healthcare;
>
> (b) draw up guidelines on: (i) a non-exhaustive list of data that are to be included in patients' summaries and that can be shared between health professionals to enable continuity of care and patient safety across borders; and (ii) effective methods for enabling the use of medical information for public health and research;

(c) support Member States in developing common identification and authentication measures to facilitate transferability of data in cross-border healthcare.

The objectives referred to in points (b) and (c) shall be pursued in due observance of the principles of data protection as set out, in particular, in Directives 95/46/EC and 2002/58/EC.

3. The Commission shall, in accordance with the regulatory procedure referred to in Article 16(2), adopt the necessary measures for the establishment, management, and transparent functioning of this network."

Since the entry into force in 2018 of Reg. EU 2016/679 (GDPR), by reason of Art. 94(2) of that regulation, the references to repealed Directive 95/46 must be red as references to the Regulation.

Moreover, recital 25 of dir. 2011/24, **underlines, on the one hand, that the right to the protection of personal data is a fundamental right recognised by Article 8 CFREU and, on the other hand, that ensuring continuity of cross-border healthcare depends on the transfer of personal data concerning patients' health.** Accordingly, this recital provides that such personal data should be able to flow from one Member State to another, but at the same time the fundamental rights of the individuals should be safeguarded.

As for data protection roles with regard to data processing within the context of the eHealth Network, Art. 7 of the Commission Implementing Decision 2019/1765 of 22 October 2019 providing the rules for the establishment, the management, and the functioning of the network of national authorities responsible for eHealth, as modified by the Commission Implementing Decision (EU) 2020/1023 of 15 July 2020, states that:

"1. **The Member States**, represented by the relevant National Authorities or other designated bodies shall be regarded **as controllers of personal data** they process through the eHealth Digital Service Infrastructure for Cross-Border eHealth Information Services and **shall clearly and transparently allocate the responsibilities between controllers.**

2. **The Commission shall be regarded as data processor for patients' personal data processed through the eHealth Digital Service Infrastructure for Cross-Border eHealth Information Services**. In its capacity as processor, the Commission shall manage the core services of the eHealth Digital Service Infrastructure for Cross-Border eHealth Information Services and shall comply with the obligations of a processor laid down in the Annex I to this Decision. The Commission shall not have access to patients' personal data processed through the eHealth Digital Service Infrastructure for Cross-Border eHealth Information Services.

3. The Commission shall be regarded as controller of the processing of the personal data necessary to grant and manage access rights to the core services of eHealth Digital Service Infrastructure for Cross-Border eHealth Information Services. Such data are contact details of users, including name, surname and email address and their affiliation."

According to recital 20 of this EU Commission decision, the respective responsibilities between controllers should be defined in a separate arrangement (on the notion of controller and joint controllership in light of the CJEU case law, including *Fashion ID,* C-40/17, see the FRICoRe Casebook

Effective Data Protection and Fundamental Rights, Chapter 2, question 3; on the position of Member States and of the Commission see also the *EDPB-EDPS Joint Opinion 1/2019 on the processing of patients' data and the role of the European Commission within the eHealth Digital Service Infrastructure (eHDSI).*

Question 3 – Principle of proportionality, the protection of collective and public health, and the processing of health data for purposes of public research

What is the relationship between the right to data protection and the collective dimension of the right to health related to scientific research?

In particular:

- What is the relationship between informed consent for participating in medical research and consent as a legal basis for processing?

- What is the impact of the principles of proportionality and Art. 8 CFR in relation to health on the "compatibility presumption" concerning the purpose of processing for scientific research (Article 5 (1) (b) GDPR)?

- What is the role of proportionality in interpreting Art. 89 GDPR, with regard to safeguards and derogations relating to processing for scientific research purposes or statistical purposes?

The legislative framework

The Articles of Reg. UE 2016/679 do not specifically define data processing for scientific research purposes (On the complex definition of scientific research boundaries, see EDPS, *A Preliminary Opinion on data protection and scientific research*, 6 January 2020). Nevertheless, according to recital 159 of the GDPR,

> "the processing of personal data for scientific research purposes should be interpreted in a broad manner including, for example, technological development and demonstration, fundamental research, applied research and privately funded research. In addition, it should take into account the Union's objective under Article 179(1) TFEU of achieving a European Research Area. Scientific research purposes should also include studies conducted in the public interest in the area of **public health**. To meet the specificities of processing personal data for scientific research purposes, specific conditions should apply in particular with regard to the publication or otherwise disclosure of personal data in the context of scientific research purposes. If the result of scientific research in particular **in the health context** gives reason for further measures in the interest of the data subject, the general rules of this Regulation should apply in view of those measures."

Several specificities of (health) data processing for scientific purposes may be recalled:

i) the presumption of compatibility of "further processing" according to Art. 5 GDPR.

Art. 5(1)(b) GDPR provides that personal data must be:

> "collected for specified, explicit, and legitimate purposes and not further processed in a manner that is incompatible with those purposes; further processing for archiving purposes in the public interest, scientific or historical research purposes, or statistical purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes ('purpose limitation')."

ii) specific rules on data storage:

According to Art. 5(1)(e) GDPR data must be:

> "kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed; personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes in the public interest, scientific or historical research purposes, or statistical purposes in accordance with Article 89(1) subject to implementation of the appropriate technical and organisational measures required by this Regulation in order to safeguard the rights and freedoms of the data subject ('storage limitation')."

iii) Art. 89 GDPR regulates safeguards and derogations relating to processing for archiving purposes in the public interest, scientific or historical research purposes, or statistical purposes.

Art. 89 reads as follow:

> 1. Processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, shall be subject to appropriate safeguards, in accordance with this Regulation, for the rights and freedoms of the data subject. Those safeguards shall ensure that technical and organisational measures are in place in particular in order to ensure respect for the principle of data minimisation. Those measures may include pseudonymisation provided that those purposes can be fulfilled in that manner. Where those purposes can be fulfilled by further processing which does not permit or no longer permits the identification of data subjects, those purposes shall be fulfilled accordingly.
>
> 2. Where personal data is processed for scientific or historical research purposes or statistical purposes, Union or Member State law may provide for derogations from the rights referred to in Articles 15, 16, 18, and 21 subject to the conditions and safeguards referred to in paragraph 1 of this Article in so far as such rights are likely to render impossible or seriously impair the achievement of those specific purposes, and such derogations are necessary for their fulfilment.
>
> 3. Where personal data is processed for archiving purposes in the public interest, Union or Member State law may provide for derogations from the rights referred to in Articles 15, 16, 18, 19, 20, and 21 subject to the conditions and safeguards referred to in paragraph 1 of this Article in so far as such rights are likely to render impossible or seriously impair the achievement of those specific purposes, and such derogations are necessary for their fulfilment.
>
> 4. Where processing referred to in paragraphs 2 and 3 serves another purpose at the same time, derogations shall apply only to processing for the purposes referred to in those paragraphs.

The regulation of data processing for scientific research purposes is relevant with regard to several fundamental rights. In this respect, the EDPB in its *Guidelines 03/2020 on the processing of data concerning health for the purpose of scientific research in the context of the COVID-19 outbreak,* adopted on April 21, 2020, stated that:

> "**Data Protection Rules nor the Freedom of Science pursuant to Article 13 of the Charter of Fundamental Rights of the EU have precedence over the other. Rather, these rights and freedoms must be carefully assessed and balanced, resulting in an outcome which respects the essence of both.**" (In the same vein, see EDPS, *A Preliminary Opinion on data protection and scientific research*, 6 January 2020, p. 11).

With regard to the specificities of processing health data for purposes of scientific research, recently the EDPB, in its *Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research*, adopted on February 2, 2021, highlighted that **the specific processing regime** provided for within the GDPR with regard to scientific research **only aims to provide for exceptions to specific requirements in specific situations and that the use of such exceptions is made dependent on the existence of 'additional safeguards'** (see Article 89(1) GDPR). Moreover, the EDPS in its *Preliminary Opinion on data protection and scientific research*, adopted on January 6, 2020, pointed out that from a data protection viewpoint, **the principles of necessity and proportionality** are essential.

In particular, the following aspects were considered:

i) Informed consent for participating in the research, consent to the processing, and lawfulness of processing according to Art. 6 and Art. 9 GDPR

The EDPS in its *Preliminary Opinion on data protection and scientific research*, adopted on January 6, 2020, and the EDPB, in its *Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research*, adopted on February 2, 2021, clarified that with regard to consent, **two different legal issues are at stake**: i) the existence and the conditions of informed consent for participation in a scientific research project and ii) the lawfulness of processing according to Art. 6 and 9 GDPR (on this issue, see above, the introduction).

Accordingly, where other legal bases and exceptions according to Art. 6 and Art. 9 GDPR apply (some examples are provided in the introduction to this chapter), health data could also be processed in the absence of consent to its processing. This does not imply that informed consent is not required (EDPB, *Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research*, adopted on February 2, 2021; see also EDPB *Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection Regulation (GDPR),* adopted on January 23, 2019).

Moreover, with regard to a data subject's consent as a legal basis for processing, the EDPB, in line with recital 43 GDPR (according to which, in order to ensure consent is freely given, consent should not be used as a legal basis for processing where there is a clear imbalance between the data subject and the controller), stated that in clinical trials such an imbalance may exist depending on the circumstances, for instance, when the data subject is not in a good health condition and there is no available therapeutic treatment outside the clinical trial. Nevertheless, the EDPB stated that:

"Explicit consent as a legal basis can still be relied upon in medical research projects where it can be established that no imbalance of power between data subjects and researchers exists and the requirements for explicit consent in GDPR can be met. However, this will require a careful assessment on a case-by-case basis" (EDPB, *Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research*, adopted on February 2, 2021).

Moreover, with regard to the Health Data Space, the EDPS in its *Preliminary Opinion 8/2020 on the European Health Data Space* on November 17, 2020 stated that, as the scope of the EHDS' creation is to enhance access to health data in order to allow for evidence-based policy decisions and for scientific research within the EU, the consent of the data subject, is not the most appropriate legal basis for processing. Rather, the EDPS considered that Article 6(1)(e) GDPR may possibly be the most appropriate legal basis for the processing of personal data in the context of the functioning of the EHDS, as the platform's main purpose will be to serve the public interest and the processing should be done in the exercise of official authority vested in the controller.

i) The presumption of compatibility of "further processing" according to Art. 5 GDPR.

The EDPB, in its *Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research*, adopted on February 2, 2021, stated that the presumption of compatibility can only be used under the condition that in such further processing for scientific research purposes adequate safeguards as required by Article 89(1) GDPR are respected.

Furthermore, according to the EDPB *Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection Regulation (GDPR),* adopted on January 23, 2019, where the compatibility presumption applies, the controller shall not be deemed exempt from the other obligations under data protection law, for example with regard to fairness, lawfulness, necessity, and **proportionality**.

ii) Specific rules on data storage

The EDPB in its *Guidelines 03/2020 on the processing of data concerning health for the purpose of scientific research in the context of the COVID-19 outbreak,* adopted on April 21, 2020, stated that the storage period should be **proportionate**, taking into account also the length and the purpose of the research.

iii) Art. 89 GDPR regulates safeguards and derogations relating to processing for archiving purposes in the public interest, scientific or historical research purposes, or statistical purposes.

The EDPS in its *Preliminary Opinion on data protection and scientific research*, adopted on January 6, 2020 highlighted that the rights of access and rectification are set out in Article 8(2) CFR, and are generally considered essential components of the right to protection of personal data. Moreover, the EDPS considered that the right of access is of particular importance as it enables data subjects to exercise other rights. Accordingly, the EDPS stated that derogations from these rights are only possible if the conditions and safeguards required under Article 89(1) are essential data subject rights and must be subject to a particularly high level of scrutiny in line with the standards required by Article 52(1) CFR, including the **proportionality** test.

Question 4 – Looking forward: sharing health data in Health data spaces

How do health and data protection, in light of the principles of effectiveness, proportionality, and the right to data protection (Art. 8 CFR) influence the definition of the processing of personal health data to be carried out within Health Data Spaces?

Looking forward: Common European Health data spaces

Within the European strategy for data ('Data Strategy') one important objective is to create Common European data spaces in strategic sectors and domains of public interest for increasing the possibilities for public authorities and businesses to access high-quality data. An important field is health, where the creation of '**a Common European health data space**' (EHDS) is considered essential by the Commission for fostering advances in preventing, detecting, and curing diseases as well as for informed, evidence-based decisions to improve the accessibility, effectiveness, and sustainability of the healthcare systems (see Communication *A European strategy for data*, 19 February 2020).

The EDPS adopted the *Preliminary Opinion 8/2020 on the European Health Data Space* on November 17, 2020, where the EDPS recalled that EHDS will be "an essential tool to improve the accessibility, **effectiveness**, and sustainability **of health systems** as well as to allow informed, evidence-based policy decisions relating to them." However, it also affirmed the importance of data protection in light of Art. 7 and Art. 8 CFR. Moreover, in assessing the right to data portability, the EDPS stated that the right to data portability is essential to enhance "control" by data subjects over their data and that imperfect data portability mechanisms that currently exist can present an obstacle to the **effectiveness** of this right.

The EDPS **cited the proportionality principle** in assessing the possibility of data processing for scientific research purposes. According to the EDPS such processing must be, under Article 89(1), based on Union or Member State law which requires the processing to be proportionate to the aim pursued, respect the essence of the right to data protection, and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject. Moreover, the EDPS referred to the principle of **proportionality, jointly with necessity,** also in assessing the sources of that data. Relying on these principles, the Board affirmed that the data made available within the EHDS should, as a general rule, be anonymized and aggregated. The EDPS considered that if this is not possible due to the nature of the data at stake and the purpose of the processing, the data should be pseudonymized.

On 3 May 2022 the European Commission presented a ***Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space***. In the Explanatory memorandum, the Commission affirms that the provisions of the proposal are complementary to data protection law and that:

"The proposal is expected to have a significant positive impact on fundamental rights related to the protection of personal data and free movement. (…) Natural persons will have additional possibilities to digitally access and transmit their electronic health data, building upon provisions in the GDPR. Market operators in the health sector (either healthcare providers or providers of digital services and products) will be obliged to share electronic health data with user-selected third parties from the health sector. The proposal will provide the means to enforce these rights (through common standards, specifications and labels) without compromising on the required safety measures to protect natural person rights under the GDPR. It would contribute to the increased protection of health-related personal data and the free movement of such data as enshrined in Article 16 TFEU and in the GDPR."

Looking at the text of the proposal, art. 3 establishes the "Rights of natural persons in relation to the primary use of their personal electronic health data". Furthermore, the proposal distinguishes between primary and secondary uses and regulates them. In particular, primary uses concerns "the processing of personal electronic health data for the provision of health services to assess, maintain or restore the state of health of the natural person to whom that data relates, including the prescription, dispensation and provision of medicinal products and medical devices, as well as for relevant social security, administrative or reimbursement services" (Art. 2 (1)(d) of the proposal), while secondary uses are identified and regulated in chapter 4 of the proposal both with regard to the categories of data (art. 33 of the proposal) and the purposes of processing (art. 34 of the proposal).

Question 5 – Health data and COVID-19 Certificates

What is the role of the principles of effectiveness, proportionality, and necessity with respect to personal data processing within the framework of the EU Digital COVID Certificate?

Regulation (EU) 2021/953 built a framework for the issuance, verification, and acceptance of interoperable COVID-19 vaccination, test, and recovery certificates (EU Digital COVID Certificate) to facilitate freedom of movement during the COVID-19 pandemic.

The adoption of the "EU digital COVID certificate" system implies the processing of special categories of personal data, such as health data, for purposes that affect the exercise of freedom of movement. In this regard, in Joint Opinion 04/2021 on the Proposal for a Regulation of the European Parliament and of the Council on a framework for the issuance, verification, and acceptance of interoperable certificates on vaccination, testing, and recovery to facilitate freedom of movement during the COVID-19 pandemic (Digital Green Certificate) the EDPS and the EDPB stated that:

> "the general principles of **effectiveness, necessity, and proportionality** must guide any measure adopted by Member States or EU institutions that involve processing of personal data to fight COVID-19" (§ 12)

Moreover, the two Authorities affirmed that:

> "Pursuant to Article 52 of the Charter, '[s]ubject to the principle of **proportionality**, limitations to the rights and freedoms recognised by the Charter may be made only if they are **necessary** and genuinely meet objectives of general interest recognised by the Union or the need to protect the rights and freedoms of others.' In accordance with this, compliance with the principles of **necessity and proportionality** by the measures introduced with the Proposal should carefully be analysed. In particular, the Proposal should achieve a fair balance between the objectives of general interest pursued by the Digital Green Certificate and the individual interest in self-determination, as well as the respect for her/his fundamental rights to privacy, data protection and non-discrimination, and other fundamental freedoms, such as freedom of movement and residence."

The Regulation applies until June 30, 2022, and the EU Commission adopted a proposal to amend Regulation 2021/953, and the EDPS and the EDPB issued joint Opinion 1/2022 on the proposal. In that Opinion, the Authorities stated:

> "(…) the **general principles of effectiveness, necessity and proportionality** must guide any measure adopted by Member States or EU institutions that involve processing of personal data

to fight COVID-19. A regular assessment on any measures to fight the COVID-19 pandemic should take place, having regard to the relevant scientific evidence and additional measures in place, **in order to continuously evaluate which actions remain effective, necessary and proportionate**."

In particular, the EDPB and the EDPS recalled that neither the original proposal for the Regulation nor the new Proposals have been accompanied by an impact assessment and that according to Art. 16 (2) of the Regulation, the Commission must submit a report to the European Parliament and the Council on the application of the Regulation by March 31, 2022, specifically containing an assessment of the impact of the Regulation on the facilitation of free movement, fundamental rights, and non-discrimination, as well as on the protection of personal data during the COVID-19 pandemic. In this respect, the Authorities stated that the new proposal should be accompanied by the abovementioned report, in order to provide a **clear justification for the necessity and proportionality** of the First Proposal, taking into account, among other things, the evolution of the epidemiological situation with regard to the COVID-19 pandemic together with the impact on fundamental rights and non-discrimination, particularly on the basis of the possession of a specific category of medical certificate.

Moreover, the Authorities affirmed **the need to continuously evaluate which measures remain effective, necessary, and proportionate with regard to the purpose of fighting the COVID-19 pandemic.**

4.3. Guidelines Emerging from the Analysis

Health data are qualified as "special categories of personal data" (Art. 9 GDPR), and accordingly, they are subject to a specific regime that takes into account the need to protect privacy and the right to data protection as well as the importance of data processing for health protection purposes (*e.g.*, the general prohibition on processing and exceptions related to health purposes).

The need to take both health and data protection into account emerges also in the interpretation and application of Art. 14 of the EU directive on patients' rights concerning data processing within the context of the eHealth network, with specific regard to the need to ensure continuity of care across Member States.

Furthermore, health and data protection are at stake in the interpretation of rules concerning data processing for purposes of scientific research, where the principle of proportionality may play a significant role (EDPS, *Preliminary Opinion on data protection and scientific research*, adopted on January 6, 2020; EDPB *Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection Regulation (GDPR),* adopted on January 23, 2019).

Moreover, the principle of proportionality, alongside necessity, should play an important role in the current planning of data processing within Health Data Spaces (EDPS *Preliminary Opinion 8/2020 on the European Health Data Space* adopted on November 17, 2020), jointly with fundamental rights (Explanatory memorandum of the *Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space*, adopted on 3 May 2022*).*

In defining the boundaries of lawful health data sharing and disclosure Art 8 ECHR, enshrining the right to respect of private and family life is of particular importance, as shown by case law. In the ECtHR case

law, the complementarity between data and health protection arises. As for complementarity, in several cases the Court stated that in cases of a lack of health data confidentiality, those in need of medical assistance may be deterred from revealing such information of a personal and intimate nature as may be necessary in order to receive appropriate treatment and, even, from seeking such assistance, thereby endangering their own health and, in the case of transmissible diseases, that of the community (*Mockutė v. Lithuania*, app. no. 66490/09, of 27 February 2018; *Z. v. Finland*, App. No. 22009/93, of 25 February 1997; see also *I v. Finland,* app. no. 20511/03, of 17 July 2008; *M.S. v. Sweden,* app. No. 74/1996/693/885, of 27 August 1997; *Avilkina and Others v. Russia*, no. 1585/09, 6 June 2013). Possible conflicts between the protection of health data and other interests emerge in assessing the "necessity in a democratic society" of existing interference with the right to private life where the Court applied the principle of proportionality (*Z. v. Finland*, App. No. 22009/93, of 25 February 1997; *Avilkina and Others v. Russia,* no. 1585/09, 6 June 2013; *M.S. v. Sweden,* app. No. 74/1996/693/885, of 27 August 1997).

Furthermore, **with regard to remedies**, the possibility of claiming compensation in cases of unlawful disclosure of personal data was considered by the ECtHR as insufficient for ensuring the respect of Art. 8 ECHR, as practical and effective protection should be provided to exclude any possibility of unauthorized access occurring in the first place (*I v. Finland,* app. no. 20511/03, of 17 July 2008).

5 Health and Non-Discrimination

Health as such is not explicitly included as a protected ground of non-discrimination in Article 21 CFREU. However, certain aspects of health have been addressed in non-discrimination cases before the CJEU. In particular, the ground of disability, which is listed in both Article 21 and in Directive 2000/78, has allowed individuals to be protected from discrimination on the basis of health-related conditions. Despite its inclusion in these instruments, there is no concrete definition of "disability," leading the Court of Justice to receive multiple referrals from national Courts requesting guidance on the definition and scope of the word. From these cases, it is possible to determine what kind of health conditions are protected from discrimination within this field of EU law.

This chapter discusses the scope of protection from discrimination based on health-related conditions, with the aim of understanding whether non-discrimination protection has a positive impact on health protection, and whether and how the CJEU has dealt with complementarity and conflicts between the right to health and other fundamental rights in cases concerning non-discrimination.[103] First, the material and personal scope of non-discrimination as it relates to health is discussed in Section 5.1, before moving on to the conflicts between health and other fundamental rights in Section 5.2. General guidelines emerging from the analysis are provided in Section 5.3.

5.1 Complementarity with Other Fundamental Rights

In this section, key CJEU judgments are examined to identify first the material scope of non-discrimination in the context of health. This includes, first, looking at the extent to which health-related conditions fall within the protection from discrimination afforded by the Charter. Here, focus is placed on the definition of disability, how this relates to certain health conditions and the impact this has on effective protection from discrimination. Second, the context of health insurance is addressed. The personal scope of non-discrimination in the context of health is then examined, with a focus on who is able to claim discrimination on the grounds of health-related conditions and whether this extends to individuals who do not themselves have the condition.

Relevant CJEU cases in this cluster:

➢ Judgment of the Court (Grand Chamber) of 11 July 2006, *Sonia Chacón Navas v Eurest Colectividades SA*, Case C-13/05 ("**Chacón Navas**")

➢ Judgment of the Court (Grand Chamber) of 17 July 2008, *S. Coleman v Attridge Law and Steve Law*, Case C-303/06 ("**Coleman**") (reference case, Question 2)

➢ Judgment of the Court (Second Chamber) of 22 December 2010, *Gowan Comércio Internacional e Serviços Lda v Ministero della Salute*, Case C-77/09 ("**Gowan Comércio Internacional e Serviços**")

➢ Judgment of the Court (Second Chamber) of 11 April 2013, *HK Danmark, acting on behalf of Jette Ring, v. Dansk almennyttigt Boligselskab and HK Danmark, acting on behalf of Lone Skouboe Werge, v. Dansk Arbejdsgiverforening, acting on behalf of Pro Display A/S, in liquidation*, Joined Cases C-335/11 and C-337/11 ("**HK Danmark**") (reference case, Question 1a)

[103] The text of this chapter is largely based on Chapter 5 of the FRICoRe Casebook on EU Fundamental Rights and Non-Discrimination: Effective Protection in Light of Article 21 of the Charter.

➢ Judgment of the Court (Grand Chamber) of 18 March 2014, *Z. v. A Government department and The Board of Management of a Community School*, Case C-363/12 ("**Z.**")

➢ Judgment of the Court (Fifth Chamber) of 22 May 2014, *Wolfgang Glatzel v Freistaat Bayern*, Case C-356/12 ("**Glatzel**")

➢ Judgment of the Court of 18 December 2014, *Fag og Arbejde (FOA), acting on behalf of Karsten Kaltoft, v Kommunernes Landsforening (KL), acting on behalf of the Municipality of Billund*, Case C-453/13 ("**FOA**") (reference case, Question 1b)

➢ Judgment of the Court (Fourth Chamber) of 29 April 2015, *Geoffrey Léger v Ministre des Affaires sociales, de la Santé et des Droits des femmes and Etablissement français du sang*, Case C-528/13 ("**Léger**") (reference case, Question 3)

➢ Judgment of the Court (Grand Chamber) of 16 July 2015, *"CHEZ Razpredelenie Bulgaria" AD v Komisia za zashtita ot diskriminatsia*, Case C-83/14 ("**CHEZ Razpredelenie Bulgaria**")

➢ Judgment of the Court (Third Chamber) of 1 December 2016, *Mohamed Daouidi v. Bootes Plus SL, Fondo de Garantía Salarial, Ministerio Fiscal,* Case C-395/15 ("**Daouidi**") (reference case, Question 1c)

➢ Judgment of the Court (Second Chamber) of 9 March 2017, *Petya Milkova v Izpalnitelen direktor na Agentsiata za privatizatsia i sledprivatizatsionen kontrol*, Case C-406/15 ("**Milkova**")

➢ Judgment of the Court (Third Chamber) of 18 January 2018, *Carlos Enrique Ruiz Conejero v Ferroser Servicios Auxiliares SA and Ministerio Fiscal*, Case C-270/18 ("**Conejero**")

➢ Judgment of the Court (First Chamber) of 15 November 2018, *Heiko Jonny Maniero v Studienstiftung des deutschen Volkes eV*, Case C-457/17 ("**Maniero**")

➢ Judgment of the Court (First Chamber) of 11 September 2019, *DW v Nobel Plastiques Ibérica* SA, Case C-397/18 ("**Nobel Plastiques Ibérica**")

Main questions addressed

Question 1 Does EU law on protection against discrimination include discrimination on the basis of health-related conditions within its scope such as:

a. Illness;

b. Obesity; and

c. Temporary incapacity?

Question 2 Does EU law on protection against discrimination on the grounds of health-related conditions protect only individuals who themselves have the condition or also members of their family or other persons associated with them?

Question 3 Does EU law, in particular Articles 20, 21, and 51(2) of the Charter, allow for a permanent or temporary deferral from blood donation for men having engaged in sexual relations with other men?

Relevant legal sources

EU level

Articles 136 and 147(1)(2) EC

Point 26 of the Community Charter of the Fundamental Social Rights of Workers

Recitals 1, 11, 12, 15, 28, and 31 and Articles 1, 2, 3, 5, 8(2), and 10(1)(2)(5) of Directive 2000/78

Articles 1, 2(1), 18, 19, 20(1), 21, 29(d), Annex IV, and Recitals 1, 2, 24, and 29 in the preamble to Directive 2002/98/EC

Articles 3 and 4, Points 2 and 4 of Annex I, and Annexes II and III of Commission Directive 2004/33/EC

Articles 3, 15, 20, 21(1), 26, 30, 31, 34(1), 35, and 52(1) of the Charter of Fundamental Rights of the European Union

International level

Article 2 United Nations Convention on the Elimination of All Forms of Racial Discrimination (adopted on 21 December 1965, entered into force on 4 January 1969) United Nations, Treaty Series, vol. 660, p. 195:

"Discrimination on the basis of disability" means any distinction, exclusion, or restriction on the basis of disability which has the purpose or effect of impairing or nullifying the recognition, enjoyment, or exercise, on an equal basis with others, of all human rights and fundamental freedoms in the political, economic, social, cultural, civil or any other field. It includes all forms of discrimination, including denial of reasonable accommodation."

Question 1a – Discrimination on the basis of illness

Does protection from discrimination under EU law, and particularly under Article 21 of the Charter, include discrimination on the basis of health conditions such as obesity and sickness more generally? What are the consequences of this for effective protection from discrimination?

This question was considered in *HK Danmark* (Joined Cases C-335/11 and C-337/11).

Relevant national law (Denmark)

Paragraph 2 of the Law on the legal relationship between employers and salaried employees (Lov om retsforholdet mellem arbejdsgivere og funktionærer, "the FL"):

"1. The employment contract between the employer and the employee may be terminated only after prior notice has been given in accordance with the rules stated below. This shall also apply to the termination of a fixed-term employment contract before expiry of the employment contract."

Paragraph 5 of the FL:

"1. If the salaried employee becomes unable to carry out his work because of illness, the resulting absence from work shall be regarded as lawful absence on his part unless he has contracted the disease

intentionally or by gross negligence during the employment relationship or he has fraudulently failed to disclose at the time when he took on the job that he was suffering from the disease in question.

2. However, it may be stipulated by written agreement in the individual employment relationship that the employee may be dismissed with one month's notice to expire at the end of a month, if the employee has received his salary during periods of illness for a total period of 120 days during any period of 12 consecutive months. The validity of the notice shall be dependent on it being given immediately on the expiry of the 120 days of illness and while the employee is still ill, but its validity shall not be affected by the employee's return to work after the notice of dismissal has been given."

Paragraph 2a of Law No 1417 amending the law on the prohibition of discrimination on the labour market (Lov nr. 1417 om ændring af lov om forbud mod forskelsbehandling på arbejdsmarkedet m.v.) of 22 December 2004 ("the Anti-Discrimination Law"), which transposed Directive 2000/78 into national law:

"Employers shall take appropriate measures, where needed in a particular case, to enable a person with a disability to have access to, participate in, or advance in employment, or to enable a person with a disability to undergo training. This does not however apply if such measures would impose a disproportionate burden on the employer. This burden shall not be regarded as disproportionate if it is sufficiently remedied by public measures."

The case

Although various issues were dealt with in this case, only those pertaining to health and the definition of disability will be addressed in the subsequent paragraphs.

The first applicant, Ms. R, was absent from work on several occasions from June 6, 2005 to November 24, 2005 due to untreatable lumbar pain. No prognosis could be made with regard to the prospect of returning to full-time employment. She was dismissed from her position in accordance with Paragraph 5(2) of the FL, after which the employer made changes to the workstation. She subsequently started a new job, working for 20 hours a week, at a normal workstation with an adjustable height desk.

The second applicant, Ms. S. W., was on sick leave from her job for three weeks after being involved in a road accident in December 2003 and was subsequently absent because of illness for a few days only. In November 2004 Ms. S. W. agreed with her employer to be on part-time sick leave for four weeks. In January 2005 she eventually went on full-time sick leave due to her inability to work and was dismissed in April 2005. Ms. S. W. subsequently underwent an assessment procedure which concluded that she could work for eight hours a week at a slow pace.

Acting on behalf of the two applicants in the main proceedings, the trade union HK brought proceedings against their employers, submitting that both employees were suffering from a disability. HK also argued that Paragraph 5(2) of the FL does not apply when absences are due to a disability.

The employers disputed that the applicants' state of health amounted to a "disability," since they were only incapable of working full-time.

Preliminary questions referred to the Court

The national Court referred several questions to the CJEU, two of which concerned the meaning of the word "disability":

1. (a) Is the condition of any person who, because of physical, mental or psychological impairments, cannot or can only perform to a limited extent his work in a period that satisfies the requirement as to the duration of time specified in Paragraph 45 of the judgment [in *Chacón Navas*] covered by the concept of disability within the meaning of [Directive 2000/78]?

   (b) Can a condition caused by a medically diagnosed incurable illness be covered by the concept of disability within the meaning of the Directive?

   (c) Can a condition caused by a medically diagnosed temporary illness be covered by the concept of disability within the meaning of the Directive?

2. Should a permanent reduction in functional capacity, which does not entail a need for special aids or the like but means solely or essentially that the person concerned is not able to work full-time, be regarded as a disability in the sense in which that term is used in [Directive 2000/78]?

Reasoning of the Court

The Court first noted that Directive 2000/78 includes disabilities that are caused by curable or incurable long-term illnesses which, in interaction with various barriers, may hinder the effective participation of a person in professional life on an equal basis with other workers, regardless of whether this person can work only to a limited extent or cannot work at all.

The Court began by acknowledging that "disability" is not defined by Directive 2000/78 itself, but was defined in its judgment in *Chacón Navas* (C-13/05, ECLI:EU:C:2006:456, paragraph 43), "as referring to a limitation which results in particular from physical, mental or psychological impairments and which hinders the participation of the person concerned in professional life." Next, the CJEU noted the definition of "disability" in the UN Convention on the Rights of Persons with Disabilities, with which the interpretation of Directive 2000/78 should be in conformity. It therefore found that "'disability' must be understood as referring to a limitation which results in particular from physical, mental or psychological impairments which in interaction with various barriers may hinder the full and effective participation of the person concerned in professional life on an equal basis with other workers," and that the impairments be long-term. This definition appears to be specific to the context of non-discrimination. According to the definition, the Court found that **illnesses as such are not a ground of discrimination** under the Directive (*Chacón Navas*, paragraph 57), but if **limitations having the abovementioned effects on a long-term basis are caused by an illness, it can be covered by the concept of "disability."**

However, "disability" does not necessarily equate to total exclusion from work or professional life, but can also cover situations where a person can only work to a limited extent. Similarly, it need not make an individual incapable of exercising an activity, as long as it provides a hindrance to exercising it.

Conclusion of the Court

The Court concluded that:

"[T]he concept of "disability" in Directive 2000/78 must be interpreted as including a condition caused by an **illness medically diagnosed as curable or incurable** where that illness entails a limitation which results in particular from physical, mental or psychological impairments which in interaction with various barriers may hinder the full and effective participation of the person concerned in professional life on an

equal basis with other workers, and the limitation is long-term. The nature of the measures to be taken by the employer is not decisive for considering that a person's state of health is covered by that concept."

Elements of judicial dialogue

This case is central to the Court's definition of "disability" under Article 1 of Directive 2000/78 and therefore to determining which situations of potential discrimination on the grounds of disability fall within the scope of Article 21 CFREU (see discussion below concerning the judicial dialogue of *Daouidi* (C-395/15)). Indeed, although the case itself is not based on the Charter of Fundamental Rights, it has been relied upon in subsequent cases that *do* deal with the Charter, such as *Milkova* (C-406/15), *Daouidi,* and *Glatzel* (C-356/12).

For example, the case of *Z.* (C-363/12) involved the question of whether, with regard to Article 21 CFREU, the refusal to grant paid leave from employment, equivalent to maternity leave and/or adoptive leave, to a woman who suffered from a disability preventing her from giving birth, whose genetic child was born through a surrogate, and who was responsible for caring for the child from birth, fell within the scope of discrimination on the grounds of disability for the purposes of Directive 2000/78. The CJEU repeatedly relied on *HK Danmark*, particularly in finding that the definition to be afforded to the word "disability" under Directive 2000/78 should be that found in the UN Convention on the Rights of Persons with Disabilities, considering the primacy of international agreements concluded by the EU over secondary instruments of EU law.[104] In the case, the Court acknowledged that the woman in question (Ms. Z) had a condition that hindered the possibility of her bearing her own child. However, the purpose of Directive 2000/78 is to enable people with a disability to have access to or participate in employment. The Court found that Ms. Z's condition did not prevent her from having access to or participating in her professional life. Hence, Ms. Z's condition was not a disability within the meaning of the Directive 2000/78. The Court then found it unnecessary to examine the validity of Directive 2000/78 in light of Article 10 TFEU and Articles 21, 26, and 34 of the Charter, which the referring Court had also requested in the event the answer to the first question was positive.

In *Glatzel* (paragraph 45), the CJEU built on this strand of case law and noted that Article 21 CFREU does not itself define "disability." The Court followed its previous case law on the meaning of disability for Directive 2000/78, which was read in light of Article 2 of the Convention on the Rights of Persons with Disabilities. This thus extended the definition adopted in relation to Directive 2000/78 to Article 21 CFREU, and beyond the context of employment, which the cases in the current cluster deal with, but which was not at issue in *Glatzel* (see below, Section 5.2 for a full summary of the case).

Also relevant to *HK Danmark*'s importance as a stepping stone in the Court's path to a comprehensive definition of "disability" was its reliance on the case of *Chacón Navas* (C-13/05 ECLI:EU:C:2006:456), which itself lay the groundwork for a concrete definition of disability in light of the lack of a definition in the text of Directive 2000/78. The significance of *Chacón Navas* can be seen above in the Court's reasoning in *HK Danmark*.

[104] The Court's judgment in *Z.* is discussed in Chapter 1.2.1 of the FRICoRe Casebook on EU Fundamental Rights and Non-Discrimination: Effective Protection in Light of Article 21 of the Charter.

A more in-depth discussion of the vertical judicial dialogue in relation to *HK Danmark* can be found below in relation to *Daouidi*. The CJEU confirmed interpretation of the notion of disability adopted in its previous case law in *Conejero* (C-270/16).

Health as a fundamental right is not explicitly discussed within CJEU cases concerning discrimination on the basis of health-related conditions. Nevertheless, the understanding of the definition of disability, which is arguably inextricably linked to health, means that in some circumstances, individuals enjoy non-discrimination in relation to their health status. Since the definition of disability is applied generally in relation to Article 21 CFREU as well as the relevant Directives discussed above (which are limited in scope, for example, to the context of employment and occupation), this could in turn have an impact on certain aspects of their enjoyment of the right to health, for example by protecting them from discrimination within a healthcare system on the basis of their health status.

Impact on national case law in Member States other than that of the Court referring the preliminary question to the CJEU

Italy

Italian judges relied on the concept of disability shaped by the CJEU. For example, the Tribunal of Padua, in its judgment of May 13, 2020, dealing with a case concerning discrimination in the workplace, relied expressly on the definition of disability adopted by the CJEU in *HK Danmark* (C-335/11 and C-337/11) and *Carlos Enrique Ruiz Conejero* (C-270/16). Accordingly, the Tribunal stated that the notion of disability does not necessarily imply total exclusion from work or professional life.

Question 1b – Discrimination on the basis of obesity

Does protection from discrimination under EU law, and particularly under Article 21 of the Charter, include discrimination on the basis of an individual's weight, specifically obesity?

This question was answered in *FOA* (C-453/13).

Relevant national law (Denmark)

Paragraph 1(1) of Law No 1417 of 22 December 2004, transposing Directive 2000/78 into Danish law by amending the Law on the principle of non-discrimination in the labour market (lov nr. 1417 om ændring af lov om forbud mod forskelsbehandling på arbejdsmarkedet m.v.), as published by Consolidated Law No 1349 of 16 December 2008 ("the Law on anti-discrimination"):

"Discrimination for the purposes of this law shall be understood to mean direct or indirect discrimination on the basis of race, skin colour, religion or belief, political affiliation, sexual orientation, age, disability or national, social, or ethnic origin."

Paragraph 2(1) of the Law on anti-discrimination:

"An employer may not discriminate against employees or applicants for available posts in hiring, dismissal, transfers, promotions or with respect to remuneration and working conditions."

Paragraph 2a of the Law on anti-discrimination:

"This means that employers shall take appropriate measures, where needed in a particular case, to enable a person with a disability to have access to, participate in, or advance in employment, or to undergo

training. This burden shall not be regarded as disproportionate when it is sufficiently remedied by public measures."

Paragraph 7(1) of the Law on anti-discrimination:

"Persons whose rights have been infringed by breaches of Paragraphs 2 to 4 may be awarded compensation."

Paragraph 7a of the Law on anti-discrimination:

"When persons who consider themselves wronged by a failure to comply with Paragraphs 2 to 4 establish facts from which it may be presumed that there has been direct or indirect discrimination, it shall be for the respondent to prove that there has been no breach of the principle of equal treatment."

The case

The Municipality of Billund hired Mr. K, as a childminder to take care of children in his own home. For the entire period during which Mr. K. was employed (approximately 15 years), he was "obese" within the meaning of the definition of the World Health Organization.

Mr. K. tried to lose weight and received financial assistance from the Municipality. After succeeding, he regained the weight he had lost. In March 2010, after a leave of one year due to family reasons, Mr. K. resumed working as a childminder. Thereafter, he was visited by the head of childminders, who observed that his weight had remained unchanged.

Owing to a decrease in the number of children in the Municipality, from the 38th week of 2010, Mr. K. had only three children to take care of instead of four, as originally authorised, so when faced with a requirement to dismiss one employee, the head of childminders chose Mr. K. for dismissal.

During a meeting with the head of childminders, Mr. K. asked why he was the only childminder to be dismissed. The parties agreed that Mr. K.'s obesity was mentioned but they differ over how it was mentioned and on the extent to which it influenced the decision.

The FOA, acting on behalf of Mr. K., brought an action before the Retten i Kolding (District Court, Kolding) claiming that, during his dismissal, Mr. K. had been discriminated against on the basis of obesity and that he ought to receive compensation for such discrimination.

Preliminary questions referred to the Court

The following four of the referring Court's questions are relevant here:

1. Is it contrary to EU law, as expressed, for example, in Article 6 TEU concerning fundamental rights, generally or particularly for a public-sector employer to discriminate on grounds of obesity in the labour market?

2. If there is an EU prohibition of discrimination on grounds of obesity, is it directly applicable as between a Danish citizen and his employer, a public authority?

3. Should the Court find that there is a prohibition under EU law of discrimination on grounds of obesity in the labour market generally or in particular for public-sector employers, is the assessment as to whether action has been taken contrary to a potential prohibition of discrimination on grounds of obesity in that case to be conducted with a shared burden of proof, with the result that the actual

implementation of the prohibition in cases where proof of such discrimination has been made out requires that the burden of proof be placed on the respondent/defendant employer …?

4. Can obesity be deemed a disability covered by the protection provided for in Council Directive 2000/78/EC … and, if so, which criteria will be decisive for the assessment as to whether a person's obesity means specifically that that person is protected by the prohibition of discrimination [on] grounds of disability as laid down in that Directive?

Reasoning of the Court

In relation to the question concerning the possible prohibition of discrimination on the grounds of obesity, the Court noted that since Article 19 TFEU does not refer to discrimination on grounds of obesity, it cannot constitute a legal basis for measures of the Council of the European Union to combat such discrimination. Nor does European Union secondary legislation lay down a general principle of non-discrimination on the grounds of obesity. In particular, Directive 2000/78 does not mention obesity as a ground for discrimination.

According to the case law of the Court, the scope of Directive 2000/78 should not be extended by analogy beyond the discrimination based on the grounds listed exhaustively in Article 1 thereof. Therefore, obesity cannot as such be regarded as a ground in addition to those in relation to which Directive 2000/78 prohibits discrimination. Consequently, the Court found nothing to suggest that the situation at issue, in so far as it related to a dismissal purportedly based on obesity as such, would fall within the scope of EU law. This then meant that the provisions of the Charter of Fundamental Rights of the European Union were likewise inapplicable to the case.

Given these findings, the Court deemed it unnecessary to answer the second and third questions referred by the national Court.

The CJEU did answer the fourth question, reformulating it to ask whether Directive 2000/78 must be interpreted as meaning that the obesity of a worker can constitute a "disability." The Court first noted that, following the ratification by the EU of the UN Convention on the Rights of Persons with Disabilities, "the concept of 'disability' must be understood as referring to a limitation which results in particular from long-term physical, mental, or psychological impairments which in interaction with various barriers may hinder the full and effective participation of the person concerned in professional life on an equal basis with other workers" (see judgments in *HK Danmark* Joined Cases C-335/11 and C-337/11; *Z.*, C-363/12, EU:C:2014:159, paragraph 76; and *Glatzel*, C-356/12, EU:C:2014:350, paragraph 45).

Obesity does not in itself constitute a "disability" within the meaning of Directive 2000/78, because, by its nature, it does not necessarily entail a limitation. However, in the event that, under given circumstances, the obesity of the worker concerned entails a limitation which results in particular from physical, mental, or psychological impairments that in interaction with various barriers may hinder the full and effective participation of that person in professional life on an equal basis with other workers, and the limitation is long-term, obesity can be covered by the concept of "disability" within the meaning of Directive 2000/78.

Ultimately, it was for the referring Court to ascertain whether, in the case of the main proceedings, Mr. K.'s obesity entailed a limitation which met the above-mentioned condition.

Conclusion of the Court

The Court concluded that obesity is not, as such, a ground of discrimination under Directive 2000/78. However, if in a particular case obesity entails a limitation which results in particular from long-term physical, mental, or psychological impairments which in interaction with various barriers may hinder the full and effective participation of the person concerned in professional life on an equal basis with other workers, and the limitation is long-term, it can be subsumed under the concept of "disability."

Elements of judicial dialogue

In *FOA* the judicial dialogue was predominantly horizontal. The approach taken by the Court matched that of the other cases in this cluster, which are relied on in the Court's reasoning (in particular *HK Danmark*, which is relied on repeatedly). As also seen elsewhere in this cluster, the Court relied heavily on the pre-Charter case of *Chacón Navas* in determining what can be considered a disability for the purposes of Directive 2000/78, as well as *Coleman* (C-303/06 ECLI:EU:C:2008:415). Here, the Court reiterated that "the scope of Directive 2000/78 should not be extended by analogy beyond the discrimination based on the grounds listed exhaustively in Article 1 thereof" (*FOA*, paragraph 36). This approach in itself has been consistently applied by the Court, which refused to extend the scope of the prohibition of discrimination beyond those specified in the relevant EU law (see also *Milkova*, C-406/15). Thus, while the wording of Article 21 of the Charter, which states that "discrimination based on any ground *such as* […]" suggests that the list of grounds found in the provision is not exhaustive, in practice only those instances of discrimination falling within the scope of grounds listed in the relevant Directive have been held to be prohibited under EU law. This makes the overall scope of the prohibition of discrimination under EU law more restrictive than that under the Council of Europe human rights system. According to Article 14 of the European Convention on Human Rights, the prohibition of discrimination applies to "any ground such as sex, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status."[105] The European Court of Human Rights (ECtHR) has interpreted "other status" to include grounds not explicitly mentioned in Article 14, such as sexual orientation, disability and discrimination.[106] Interestingly, other characteristics such as "health or any medical condition" have also been held by the ECtHR to be protected grounds, greatly widening the scope of protection as compared to that of Directive 2000/78 (for example) as interpreted by the CJEU. The restrictive scope of the CJEU may also prevent protection from discrimination from having a positive impact on the protection of the right to health of individuals under Article 35 CFREU.

Impact on national case law in Member States other than that of the Court referring the preliminary question to the CJEU[107]

[105] Council of Europe, European Convention for the Protection of Human Rights and Fundamental Freedoms, as amended by Protocols Nos. 11 and 14, 4 November 1950, ETS 5.

[106] European Union Agency for Fundamental Rights and the European Court of Human Rights, 'Handbook on European non-discrimination law: 2018 edition' 2018) 226-227. Available at <https://fra.europa.eu/en/publication/2018/handbook-european-non-discrimination-law-2018-edition> accessed 1 July 2021.

[107] This information is taken from the European University Institute, 'ACTIONES Handbook on the Techniques of Judicial Interactions in the Application of the EU Charter: Module 6 – Non-discrimination' (2017) 70-71. Available at <https://cjc.eui.eu/projects/actiones/actiones-platform/> accessed 1 July 2021.

Belgium

Obesity as a ground of discrimination arose in a Belgian case in 2016. Here, the applicant had applied for a job as a driving instructor. After an interview, her application was rejected because according to the respondent, her "physical profile" was not suitable for the job, and it was suggested that her weight was a "handicap for this job." The Labour Court hearing the case followed the definition of disability provided by the CJEU in *HK Danmark* (followed in *FOA* in relation to obesity) and found that direct discrimination had occurred. The difference in treatment could not be justified on the basis of a genuine and determining occupational requirement, as argued by the respondent (on the basis of students' and instructors' need for security) as the respondent could not apply the justification in concrete terms to the specific case at hand. There was also no reasonable accommodation provided by the respondent.

Question 1c – Discrimination on the basis of temporary incapacity

> Should Directive 2000/78 be interpreted as meaning that the fact that a person finds himself or herself temporarily unable to work, as defined in national law, for an indeterminate period of time by reason of an accident at work, implies, by itself, that the limitation of that person's capacity can be defined as 'long-term', within the meaning of 'disability' under that Directive?

This question was dealt with in *Daouidi* (C-395/15).

Relevant national law (Spain)

Article 9(2) Spanish Constitution:

"It is the responsibility of the public authorities to promote conditions ensuring that freedom and equality of individuals and of the groups to which they belong are real and effective, to remove the obstacles preventing or hindering their full enjoyment, and to facilitate the participation of all citizens in political, economic, cultural and social life."

Article 14 Spanish Constitution:

"Spaniards are equal before the law and may not in any way be discriminated against on account of birth, race, sex, religion, opinion or any other personal or social condition or circumstance."

Paragraphs 3 to 6, Article 55 of Real Decreto Legislativo 1/1995, por el que se aprueba el texto refundido de la Ley del Estatuto de los Trabajadores (Royal Legislative Decree 1/1995 approving the consolidated text of the Law on the Workers' Statute) of 24 March 1995 (BOE No 75 of 29 March 1995, p. 9654), in its version applicable at the time of the facts in the main proceedings ("the Workers' Statute"):

> 3. Dismissals shall be classified as fair, unfair, or null and void.
>
> 4. A dismissal shall be regarded as fair when the failure to perform duties alleged by the employer in the letter of notice is proved. If that is not the case, or if its form does not satisfy the requirements under paragraph 1 of the present Article, the dismissal shall be considered unfair.
>
> 5. Any dismissal on one of the grounds of discrimination prohibited by the Constitution or by law or occurring in breach of the fundamental rights and public freedoms of workers shall be void. …

6. Nullity of a dismissal shall entail the immediate reinstatement of the worker, with payment of unpaid wages or salary.

Article 56(1) of the Real Decreto Legislativo 1/1995:

"Where a dismissal is declared to be unfair, the employer, within five days of notice of the judgment being served, may choose either to reinstate the worker or to pay compensation."

Article 96(1) of Ley 36/2011, reguladora de la jurisdicción social (Law 36/2011 governing social jurisdiction) of 10 October 2011 (BOE No 245 of 11 October 2011, p. 106584):

"In proceedings in which the applicant's allegations give rise to an inference that there are substantiated indications of discrimination on grounds of sex, sexual orientation or identity, racial or ethnic origin, religion or beliefs, lack of capacity, age, harassment and in any other case of infringement of a fundamental right or public freedom, the defendant shall be required to produce objective, reasonable, and adequately proved justification for the measures adopted and for their proportionality."

Article 2 of Real Decreto Legislativo 1/2013, por el que se aprueba el Texto Refundido de la Ley General de derechos de las personas con discapacidad y de su inclusión social (Royal Legislative Decree 1/2013 on the rights of persons with disabilities and their social inclusion) of 29 November 2013 (BOE No 289 of 3 December 2013, p. 95635) contains the following definitions:

"…

(a) "Disability" refers to the situation of persons with long-term impairments which, in interaction with various barriers, may hinder their full and effective participation in society on an equal basis with others.

…

(c) "Direct discrimination" refers to a situation in which a person with a disability finds himself or herself being treated less favourably than another person in a comparable situation, on grounds of, or as a result of, his or her disability.

(d) "Indirect discrimination" exists if a statutory or regulatory provision, a clause in an agreement or contract, an individual agreement, a unilateral decision, a criterion or practice, or an environment, product or service, ostensibly neutral, is liable to give rise to a particular disadvantage for one person in comparison with another on grounds of, or by reason of, disability, on condition that, objectively, it does not satisfy a legitimate objective and the means of achieving that objective are not appropriate and necessary.

…"

The case

Mr. D. was hired by Bootes Plus to work as a kitchen assistant. On October 3, 2014, he slipped on the kitchen floor and dislocated his left elbow, which had to be put in a plaster cast. That day, he commenced the procedure to have his temporary incapacity for work recognised. On November 26, 2014 he received a notice of disciplinary dismissal.

He submitted that his dismissal was null and void (according to Article 108(2) of Law 36/2011), on the basis that: 1) it violated his right to physical integrity (Article 15 of the Spanish Constitution), since the

manager had asked him to return to work while he was still unable to do so; and 2) it was discriminatory, because his temporary incapacity amounted to a "disability."

The referring Court, while noting that Spanish case law indicated that dismissal on grounds of illness or temporary disability was not discriminatory, observed that such dismissals could infringe EU norms, namely: the principle of non-discrimination, protection against unjustified dismissal, right to fair and just working conditions, entitlement to social security benefits, and the right to health protection (Articles 21(1), 30, 31, 34(1) and 35 of the Charter, respectively).

The Court enquired as to whether there was discrimination based on "disability" (according to Directive 2000/78).

Preliminary questions referred to the Court

Five questions were referred to the CJEU, of which the following four are relevant to our analysis:

1. Must the general prohibition of discrimination affirmed in Article 21(1) of the Charter of Fundamental Rights of the European Union be interpreted as including, within the ambit of its prohibition and protection, the decision of an employer to dismiss a worker, previously well regarded professionally, merely because of his finding himself in a situation of temporary incapacity for work — of uncertain duration — as a result of an accident at work, when he was receiving health assistance and financial benefits from Social Security?

2. Must Article 30 of the Charter be interpreted as meaning that the protection that must be afforded a worker who has been the subject of a manifestly arbitrary and groundless dismissal must be the protection provided for in national legislation for every dismissal which infringes a fundamental right?

3. Would a decision of an employer to dismiss a worker previously well regarded professionally merely because he was subject to temporary incapacity — of uncertain duration — as a result of an accident at work, when he is receiving health assistance and financial benefits from Social Security, come within the ambit and/or protection of Articles 3, 15, 31, 34(1), and 35(1) of the Charter (or any one or more of them)?

4. If the four foregoing questions should be answered in the negative, would the decision of an employer to dismiss a worker, previously well regarded professionally, merely because he was subject to temporary incapacity — of uncertain duration — by reason of an accident at work, be encompassed by the term "direct discrimination on grounds of disability" as one of the grounds of discrimination envisaged in Articles 1, 2, and 3 of Directive 2000/78?

Reasoning of the Court

The Court found it most appropriate to deal with the question regarding direct discrimination on the basis of disability first. It noted as a preliminary point, that disability is a protected ground of non-discrimination in Article 1 of Directive 2000/78. Pursuant to Article 3(1)(c) the Directive applies, within the limits of the areas of competence conferred on the European Union, to all persons, in both the public and private sectors, in relation to, inter alia, the conditions governing dismissal.

The Court then reiterated its finding in *HK Danmark* (paragraph 38) that "disability" under Directive 2000/78 should be interpreted in line with the United Nations Convention on the Rights of Persons with Disabilities (see Section 5.1.1 above). Therefore, "if an accident entails a limitation resulting in particular

from long-term physical, mental or psychological impairments which, in interaction with various barriers, may hinder the full and effective participation of the person concerned in professional life on an equal basis with other workers, and if that limitation is long-term, it may come within the concept of "disability" within the meaning of Directive 2000/78. The question to ask was whether the injury that was preventing the individual from carrying out his professional duties (due to his elbow being in a cast) was reversible in principle.

Going further, the Court noted that the fact that the person concerned finds himself or herself in a situation of temporary incapacity to work, as defined in national law, for an indeterminate amount of time and as the result of an accident at work, does not mean in itself that the limitation of that person's capacity can be classified as being "long-term" within the meaning of the definition of "disability" laid down by Directive 2000/78, read in light of the United Nations Convention on the Rights of Persons with Disabilities.

The evidence that makes it possible to find that such a limitation is "long-term" includes the fact that, at the time of the allegedly discriminatory act, the incapacity of the person concerned does not display a clearly defined prognosis with regard to short-term progress or the fact that that incapacity is likely to be significantly prolonged before that person has recovered.

In the context of the verification of that "long-term" nature, the CJEU found that the referring Court must base its decision on all of the objective evidence in its possession, in particular on documents and certificates relating to that person's condition, established on the basis of current medical and scientific knowledge and data. The Court did not mention which party has the burden of providing such evidence.

Moving to the remaining issues, the Court noted that it only has jurisdiction over legal situations falling within the scope of EU law. The Charter, which formed the core of the previous questions discussed by the Court, is only addressed to Member States when they are implementing EU law – the Charter cannot on its own form the basis of the Court's jurisdiction over a dispute (*Åkerberg Fransson*, C-617/10, EU:C:2013:105, paragraph 22; and *Aiudapds*, C-520/15, not published, EU:C:2016:124, paragraph 20). Since the CJEU had established that temporary incapacity for work for an indeterminate period of time due to an accident that happened at work does not on its own mean that the individual suffers from a "disability" for the purposes of Directive 2000/78, the Court did not find it necessary to answer the remaining issues.

Conclusion of the Court

The Court concluded that Directive 2000/78 must be interpreted in light of the United Nations Convention on the Rights of Persons with Disabilities. Incapacity should be regarded as long-term and, therefore, covered by the provisions concerning disability of Directive 2000/78 when: a) it does not display a clearly defined prognosis of short-term progress; or b) it is likely to be significantly prolonged before that person has recovered. The above-mentioned factors should be assessed on the basis of current medical and scientific knowledge and data.

Elements of judicial dialogue

Significantly, this case builds on the CJEU's case law discussed in Questions 1a and 1b above. As mentioned above, the Court in *Daouidi* applied the same definition of "disability" as was developed and adopted in *HK Danmark* (Joined Cases C-335/11 and C-337/11). The CJEU relied on the latter case repeatedly in finding that an accident may come within the meaning of "disability" if it causes long-term

physical, mental or psychological impairments that result in limitations which, in interaction with various barriers, may hinder the full and effective (but not necessarily complete) participation of the person concerned in professional life on an equal basis with other workers. The pre-Charter case of *Chacón Navas* (C-13/05), which was cited repeatedly by the Court in *HK Danmark* and *FOA* (see above, Sections 5.1.1 and 5.1.2, respectively) was also referred to in *Daouidi*, solidifying this strand of case law and the Court's concrete definition of "disability" for the purposes of Article 1 of Directive 2000/78.

In turn, this also strengthened the vertical dialogue built up throughout the cases in this cluster – a clear and concrete rule for national Courts as to: 1) what can be considered a disability for the purposes of the prohibition of non-discrimination; and 2) when legal situations ostensibly concerning discrimination on the grounds of disability can be adjudicated on the basis of Article 21 CFREU. Although the cases in this cluster do not apply the Charter, they shed much light on when the Charter could be applied to situations of discrimination – to know when the Charter applies, it is first necessary to know when Directive 2000/78 (or another source of EU law) applies. The guidance provided in *Daouidi* is therefore, as in *HK Danmark*, of importance to national Courts.

Furthermore, *Daouidi* has been relied on in subsequent cases applying the Charter. For example, in the judgment of *DW v Nobel Plastiques Ibérica* SA (C-397/18), the Court reiterated its comments on how to determine whether a limitation is "long-term" for the purposes of discrimination on the grounds of disability.

Further, in *Milkova* (C-406/15), the CJEU applied the definition of disability provided in *Daouidi* (and indeed developed throughout this cluster of cases). The Court held that the mental illness from which the applicant suffered (for which she had a disability rating of 50%) did fall within the meaning of "disability" in Directive 2000/78. In *Milkova*, it was therefore possible for the Court to apply the Charter of Fundamental Rights of the European Union, since, unlike in *Daouidi*, the situation fell within the scope of EU law. The Court therefore went on to apply the principle of equal treatment as enshrined in Articles 20 and 21 CFREU to make an assessment of whether there was: 1) a difference in treatment of comparable situations (which requires an assessment in light of all the factors characterising those situations, and in a specific and concrete manner in light of the objective and of the aim of the national legislation creating the distinction at issue – paragraph 57); and 2) if so, whether this was justified ("based on an objective and reasonable criterion, that is, if the difference relates to a legally permitted aim pursued by the legislation in question, and it is proportionate to the aim pursued by the treatment," following the judgment of *Glatzel*, C-356/12 – see Section 5.2. below).

From this analysis, it is clear that the definition of disability applied in relation to the relevant Directive has an impact on whether the Court is able to invoke the CFREU. This could be significant for enjoyment of the right to health, as it may enable the CJEU to invoke Article 35 CFREU as well as Articles 20 and 21.

Impact on national case law in Member States other than that of the Court referring the preliminary question to the CJEU

United Kingdom

The CJEU's judgment in *Daouidi* was relied on by the Employment Appeal Tribunal of the United Kingdom. In the case of *B. v. Birmingham City Council (Disability Discrimination) (Rev 1)* [2019] UKEAT 0291_18_1608, the Claimant was a social worker employed by the Respondent beginning in December 2008 until he was dismissed with effect on May 15, 2017. The reason given by the respondent at the time

of the claimant's dismissal was capability. Following this, the Claimant presented a claim with the Employment Tribunal complaining of treatment over a number of years, and with regard to the dismissal. The Claimant argued that he was a person with disabilities for the purposes of the United Nations Convention on the Rights of Persons with Disabilities (CRPD) and therefore the Equality Act 2010 and EU Directive 2000/78 as read in light of the CRPD. This was due to suffering from either depression, anxiety, dysexecutive syndrome or sleep apnoea, and sometimes all of them, at all times material to the case as well as a 'disposition to long-term impairments of sleep apnoea and depression in the future'.

The Respondent denied that there had been any unlawful discrimination and asserted that the Claimant had been fairly dismissed for a reason related to capability arising from long-term ill health. In the decision of the Employment Tribunal, the judge found that the national CPRD was not incorporated into UK law and did not provide the Claimant with a route to claim disability discrimination outside of the Equality Act 2010, to which he claimed to have been subjected. The Claimant appealed to the Employment Appeal Tribunal. In reiterating that the CRPD has indirect effect in the UK, the Appeal Tribunal referred, as the Claimant had done, to the CJEU's judgment in *Daouidi*, C- 395/15. The Tribunal noted that 'it has been clearly held by the CJEU that the CRPD may be relied upon for the purposes of interpreting [Directive 2000/78] which must, so far as possible, be interpreted in a manner consistent with it.'

Consequently, the Claimant was able to seek to rely on any provision of the CRPD as 'having a bearing, by any of the techniques which may be deployed, in accordance with the *Marleasing* jurisprudence, on the interpretation of any relevant provision' of the Equality Act (paragraph 42).

Question 2 – Personal scope of protection from discrimination based on health-related conditions

Does protection from discrimination under EU law, and particularly under Article 21 of the Charter, include discrimination on the basis of health conditions only of people with those conditions themselves, or also of individuals associated with such people? What are the consequences of this for effective protection from discrimination?

This question was dealt with in *Coleman* (C-303/06).

Relevant national law (United Kingdom)

According to Section 3A(1) of the Disability Discrimination Act 1995 ("the DDA"), as amended by the Disability Discrimination Act 1995 (Amendment) Regulations 2003 ("the DDA as amended in 2003"):

"… a person discriminates against a disabled person if –

(a) for a reason which relates to the disabled person's disability, he treats him less favourably than he treats or would treat others to whom that reason does not or would not apply, and

(b) he cannot show that the treatment in question is justified."

Section 3A(4) of the DDA as amended in 2003 nonetheless specifies that the treatment of a disabled person cannot be justified if it amounts to direct discrimination falling within Section 3A(5), according to which:

"A person directly discriminates against a disabled person if, on the ground of the disabled person's disability, he treats the disabled person less favourably than he treats or would treat a person not having that particular disability whose relevant circumstances, including his abilities, are the same as, or not materially different from, those of the disabled person."

"Harassment" is defined in Section 3B of the DDA as amended in 2003:

"(1) ... a person subjects a disabled person to harassment where, for a reason which relates to the disabled person's disability, he engages in unwanted conduct which has the purpose or effect of –

(a) violating the disabled person's dignity, or

(b) creating an intimidating, hostile, degrading, humiliating or offensive environment for him.

(2) Conduct shall be regarded as having the effect referred to in paragraph (a) or (b) of subsection (1) only if, having regard to all the circumstances, including in particular the perception of the disabled person, it should reasonably be considered as having that effect."

Under Section 4(2)(d) of the DDA as amended in 2003, it is unlawful for an employer to discriminate against a disabled person whom he employs by dismissing him or by subjecting him to any other detriment.

Section 4(3)(a) and (b) of the DDA as amended in 2003 provides that it is also unlawful for an employer, in relation to employment by him, to subject to harassment a disabled person whom he employs or a disabled person who has applied to him for employment.

The case

Ms. C. worked as a secretary for a law firm in London. She had a severely disabled child, for whom she was the primary carer. In 2005, she accepted a voluntary redundancy, which ended her employment contract. As a response, Ms. C. lodged a claim with the Employment Tribunal claiming that she had been subject to unfair constructive dismissal. Ms. C. listed numerous occasions on which she was subjected to treatment less favourable than that of other employees on the basis that she was the primary carer of a disabled child.

Preliminary question referred to the Court

The Employment Tribunal referred the following questions to the CJEU:

1. In the context of the prohibition of discrimination on grounds of disability, does [Directive 2000/78] only protect from direct discrimination and harassment persons who are themselves disabled?

2. If the answer to Question (1) above is in the negative, does [Directive 2000/78] protect employees who, though they are not themselves disabled, are treated less favourably or harassed on the ground of their association with a person who is disabled?

3. Where an employer treats an employee less favourably than he treats or would treat other employees, and it is established that the grounds for the treatment of the employee is that the employee has a disabled son whom the employee cares for, is that treatment direct discrimination in breach of the principle of equal treatment established by [Directive 2000/78]?

4. Where an employer harasses an employee, and it is established that the grounds for the treatment of the employee is that the employee has a disabled son whom the employee cares for, is that harassment a breach of the principle of equal treatment established by [Directive 2000/78]?

Reasoning of the CJEU

The Court dealt with the first half of question one together with questions two and three, and then answered the second part of question one together with question four.

As to the first part, the Court looked at the problem of assessing whether the Directive in question is limited to persons who are themselves disabled. The Court noted the Directive's purpose of combatting *all forms of discrimination* on grounds of disability, and that the principle of equal treatment enshrined in Directive 2000/78 "applies not to a particular category of person but by reference to the grounds mentioned in Article 1" of the Directive (paragraph 38). Further, although some provisions of Directive 2000/78 apply only to people who are themselves disabled (e.g. the obligation of reasonable accommodation in Article 5), this is because the provisions concern either positive discrimination in favour of disabled people, or specific measures that would be meaningless or disproportionate if not limited to disabled persons.

Ultimately, the Court emphasised that the **principle of equal treatment** and the scope of the Directive *ratione personae* should not be interpreted strictly. It also emphasised that "limiting [the Directive's] application only to people who are themselves disabled is liable to deprive that directive of an important element of its **effectiveness** and to reduce the protection which it is intended to guarantee" (paragraph 51).

The Court then turned to the issue of burden of proof, based on Article 10(1) and (2) of Directive 2000/78. Pursuant to Article 10(1), Member States are to take such measures as are necessary, in accordance with their national judicial systems, to ensure that when the claimant has "establish[ed], before a Court or other competent authority, facts from which it may be presumed that there has been direct or indirect discrimination, it is for the *respondent* to prove that there has been no breach of that principle" (paragraph 52).[108] Furthermore, according to Article 10(2) of the Directive, **the introduction by Member States of rules on the burden of proof that are more favourable to claimants than respondents is not precluded by Article 10(1)**. Ms. C. must therefore establish the facts from which it could be presumed that direct discrimination contrary to the Directive had occurred. If this were done, "the **effective application** of the **principle of equal treatment** then requires that the burden of proof should fall on the respondents" (paragraph 54) to show that there was no breach of the principle by, for example, demonstrating that the difference in treatment was justified according to the Directive.

The same reasoning was applied to the referring Court's questions regarding harassment on the grounds of disability, prohibited by Article 2(3) of Directive 2000/78. Here, the Court held that where "unwanted conduct amounting to harassment which is suffered by an employee who is not himself disabled is related to the disability of his child, whose care is provided primarily by that employee, such conduct is contrary to the prohibition of harassment" (paragraph 63).

Conclusion of the Court

[108] Emphasis added.

The Court concluded that:

"Council Directive 2000/78/EC of 27 November 2000 establishing a general framework for equal treatment in employment and occupation, and, in particular, Articles 1 and 2(1) and (2)(a) thereof, must be interpreted as meaning that the prohibition of direct discrimination laid down by those provisions is not limited only to people who are themselves disabled. Where an employer treats an employee, who is not himself disabled, less favourably than another employee is, has been, or would be treated in a comparable situation, and it is established that the less favourable treatment of that employee is based on the disability of his child, whose care is provided primarily by that employee, such treatment is contrary to the prohibition of direct discrimination laid down by Article 2(2)(a)."

Impact on the follow-up case

In the follow-up case to the CJEU's ruling[109] the Employment Appeals Tribunal confirmed that the Disability Discrimination Act 1995 should be interpreted to provide protection from "associative discrimination." In other words, the Act covers discrimination not only for individuals who have a disability themselves, but also those who are discriminated against due to their association with a person with disabilities.

Elements of judicial dialogue

In *Coleman*, the CJEU discussed in some detail the case of *Chacón Navas* (Case C-13/05, ECLI:EU:C:2006:456). The United Kingdom, Italian, and Dutch Governments contended that the judgment in *Chacón Navas* provided that the scope *ratione personae* of Directive 2000/78 must be interpreted strictly. In *Chacón Navas*, the CJEU held that the prohibition of discrimination in Directive 2000/78 precluded "dismissal on grounds of disability which, in light of the obligation to provide reasonable accommodation for people with disabilities, is not justified by the fact that the person concerned is not competent, capable, and available to perform the essential functions of his post" (*Coleman*, paragraph 45). That does not, however, lead to the conclusion that the principle of equal treatment and the prohibition of direct discrimination in the Directive could not apply to a situation such as that at hand regarding the primary carer of a child with disabilities. Furthermore, while the Court in *Chacón Navas* found that the scope of Directive 2000/78 cannot be extended beyond the discrimination based on the grounds listed exhaustively in Article 1 of the Directive, it "did not hold that the principle of equal treatment and the scope *ratione personae* of that directive must be interpreted strictly with regard to those grounds." In other words, the limitations on the scope *ratione materiae* of the prohibition of discrimination on the grounds found in Article 1 of Directive 2000/78 does not have a limiting effect on the scope *ratione personae* of the prohibition.

The judgment in *Coleman* was relied upon in subsequent cases, most notably that of *CHEZ Razpredelenie Bulgaria* (C-83/14, ECLI:EU:C:2015:480). The Court's ruling in that case, which concerned Directive 2000/43, in effect confirmed that the main finding in *Coleman* was not limited to situations of discrimination on the grounds of disability (or other grounds protected by Directive 2000/78), but also to other grounds of discrimination prohibited by EU law, given that the principle of equal treatment applies across the scope of EU law. With reference to *Coleman* by analogy, in *CHEZ Razpredelenie Bulgaria* the Court found that the **principle of equal treatment** "applies not to a particular category of person but by reference to the grounds mentioned in Article 1 [of the Directive], so that that **principle is**

[109] *EBR Attridge Law LLP v Coleman* (2009) UKEAT 0071/09.

intended to benefit also persons who, although not themselves a member of the race or ethnic group concerned, nevertheless suffer less favourable treatment or a particular disadvantage on one of those grounds" (paragraph 56). Therefore, since ethnic origin was the factor on the basis of which the claimant considered that she had suffered less favourable treatment or a particular disadvantage, it did not matter that the claimant herself was not of the relevant ethnic origin and therefore did not have the protected characteristic. The Court's approach in *CHEZ Razpredelenie Bulgaria* was further solidified in *Maniero* (C-457/17, ECLI:EU:C:2018:912). In this case, the Court reiterated in paragraph 23 that:

"'discrimination on the grounds of ethnic origin,' referred to in Article 1 and in Article 2(1) of Directive 2000/43, is intended to apply without distinction, irrespective of whether the measure concerned affects persons who have a certain ethnic origin or those who, without possessing that origin, suffer, together with the former, the particular disadvantage resulting from that measure."

The fact that these later cases (particularly *CHEZ Razpredelenie Bulgaria*) did concern Article 21 CFREU, whereas *Coleman* did not, supports suggestions that the meaning and scope of non-discrimination under Article 21 CFREU are the same as those under the relevant directives. Presumably, this is due to the fact that across cases of alleged discrimination contrary to EU law, the principle of equal treatment, which was first given expression in the directives and is now enshrined in Article 21 CFREU, applies.

Impact on national case law in Member States other than that of the Court referring the preliminary question to the CJEU

Czech Republic

The Court's decision in *Coleman* was relied on by the Supreme Court of the Czech Republic (ECLI:CZ:NS:2017:30.CDO.2260.2017.1). The case concerned the interpretation of the term "the person affected by such act" as stated in section 10 (1) of the Anti-discrimination Act and whether this term should be interpreted restrictively and include only the person that was the subject of such a discriminatory act.

The applicants' daughter died. The applicants argued that the daughter's state of health required her to be transferred to the department of anaesthesiology, resuscitation, and intensive medicine. However, the doctors repeatedly refused to do so, as they argued that her state of health would result in her death regardless. The applicants argued that she was therefore discriminated against based on her state of health and was denied healthcare which resulted in her death. They demanded a written apology and financial compensation from the defendant (Fakultní nemocnice Motol/University hospital Motol) for the non-pecuniary damage suffered based on the Anti-discrimination Act.

In its reasoning, the Supreme Court referred to the CJEU's decision in Coleman, stating that the interpretation of discrimination in national law should be in line with the aim of Directive 2000/78/EC and CJEU case law. If an interpretation in conformity with European law is possible, preference will be given to such an interpretation.

Further, the Supreme Court ruled that the wording of section 10 of the Anti-discrimination Act should not be interpreted restrictively in a way that only the person affected by such an act shall have the right to a claim before the Court. This term 'discrimination' also includes persons that are close to the person directly affected by the discrimination. Therefore, the applicants had the right to a claim before the Court.

Question 3 - Non-discrimination and the definition of public health

Does EU law, in particular Articles 20, 21, and 51(2) of the Charter, allow a permanent or temporary deferral from blood donation for men that have engaged in sexual relations with other men?

This question was dealt with in *Léger* (C-528/13).

Relevant national legal sources (France)

Article 1(V)(1) of Decree of 12 January 2009 laying down the selection criteria for blood donors:

"At the interview prior to donation, it is for the person authorised to carry out the selection of donors to assess the possibility of donation in light of any contraindications and their duration, precedence in time and development, using questions supplementary to the questionnaire prior to the donation.

…

The prospective donor shall defer giving blood if he presents a counter indication mentioned in one of the tables set out in Annex II to the present decree…

…"

The case

Mr. L. attended the collection centre of the Établissement français du sang (French Blood Agency) in Metz, France, in order to give blood.

By a decision of April 29, 2009, the doctor responsible for donations refused the blood donation on the grounds that Mr. L. had had sexual relations with another man. The doctor based his decision on the Decree of January 12, 2009. Table B in Annex II thereto provided, with regard to the risk of exposure of a prospective donor to a sexually transmissible infectious agent, for a permanent contraindication to blood donation for a man who has had sexual relations with another man.

Mr. L. brought an action against that decision before the Tribunal Administratif de Strasbourg (Administrative Court, Strasbourg) arguing, *inter alia*, that Annex II to the Decree of January 12, 2009 was incompatible with the provisions of Directive 2004/33.

Preliminary question referred to the Court

1. In light of Annex III to Directive [2004/33], does the fact that a man has sexual relations with another man constitute in itself sexual conduct that places him at a risk of acquiring severe infectious diseases that can be transmitted by blood, therefore justifying a permanent deferral from blood donation for persons having engaged in such sexual behaviour, or is it merely capable of constituting, in light of the circumstances of the individual case, sexual behaviour that places him at a risk of acquiring infectious diseases that may be transmitted by blood, therefore justifying a temporary deferral from blood donation for a period determined after cessation of the risky behaviour?

Reasoning of the Court

The Court established that Directive 2004/33 itself distinguishes between temporary and permanent deferral, based on the degree of the risk of transmission. Therefore, if the person in question engaged in activity with a high risk of transmitting an infectious disease, the permanent ban would be an appropriate response in light of Directive 2004/33.

The Court noted that Member States have leeway in implementing the Directive with regard to the categories of persons and actions reaching the threshold of "high risk." First, the Court discussed the gravity of sexually transmitted diseases among men in a sexual relationship with another man, by referring to two statistics. Secondly, the Court went on to discuss whether a permanent deferral from blood donation, such as that at issue in the main proceedings, may be compatible with the fundamental rights recognised by the EU legal order. The Court made a particular reference to non-discrimination on the grounds of sexual orientation (Article 21(1) of the Charter) and equal treatment (Article 20 of the Charter). The Court noted that in that regard, Table B of Annex II to the Decree of January 12, 2009 treated homosexual men less favourably than it treated heterosexual men, constituting discrimination. Accordingly, the Court moved to discuss the justifications for this kind of discrimination in light of Article 52(1) of the Charter.

Firstly, **according to Article 52(1), the basis of the limitation must be provided by law**, which the Court confirmed in this case (given its basis in the Decree of January 12, 2009). Secondly, it **must respect the essence of the right** (read here as the principle of non-discrimination), which the Court also confirmed, as "the limitation concerned only the question, which is limited in scope, of deferrals from blood donation in order to protect the health of recipients" (paragraph 54). Next, the Court discussed whether the **limitation met an objective of general interest**. The aim of the limitation to "minimise the risk of transmitting an infectious disease to recipients" contributed to the general objective of ensuring a high level of human health protection. This is an objective recognised by EU law (Articles 152(4)(a) and (5) EC and Article 35 CFREU). The Court then looked at the proportionality of the restriction, stating that "it follows from the case-law of the Court that the measures laid down by national legislation must **not exceed the limits of what is appropriate and necessary in order to attain the objectives legitimately pursued** by that legislation; when there is a choice between several appropriate measures, recourse must be had to the least onerous among them, and the disadvantages caused must not be disproportionate to the aims pursued" (paragraph 58).

The Court accepted that in light of the **principle of proportionality** there were less onerous means than targeting the whole group of homosexual men. Nonetheless, the effectiveness of such measures was contested by the French authorities and the Court left the question to the referring Court. Overall, the lawfulness of the restriction would depend upon the proportionality test and whether there are less onerous measures available, which is left for the referring Court to decide.

Conclusion of the Court

The Court concluded that:

"Point 2.1 of Annex III to Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council with regard to certain technical requirements for blood and blood components must be interpreted as meaning that the criterion for permanent deferral from blood donation in that provision relating to sexual behaviour covers the situation in which a Member State, having regard to the prevailing situation there, provides for a permanent contraindication to blood donation for men who have had sexual relations with other men where it is established, on the basis of current medical, scientific and epidemiological knowledge and data, that such sexual behaviour puts those persons at a high risk of acquiring severe infectious diseases and that, with due regard to the principle of proportionality, there are no effective techniques for detecting those infectious diseases or, in the absence of such techniques, any less onerous methods than

such a counter indication for ensuring a high level of health protection of the recipients. It is for the referring Court to determine whether, in the Member State concerned, those conditions are met."

Elements of judicial dialogue

Léger constitutes one of the CJEU's most comprehensive discussions of Article 21 CFREU, with the Court's reasoning being based almost exclusively on the Charter. This was perhaps to be expected given that the Directive applicable in the case (2004/33/EC) does not itself deal with discrimination or equal treatment (unlike, for example, Directives 2000/78, 2000/43 and 2006/54), but is very interesting given that the referring Court did not actually mention Article 21 (or indeed the Charter more generally) in the preliminary questions referred to the CJEU. The judgment can therefore be said to fill some gaps left by the Court's other case law on non-discrimination, particularly for what concerns the definition of discrimination under Article 21 and the justifications for limitations of rights contained in the CFREU laid out in Article 52(1) of the Charter.

In applying the **principle of proportionality**, as mentioned in Article 52(1), to the situation in *Léger*, the Court built on previous case law concerning the principle to find that "the measures laid down by national legislation must not exceed the limits of what is appropriate and necessary in order to attain the objectives legitimately pursued by that legislation; when there is a choice between several appropriate measures, recourse must be had to the least onerous among them, and the disadvantages caused must not be disproportionate to the aims pursued (see judgments in *ERG and Others*, C-379/08 and C-380/08, EU:C:2010:127, paragraph 86; *Urbán*, C-210/10, EU:C:2012:64, paragraph 24; and *Texdata Software*, C-418/11, EU:C:2013:588, paragraph 52)." The same meaning of proportionality is therefore to be applied in the context of Article 52(1) and the justification of limitations to Article 21 as in the context of the objective justification of an apparently neutral provision, criterion, or practice for the purposes of determining an instance of indirect discrimination on other grounds of non-discrimination, namely religion or belief, disability, age or sexual orientation, under Directive 2000/78. Furthermore, the same test of proportionality appears to be applied by the Court whether or not a fundamental right, such as health, is at play in a particular case. This brings coherence to the application of EU law on non-discrimination, even though the law itself is somewhat fragmented.

Interestingly, while the Court did refer to the fact that "Member States must make sure they do not rely on an interpretation of wording of secondary legislation which would be in conflict with […] fundamental rights" (and thereby, in their application of directives, ensure that they respect fundamental rights, including health) earlier in its judgment, fundamental rights were not mentioned at all in the Court's discussion of proportionality.

5.2 Conflict Between Health and Other Fundamental Rights

Relevant CJEU cases in this cluster:

➢ Judgment of the Court (Fifth Chamber) of 22 May 2014, *Wolfgang Glatzel v Freistaat Bayern*, Case C-356/12 ("**Glatzel**")

Relevant legal sources

EU level

Articles 20, 21, and 26 Charter on Fundamental Rights of the European Union

Article 8 and Point 6.4 of Annex III to Directive 2006/126/EC (Recast)

National legal sources (Germany)

Paragraph 2(2) of the German road traffic act (Straßenverkehrsgesetz):

"A driving licence must be issued for the category concerned where the applicant

…

3. is fit to drive motor vehicles,

…"

Paragraph 2(4) of the German road traffic act (Straßenverkehrsgesetz)

"Any person who satisfies the physical and mental requirements for driving power-driven vehicles who has not committed any serious or repeated offences against the road traffic provisions or the provisions of criminal law is to be deemed fit to drive power-driven vehicles."

Point 2.2.1 of annex 6 to that regulation:

"Central daytime visual acuity:

Any sight defect must be corrected, provided that such correction is possible and well tolerated, so as to comply with the following minimum values of visual acuity: acuity of the better eye or binocular visual acuity of 0.8; acuity in the worse eye of 0.5,

…

In certain special cases, taking driving experience and the use of the vehicle into account, the visual acuity of the worse eye may be less than 0.5 for categories C, CE, C1 and C1E, provided that it is no less than 0.1"

Question 4 – Justifying discrimination on the basis of health-related issues

What are the limits to justifications of differences in treatment on the basis of disability which are invoked for health-related reasons, such as the protection of the health of certain individuals?

The case

After driving under the influence of alcohol, Mr. G. lost his driving licence by a judgment delivered in April 2010. By an administrative decision in November 2010, the Landratsamt Schwandorf partially upheld Mr. G's application for a new driving license in categories A, A1, and BE. However, it refused his application for a new driving licence in categories C1 and C1E, which would allow him to drive heavy goods vehicles. The decision was justified on the ground that the visual acuity in Mr. G's right eye did not satisfy the requirements laid down by German law for issuance of a driving licence for vehicles in the latter categories. After unsuccessfully objecting to the decision, Mr. G. brought an action before the

Administrative Court of Regensburg. Since that Court dismissed his action, he filed an appeal before the referring Court, the Bayerischer Verwaltungsgerichtshof. The Bayerischer Verwaltungsgerichtshof took the view that Mr. G.'s appeal should be upheld and that he should be issued a driving licence for vehicles in categories C1 and C1E. Nonetheless, it decided to stay the proceedings and to refer to the CJEU for a preliminary ruling.

Preliminary question referred to the Court

1. Is point 6.4 of Annex III to Directive 2006/126 compatible with Article 20, Article 21(1) and Article 26 of the Charter in so far as that provision requires — without permitting any derogation — that applicants for Category C1 and Category C1E driving licenses have a minimum visual acuity of 0.1 in their worse eye even if those persons use both eyes together and have a normal field of vision when using both eyes?

National Court's decision to refer the case to the CJEU

Judgment of Verwaltungsgerichtshof München (Administrative Court of Munich), 5.07.2012, 11 BV 11.1764

The Administrative Court of Munich took the view that Mr. G's appeal should be upheld, that both the decision by the Landratsamt Schwandorf and the judgment of the Administrative Court Regensburg should be set aside and that Mr.G. should be issued with driving licences for categories C1 and C1E. It argued that point 6.4 of Annex III to Directive 2006/126 was invalid, because it was in breach of the fundamental right to equality before the law (Article 20 CFREU), the right to non-discrimination on the grounds of disability (Article 21(1) CFREU) and the right to integration of persons with disabilities (Article 26 CFREU). Furthermore, it argued that there were no "necessary" reasons pursuant to Article 52(1) CFREU for restricting the right of people with a visual acuity under 0.1 on one eye to drive heavy goods vehicles in so far as: the person concerned has binocular visual acuity that meets the requirements of point 6.4 of Annex III to the Directive when using both eyes together, and if they learned to compensate for any existing deficiencies.

As the Court was not competent to rule on matters concerning the validity of EU law, it decided to stay the proceedings and to refer the abovementioned question to the Court of Justice of the European Union.

Reasoning of the CJEU

First, the Court highlighted the need to address whether the EU rules at issue, laying down requirements for visual acuity for the drivers of vehicles in categories C1 and C1E, were contrary to Article 21(1) of the Charter, which prohibits any discrimination against persons with disabilities. It then turned to Article 52(1) of the Charter, which "provides that any limitation on the exercise of the rights and freedoms recognised by the Charter must be provided for by law and must respect the essence of those rights and freedoms. Subject to the **principle of proportionality**, limitations may be imposed only if they are necessary and genuinely meet objectives of general interest recognised by the Union or the need to protect the rights and freedoms of others."

Considering the meaning of disability, the Court noted that it is not defined in Article 21 CFREU. It therefore relied on previous case law in which a definition of "disability" under Directive 2000/78 (and

therefore in the context of employment) was developed.[110] Moving on to apply the definition of disability to Mr. G., the Court noted that he suffered from "long-term sensory impairment" but still had "full acuity" when he used both eyes. Therefore, the Court did not have enough information to determine whether or not this constituted a disability for the purposes of Article 21 CFREU. Nonetheless, the Court found that this was not necessary in order to assess whether the difference in treatment could be objectively justified in light of overriding conditions of road safety.

The Court recalled its previous case law on the **general principle of equal treatment** in the context of the grounds of age and sex (concerning age discrimination: *Wolf*, C-229/08 EU:C:2010:3, paragraph 35; and *Prigge and Others*, C-447/09*,* EU:C:2011:573, paragraph 66; and concerning sex discrimination: *Johnston*, C-222/84, EU:C:1986:206, paragraph 40; and *Sirdar*, C-273/97, EU:C:1999:523, paragraph 25) whereby, "by reason of the nature of the particular occupational activities concerned or of the context in which they are carried out, such a characteristic constitutes a genuine and determining occupational requirement, provided that the objective is legitimate and the requirement is proportionate" (paragraph 49). Extending this to the context of Mr. G's situation, which was not in the field of employment, the Court noted that the **difference in treatment in question may not be contrary to Article 21(1) if it (a) fulfils an objective of public interest; (b) is necessary; and (c) is not a disproportionate burden**.

According to the Court, Directive 2006/126 aims to improve road safety and thus to attain an objective of general interest. Regarding the necessity of the minimum standards for vision of drivers, the Court held that the more someone's visual function is reduced, the more it becomes necessary to take into consideration requirements relating to road safety. The minimum standards for vision of drivers were therefore indeed necessary and constituted an effective means of improving road safety. It remained to be determined whether such a prohibition constituted a disproportionate burden. Again, drawing on previous case law (*Johnston,* C-222/84, EU:C:1986:206, paragraph 38; *Sirdar*, C-273-97, EU:C:1999:523, paragraph 26; and *Kreil*, C-285/98, EU:C:2002:2, paragraph 23), it was held that **proportionality** required "the **principle of equal treatment** to be reconciled as far as possible with the requirements of road safety which determine the conditions for driving motor vehicles" (paragraph 56). Considering that according to Article 8 of Directive 2006/126, in the case of scientific uncertainties, the EU legislature may give priority to considerations relating to the improvement of road safety, the fact that the legislature decided not to eliminate all minimum requirements for visual acuity of the worse eye for group 2 drivers, did not make the adaptation measure disproportionate. Finally, with regard to the question whether the treatment of Mr. G. may constitute discrimination under Article 2 of the UN Convention on Disabilities, the Court found that as it did not contain "unconditional and sufficiently precise conditions," said provision of the UN Convention does not allow a review of the validity of the measure of EU law in light of the provisions of that Convention. However, due to the primacy of international agreements concluded by the EU, secondary legislation, including Directive 2006/126, must be interpreted in a manner consistent with the Convention as far as possible.

[110] This case law was discussed in Section 5.1 of the present chapter. The definition as applied in *Glatzel* reads as follows: '[A] limitation resulting, in particular, from long-term physical, mental or psychological impairments which in interaction with various barriers may hinder the full and effective participation of the person concerned in professional life on an equal basis with other persons, unless such a difference in treatment is objectively justified.' *Glatzel*, paragraph 46.

Bearing all of these considerations in mind, the Court was unable to determine that the validity of point 6.4 of Annex III to Directive 2006/126 was affected by Article 21(1) of the Charter.

Secondly, the Court had to determine whether Article 26 of the Charter, which enshrines the principle of integration of persons with disabilities, precluded point 6.4 of Annex III to Directive 2006/126. It stated that although Article 26 of the Charter required the EU to respect and recognise the right of persons with disabilities to benefit from integration measures, the principle enshrined by that Article does not require the EU legislature to adopt any specific measure. Rather, it must be given more specific expression in European Union or national law. Article 26 cannot therefore by itself confer on individuals a subjective right which they may invoke as such (see *Association de mediation sociale*, C-176/12, EU:C:2014:2, paragraphs 45 and 47, in relation to Article 27 CFREU).

Thirdly, the Court had to determine whether it was contrary to Article 20 of the Charter (equality before the law) that drivers of certain heavy goods vehicles did not have the opportunity to show, by means of an individual medical examination, that they were fit to drive such vehicles, whereas other drivers of certain other types of vehicles did have such a possibility. Article 20 of the Charter aims to ensure that comparable situations do not receive different treatment. However, due to differences in characteristics of the vehicles concerned, the situations of the drivers of such vehicles were not comparable and did not therefore violate the right of drivers to equality before the law.

Conclusion of the Court

The Court concluded that:

"[T]he examination of the question does not reveal any information capable of affecting the validity of point 6.4 of Annex III to Directive 2006/126/EC of the European Parliament and of the Council of 20 December 2006 on driving licences, as amended by Commission Directive 2009/113/EC of 25 August 2009 in light of Articles 20, 21(1) or 26 of the Charter of Fundamental Rights of the European Union."

Impact on the follow-up case

Judgment of Verwaltungsgerichtshof München (Administrative Court of Munich), 14.01.2015, 11 BV 14.1345

Based on the CJEU's preliminary ruling, the Administrative Court of Munich decided to reject Mr. G.'s appeal, meaning that he would not be issued driving licences for categories C1 and C1E.

Elements of judicial dialogue

Interestingly, despite having discussed the comparability of situations in recent previous cases (see Section 1.2.1.2 of the FRICoRe Casebook on EU Fundamental Rights and Non-Discrimination), in *Glatzel* the Court did not refer to the guidelines applied in these cases when determining whether the situations in question were, in fact, comparable. However, the circumstances considered in *Glatzel* (namely the characteristics of the vehicles concerned – see paragraph 83) do suggest that the same general approach was taken by the Court as it established, for example, in *MB* (C-451/16, ECLI:EU:C:2018:492).[111]

[111] This case is discussed in detail in Chapter 1.2.1.2 of the FRICoRe Casebook on EU Fundamental Rights and Non-Discrimination: Effective Protection in the Light of Article 21 of the Charter.

The Court did explicitly rely heavily on its previous jurisprudence in first assessing the meaning of disability under Article 21 CFREU, and second, whether or not the difference in treatment at play in *Glatzel* could be justified. Interestingly, many of the cases referred to did not deal with Article 21, and many were situations concerning employment and Directive 2000/78 (e.g. *Wolf*, C-229/08, ECLI:EU:C:2010:3). As mentioned above in the discussions of judicial dialogue in Section 5.1, the reliance on these cases in *Glatzel*, at the core of which is the Charter of Fundamental Rights of the European Union, demonstrates that the Court's understanding of "disability" under the Charter is the same as that under Directive 2000/78. Furthermore, the same steps are taken by the Court to determine whether or not discrimination exists (i.e. whether there is a difference in treatment on a particular ground and if so, whether this can be justified in certain instances) regardless of whether or not the Charter (or Directive 2000/78) is applied in a particular case.

Moreover, *Conejero* (C-270/18) is of particular interest. In that judgment the CJEU stated that national legislation under which an employer may dismiss a worker on the grounds of his intermittent absences from work, even if justified, in a situation where those absences are the consequence of sickness attributable to a disability suffered by that worker, is consistent with Article 2(2)(b)(i) of Directive 2000/78 only if that legislation, while pursuing the legitimate aim of combating absenteeism, does not go beyond what is necessary in order to achieve that aim. The Court stated that that assessment was a matter for the referring Court.

The judicial dialogue relating to *Glatzel* also demonstrates the impact that the case has had on the CJEU's subsequent jurisprudence. For example, the relationship between Articles 20 and 21 CFREU was laid out in *Glatzel*, with the Court stating in paragraph 43 that "the **principle of equal treatment** is a general principle of EU law, enshrined in Article 20 of the Charter, of which the **principle of non-discrimination** laid down in Article 21(1) of the Charter is a particular expression." Cases concerning both Article 20 and Article 21 since *Glatzel*, such as *Léger* (C-528/13, ECLI:EU:C:2015:288, paragraph 48 – also in the context of health), have applied this same understanding. Furthermore, although the judgment in *Glatzel* is itself based on previous case law with regard to the general conditions for assessing whether discrimination has occurred or not, it has been repeatedly used as an authority on this matter (also in cases not dealing with health as a fundamental right), particularly for the more specific conditions for determining whether a difference in treatment can be justified (see *Fries*, C-190/16, ECLI:EU:C:2017:198, paragraph 59; *Milkova*, C-406/16, ECLI:EU:C:2017:198, paragraph 55; *RPO*, C-390/15, ECLI:EU:C:2017:174, paragraph 53).

Overall, the Court's approach to the justification of otherwise discriminatory treatment in *Glatzel* is very similar to its approach in non-health related cases (see Chapter 1 of the FRICoRe Casebook on EU Fundamental Rights and Non-Discrimination). However, the Court's decision here is based on Article 52(1) of the Charter rather than the relevant provisions of the equal treatment directives allowing for the justification of differences in treatment. With the addition of being "provided for by law and respect[ing] the essence of […] rights and freedoms" protected in the CFREU, Article 52(1) reflects the same requirements for justifications as some of the types of justifications provided for in the equal treatment directives. This includes justification of indirect discrimination, which can be objectively justified in order to achieve a legitimate aim, and justifications on the specific grounds of age. Each of these justifications essentially require differences in treatment must be necessary and appropriate to the achievement of a legitimate aim, and that they must be proportionate. This is reflected in Article 52(1), which provides that "[s]ubject to the principle of proportionality, limitations may be made only if they are necessary and

genuinely meet objectives of general interest recognised by the Union or the need to protect the rights and freedoms of others." It is interesting that the CJEU also referenced "genuine and determining occupational requirements" in *Glatzel* despite the fact that Mr. G's complaint did not relate to employment. All of this suggests that the common requirements of most justifications found in the equal treatment directives are applicable, through Article 52(1), in situations in which the relevant source of secondary EU law applicable is not one of the equal treatment directives themselves.

In relation to the need to respect the essence of rights and freedoms found in the Charter, the specific context of health did not seem to play a role in the Court's reasoning, as focus was placed entirely on non-discrimination and Article 21 CFREU. The fundamental right to health of other individuals (i.e. road users) was also not mentioned in the CJEU's judgment, although the objective of ensuring "road safety" could conceivably concern other's health. For example, the limitation on the right to non-discrimination of Mr. G. (and other people with visual disabilities) could, if leading to fewer accidents on the roads, have the effect of increased protection of other road users' health. Whether or not this could be an issue of fundamental rights *per se* and involve the balancing of rights against one another was not discussed by the Court.

Finally, *Glatzel* has recently be referred to in a case concerning the meaning of genuine and determining occupational requirement and discrimination on the ground of disability (*Komisia za zashtita ot diskriminatsia*, C-824/19, ECLI:EU:C:2021:862). In this judgment, the Court reiterated that 'vision has an essential function for driving power-driven vehicles, so that a requirement for minimum visual acuity imposed by the EU legislature for the purpose of employment as a lorry driver is in accordance with EU law with regard to the objective of ensuring road safety'. In this case, the question had arisen whether the specific disability of a permanently blind person, as a characteristic constituting a genuine and determining requirement of the activity of a juror, justified a difference of treatment and did not constitute discrimination based on the characteristic of 'disability'.

Impact on national case law in Member States other than that of the Court referring the preliminary question to the CJEU

United Kingdom

Although not in the context of health, the CJEU's judgment in Glatzel, as discussed in *Milkova* (C-406/15) was referred to by the Upper Tribunal of the Administrative Appeals Chamber in the UK. The case of *SK and LL v Secretary of State for Work and Pensions* [2020] UKUT 145 (AAC) concerned two claims of discrimination in relation to a rule laid down in national legislation that a claimant for the 'Sure Start Maternity Grant,' with respect to an infant, will not be eligible if there is another child under 16 years of age in the family for whom they are responsible (the "first child only rule"). The issue was whether those conditions discriminated unlawfully against the Appellants under EU law and/or under human rights law. The first claimant, SK, had come to the UK in 2015 and claimed asylum with her son of 3.5 years old. She was granted leave to remain in 2017 and made a claim for the maternity grant when pregnant with her daughter, who was born in the UK. SK's claim was refused on the basis that she was not eligible for the grant under national law because there was an existing member of her family under the age of 16 for whom she was responsible (i.e. her son, who had been born in Iraq), and her situation did not fall within the exceptions to the first child only rule.

In response to SK's claim of direct discrimination the respondent argued that the claim did not fall under EU non-discrimination law, which unlike the prohibition of discrimination under Article 14 ECHR, was restricted to specific, limited grounds of discrimination. The Court noted that while this was correct, the

CJEU did note in *Milkova*, on the basis of *Glatzel* and other previous cases, that the principle of equal treatment enshrined in Article 20 and 21 CFREU is a general principle of EU law. The Tribunal understood this to mean that the prohibition of discrimination under EU law could not be limited to the extent that the respondent sought to argue. However, the Tribunal did not discuss this in any further detail, as the judge found that the situation was more suited to a claim of indirect discrimination on the grounds of nationality. The Court ultimately concluded that there was no indirect discrimination because it was not intrinsically more likely that the 'first child only' test would affect refugees more than it would affect UK nationals, even though refugees with pre-flight children were likely to be disadvantaged in terms of the greater severity of the impact of the provision on them given their likely lack of childcare items.

5.3 Guidelines Emerging from the Analysis

Several general guidelines concerning non-discrimination in health-related cases can be extracted from the case law of the CJEU discussed in this chapter, most of which relate to cases brought concerning discrimination on the grounds of disability:

- The scope *ratione materiae* of Directive 2000/78 should not be extended by analogy beyond the discrimination based on the grounds listed exhaustively in Article 1 thereof. This matches the approach taken and discussed in cases concerning other aspects of non-discrimination law, such as *MB* (C-451/16, ECLI:EU:C:2018:49). This does not appear to be impacted by the fact that health is a fundamental right. However, the definition of disability itself, which is relatively broad, allows individuals with health issues such as sickness and obesity to be protected from discrimination on the grounds of disability in some circumstances despite the fact that these are not protected grounds in themselves.

Effective protection

In the view of the CJEU as expressed in *Coleman* (C-303/06):

- In order to ensure effective protection from discrimination, it is crucial that individuals who are treated differently on the basis of a particular protected characteristic fall within the scope *ratione personae* of the principle of non-discrimination. This would include, for example, the primary *carer* of a person with health conditions amounting to a disability as well as the person with a disability themselves.

Definition and scope of "disability"

- "Disability" is defined by the CJEU in the same way whether or not the Charter applies in a particular case. It can therefore be inferred that "disability" has the same definition when applied in relation to Article 21 of the Charter as in relation to Directive 2000/78, suggesting in turn that there is a common concept of disability regardless of which source of EU non-discrimination law applies. This definition is based on that found in the UN Convention on the Right of Persons with Disabilities.

In the view of the CJEU as expressed in *HK Danmark* (Joined Cases C-335/11 and C-337/11):

- For the purposes of EU non-discrimination law, "disability" means a limitation which results in particular from physical, mental, or psychological (i.e. health) impairments which, in interaction with various barriers, may hinder the full and effective participation of the person concerned in professional life on an equal basis with other workers.

- Illnesses as such are not a ground of discrimination under the Directive (*Chacón Navas*, paragraph 57), but if limitations having the abovementioned effects on a long-term basis are caused by an illness, they can be covered by the concept of "disability."

- "Disability" does not necessarily equate to total exclusions from work or professional life, but can also cover situations where a person can only work to a limited extent.

- A "disability" need not make an individual incapable of exercising an activity, as long as it provides a hindrance to exercising it.

In the view of the CJEU as expressed in *FOA* (C-453/13):

- If the obesity of a worker causes a limitation as explained above, and the limitation is long-term, obesity can be covered by the concept of "disability" within the meaning of Directive 2000/78.
    - "Long-term" includes the fact that, at the time of the alleged discriminatory act, the incapacity of the person concerned does not display a clearly defined prognosis with regard to short-term progress or the fact that that incapacity is likely to be significantly prolonged before that person has recovered.
    - A national Court must base its decision on all of the objective evidence in its possession, in particular on documents and certificates relating to that person's condition, established on the basis of current medical and scientific knowledge and data. Since this evidence falls under the question of whether or not an applicant does indeed have a disability, it may be inferred that it is for the applicant to provide such evidence in order to establish a *prima facie* case of discrimination (based on the rules of burden of proof established in Recital 31 and Article 10 of Directive 2000/78 – see Section 3.3 of the FRICoRe Casebook on EU Fundamental Rights and Non-Discrimination: Effective Protection in Light of Article 21 of the Charter).

Article 52(1) CFREU

In view of the CJEU as expressed in *Glatzel* (C-356/12):

- When assessing whether a limitation on the right to non-discrimination contained in Article 21 of the Charter is permissible under Article 52(1) of the same Charter, it is for national Courts to determine whether the limitations respect the principle of proportionality.

  From the Court's application in this case, it appears that the limitations allowed under Article 52(1) generally mirror the justifications for differences in treatment found in the equal treatment directives. In the cases discussed in this chapter, health as a fundamental right did not appear to play a role in the proportionality test applied, beyond the requirement in Article 52(1) CFREU that limitations to rights and freedoms protected by the Charter "respect the essence of those rights and freedoms."

6 Migration, Asylum and Health

Relevant CJEU case

- CJEU - C-562/13, Centre public d'action sociale d'Ottignies-Louvain-La-Neuve v Moussa AbdidaC-368/98 Vanbraekel [2001] ECR I-05363. ECLI:EU:C:2001:400
- CJEU - C 402/19, LM v Centre public d'action sociale de Seraing (30 September 2020)
- CJEU – C-233/19, B. v Centre public d'action sociale de Liège (CPAS) (30 September 2020)
- CJEU – C-353/16, MP v Secretary of State for the Home Department (24 April 2018)
- CJEU - C-542/13, Mohamed M'Bodj v État belge (18 December 2014)
- CJEU - C-578/16 PPU, C.K. and others (16 February 2017)
- CJEU - C-163/17, Jawo e nelle cause riunite C-297/17, C-318/17 Ibrahim, C-319/17 Sharqawi e a. e C-438/17 Magamadov (19 March 2019)
- CJEU – C-519/18, TB v Bevándorlási és Menekültügyi Hivatal (12 December 2019)
- CJEU – C-79/13, Federaal agentschap voor de opvang van asielzoekers v Selver Saciri, Danijela Dordevic, Danjel Saciri (27 February 2014)

Main questions addressed

Question 1 Does the duty to protect a migrant's health increase effective protection during the return procedure? Can the risk of inhuman treatment ex Art. 19.2 CFREU be interpreted as also including the risk of grave and irreversible deterioration of a migrant's health provoked by the enforcement of a return decision? Is Art. 47 CFREU relevant in imposing on MSs a duty to suspend a return procedure due to reasons linked to a migrant's health conditions? Is there a duty for MSs to at least guarantee a migrant's basic needs during the return procedure, including those related to health?

Question 2 Does a Member State have the duty to grant social welfare and healthcare benefits associated with subsidiary protection to a migrant who stays in its territory in application of the principle of non-refoulement? In case of positive answer, which requirement is to be met? What is the role of national judges in assessing the intentional nature of the deprivation of healthcare in the country of origin? Is there a prohibition on the removal of a victim of torture that risks a severe deterioration of his/her health status? Is there a related duty to grant subsidiary protection?

Question 3 Is there a duty for Member States to assess the potential impact on asylum seeker's health as a consequence of transfer under the Dublin Regulation? Might this risk cause a duty to suspend such transfers? What are the main criteria which States must assess? Is there a duty to examine the application due to a migrant's health condition in case of a long-term suspension? Does the same standard also apply to a case in which the asylum seeker must be transferred to a State where he/she is expected to encounter poorer living condition? On which grounds?

Question 4 Are Member States bound to provide for family reunification under Article 10.2 of Directive 2003/86? Can family reunification be conditioned to the existence of a condition of dependency related to the health status of the applicant? Does the relevance of the state of health limit Member States' discretion in defining the requirements for integrating the state of dependency?

6.1 Migrants' Health and Return Procedure: the Suspensive Effect of Appeals and Basic Healthcare Needs

Question 1 – The risk of a grave and irreversible deterioration in the state of health and the suspension of a return procedure

Does the duty to protect a migrant's health increase effective protection during the return procedure? Can the risk of inhuman treatment ex Art. 19.2 CFREU be interpreted as also including the risk of grave and irreversible deterioration of a migrant's health provoked by the enforcement of a return decision?
Is Art. 47 CFREU relevant in imposing on MSs a duty to suspend the return procedure due to reasons linked to migrant's health conditions?
Is there a duty for MSs to at least guarantee a migrant's basic needs during the return procedure, including those related to health?

The analysis is based on *Abdida* (C-562/13)

The case

The case stems from an appeal lodged by Mr. Moussa Abdida against the decision of the Centre public d'action sociale d'Ottignies-Louvain-la-Neuv (CPAS) to revoke social assistance that was previously guaranteed. The CPAS's reasons were grounded on the refusal of competent Belgian authorities to grant a residence permit for health reasons. National authorities assessed that in his country of origin, Mr. Abdida should have had adequate medical infrastructure for caring for persons suffering from the illness affecting him. Therefore, he was notified of that decision and ordered to leave Belgium.

According to Belgian law (Law. 15 December 1980), "A foreign national residing in Belgium who can prove his identity in accordance with paragraph 2 and who suffers from an illness occasioning a real risk to his life or physical integrity or a real risk of inhuman or degrading treatment where there is no appropriate treatment in his country of origin or in the country in which he resides may apply to the Minister or his representative for leave to reside in the Kingdom of Belgium."

In the first instance, the competent Court (Labour Court, Nivelles) granted Mr. Abdida's application and ordered the CPAS to pay social assistance to Mr. Abdida equivalent to income support for a single person. The Court grounds rested especially on the fact that the right to social assistance was an essential prerequisite for the effective exercise of a right to appeal; thus, social assistance granted to Mr. Abdida must be maintained pending a decision on his appeal against the decision for him to leave.

On appeal, the Higher Labour Court stated that, according to Belgian law, no judicial remedy was available to Mr. Abdida for suspension of the decision refusing him leave to reside; accordingly, he was not entitled to any form of social assistance other than emergency medical assistance, pending the

decision on his appeal. In those circumstances, the Court decided to stay proceedings and refer a preliminary ruling to the Court of Justice.

Preliminary questions referred to the Court

The Belgian Court asked the Court of Justice whether a Member State which provides that a foreign national has the right to subsidiary protection for the purposes of Article 15(b) of [Directive 2004/83], if that person "suffers from an illness occasioning a real risk to his life or physical integrity or a real risk of inhuman or degrading treatment where there is no appropriate treatment in his country of origin," has the duty to:

- provide for a remedy with suspensive effect with regard to the administrative decision refusing leave to remain and/or subsidiary protection, and ordering the person concerned to leave the territory of that State;
- make provision under its social security or reception system for the basic needs of the person applying for subsidiary protection (other than his medical needs) to be met pending a ruling on his appeal against that administrative decision.

Secondly, if the answer to Question 1 is in the negative, the Court asked whether the same duties may derive from the CFREU, in particular Arts. 1 to 3, 4, 19(2), 20 and 21, and/or 47.

Reasoning of the Court

The Court preliminarily redefined the proper scope of the questions referred. It stated the irrelevance of cited directives, as Mr. Abdida's application could not be considered a request for international protection; on the contrary, the decision ordering Mr. Abdida to leave Belgian territory had to be qualified as a 'return decision' within the meaning of Article 3 of Directive 2008/115 on common standards and procedures in Member States for returning third-country nationals who were staying illegally ("return" directive). Thus, the Court redefined the scope of the preliminary ruling, to assess whether Directive 2008/115, with reference to the remedies and safeguards available to migrants subject to a return decision (Articles 13 and 14), precludes national legislation "which does not grant suspensive effect to an appeal lodged against a return decision which does not provide for the primary needs of the third-country national concerned to be taken into account until such time as the appeal has been determined."

According to the Court, the case concerned the determination of safeguards to be provided until a ruling was given on an appeal of a return decision on the basis that the migrant was staying illegally in a Member State (§ 38). With regard to suspensive effect of the appeal, Arts. 13 and 14 of the return Directive do not require that the remedy provided for in Article 13(1) (effective remedy to appeal) should necessarily have a suspensive effect (§ 44). Notwithstanding, the Court considered that the Directive must be interpreted in light of the CFREU, in particular Arts. 47 and 19.2 of the Charter. Thus, on one hand, the concrete content of the remedy against a return decision must be determined in a manner consistent with Article 47 of the Charter, which constitutes a reaffirmation of the principle of effective judicial protection and provides that everyone whose rights and freedoms guaranteed by EU law are violated has the right to an effective remedy before a tribunal in compliance with the conditions laid down in that Article (§ 45). On the other, Art. 47 must be read in conjunction with Article 19(2) of the Charter, according to which no one may be removed to a State where there is a serious risk that he or she would be subjected to inhuman or degrading treatment (principle of non-refoulement; § 46).

By referring to the ECtHR's case law (see below), the Court stated that "In the very exceptional cases in which the removal of a third country national suffering a serious illness to a country where appropriate treatment is not available would infringe the principle of non-refoulement, Member States cannot therefore, as provided for in Article 5 of Directive 2008/115, taken in conjunction with Article 19(2) of the Charter, proceed with such removal" (§ 48). When a return decision entails the removal of a migrant suffering from a serious illness to a Country in which appropriate treatment is not available, its concrete enforcement may constitute, in certain cases, an infringement of Article 5 of Directive 2008/115, which asks Member States to take due account of – among other circumstances – "the state of health of the third-country national concerned."

The Court went further and specified the exact scope of those "exceptional cases" in which a negative effect on a migrant's health as a consequence of a return decision may cause a violation of Art. 5 of the Return Directive. These cases must be characterised by the seriousness and irreparable nature of the harm that may be caused by the removal of a third country national to a country in which there is a serious risk that he will be subjected to inhuman or degrading treatment (§ 50). In order to be effective, an appeal against a return decision must have suspensive effect, when its enforcement may expose the third country national concerned to a serious risk of grave and irreversible deterioration in his state of health. During this time, the competent Court must have the opportunity to examine an appeal alleging infringement of Article 5 of Directive 2008/115, taken in conjunction with Article 19.2 of the Charter (§ 50). It is worth mentioning that the Court referred explicitly to the explanations relating to Art. 47 CFREU, which referred to the ECTHR's case-law on Art. 3 ECHR (§ 51; see below).

Accordingly, the Court considered that "Articles 5 and 13 of Directive 2008/115, taken in conjunction with Articles 19(2) and 47 of the Charter, must be interpreted as precluding national legislation which does not make provision for a remedy with suspensive effect in respect of a return decision whose enforcement may expose the third country national concerned to a serious risk of grave and irreversible deterioration in his state of health" (§ 53).

With regard to the State's duty to provide for the basic needs of a third country national, subject to removal procedure, the Court considered that Member States are required to provide safeguards to a third country national suffering from a serious illness who has appealed against a return decision whose enforcement may expose him to a serious risk of grave and irreversible deterioration in his state of health, pending return, established in Article 14 of Directive 2008/115 (§ 58). In particular, the Court considered that – in the concrete case – the requirement set forth by national law to provide only emergency healthcare and essential treatment of illness may be inadequate to guarantee the effective protection of a migrant's health (§ 60). At the same time, the Court considered that it belonged to the Member State to determine the form in which such provision for the basic needs of the third country national concerned was to be made (§ 61).

Conclusion of the Court

With regard to the suspensive effect of the appeal, the Court considered that "Articles 5 and 13 of Directive 2008/115, taken in conjunction with Articles 19(2) and 47 of the Charter, must be interpreted as precluding national legislation which does not make provision for a remedy with suspensive effect in respect of a return decision whose enforcement may expose the third country national concerned to a serious risk of grave and irreversible deterioration in his state of health" (§ 53).

With regard to the duty to at least guarantee a migrant's basic needs pending the appeal, under the circumstances of the referred case, the Court concluded that "Article 14(1)(b) of Directive 2008/115 must be interpreted as precluding national legislation which does not make provision, in so far as possible, for the basic needs of a third country national suffering from a serious illness to be met, in order to ensure that such a person may in fact avail himself of emergency health care and essential treatment of illness during the period in which the Member State concerned is required to postpone removal of the third country national following the lodging of an appeal against a decision ordering that person's return" (§ 62).

Elements of judicial dialogue

The Abdida case was followed by other decisions where the Court of Justice was called to further develop its case-law on the relationship between the possible impact to a migrant's health condition produced by the enforcement of a return decision, on the one hand, and the existence of a duty to suspend the latter while pending appeal, on the other. From this perspective, two judgments become especially relevant, as they explicitly referred to the Adbida case reasoning and went on to expand further – even if under specific circumstances – the role that a migrant's health needs, in terms of serious risks for his/her health deriving from such a decision, may have in terms of safeguards to be guaranteed during the removal procedure.

In B. case (C-233/19, 30 September 2020), the Court of Justice's ruling in the Abdida case was the starting point of the question referred by the national judge. The question aimed to understand the exact degree of judicial assessment required in order to meet the standard of protection provided by Articles 5 and 13 of the Return Directive, as interpreted in Abdida. More concretely, the Belgian Court asked the CJE whether the mere introduction of an appeal was sufficient to suspend the enforcement of a return decision, or if at least a "marginal review" of the admissibility of a complaint must be performed by a competent judge; or, eventually, whether a full and comprehensive judicial review carried out by the Courts in order to determine whether the enforcement of that decision was liable to expose the appellant to a serious risk of grave and irreversible deterioration in his or her state of health (§ 21[112]). The circumstances of the case were very similar to those of Abdida, as also in B. The appellant unsuccessfully applied for leave to reside on medical grounds and she was granted only emergency medical assistance pending the return procedure. In its reasoning, the Court made wide reference to Abdida.

First, it confirmed that the characteristics of a remedy against a return decision must be determined in accordance with Article 47 of the Charter and the principle of non-refoulement (Art. 19.2 CDFEU). In light of this, especially in order to give effective enforcement to the latter principle, an appeal against a return decision must have automatic suspensive effect, in particular, where the enforcement of a return

[112] "what are the circumstances in which Articles 5 and 13 of Directive 2008/115, read in light of Article 19(2) and Article 47 of the Charter, must be interpreted as meaning that a national Court, hearing a dispute on social assistance, the outcome of which is linked to the possible suspension of the effects of a return decision made with respect to a third country national suffering from a serious illness, must hold that an action for annulment and suspension of that decision automatically entails suspension of that return decision, even though that suspension does not result from the application of national legislation."

decision may expose a third-country national suffering from a serious illness to a serious risk of grave and irreversible deterioration in his or her state of health (§ 45-47). By expressly referring to Art. 47 CFREU, the CJEU stated that when it emerges that the national Court concludes that the relevant law does not offer a remedy against the return decision governed by clear, precise, and foreseeable rules and leading to the automatic suspension of that decision, it is for competent national Court to hold that the appeal brought by the third-country national has suspensive effect for the purposes of the annulment or suspension of the return decision made in respect of that third-country national. If it is the case, the Court is also entitled to refusing the application of the national legislation precluding that appeal from having such an effect (§ 57). The CJEU further underlined that, based on the direct effect resulting from Article 13.1 of the Return Directive and Article 19.2 and 47 of the Charter, a national judge may decide to grant automatic suspensive effect, even if the national Court does not have that jurisdiction under national law (§ 59).

Secondly, the Court, based on Abdida, concluded that the automatic suspensive effect must be guaranteed to appeals brought against a return decision, the enforcement of which 'may' expose a third-country national suffering from a serious illness to a 'serious risk' of a grave and irreversible deterioration in his or her state of health (§ 63). At the same time, it clarified that national authority must confine itself to assessing whether the appeal brought against the return decision contains an argument that the enforcement of that decision would expose a third-country national suffering from a serious illness to a serious risk of grave and irreversible deterioration in his or her state of health that does not appear to be manifestly unfounded. If that is the case, it is incumbent upon that authority to suspend the return procedure with automatic effect, from the lodging of that appeal, and to give due effect to that finding under its powers (§ 66).

Eventually, the CJEU defined two conditions to be satisfied in order for a national Court to grant the suspension of the effects of a return decision made in respect of a third-country national suffering from a serious illness: the existence of "arguments seeking to establish that the enforcement of that decision would expose that third-country national to a serious risk of grave and irreversible deterioration in his or her state of health, which do not appear to be manifestly unfounded;" and, the absence of "any other remedy, governed by clear, precise and foreseeable rules, which automatically entail the suspension of such a decision" (§ 68).

A further development of Abdida was represented by the LM case (CJEU - C 402/19, LM v Centre public d'action sociale de Seraing (30 September 2020), which concerned the withdrawal of social assistance – in order to cover basic needs – of a third country national who appealed against a return decision, when that person had a seriously ill, dependent, adult child who required the parent's presence and where an appeal was lodged on behalf of that adult child against a return decision which could expose them to a serious risk of grave and irreversible deterioration of health.

On the one hand, by recalling Abdida, the Court recognised that the appellant was not, by virtue of that status alone, directly exposed to a risk of being subjected to treatment contrary to Article 19(2) of the Charter in the event of enforcement of a return decision (§ 37). On the other hand, it further clarified Abdida, in the sense that the purpose of the duty to ensure, in certain cases, remedy with automatic suspensive effect against a return decision concerning a third-country national suffering from a serious illness was to enable the person concerned to remain temporarily in the territory of the Member State that had adopted a return decision with respect to him or her (§ 39).

When that person is, because of his or her state of health, entirely dependent on a parent whose presence at that person's side is essential, the safeguard related to the suspensive effect of an appeal should transfer to that parent, when the latter is exposed to a return procedure (§ 40). Therefore, in order to ensure the effectiveness of protection under Articles 5 and 13 of Directive 2008/115, read in light of Article 19(2) and Article 47 of the Charter, the parent of that child must be entitled to an appeal with automatic suspensive effect against a return decision taken with respect to him or her (§ 41). In accordance with those guarantees, the Member States must, pursuant to Article 14(1)(a), (b) and (d) of that directive, ensure that, as far as possible, family unity with family members present in their territory is maintained, emergency health care and essential treatment for illness are provided, and the special needs of vulnerable persons are taken into account (§ 51), even if only where that third-country national lacks the means to make such provision for himself or herself (§ 53) and if the enforcement of a return decision could expose them to a serious risk of a grave and irreversible deterioration of their health (§ 55).

In terms of judicial dialogue, it is worth noting that the ECJ – especially in Abdida – grounded its interpretation of Art. 19.2 CFREU on the ECtHR's case-law on Art. 3 ECHR, in order to define the concrete mechanisms and safeguards to effectively guarantee the principle of non-refoulement, read in conjunction with Art. 47 CFREU. It derived from it – especially from N. v. the United Kingdom [GC], no. 26565/05, § 42, ECHR 2008 – the principle according to which a decision to remove a foreign national suffering from a serious physical or mental illness to a country where the facilities for the treatment of said illness are inferior to those available in that State may raise an issue under Article 3 ECHR in very exceptional cases, where the humanitarian grounds against removal are compelling. In those cases, also according to the ECtHR, when there is a risk of being exposed to a real risk of ill-treatment contrary to Art. 3 ECHR, the right to an effective remedy provided for in Article 13 ECHR requires that a remedy enabling suspension of enforcement of the measure authorising removal should, ipso jure, be available to the persons concerned.

To conclude on this issue, the ECJ seems to acknowledge the need to protect migrants with an irregular status affected by serious illness by the ability to broaden the range of cases in which national judges, even by dis-applying national laws contrary to this purpose (see case B.), must guarantee suspension of the enforcement of a return decision, pending appeal. It is worth noting that this approach is grounded on the interpretation of Articles 5 and 13 of the Return Directive in light of Articles 47 and 19.2 CFREU, through which the Court considered that in order to guarantee effective protection against refoulement, national authorities must also assess the potential impact that a migrant's return may have on his/her health status. The Court did not recognise a general duty to acknowledge suspensive effect to an appeal in all cases where a seriously-ill migrant is involved, as it clarified that it must occur only when the latter may be exposed to a serious risk of a grave and irreversible deterioration of his or her health. The special nature of the goods at stake (the right to health, even if the Court does not refer to health as a right but to the principle of non-refoulement in case of a risk of inhuman treatment) led the Court to broaden the scope of application of a procedural safeguard – the suspension of a return procedure pending appeal – and to ask national Courts (case B.) to assess whether the serious risk of a grave and irreversible deterioration of a migrant's health is not manifestly unfounded. The need to guarantee a migrant's health that is seriously ill led the Court to affirm the duty of the Member State to ensure at least basic health care (emergency and essential treatments) until the conclusion of the appeal (Abdida and LM).

6.2 Subsidiary Protection and Migrant Health: the Requirement of the (Intentional) Deprivation of Healthcare in the Country of Origin

Question 2 – Intentional deprivation of healthcare and the right to subsidiary protection

Does a Member State have the duty to grant social welfare and healthcare benefits associated with subsidiary protection to a migrant who stays in its territory in application of the principle of non-refoulement? In case of a positive answer, what is the requirement to be met? What is the role of national judges in assessing the intentional nature of the deprivation of healthcare in the country of origin? Is there a prohibition on removal of a victim of torture that risks a severe deterioration of his/her health status? Is there a related duty to grant subsidiary protection?

The analysis is based on *M'Bodj*, (C-542/13)

The case

After his applications for asylum and, then, for leave to reside on medical grounds were refused, Mr. M'Bodj, a Mauritanian national, was granted a residence permit on medical grounds, pursuant to Article 9b of the Law of December 15, 1980, on the basis of the serious after-effects he was suffering as a result of an assault he had been the victim of in Belgium. He was recognised to have a reduction in earnings capacity and loss of independence by Belgian authorities and, on these grounds, he applied for loss of income allowance and income support (disability allowance). The request was refused, as he did not comply with the requirements provided by national law to receive this allowance, as he had been granted neither refugee status nor subsidiary protection, according to the Belgian law transposing the Directive 2004/83 (Qualification Directive).

Preliminary questions referred to the Court

Two preliminary questions were referred by the Belgian Constitutional Court. Firstly, it was asked whether Articles 2(e) and (f), 15, 18, 28 and 29, of Directive 2004/83, must be interpreted as meaning that a foreign national who has been granted leave to reside in the territory of a Member State, and who suffers from an illness occasioning a real risk to his life or physical integrity or a real risk of inhuman or degrading treatment where there is no appropriate treatment in his country of origin or in the country in which he resides (humanitarian grounds) must be compared to who is entitled with a subsidiary protection status, in light of the enjoyment of social welfare and health care referred to in Articles 28 and 29 of the same Directive.

Secondly, in case of a positive answer to the first question, whether Articles 20(3), 28(2), and 29(2) of Directive 2004/83 can be interpreted as meaning that the obligation imposed on Member States to take into account the specific situation of vulnerable persons such as the disabled implies that the latter must be granted the allowances provided for by the Law of February 27, 1987 in view of the fact that social assistance which takes account of disability may be granted pursuant to the Basic Law of July 8, 1976 on public social welfare centres.

Reasoning of the Court

The CJEU clarified that benefits provided by Articles 28 and 29 of Directive 2004/83 are applicable only to persons with refugee status or subsidiary protection. Thus, Member States have the duty to guarantee such benefits only where leave to remain is to be regarded as also conferring subsidiary protection status (§ 28). Assessing the scope of the three grounds for granting subsidiary protection defined by Article 15 of the same Directive, the Court assessed the possibility of deriving the existence of a real risk of such harm if returned to the country of origin concerned (§ 30) a risk of a deterioration in the migrant's state of health where this risk is not the result of that person being intentionally deprived of health care. It concluded that this case was not covered by Article 15 (a) and c)). Notwithstanding, the case may be referred to letter b) of Article 15 ("torture or inhuman or degrading treatment or punishment of an applicant in the country of origin"), when interpreted in a manner consistent with the principle of non-refoulement (Art. 19.2 CFREU); at the same time, the CJEU specified that to enjoy the protection granted by this provision the mere lack of appropriate treatment in the country of origin is not sufficient, but this condition must be the result of an intentional deprivation of healthcare (§ 41). All the more, the Directive does not allow a Member State to grant subsidiary protection to a seriously-ill migrant only on the grounds of the mere fact that adequate treatments are not available in the country of origin (§ 43).

Conclusion of the Court

According to the Court, national law cannot be interpreted as introducing more favourable standards for determining beneficiaries of subsidiary protection; thus Mr. M'Bodj, who was only granted leave to reside in Belgium on humanitarian grounds ("on a discretionary basis on compassionate or humanitarian grounds," § 46), cannot be eligible for subsidiary protection status (§ 45). Thus, reception standards provided by Articles 28 and 29 of the Directive did not apply to him even when he suffered from an illness occasioning a real risk to his life or physical integrity, or a real risk of inhuman or degrading treatment, where there is no appropriate treatment in his country of origin (or in the third country in which he resided previously), unless in case of the intentional deprivation of health care (§ 47).

Impact on the follow-up case (word style: sections)

The Belgian Constitutional Court, in applying the CJEU ruling, affirmed that the difference in treatment between the two statuses – subsidiary protection and humanitarian grounds – was based on an objective and appropriate criterion, as it was not possible to derive from M'Bodj a duty for the national legislature to treat foreigners who challenge a refusal decision made on the basis of Article 9 ter of the Law of 15 December 1980 in the same way, on the one hand, and asylum seekers or foreigners applying for subsidiary protection, on the other, since the first category did not benefit from international protection status to which the other categories are entitled (Arrêt n° 13/2016 du 27 janvier 2016, § B.37.2).

Elements of judicial dialogue

In a subsequent judgment – MP case (CJEU – C-353/16, MP v Secretary of State for the Home Department (24 April 2018)) – the CJEU seems to have softened the scope of the requirement for the intentional deprivation of appropriate health care. The case was referred to a third country national who was tortured by the authorities of his country of origin and no longer faced a risk of being tortured if returned to that country, but whose physical and psychological health could, if so returned, seriously deteriorate, leading to a serious risk of him committing suicide on account of trauma resulting from the torture he was subjected to. The Court stated that, although there was not a duty to grant subsidiary protection when the individual was no longer at risk of torture as a consequence of his or her return, the removal of a third country national with a particularly serious mental or physical illness constituted inhuman and degrading treatment, within the meaning of Article 4 CFREU, where such removal would result in a real and demonstrable risk of significant and permanent deterioration in the state of health of the person concerned (§ 41).

In doing so, the CJEU made systematic reference to the ECtHR's case-law on Art. 3 ECHR (especially Paposhvili v. Belgium, 13 December 2016, § 178 and 183). According to the Court, particular attention must be paid to the specific vulnerabilities of persons whose psychological suffering, which is likely to be exacerbated in the event of removal, is a consequence of torture or inhuman or degrading treatment in their country of origin (§ 42). On this ground, the Court concluded that Article 4 and Article 19(2) of the Charter, interpreted in light of Article 3 of the ECHR, precludes a Member State from expelling a third country national where such expulsion would, in essence, result in the significant and permanent deterioration of that person's mental health disorders, particularly where, as in the present case, such deterioration would endanger his or her life (§ 43).

On the different grounds of the right to be granted with subsidiary protection status, the Court confirmed M'Bodj doctrine, according to which it was not possible to derive from the prohibition of removal under such circumstances the duty of the State to grant subsidiary protection. Also, in cases of serious illness provoked from long-term trauma following torture suffered in the Country of origin, the serious harm referred to in Article 15(b) of Directive 2004/83 must be the result of an intentional deprivation of healthcare (§ 51). Notwithstanding, the Court specified that – by referring to safeguards provided by Article 14 of the Convention against Torture, among which the Court identifies also the victim's right to obtain the resources necessary to achieve as full a rehabilitation as possible – it belonged to national Courts to assess whether, in the concrete case and in light of all current and relevant information, the individual – MP – was likely, if returned to his country of origin, to face a risk of being intentionally deprived of the appropriate care for physical and mental after-effects resulting from the torture he was subjected to by the authorities of that country (§ 57). This may occur, according to the CJEU, when national authorities are not prepared to provide for the person's rehabilitation, or if they intentionally adopt a discriminatory policy with regard to access to healthcare, thus making it more difficult for certain ethnic groups or certain groups of individuals to obtain access to appropriate care (§ 57). Only in circumstances like these may the individual be eligible for subsidiary protection (§ 58).

In terms of judicial dialogue, the Court followed M'Bodj doctrine while at the same time went further to broaden the scope of the application of subsidiary protection to cases in which the risk to a migrant's health upon return derived from being previously subject to torture in his/her own country of origin. In MP, the CJEU referred plainly to the ECtHR's case-law when interpreting the scope of Art. 4 CFREU, while it is worth mentioning that in M'Bodj provided a different interpretation of the concept of

"inhuman treatment." According to the Court, "the fact that a third country national suffering from a serious illness may not, under Article 3 ECHR as interpreted by the European Court of Human Rights, in highly exceptional cases, be removed to a country in which appropriate treatment is not available does not mean that that person should be granted leave to reside in a Member State by way of subsidiary protection under Directive 2004/83" (§ 40).

In cases analysed under paragraph 2, a migrant's health condition seems to play a two-fold role. When the CJEU is required to assess whether the removal of a third country national with a particularly serious mental or physical illness constitutes inhuman and degrading treatment, within the meaning of Article 4 CFREU, the protection of the migrant's health seems to be essential, where such removal would result in a real and demonstrable risk of significant and permanent deterioration in the state of the health of the person concerned. This approach is coherent with the doctrine of the suspensive effect of an appeal lodged against a return decision which was analysed in paragraph 1 of this Chapter.

Instead, when the assessment of the detrimental impact on a migrant's health refers to the legal status acknowledged to a seriously-ill third country national – i.e. subsidiary protection – as well as the enjoyment of a level of assistance compared to such status – i.e. the standard of social and health care assistance guaranteed by Articles 28 and 29 of the Qualification Directive – a State's margin of appreciation is broad and the relevance of the migrant's health condition becomes secondary, even if the concrete characteristics and causes of the illness at stake – an assault suffered in the Member State (M'Bodj) or torture in the country of origin (MP) – seem to be considered relevant by the CJEU.

6.3 The Dublin Transfer and Non-Refoulement Principle in Light of an Asylum Seeker's Health

Question 3 – The risk to an asylum seeker's health and suspension of a Dublin transfer

Is there a duty for Member States to assess the potential impact on an asylum seeker's health as a consequence of a transfer under the Dublin Regulation?
Might this risk cause a duty to suspend such transfers?
What are the main criteria which States must assess?
Is there a duty to examine the application in case of a long-term suspension due to a migrant's health condition?
Does the same standard apply also to cases in which the asylum seeker must be transferred to a State where he/she is expected to encounter poorer living conditions? On what grounds?

The analysis is based on C-578/16PPU *C.K. and Others*

The case

The case stems from the proceeding before the Slovenian Supreme Court in which S.K., a national of the Syrian Arab Republic, and her family (with children) appealed transfer to Croatia, designated as the Member State responsible for examining their application for international protection, ordered by the competent authorities in application of the Dublin III Regulation (n. 604/2013, Art. 12.2). S.K. was diagnosed with post-natal depression and periodic suicidal tendencies, mainly caused by uncertainty regarding her status and the resulting stress. During the case, the Slovenian Constitutional Court stated the existence of the duty of national authorities –Courts included – to examine all the circumstances of significance for observance of the principle of non-refoulement, including the state of health of the person concerned, in the case where an asylum seeker claimed that the Member State responsible for his or her application was not a 'safe State' for him or her. In that context, those authorities must take the applicant's personal situation in Slovenia into account and assess whether the mere fact of transferring that person might in itself be contrary to the principle of non-refoulement (§ 44). Thus, the Constitutional Court asked the Supreme Court, which was competent for the appeal brought by the asylum seekers against the transfer decision, to verify whether transfer to that Member State, considered in isolation, was compatible with Article 3 of the ECHR.

In this context, the Supreme Court decided to refer a number of questions to the CJEU.

Preliminary questions referred to the Court

First, the Supreme Court asked whether the application of the "discretionary clause" under Article 17.1 was governed exclusively by national law and by the interpretation given by national constitutional Courts, or if it was a question of interpretation of EU law within the meaning of Article 267 TFEU.

Secondly, the Court asked the CJEU to ascertain whether the assessment of the circumstances under Article 3.2 (systematic flaws in asylum procedure and reception system) was sufficient to satisfy the requirements of Article 4 and 19.2 CFREU, interpreted in conjunction with Art. 3 ECHR and 33 of the Geneva Convention.

Thirdly, it sought to clarify whether the duty to apply the discretionary clause must be derived from Article 17.1 of the Dublin III Regulation when it is necessary to ensuring effective protection against infringement of the rights under Article 4 CFREU, in which the risk to health must be included, thus provoking a prohibition on transfer to a competent Member State which has accepted its responsibility.

Finally, if such a duty exists, whether its concrete application must be invoked exclusively by the applicant for international protection, or also ex officio by competent administrative or judicial authorities.

Reasoning of the Court

First, the CJEU claimed its competence over the concrete interpretation of the discretionary clause provided by the Dublin III Regulation. Then, it examined the following questions in conjunction, in order to understand whether Article 4 of the Charter must be interpreted as meaning that, in circumstances in which the transfer of an asylum seeker with a particularly serious mental or physical illness would result in a real and proven risk of a significant and permanent deterioration in their state of health, that transfer would constitute inhuman and degrading treatment, within the meaning of that Article (§ 55).

In answering this question, the Court broadened the scope of application of Art. 4 CFREU beyond cases of the existence in the receiving State of systemic flaws in the asylum procedure and reception conditions of applicants (see N. S. and Others (C-411/10 and C-493/10, EU:C:2011:865, paragraphs 86 to 94 and 106). Accordingly, it was not possible to exclude the possibility from the outset that, given the particularly serious state of health of an asylum seeker, his or her transfer pursuant to the Dublin III Regulation may result in a risk of inhuman or degrading treatment under Art. 4 CFREU (§ 66). Although the Court recognised the existence of a strong presumption that medical treatments offered in the receiving State would be adequate, it clarified that notwithstanding, in cases of particularly serious health conditions, the transfer may in itself result in a real risk under Article 4 CFREU, irrespective of the quality of the reception and the care available in the Member State responsible for examining his or her application (§ 73).

Towards that aim, the CJEU recalled the standard of the "real and proven risk of a significant and permanent deterioration in his state of health," in cases of an asylum seeker with a particularly serious mental or physical illness (§ 74). In terms of procedural guarantees, national authorities cannot merely ignore health evidence provided by the person concerned, as there is a duty to assess the risk that such consequences in terms of health status may occur during the transfer decision; Courts, when assessing the legality of such decisions, must also evaluate whether execution may lead to a violation of Article 4 CFREU (§ 75). It belonged to such authorities to eliminate any serious doubts concerning the impact of a transfer on the health conditions of the persons concerned.

The Court did not leave an unlimited margin of appreciation to national authorities, but it did set a standard which they must comply with: not only physical consequences directly linked with the transfer must be assessed, but "all the significant and permanent consequences that might arise from the transfer" (§ 77). Among them, the Court listed the need to implement special precautions during the transfer when it is considered appropriate and sufficient for excluding such risks; to this end, the two States must cooperate and the receiving State must be able to ensure adequate, effective, and prompt care (§ 82). Whether, after the Court's assessment, such precautions were considered sufficient to exclude any real risk, the Court must take the necessary measures to ensure that they are implemented by the authorities of the requesting Member State before the person concerned is transferred (§ 84). If, on the contrary, precautions cannot be considered sufficient, with regard to the particular seriousness of the illness, national authorities must suspend the transfer for such a time as the migrant's state of health renders him or her unfit for such a procedure and makes the transfer practically possible under Article 9 of the Regulation (§ 85-86).

If the state of health is not expected to improve in the short term, or if a long-period suspension may risk worsening a migrant's health – especially physiological – the requesting Member State may decide to activate the "discretionary clause" under Article 19.1 of the Dublin III Regulation. Notwithstanding, the Court did not recognise the existence of a State's duty to automatically activate such a clause, even when interpreted in light of Article 4 CFREU (§ 88). Such an obligation may arise only if a period of six months under Art. 29.1 of the same Regulation expires (§ 89).

Conclusion of the Court

The Court concluded that:

- even where there are no substantial grounds for believing that there are systemic flaws in the Member State responsible for examining an application for asylum, the transfer of an asylum

seeker within the framework of the Dublin III Regulation can only take place in conditions which exclude the possibility that transfer might result in a real and proven risk of the person concerned suffering inhuman or degrading treatment, within the meaning of that Article.

- in circumstances in which the transfer of an asylum seeker with a particularly serious mental or physical illness would result in a real and proven risk of a significant and permanent deterioration in the state of health of the person concerned, that transfer would constitute inhuman and degrading treatment, within the meaning of that Article;
- it is for the authorities of the Member State that must carry out the transfer and, if necessary, its Courts to eliminate any serious doubts concerning the impact of the transfer on the state of health of the person concerned by taking the necessary precautions to ensuring that the transfer takes place in conditions that enable an appropriate and sufficient protection of that person's state of health. If, taking into account the particular seriousness of the illness of the asylum seeker concerned, taking those precautions is not sufficient to ensuring that his or her transfer does not result in a real risk of a significant and permanent worsening of their state of health, it is for the authorities of the Member State concerned to suspend execution of the transfer of the person concerned for such time as their condition renders them unfit for such a transfer, and
- where necessary, if it is noted that the state of health of the asylum seeker concerned is not expected to improve in the short term, or that the suspension of the procedure for a long period would risk worsening the condition of the person concerned, the requesting Member State may choose to conduct its own examination of that person's application by making use of the 'discretionary clause' laid down in Article 17(1) of the Dublin III Regulation.

Impact on the follow-up case

In light of the CJEU ruling, the Slovenian Supreme Court interpreted Article 17.1 of the Dublin III Regulation as establishing the right of a State, based on its sovereign decision, to accept or not the assessment of an asylum application, and not its duty. The Supreme Court also applied the standard set forth by the CJEU - the state of health of the asylum seeker concerned is not expected to improve in the short term, a risk of the worsening of a condition due to a prolonged suspension for a long period – and concluded that only when these criteria are met should the requesting Member State choose to conduct its own examination of the application by making use of the 'discretionary clause' laid down in Article 17.1. According to the national Court, in the case in question no evidence existed that C.K.'s health situation would be particularly serious and could have such significant and irreversible consequences. The Supreme Court therefore upheld the appeal and declared the action to dismiss as unfounded. As a consequence, the transfer order of the family to the Republic of Croatia by the Ministry of the Interior was upheld (see https://cjc.eui.eu/wp-content/uploads/2020/05/eNACT_Handbook_asylum-compresso.pdf, p. 38).

Elements of judicial dialogue

The CJEU relies widely on the ECtHR's case law in the application of Article 3 ECHR and the relevance in this regard of the risk of serious exacerbation of a pre-existing physical or psychological illness, provoked by detention or expulsion (see in particular Paposhvili v. Belgium, quoted in § 68 of C.K. and Others v. Slovenia). In order to highlight the circular nature of judicial dialogue, it is worth mentioning that the ECtHR referred to the C.K. and Others v. Slovenia judgment in a case where the ECtHR further developed standards previously defined in Paposhvili (Savran v. Denmark, GC, 7 December 2021, no. 57467/15, § 83).

With regard to the development in the CJEU case law, the cases Jawo and Ibrahim should be recalled, where the Court seems to apply a stricter standard when the suspension of a transfer under the Dublin III Regulation may derive from the need to avoid a serious risk of suffering inhuman and degrading treatment (Article 4 CFREU) on account of the living conditions that he or she could be expected to encounter as a beneficiary of international protection in the receiving Member State. According to the Court, the deficiencies of the national asylum or reception system from which the risk may derive must attain a particularly high level of severity, which depends on all the circumstances of the case (§ 91). More specifically, it must be the case of a person wholly dependent on State support finding themselves, irrespective of their wishes and personal choices, in a situation of extreme material poverty that does not allow them to meet their most basic needs, such as, inter alia, food, personal hygiene, and a place to live, and which undermines their physical or mental health or puts them in a state of degradation incompatible with human dignity (§ 92). Accordingly, the standard of a real risk of suffering a condition of "extreme material poverty" must be satisfied.

See also Ibrahim (Joined Cases C-297/17, C-318/17, C-319/17 and C-438/17, 19 March 2019).

In the context of the Dublin transfer, the possible impact on the health status of an asylum seeker involved is considered relevant by the CJEU in light of assessing the compatibility of such procedures with safeguards provided by Article 4 CFREU. The need to preserve health status even from possible risks, which in any case must be concretely assessed, real, and serious, goes to broaden the scope of application of the latter Article and, as a consequence, the level of protection guaranteed to asylum seekers, when they suffer from serious physical or psychological illness which may be aggravated by the enforcement of a transfer decision under Dublin III Regulation. Notwithstanding, such protection does not imply the identification of a duty for the host Member State to take charge of the responsibility to assess asylum applications, as it is an evaluation which still belongs to the exercise of its own sovereignty; at the same time, the CJEU derives from the need to guarantee the long-term health of asylum seekers from the detrimental effects provoked by an unreasonable extension of the transfer suspension, the duty to exercise the "discretionary clause" when a term of six months has needlessly elapsed. It is worth noting that the standard required by the Court – "a real and proven risk of a significant and permanent deterioration in the state of health of the person concerned" – substantially coincides with that introduced by the same Court in the context of the suspension of the removal of irregular migrants (see Point 1 of the Chapter). At the same time, when a risk directly linked with the health status of an asylum seeker is not at stake, the standard to be met becomes stricter (see Jawo and Ibrahim).

Impact on national case law in Member States other than that of the Court referring the preliminary question to the CJEU (word style: sections)

The Court of Justice of The Hague (11 April 2017; ECLI:NL:RBDHA:2017:4029) annulled the decision by the Dutch Immigration and Naturalisation Service (IND) to transfer an Armenian asylum seeker to the Czech Republic, due to an assessment of the applicant's state of psychological health. According to the Dutch Court, the IND must ensure sufficient safeguards in order to avoid a deterioration of health due to the transfer. In the concrete case, concerning a person affected by serious psychological disorders provoked by being a victim of forced prostitution in Czech Republic, the transfer to the latter State would have disastrous implications on her mental health (source: EDAL Database – https://www.asylumlawdatabase.eu/en/content/netherlands-no-dublin-transfer-asylum-seeker-mental-health-issues-application-ck-and-others).

6.4 Migrant Health and Family Reunification: the Concept of Dependency under Directive 2003/86

Question 4 - Migrant health and family reunification: the concept of dependency under Directive 2003/86

Are Member States bound to provide for family reunification under Article 10.2 of Directive 2003/86?
Can family reunification be conditioned upon the existence of a condition of dependency related to the health status of the applicant?
Does the relevance of the state of health limit Member States' discretion in defining the requirements for integrating the state of dependency?

The analysis is based on C-519/18, *TB*, 12 December 2019

The case

TB, an Iranian national, was granted refugee status in Hungary and her sister then applied for a residence permit for the purpose of family reunification in that State. Hungarian authorities denied the status, on the grounds that TB's sister was not able to demonstrate her lack of autonomy in providing for her own needs, due to her state of health (depression which required regular medical supervision, according to medical documents submitted).

TB brought an action against that rejection, by submitting incompatibility with Article 10.1 and 2 of Directive 2003/86 of the national law, which subordinates the granting of family reunification to a refugee's sibling only if the inability to provide for her own needs on account of her state of health is proven.

Preliminary questions referred to the Court

The competent Court – the Administrative and Labour Court, Budapest – first asked whether Article 10.2 of Directive 2003/86/EC must be interpreted as meaning that a Member State, under that Article, must authorise the entry of a family member other than those referred to in Article 4 [of that directive], only if that family member is "dependent on the refugee". The CJEU was then asked to clarify the exact meaning of the concept of "dependent" in this context.

Reasoning of the Court

First, the CJEU clarified that the extension of subjects – other than those typified in Article 4 – that may benefit from family reunification under Article 10.2 is optional and not mandatory for States, which are only limited to providing for cases where subjects are dependent on the refugee (§ 39-41). Then, the Court also stated the need to provide an independent and uniform definition of the latter condition, in order to guarantee the principles of a uniform application of EU law and equality (§ 44).

Taking the general condition of fragility and risk to which refugees and their family members are commonly exposed into consideration, the Court provided for a complex definition in the sense that "a member of a refugee's family must be considered dependent on that refugee, within the meaning of Article 10(2) of Directive 2003/86, where the family member is genuinely dependent in the sense that, first, having regard to his or her financial and social conditions, the family member is not in a position to support himself or herself in his or her State of origin or the country whence he or she came and, secondly, it is ascertained that the family member's material support is actually provided by the refugee, or that, having regard to all the relevant circumstances, such as the degree of relationship of the family member concerned with the refugee, the nature and solidity of the family member's other family relationships and the age and financial situation of his or her other relatives, the refugee appears as the family member most able to provide the material support required" (§ 52).

Beyond this common ground, each Member State may legitimately introduce additional requirements relating to the nature of the relationship of dependence (§ 55), as this form of protection is only optional and States may implement it with a margin of discretion. Notwithstanding, in exercising such discretion, Member States cannot go against the effectiveness and the aims of the Directive. Thus, national legislation implementing the option provided for in Article 10(2) must observe: a) the fundamental rights enshrined in the Charter and b) the principle of proportionality; and c) must not prevent an application for family reunification from being examined on a case-by-case basis, and that d) examination must also be carried out with regard to the special situation of refugees (§ 67).

Conclusion of the Court

In the concrete case at stake, Hungarian law can legitimately require that the "dependency" between the refugee and her family member is caused by the latter's state of health (§ 70), in the sense that her material support is actually provided by the refugee or the refugee appears to be the family member more able to provide such support. This assessment must be carried out on a case-by-case basis, taking all the relevant aspects of the personal situation of the refugee's sister into account (her age, level of education, professional and financial situation), her state of health included (§ 75).

Accordingly, the CJEU concluded that the Directive did not preclude a Member State from allowing family reunification under Article 10.2 subject to the existence of a relationship of dependence which derived from the state of health of the refugee's sister; but the fulfilment of such condition must be assessed on a case-by-case examination which must take all relevant factors into account (see § 72).

Elements of judicial dialogue

From the case it is possible to derive the principle according to which Member States are not bound to apply the clause under Article 10.2 of the Family Reunification Directive in the sense of recognising such rights of a person – i.e. a sister – considered to be in a condition of dependence on a refugee. In that regard, States may legitimately provide for additional requirements related to the nature of such

dependency, which must be satisfied in order to integrate such a concept. In any case, once a State has envisaged this possibility, the discretion afforded cannot be used in order to undermine the objective and the effectiveness of the Directive 2003/86.

The reference to the principle of effectiveness of the Directive, and accordingly to the objectives of protection of refugees and their family members a condition linked to that act, calls upon Member States to pay particular attention to the concrete situation of refugees and to assess applications on a case-by-case basis. The CJEU also recalled the need to take the CFREU in due account, where Article 7 acquires special relevance in this context. Thus, Member States are free to decide whether to introduce such forms of protection, but their discretion in designing the concrete scope and requirement, as well as the scope of the assessment in any concrete case, is limited by the respect of the principles and criteria mentioned above.

Impact on national case law in Member States other than that of the Court referring the preliminary question to the CJEU

Tribunal Superior de Justicia, 1 June 2020, STSJ M 10710/2020 - ECLI:ES:TSJM:2020:10710 (Spain): The Tribunal referred to the case to assess the appeal brought against a refusal of family reunification for the mother of an EU citizen and applied the concept of "dependency" as defined by the CJEU. After assessing the concrete characteristics of the case and referring also to the mother's health condition, the Spanish Court did not uphold the appeal, since it was not possible to ascertain whether the applicant, in a real and effective, and not merely formal way, was an integral part of her daughter's family and who therefore had to support her in every way necessary to live in dignity (Article 7 of the ECHR).

6.5 Guidelines for Analysis

In the context of international protection, EU law provides for specific safeguards when the need to protect migrants' health in considered. This occurs in different areas, such as reception conditions (Article 19 of Directive 2013/33/EU), return procedures (Article 14 of the Return Directive), and with regard to the beneficiaries of international protection (Article 30 of Directive 2011/95/EU).

This Chapter shows that the health status of a migrant can play a role even when its protection – or its relevance within the concrete area covered by EU law – is not formally requested. Thus, it may be said that there is a need to also consider this aspect – more concretely, the impact of a national authority's decision in terms of a migrant's health – when Member States use their legitimate discretion to implement EU law (return, reception, family reunification). It becomes a criterion which goes further towards integrating the concrete enforcement of different areas of migration law and international protection in particular. This may occur in different areas of EU migration law, such as in cases – among others – of irregular migrants, asylum seekers under the Dublin III Regulation, residence permitting on health grounds, and family reunification. From this perspective, it is worth underlining that it is possible to derive the identification of "inter-sectorial" concepts and criteria which become relevant in different contexts from the CJEU case-law such as "a grave and irreversible deterioration of health," "serious illness," and "dependency."

At the same time, a migrants' health situation does not automatically become relevant, possibly limiting Member States' scope of intervention. To the contrary, States are often free to decide whether to protect on this ground (i.e. family reunification) as well as on the concrete safeguards to be provided with the aim of protecting migrants' health (i.e. cases related to the absence of the duty to grant subsidiary protection). At the same time, States' choices must be measured – in terms of proportionality,

effectiveness of the protection, and compatibility with the CFREU – also in light of a proper/adequate assessment of the relevance of a migrant's state of health. This happens especially in cases of serious illness affecting a migrant (suspensive effect of appeal against a denial of international protection) and the need to protect a migrant's health may become an "indirect" reason of protection, such as when it contributes to guaranteeing the effectiveness of the principle of non-refoulement or when it provokes the suspension of transfers to other Member States under the Dublin III Regulation. It must also be underlined that it seems to express a procedural – more than a substantive – relevance within the CJEU assessment. In general terms, it appears from the CJEU case-law that when a migrant's health is concerned, special procedural safeguards must be implemented when Member States assess migrants' applications.

Significantly enough, in many of the analysed cases, reference to Article 47 – often in conjunction with Articles 4 or/and 19.2 – of the CFREU became essential to giving relevance to health status; at the same time, the latter became a condition for the concrete respect of the former, as in the case of the need to confer a suspensive effect of an appeal against a return decision (Abdida). The link between health and effectiveness of protection guaranteed by EU law may lead to a broadening of the scope of the latter up to also including third subjects related to migrants affected by a serious illness (LM).

To this end, the CJEU often calls upon national judges to provide scrutiny targeted at assessing the existence – and the proper and effective enforcement – of adequate procedural safeguards when health status becomes relevant. This may also happen by exercising a duty to cooperate, for instance by assessing existing evidence on the concrete case or acting ex officio, when the special nature of rights or principles (i.e., the principle of non-refoulement) at stake requires it (S.K.), or even by not applying national law that is contrary to EU law and principles (B.).

7 Health and COVID[113]

7.1. Introduction

This chapter deals with the role of the Courts with regard to the relationship between the right to health and other fundamental rights, such as the freedom of movement, freedom of information, freedom of enterprise, and looking at the relevance of the principles of proportionality, necessity, effectiveness, as well as Article 47 CFR.

In particular, this chapter addresses legal issues related to healthcare management within the COVID-19 crisis (*e.g.*, vaccination, therapies against COVID-19) and to the relationship between health (mainly in its collective dimension) and other fundamental rights. As for the latter, the chapter examines the role of the principle of effectiveness and, when applicable, that of Art. 47 CFR, in interpreting national procedural rules adopted due to the COVID-19 emergency, taking into account CJEU case law and national litigation concerning modifications of procedures related to COVID-19. Moreover, the Chapter addresses, from a European perspective, the legal issues which have arisen in national case law related to the relationship between health protection and a selection of other fundamental rights: freedom of information (including the right to be informed), freedom of movement, freedom to conduct a business, right to data protection. The role of health protection in migration law is not considered in this casebook, as it has been examined in the FRICoRe Casebook *Effective Justice, International Protection and Fundamental Rights In Asylum And Migration* (Part III, 2; see also the document issued by the EASO *COVID-19 emergency measures in asylum and reception systems*, No. 2, July 2020). In the analysis, particular attention is devoted to the application of general principles such as proportionality and necessity.

7.2. Access to Justice, Right to a Fair Trial and COVID-19

Question 1 - The role of Art. 47 and the principle of effectiveness in interpreting national procedural rules adopted due to the COVID-19 emergency

What is the role of the principle of effectiveness and, if applicable, Art. 47 CFR in interpreting national rules which modify judicial proceedings regulation due to the COVID-19 emergency whenever these shall be applied in the field of application of EU law?

The pandemic had a very significant impact on procedural law with special regard to the suspension of deadlines, changes to procedural rules, a reduction of the adversarial process, etc. National Courts were requested to assess the compatibility of these measures with the principles of due process and the fundamental right of access to justice, recognized by many national constitutions and, when applicable, by the European Charter of Fundamental Rights (Art. 47) and the European Convention on Human Rights (Art. 6).

The following paragraphs will examine some relevant case law on these aspects, at the European and national levels.

Suggestions from CJEU case law

[113] Chiara Angiolini wrote this chapter. Further specification with regard to co-authorship with regard to some paragraphs are made in the footnotes.

In order to assess the possible relevance of the principle of effectiveness and Article 47 CFR in the application and interpretation of national procedural rules adopted to address the COVID-19 emergency, several aspects come into play. In particular, with regard to **Art. 47 CFR**, the following issues are of particular importance: i) the interpretation of Art. 47 CFR in light of Art. 51 CFR in the field of application of the Charter; ii) the relationship between Art. 47 CFR and Art. 19 TEU; iii) the direct applicability of Art. 47 in the field of application of EU law. Moreover, the CJEU interpretation of the **principle of effectiveness** with regard to national procedural rules is at stake.

a) With respect to the **application of Article 47 CFR**,

i) a central provision is **Article 51 CFR**, which states:

> 1. The provisions of this Charter are addressed to the institutions and bodies of the Union with due regard for the principle of subsidiarity and to the Member States only when they are implementing Union law. They shall therefore respect the rights, observe the principles, and promote the application thereof in accordance with their respective powers.
>
> 2. This Charter does not establish any new power or task for the Community or the Union, or modify powers and tasks defined by the Treaties.

In this respect, the ordinance of the **CJEU *XX* (C-220/20, of 10 December 2020) is of particular interest**. In that case, the referring judge was hearing a case concerning compensation for damages arising from a traffic accident and set the hearing date for the personal appearance of the parties on May 4, 2020. Subsequently, the Italian government adopted various measures (Decree Law No. 18/2020 and subsequent guidelines adopted by the president of the Court), pursuant to which the referring judge had to postpone the hearings several times. The referring judge stated that most of the provisions of domestic law applicable to the case at stake were provisions which implemented EU law in the Italian legal system. The judge therefore submitted a question to the Court for a preliminary ruling concerning the compatibility of several provisions which modified Italian procedural rules due to the COVID emergency regarding the principle of independence of judges, due process of law, and Articles 1, 5, 20, 21, 31, 34, 45, and 47 CFR.

The Court declared that the reference for a preliminary ruling made by the *Giudice di pace* of Lanciano (Italy), by order of May 18, 2020 was manifestly inadmissible.

The Court's reasoning was twofold. First, the Court considered that the reference for a preliminary ruling did not satisfy the requirements provided for by Art. 267 TFEU with regard to the specific identification of the facts of the case and of the judges' question concerning EU law.

Second, **with regard to the applicability of the Charter**, the Court stated that, according to Article 51(1) CFR, the provisions of the Charter apply to the Member States only when they are implementing Union law. Then, the Court affirmed, where a legal situation does not fall within the scope of Union law, the Court has no jurisdiction over it and the provisions of the Charter which may be invoked cannot in themselves justify such jurisdiction.

In *XX* (C-220/20), the Court relied on previous case law. In particular, the Court referred to ***Unesa et al.,* C-80/18, C-81/18, C-82/18, C-83/18, of 7 November 2019** and ***Corporate Commercial Bank,* C-647/18, 15 January**, where the CJEU confirmed its settled case-law, according to which the fundamental rights guaranteed in the legal order of the European Union are applicable in all situations governed by EU law, but not outside such situations. Consequently, the Court stated that, where a legal situation does not come within the scope of EU law, the Court does not have jurisdiction to rule on it and any provisions of the Charter relied upon cannot, of themselves, form the basis for such jurisdiction. Generally speaking, CJEU case law is consistent with this interpretation (see, for example *Delvigne,* C-650/13, 6 October 2015 §§ 25-27; *Torralbo Marcos*, C-265/13, of 27 March 2014). ***Fransson*** (C-617/10, 26 February 2013) is a key judgment in that respect. In that judgment, the Court stated:

> "Since the fundamental rights guaranteed by the Charter must therefore be complied with where national legislation falls within the scope of European Union law, situations cannot exist which are covered in that way by European Union law without those fundamental rights being applicable. The applicability of European Union law entails applicability of the fundamental rights guaranteed by the Charter.
>
> Where, on the other hand, a legal situation does not come within the scope of European Union law, the Court does not have jurisdiction to rule on it and any provisions of the Charter relied upon cannot, of themselves, form the basis for such jurisdiction"

Moreover, several recent judgments of the Court are of particular interest. In *PPU II* (C-648/20 of 10 March 2021), a case concerning European Arrest Warrant legislation, the CJEU affirmed that when implementing EU law the Member States retain, in accordance with their procedural autonomy, the option of adopting rules which may differ from one Member State to another, they must ensure that those rules do not frustrate the requirements set forth within EU law, in particular with regard to judicial protection, guaranteed by Article 47 CFR, which underpins it (§ 58; see also *Torubarov*, C-556/17, 29 July 2019; see also on this issue: *PPU,* C-414/20, 13 January 2021). When applicable, Art. 47 CFR may play a strong role.

In *AB et al* (C- 824/18, of 2 March 2021), the Court stated that Article 47 CFR constitutes a reaffirmation of the **principle of effective judicial protection** and enshrines the right to an effective remedy before a tribunal for everyone whose rights and freedoms guaranteed by EU law are infringed. The Court then stated that the application of the right provided for by Art. 47 CFR presupposes that the person invoking that right is relying on rights or freedoms guaranteed by EU law.

ii) With regard to the **direct applicability** of Art. 47 CFR, CJEU case law (*Egenberger*, C-414/16, EU, 17 April 2018, § 78; *Torubarov*, C-556/17, 29 July 2019, § 56; *État Luxembourgeois*, C-245/2019 and C-246/2019, 6 October 2020; *AB et al* (C- 824/18, of 2 March 2021, § 145) acknowledges that **Article 47 CFR** on the right to effective judicial protection i**s sufficient in itself and does not need to be made more specific by provisions of EU or national law to confer on individuals a right which they may rely on as such.**

iii) In order to assess the applicability of Art. 47 in the interpretation of national procedural laws, **the relationship between Art. 47 and Art. 19 TEU is of particular importance**. The latter states that Member States shall provide remedies sufficient to ensure effective legal protection in the fields

covered by Union law. In this respect, the Court in *Ab et al.* (C-824/18) recalling previous case law, stated that:

> "Under the second subparagraph of Article 19(1) TEU, every Member State must thus in particular ensure that the bodies which, as 'Courts or tribunals' within the meaning of EU law, come within its judicial system in the fields covered by EU law and which, therefore, are liable to rule, in that capacity, on the application or interpretation of EU law, meet the requirements of effective judicial protection" (§ 112)

This case law is consistent with *EU Commission v. Republic of Poland* (C-192/18, 5 November 2019), where the Court stated that according to Art. 19(2) TEU every Member State must ensure that Courts or tribunals come within its judicial system in the fields covered by EU law and which, in that capacity, rule on the application or interpretation of EU law and meet the requirements of **effective judicial protection**. Furthermore, in that judgement the Court stated that the principle of the effective judicial protection of individuals' rights under EU law, set forth in Art. 19 TEU, is a general principle of EU law, which is reaffirmed by Article 47 CFR.

b) With regard to the **principle of effectiveness**, the Court has been deciding cases concerning the scope of application of general principles of EU law for several decades (See for example *ERT* C-260/89, 18 June 1991; *Roquette Frères*, C-94/00, 22 October 2002, §§ 25-26).
Generally speaking, according to CJEU case law, the principle of effectiveness requires that national rules, including procedural ones, do not make it impossible or excessively difficult in practice to exercise the rights conferred by the EU legal order (see the case law of the last two years: *BT*, C-501/18, 25 March 2021; *H.K.*, C-746/18, 2 March 2021; *Caisse de retraite*, C-370/17 and C-37/18, 2 April 2020, § 91; CTT, C-661/18, 30 April 2020; *Nestrade SA,* C-562/17, 14 February 2019; *SC Raiffeisen Bank SA*, C-698/18 and C-699/18, 9 July 2020; *Cabinet de avocat UR*, C-424/19, 16 July 2020; JP, C-651/19, 9 September 2020; *La Quadrature du Net,* C-511/18, C-512/18 e C-520/18, 6 October 2020). As an example, in *SC terracult SRL* (C-835/18, 2 July 2020), the Court stated that the principle of effectiveness "requires that a national procedural provision must not make the exercise of the rights conferred on individuals by EU law practically impossible or excessively difficult" (§ 32).

To sum up, also in times of a pandemic, Art. 47 applies as a limit to the reduction of due process rights of claimants but only to the extent that the latter assert claims based on Union law.

Question 2 – Restrictive procedural measures, Art. 47 and the right to be heard

Are pandemic-related restrictive measures concerning proceedings (lack of public hearings and lack of hearings, online mode, suspensions of terms) compatible with Art. 47, whenever applicable, and the right to be heard? What are the criteria adopted by Courts for balancing the right to a fair trial and to access to justice with other fundamental rights, if any?

The Court of Justice has not yet addressed the above issues, which have been addressed by Courts at the national level. Nevertheless, a request for a preliminary ruling *Uniqa* C-18/21, concerning the compatibility of national law suspending procedural terms with the application of Reg. UE 1896/2006 concerning the order for paying procedure, is pending. Therefore, national case law will be examined.

Suggestions from Member State case law

- *Lack of a hearing*

Some Member States, due to the COVID-19 emergency, provided the possibility of conducting proceedings without hearings. Those provisions were judged by several Courts on their compatibility with the right to a defence and a fair trial.

As for the case law, the applicants and the Courts in some cases referred to **national constitutional provisions** enshrining the right to a fair trial as well as the right to be heard (decision of the French Constitutional Council n°2020-866 QPC of 19 November 2020, concerning a competition law case; judgement of the Regional Administrative Tribunal of Puglia, no. 742 of 25 November 2020, concerning a tax case). Furthermore, in a Dutch case concerning migration law the judge recalled Art. 5 **ECHR**, which protects the right to liberty and security (Council of State of the Netherlands, decision of 7 April 2020 no. 202001949/1/V3). Moreover, the French Constitutional Council in the abovementioned decision stated that it was not competent to examine the conformity of a legislative provision with the stipulations of a treaty or international agreement (in the case, Article 6 ECHR).

In their decisions, the Courts interpreted emergency legislation **balancing different rights**. It is of particular interest to look at the different elements the Courts considered within that assessment.

The **French Constitutional Council, in decision n°2020-866 QPC of 19 November 2020**, assessed the constitutionality of an Ordinance passed on March 25, 2020, applicable during the state of the health emergency and for one month thereafter, which allowed judges of non-criminal matters to decide proceedings without a hearing. The Council affirmed the **reasonableness** of the contested measure in the specific context of the COVID-19 pandemic. Within its assessment, the Court took into account the following elements: i) the function of the provision within the implementation of the constitutional principle of continuity in the functioning of justice in the particular context of the COVID-19 pandemic; ii) the temporary nature of the measure; iii) the role of the provision with regard to the function of the proceeding; iv) the existence of a guarantee for the parties to defend their case effectively in a written procedure with the help of counsel. The French Constitutional Council (dec. n°2020-866 QPC of 19 November 2020), after assessing the reasonableness of the measure, affirmed its constitutionality.

In **Italy**, the **Regional Administrative Tribunal of Puglia, in its decision no. 742 of 25 November 2020**, decided a case concerning a procedure under a provincial tax commission. In the case, although the law (Art. 27 of the decree law 137/2020) provided, under certain conditions relating to the availability of IT equipment, for the possibility of an online hearing, the Chairman of the tax commission ruled out the possibility of hearings (both face-to-face and online) and instead allowed only written pleadings for all cases. The applicant sought an action before the Regional Administrative tribunal of Puglia. The tribunal affirmed that the right to health is a priority and that, accordingly, it may justify a partial and temporary sacrifice of the right to defence. Nevertheless, the tribunal affirmed that, according to the principles of **reasonableness and proportionality**, it was necessary that authorities make any possible effort to find solutions to replace the ordinary procedural methods in order to guarantee, at least partially, access to justice and a fair trial. In this respect, the Court stated that in case of conflict between the right

to health and other fundamental rights, the limitation of the latter must be reasonable and proportionate, yet take the health emergency into account. The Court stated that there was no evidence that these efforts were made in the case in question. As a conclusion, the Regional Administrative Tribunal of Lazio, in its **decision no. 742 of 25 November 2020** stated that the results of the required assessment on the possibility of holding a remote hearing did not emerge from the contested decision, as the Commission did not explain why it was impossible to authorize a hearing via remote connection, and there was no evidence of the existence of technical or public interest reasons that would have made remote connection impracticable or administratively inappropriate. Consequently, the Administrative Court granted the provisional measures requested, by ordering that the chairman of the tax commission reassess the situation and to establish the rules of hearings once again.

In the **Netherlands**, the Council of State, **in its decision of 7 April 2020 no. 202001949/1/V3**, encompasses the main arguments of the reasoning of the two decisions analysed above (French Constitutional Council, decision n°2020-866 QPC of 19 November 2020; Regional Administrative Tribunal of Puglia, in its decision no. 742 of 25 November 2020). The case concerned a foreign national awaiting expulsion who appealed a detention decision and was not heard in his appeal proceedings due to COVID-19 measures, which made a physical hearing temporarily impossible. Instead, his case was settled in writing. The question at stake was whether settling the case in writing violated the foreign national's **right to be heard** under national law and Article 5 of the ECHR. In its reasoning, the Council: i) took the exceptional and temporary character of the measures for fighting COVID-19 into account; ii) highlighted that the right to be heard is a fundamental part of a foreign national's ability to challenge his detention, though it is not absolute; iii) considered the necessity to ensure judicial review of detention decisions concerning foreign nationals; iv) considered other fundamental rights at stake (right to privacy, and right to health); v) affirmed that holding hearings by videoconference in all cases was impossible, as there was insufficient capacity and the videoconferencing facilities did not allow for participation in a videoconference from other locations, such as the homes or office addresses of the interpreter and lawyer, and considering that it is often impossible to ensure a safe distance between persons within hearings rooms as required by the COVID-19 measures. As a conclusion, the Council of State affirmed that refraining from hearing a foreign national is possible given the special circumstances of the COVID-19 crisis, but only once an individual and recognizable assessment of all interests at stake has been made. In particular, the Court considered that: i) if the parties' representatives agree to handling the case in writing or to conduct the hearing via a telephone connection, the proceeding would be conducted in this way. The Council stated that in these cases the adversarial procedure should be safeguarded as much as possible, and the foreign national's authorized representative must be given the opportunity to consult with the foreign national on specific questions; ii) if the foreign national, stating reasons, does not waive his right to be heard by the Court in person, the Court should make every effort to provide the foreign national with the opportunity to address the Court in person. Nevertheless, the Court considered that there might be cases where it is not possible to hear the foreign national in person.

Furthermore, with regard to the application of the **right to be heard in administrative proceedings**, this right was applied with regard to **a Slovenian administrative decision concerning cross-border freedom of movemen**t. In that case, the plaintiff came to Slovenia from Croatia where he picked up his wife, who is a person with disabilities, and his daughter and returned to Slovenia within 20 hours, and

the Minister of health issued an individual administrative decision by which he imposed a 14-day quarantine on the plaintiff for coming to Slovenia from a neighbouring country, which was on the Governmental list of "red" countries (with a significant number of Covid-19 cases). The plaintiff filed a lawsuit against the administrative decision of the Minister and argued that at the border, where he was stopped by border police and informed about the obligatory quarantine, he could not invoke an exception to the limitation of freedom of movement based on a particular provision of the Governmental decree, and, therefore, that his rights to be heard and to submit evidence in order to defend himself had been violated. The **Slovenian Administrative Court, in decision no. II U 261/2020-18, of 2 September 2020**, granted the lawsuit and quashed the contested decision, because the motivation of the contested decision was not sufficiently justified. Accordingly, the Administrative Court stated that the rights of the plaintiff to equal protection, to be heard, and to effective remedy had been violated within the administrative proceeding.

- *Video conferencing*

In its **decision of 4 June 2021, No. 2021-911/919 QPC, the French Constitutional Council** carried out a constitutional review of Article 2 of Order No. 2020-1401 of 18 November 2020, which allowed for the use of videoconferencing before criminal Courts without the need to obtain agreement from the parties. The Constitutional Council concluded that the contested measure infringed upon the rights of the defence and declared it unconstitutional. The Court relied on Article 16 of the Declaration of the Rights of Man and of the Citizen of August 26, 1789, which guaranteed the rights of defence and affirmed that the contested measure aimed to promote the continuity of the activity of criminal Courts despite the emergency health measures taken to combat the spread of COVID-19, in pursuit of the constitutional objective of health protection and in implementation of the constitutional principle of continuity in the functioning of justice. Nevertheless, the Court considered that i) the contested provisions allowed the criminal Courts to require the use of audiovisual communication in a large number of cases and that ii), although the use of audiovisual telecommunication was only an option for the judge, the contested provisions did not make its use subject to any legal conditions and did not set any criteria for its use. The Constitutional Council also recalled the importance of the guarantee related to the physical presence of the accused person before criminal Courts.

- *Public hearings, public disclosure of judgements and COVID-19 restrictive measures*

Another set of cases concerned the application of the principles of publicity of hearings and the public disclosure of judgements in the context of restrictive measures adopted to fight COVID-19. Generally speaking, the issue of a lack of publicity for hearings is of particular importance in criminal proceedings. As an example, in the Netherlands, with regard to periods when Court buildings were closed to the general public due to the COVID-19 emergency, the Supreme Court (decision of 15 December 2020, no. 20/01476) and the Council of State (7 April 2020, no. 202002016/1/V3) addressed the issue.

In particular, the **Supreme Court of the Netherlands of 15 December 2020**, no. 20/01476, addressed two questions, concerning the notion of a "publicly accessible hearing" and respect of the principle of public disclosure of judgments. The judgement of the **Council of State, 7 April 2020, no.**

202002016/1/V3 concerned a ruling of a District Court that was not made public through a so called disclosure session, but was only sent to the parties involved and made available online for others interested.

In both cases the Courts relied on Art. 6 ECHR in their decisions; the Supreme Court referred to the cases *Riepan v Austria,* 14 December 2000, with regard to the criteria for assessing whether the principle of publicity of hearings was respected and to *Sutter v. Switzerland,* 22 February 1984. The Council of State considered, in light of the ECtHR judgement *Pretto e.a. tegen Italie*, that according to Art. 6 ECHR the principle of publicity aims at maintaining confidence in the judiciary, at the public control of the judiciary, and at guaranteeing the right to a fair trial.

With regard to the Court's **reasoning**, the Supreme Court considered that: i) closure measures were necessary due to the threat that Covid-19 posed to public health and the health and safety of those working at the Court houses, ii) the temporary character of the measures; iii) the presence of the press was allowed, despite the closure; iv) there were other possibilities for the general public to take notice of the hearing, for example via live stream, if the circumstances called for it.

The Council of State affirmed in its reasoning that in order to ensure the public disclosure of judgements, the communication of a decision to the parties involved in the proceedings was insufficient, as parties not involved in the proceedings (interested parties) must also be able to take notice of the text of judgments in a simple manner. Accordingly, the Council of State found that sending judgment to the parties involved was not a solution for other interested parties. The Council considered that, during the period of Court closure a possible solution was that proposed by the judiciary, according to which interested parties can catch up on public hearings at the re-opening of the Court buildings, so that they can then still take note of the judgments delivered during the period the Court buildings were closed. Nevertheless, due to the uncertainty concerning the date of such a reopening, the Council of State described other options: i) the publication of all judgments on www.rechtspraak.nl; ii) the provision of an official record of the judgements made every day. The Council of State affirmed that, with a combination of publishing the judgment and sending it oto the parties and an opportunity for interested parties to take note of the judgment, the essence of the principle of public administration of justice was fulfilled in an acceptable manner in the then, very exceptional circumstances, where the measures taken were temporary.

With regard to the Courts' decision, the Supreme Court concluded that the judgment had been pronounced in public. The Council of State considered that the appealed decision was not delivered in public, as the Court building was not open to the public on that day. However, this conclusion did not lead to an annulment of the Court's judgment as it was not disputed that the parties were able to take notice of the judgment in time. The Council provided a remedy for the lack of publicity of the decision by itself ruling in public in this specific case and by mentioning its own decision made by the Court.

- *Composition of the Court and the physical presence of judges in criminal and migration cases*

During the emergency Courts also dealt with issues related to their composition. Two cases are analysed here. The first, decided by the **Supreme Court of the Netherlands, on 15 December 2020, with judgement no. S20/03532,** concerned the possibility during a hearing to have two of three judges

present which composed the bench panel , and the other connected to the hearing remotely, due to the fact that he was subjected to self-quarantine. The second case was brought by several lawyers associations and migrant rights associations before the French Council of State in decision **nn. 440717, 440812, 440867 of 8th June 2020.** These associations asked the Council of State to urgently suspend the dispositions of the ordinance of May 13, 2020, according to which appeals to the National Court of asylum will be judged by a single judge until the end of the health emergency, unless the judge referred to a panel of judges in cases where the judge determined there was a serious difficulty, and that the members of administrative jurisdictions would be able to watch the judgement from a separate place, by means of videoconference.

In both cases the judges applied balancing techniques. In **the judgement of the Supreme Court of the Netherlands, of 15 December 2020, no. S20/03532** the Court balanced the right to a fair hearing with the need to not cause a delay within the proceeding. The Supreme Court stated that in principle the physical presence of judges was required. However, the Supreme Court also considered that the law did not exclude the possibility of using electronic means of communication during a hearing and that the goal of the Temporary Covid Act was to prevent any delays in criminal proceedings because of the Covid-19 outbreak. The Court further affirmed that the interests served by prescribing the physical presence of judges and the requirement of publicity were not jeopardized if one of the judges were present via electronic means of communication, provided that i) their physical absence be the direct consequence of Covid-19; ii) the other judges were physically present; and iii) that the judge that was physically absent **was able to see the goings on inside the Court room and was able to properly communicate with the parties present in the room**.

The **French Council of State in its judgement nn. 440717, 440812, 440867 of 8 June 2020,** pointed out that, even if the law of March 23 allowed the government to modify some justice procedures in the context of the state of a health emergency, **such measures must be proportionate and justified by the health situation in the country**. However, the judge determined that there was serious doubt about the proportionality and justification of the generalisation of judgements made by a single judge of the National Court of Asylum during the state of the health emergency as long as the one-judge procedure was not justified by the very characteristics of the cases. The Council therefore suspended this measure. It should be noted that the National Court of Asylum had no audience to apply this measure, which remains unapplied. Yet, the Council of State considered that the appeals did not provide sufficient arguments to raise a doubt about the legality of the dispositions allowing administrative judges to participate in front of an audience by means of videoconferencing. In the same vein, in a migration law matter, the French Court of Toulouse, in its decision of 17 March 2020, n°20/00271 considered that the use of videoconferencing did not deprive the person concerned of the guarantees of the due process of law and the right of access to Courts.

With regard to the conclusions, the Netherlands Supreme Court defined the condition under which it was possible for a judge on a bench panel to participate via a video-conferencing system during a hearing in criminal proceedings. The French Council of State accepted the appeal of the complainants regarding the single judge at the National Court of asylum, but rejected the conclusions against the use of videoconference by administrative judges.

- *Suspension of the limitation period for crimes during the suspension of judicial activity provided in the spring of 2020 by reason of the COVID-19 pandemic*

In Italy, COVID-19 restrictive measures provided for the suspension of the limitation period for crimes while judicial activity was suspended due to the COVID-19 pandemic, beginning March 9, 2020, until March 22, 2020. The **Italian Constitutional Court** assessed the constitutionality of the measure in its **judgement n. 278 of 23 December 2020**. In that case, the Court stated that the short duration of the suspension of the limitation period was fully compatible with the principle of the reasonable duration of the process and, on the other hand, that, **in terms of reasonableness and proportionality, the measure was justified by the purposes of protecting the good of collective health (Art. 32 of the Italian Constitution), *i.e.*, to contain the risk of contagion from COVID-19 in an exceptional moment of health emergency.**

With regard to the decision, the Court declared the contested legislation concerning the time suspension to be constitutional. More specifically, the Court declared the question concerning the violation of the principle of legality (Art. 25 Constitution) unfounded and the alleged contrast with Art. 7 ECHR and Art. 49 CFREU, providing the principle of legality at the European level, to be inadmissible. **With regard to Art. 49, the Court declared the question inadmissible because the Charter of Fundamental Rights was not applicable, since it is limited to cases where EU law should be applied.** In that regard, one may wonder if this interpretation could change if a national referring Court posed the question where criminal law, implementing EU law, was within its scope.

Question 3 - COVID-19 outbreak and the renewal of procedural deadlines

In light of Art. 47 CFR, whenever applicable, and of the principle of effectiveness, could the existence of a COVID-19 outbreak justify an extension or a renewal of procedural deadlines during the first emergency period?

The issue of the impact of the COVID-19 emergency on procedural deadlines concerned several Member States. As for the case law, two examples come from Croatia and Lithuania.

With regard to the first, the Commercial Court in Osijek in decision no. St-461/2019, of 21 August 2020, decided a case where the interpretation of procedural rules concerning bankruptcy proceedings were at stake, according to which pre-bankruptcy proceedings must be completed within 300 days from the day of the opening of such, with the exceptional possibility of an extension for a further 60 days. With regard to the COVID-19 epidemic, no law was passed in Croatia for extending procedural deadlines. The Court noted that when passing this provision, the legislature had the normal functioning of the Court in mind and clearly not the state of emergency caused by the proclamation of the COVID-19 epidemic. However, the Court considered that in this case the debtor and his creditors were denied the right to access the Court and the normal conduct of the pre-bankruptcy agreement, due to the declaration of the pandemic, which neither the Court nor the debtor could influence or eliminate. Accordingly, the Court stated that an extension of the deadline for concluding a pre-bankruptcy agreement in this legal matter was permitted, for a further 60 days, in order to exercise the right of access to the Court.

In Lithuania, in several cases Courts decided on the possibility of renewing procedural deadlines for reasons related to COVID-19 (Supreme Administrative Court, 25 November 2020, made in administrative case No. eAS-779-602/2020; 7 October 2020 decision made in administrative case No. eAS- 607-1062/2020; 7 October 2020 decision made in administrative case No. eAS- 646-602/2020; 30 September 2020 decision made in administrative case No. AS-604-575/2020; 30 September 2020 decision made in administrative case No. eAS-551-525/2020; 9 September 2020 decision made in administrative case No. eAS-546-525/2020; 19 August 2020 decision made in administrative case No. eAS- 461-261/2020; 12 August 2020 decision made in administrative case No. AS- 516-662/2020; 18 August 2020 decision made in administrative case No. AS- 538-520/2020; 17 June 2020 decision made in administrative case No. AS- 405-438/2020). In those cases, applicants asked to renew missed deadlines for lodging complaints relying on the following arguments 1) the quarantine led lawyers to tighten requirements for client visits by requiring pre-registration, because of that the applicant's ability to communicate and arrange a meeting with professional lawyers was time limited; 2) The quarantine prevented applicants and their representatives from communicating directly and expeditiously; 3) (a few) applicants belonged to the group of those at greater risk from Covid-19; 4) Sickness, other than Covid-19; 5) Lack of technological knowledge; 6) the quarantine restricted access to documents.

In 8 of these cases the Supreme Administrative Court of Lithuania dismissed the complaints, on the basis of the following arguments: i) the quarantine cannot in itself be recognized as an objective reason that complicated the exercise of the right to access justice; ii) during the quarantine, all procedural documents in Court were received by electronic means, therefore it was possible to submit complaints to the Court during the quarantine; iii) the applicants (their representatives) were not prompt and diligent enough; iv) the applicants' arguments concerning the quarantine were abstract, unspecified; v) the applicants did not

provide evidence proving their arguments (for instance, pre-registration meetings with lawyers were delayed) vi) the need to ensure the stability of legal relationships.

Only in two cases (18 August 2020 decision made in administrative case No. AS- 538-520/2020; 17 June 2020 decision made in administrative case No. AS- 405-438/2020) did the Court uphold complaints on the basis of various arguments, including renewal of the time limit to submit an appeal because the evidence demonstrated that the applicant was ill when the time limit for lodging an appeal had expired.

Insights from the case law analysis

Generally speaking, there may be cases where Art. 47 CFR and the principle of effectiveness are relevant for the interpretation of national rules which modify judicial proceedings regulations due to the COVID-19 emergency whenever these rules shall be applied in the field of the application of EU law (see the preliminary reference, for example, made by the Austrian Supreme Court, *Uniqa,* C-18/21, concerning the compatibility of national law for suspending procedural terms with the application of Reg. UE 1896/2006 concerning the paying procedure order). Accordingly, in assessing the relevance of Art. 47 CFR and the principle of effective judicial protection, national Courts should consider whether the applicable legislation falls within the scope of EU law or in the fields covered by EU law. Moreover, national Courts should also consider that, according to the principle of effectiveness, a national procedural provision must not make the exercise of the rights conferred on individuals by EU law practically impossible or excessively difficult.

In order to address the general question concerning the **compatibility of restrictive measures concerning proceedings aimed at protecting public health** (lack of public hearings and lack of hearings, online mode, suspensions of terms) with Art. 47, whenever applicable, and the right to be heard, as well as the criteria adopted by Courts for balancing the right to a fair trial and to access to justice with other fundamental rights, several groups of decisions can be classified.

A first group of cases concerns the lack of a hearing, provided for by law in the context of COVID-19. In these cases, the Courts considered the need to balance the fundamental rights related to the right to a fair trial with the right to health, referring to national (French Constitutional Council, dec. n°2020-866 QPC of 19 November 2020) and supranational legal texts (see: Netherland Council of State, decision of 7 April 2020 no. 202001949/1/V3) enshrining these rights. Using the balancing test, the Courts, taking into account the specific circumstances of COVID-19, applied reasonableness (French Constitutional Council, dec. n°2020-866 QPC of 19 November 2020) and the principle of proportionality (the Regional Administrative tribunal of Puglia applied both in decision no. 742 of 25 November 2020).

Furthermore, the decision of 4 June 2021, No. 2021-911/919 QPC of the French Constitutional Council addressed the relationship between the guarantee of the right to a defence and the use of video-conferencing means.

In a second group of cases the Courts addressed the application of the principles of publicity of hearings and public disclosure of judgements in the context of restrictive measures adopted to fight the COVID-19. The Dutch case law is of particular interest: Courts referred to Art. 6 ECHR and the related ECtHR case law, and in their reasoning they took the necessity of the measure for ensuring public health into

account, and considered whether procedural rights were sufficiently safeguarded (Supreme Court of the Netherlands of 15 December 2020, no. 20/01476; Council of State, 7 April 2020, no. 202002016/1/V3).

A third group of cases concerns the impact of COVID-19 measures on the composition of the Court (Supreme Court of the Netherlands, judgement no. S20/03532, 15 December 2020; French Council of State, decision nn. 440717, 440812, 440867 of 8th June 2020). In these cases, the judges applied balancing techniques, and the French Court evaluated the procedural measure in light of its proportionality and justification by the health situation in the country.

Furthermore, the Italian case concerning suspension of the limitation period for criminal cases during the suspension of judicial activity during the first wave of COVID-19 in the spring of 2020 clearly shows that substantive and procedural rules are intertwined, the key role of the principle of legality in the regulation of criminal matters, and raises the question of the applicability of Art. 49 CFR, establishing the principles of legality and proportionality of criminal offences and penalties, with regard to legislation at the crossroads between substantive and procedural rules, at least when national criminal law implementing EU law is at stake.

7.3. Healthcare Management: the Collective and Individual Dimensions of Health Protection

Question 4 - Collective and individual dimensions in the definition of vaccination strategy

Taking the individual right to health into account, what is the impact of the principles of proportionality and effectiveness in the definition of the vaccination strategy undertaken by the EU and MSs in the context of the Covid-19 pandemic?

This question has several facets, some of which have been addressed by the Courts, regarding COVID-19 vaccines directly as well as other types of vaccines. In this section, the following aspects are analysed:

- The impact of the principle of proportionality and effectiveness with regard to the relationship between medical self-determination and vaccination
- The ways to ensure non-discriminatory access to vaccines.

Question 4a – Case law concerning the relationship between medical self-determination and vaccination: proportionality and effectiveness of health protection in its individual and collective dimensions

What is the impact of the principles of proportionality and effectiveness on the definition of the relationship between medical self-determination and vaccination?

To answer this question the case law on vaccination, and notably on compulsory vaccination, which has been developed by the ECHR as well as by national Courts, is of particular importance.

Suggestions from ECtHR case law: the recent case Vavřička and Others v. the Czech Republic, of 8 April 2021

In the recent case ***Vavřička and Others v. the Czech Republic*, of 8 April 2021, the ECtHR** assessed the compatibility of legislation providing mandatory vaccination for children against nine diseases well-

known to medical science, and the subsequent duty of parents to vaccinate children, with Art. 8 ECHR that protects private and family life. The legislation provided that i) compliance with the duty cannot be physically enforced; ii) parents who fail to comply, without good reason, can be fined; iii) Non-vaccinated children were not accepted in nursery schools (an exception is made for those who cannot be vaccinated for health reasons). In the first case, the first applicant was fined for failure to comply with the vaccination duty in relation to his two children. The other applicants were all denied admission to nursery school for the same reason.

The Court assessed the compatibility of that legislation assessing:

i) the existence of interference with Art. 8 ECHR.

The Court stated, relying on previous case law (*Solomakhin v. Ukraine*, no. 24429/03, § 33, 15 March 2012), that compulsory vaccination represents an interference with physical integrity and the right to respect for private life, protected by Art. 8 ECHR.

ii) justification of the interference (in accordance with the law; necessity in a democratic society, including proportionality test)

According to Art. 8 (2) ECHR, the Court assessed the justification for the interference evaluating whether it was "**in accordance with the law**," **pursued one or more of the legitimate aims** specified therein, and to that end was "**necessary in a democratic society**."

The Court stated that the inference was provided for by law. Moreover, the ECtHR considered that the Czech policy pursued **the legitimate aims** of protecting health as well as the rights of others, noting that vaccination protects both those who receive it and also those who cannot be vaccinated for medical reasons and are therefore reliant on herd immunity for protection against serious contagious diseases.

As **to the necessity of the interference in a democratic society**, the Court relied on previous case law on this aspect (*Dubská and Krejzová v. the Czech Republic* [GC], nos. 28859/11 and 28473/12, 15 November 201), according to which **an interference will be considered "necessary in a democratic society" for the achievement of a legitimate aim if it answers a "pressing social need" and, in particular, if the reasons adduced by national authorities to justify it are "relevant and sufficient" and if it is proportionate to the legitimate aim pursued.**

In that regard, the Court considered that the assessment made by national authorities remains subject to review by the Court, which should make the final evaluation as to whether an interference in a particular case is "necessary," as that term is to be understood within the meaning of Article 8 ECHR. Nevertheless, a certain **margin of appreciation** is, in principle, afforded to domestic authorities with regard to that assessment. As for the case under consideration, the Court recalled that healthcare policies are in principle within the margin of appreciation of domestic authorities, who are best placed to assess priorities, use of resources, and social needs (*Hristozov and Others v. Bulgaria,* nos. 47039/11 and 358/12, ECHR 2012). Furthermore, **an element considered by the Court was the existence of consensus among contracting parties.** In this respect, the Court first considered that there was a general consensus among the Contracting Parties, strongly supported by specialised international bodies, that vaccination is one of the most successful and cost-effective health interventions and that each State should aim to achieve the

highest possible level of vaccination among its population. Second, the Court affirmed that when it comes to the best means of protecting the interest at stake, there is no consensus over a single model, and that Contracting Parties adopted a spectrum of policies on the vaccination of children, ranging from:

- one based wholly on recommendation,
- through those that make one or more vaccinations compulsory,
- to those that make it a matter of legal duty to ensure the complete vaccination of children.

In other words, "the Court takes the view that in the present case, which specifically concerns the compulsory nature of child vaccination, that margin should be a wide one." The following conclusions of the Court are particularly relevant:

> "the Court would clarify that, ultimately, the issue to be determined is not whether a different, less prescriptive policy might have been adopted, as has been done in some other European States. Rather, it is whether, in striking the particular balance that they did, the Czech authorities remained within their wide margin of appreciation in this area. It is the Court's conclusion that they did not exceed their margin of appreciation and so the impugned measures can be regarded as being "necessary in a democratic society"

However, with regard to **the existence of a "pressing social need**," the Court affirmed that it is the basis of the contested law, as the vaccination duty represents the answer of domestic authorities to the pressing social need to protect individual and public health against the diseases in question and to guard against any downward trend in the rate of vaccination among children. In its reasoning, the Court, relying on previous case law (*L.C.B. v. the United Kingdom*, 9 June 1998; *Budayeva and Others v. Russia*, nos. 15339/02 and 4 others; *Furdík v. Slovakia (dec.),* no. 42994/05, 2 December 2008; *Hristozov and Others*; *İbrahim Keskin v. Turkey*, no. 10491/12, 27 March 2018; *Kotilainen and Others v. Finland*, no. 62439/12, 17 September 2020), recalled that States must, according to Articles 2 and 8 ECHR, take appropriate measures to protect the life and health of those within their jurisdiction.

With regard to **the existence of relevant and sufficient reasons sustaining the mandatory nature of vaccination**, the Court considered that, while a system of compulsory vaccinations is not the only, or the most widespread, model adopted by European States, in matters of health-care policy, it is the domestic authorities who are best placed to assess priorities, the use of resources and social needs. The Court then stated that "all of these aspects are relevant in the present context, and they come within the wide margin of appreciation that the Court should accord to the respondent State."

With regard to the **proportionality** of the legislation establishing mandatory vaccination, the Court stated that contested legislation complies with Art. 8 ECHR. In the proportionality assessment, the Court considered several elements: **i)** the general consensus of States on the effectiveness of vaccination as a means of vital importance for protecting populations against diseases that may have severe effects on individual health, and that, in the case of serious outbreaks, may cause disruption to society**; ii)** with regard to the safety of vaccines, as risk of significative negative consequences is very low, the Court considered that the State had taken the necessary precautions before vaccination (*e.g.*, checking in each individual case for possible side-effects; monitoring of vaccine in use); **iii)** within national legislation vaccination is a legal duty, but cannot be directly imposed (i.e., there is no provision allowing for

vaccination to be forcibly administered); the duty is enforced indirectly with sanctions, which are moderate; **iv)** the legislative approach employed makes it possible for the authorities to react with flexibility to the epidemiological situation and to developments in medical science and pharmacology; **v)** the transparency of decision making (in this case, the publication of the minutes of meetings of the National Immunisation Commission on the Government website; **vi)** the existence of a conflict of interest by authorities which made the decision was not proven by the applicants.

Furthermore, with regard to the non-admission to preschool as a consequence of a lack of mandatory vaccination, the Court considered that the provision aimed to safeguard the health of young children and the existence of procedural safeguards in domestic proceedings. Moreover, the Court considered that it cannot be regarded as disproportionate for a State to require those, for whom vaccination represents a remote risk to personal health, to accept this universally practised protective measure, as a matter of legal duty and in the name of social solidarity, for the sake of the small number of vulnerable children who are unable to benefit from vaccination.

Suggestions from national case law

Within national case law, two groups of cases can be identified. A first group concerns mandatory vaccination and its justification, and the second concerns cases of vaccination of people with disabilities.

- *Mandatory vaccination within MSs' case law*

The abovementioned ECtHr decision *Vavřička and Others v. the Czech* ***Republic***, of 8 April 2021 considered existing national case law as relevant material for comparative analysis. Indeed, national **case law developed over the past years** is particularly interesting for understanding the judicial trends among European Countries, and of the role of the principles of **proportionality and effectiveness** in the definition of national vaccination strategies.

Three different legal issues emerged within the case law: a) the lawfulness of the provisions establishing mandatory vaccination; b) the remedies available c) the lawfulness of the exclusion of unvaccinated children from educational services, as part of the provisions of mandatory vaccination.

a. In several Member States there is significant case law concerning **provisions establishing mandatory vaccination** (not necessarily related to Covid-19). In several cases, the Courts considered the lawfulness of mandatory vaccination relying upon various arguments:

i) that the legislature **has discretion to define vaccination policy in order to protect the health of individuals and society at large, including the liberty to modify the vaccination policy in order to account for developments in scientific, medical and epidemiological knowledge**. As an example, the French Constitutional Council, in decision no. 2015-458 QPC of 20 March 2015, concerning compulsory vaccination against diphtheria, tetanus, and poliomyelitis for children, stated that it is not for the Constitutional Council, which does not have the general appreciation or decision-making power of the same nature as that of Parliament, to call into question the provisions enacted by the legislature, with regard to the state of scientific knowledge, or to attempt to ascertain whether the health protection's objective set by the legislature could have been achieved by alternative means, where the arrangements adopted by the Law are not manifestly inappropriate for the objective pursued. In its decision 5/2018,

the Italian Constitutional Court, assessing the constitutional legitimacy of the provision increasing the number of mandatory vaccines for children, adopted a reasoning similar to the French Constitutional Council with regard to the discretion of the legislation in defining vaccination strategies, also considering that various constitutional values were at stake in these decisions. The existence of the discretion of the legislature was also at the basis of the decision of the **Hungarian Constitutional Court of 20 June 2007, no. 39/2007**, where the Court stated that the provision of mandatory vaccination for children did not violate the Constitution, if the legislature demonstrated, relying on scientific knowledge, that benefits of vaccination for both the individual and society outweighed any possible harm due to side-effects.

ii) that the protection of Health within the Constitution requires the necessary **balance** of the individual's right to health (also in the negative sense of not being subjected to health treatments that are not requested or accepted) with the coexisting and reciprocal right of each individual and with the health of the community (*inter alia*: Italian Constitutional Court, **judgment no 307/1990 of 14 June 1990; judgement no. 258 of 23 June 1994**). The Italian Constitutional Court in its decision 5/2018 stated that a law imposing a health-related treatment was not incompatible with the Constitution if, *inter alia*: i) the treatment was intended not only to improve or maintain the health of the recipient, but also to preserve the health of others; ii) the treatment was not expected to have a negative impact on the health of the recipient, with the exclusive exception of those consequences that normally arise and, as such, were tolerable.

iii) the **precautionary principle applies** (Italian Constitutional Court in its decision 5/2018):

> "Faced with unsatisfactory vaccination coverage in the present and prone to criticality in the future, this Court believes that it is within the discretion - and the political responsibility - of the governing bodies to appreciate the urgency to intervene, in light of new data and epidemiological phenomena that has emerged in the meantime, even in the name of the precautionary principle that must govern an area which is so critical for public health as is that of prevention" (unofficial translation).

b. As to **available remedies**, the **Hungarian Constitutional Court of 20 June 2007, no. 39/2007** considered that against the order for vaccination the State should provide the possibility to challenge the order, and to granting the right to an **effective legal remedy** that permits applicants to seek an action against the refusal of exemptions from compulsory vaccination (in this vein see also: Slovenia, judgement U-I-127/01, of 12 February 2004). Furthermore, in Italy with regard to **compensation**, since judgment no 307/1990 of 14 June 1990 of the Constitutional Court considered that, as the risk of damage to an individual's health cannot be completely avoided, the legislation struck a balance, giving precedence to the collective aspect of health, but nobody could be asked to sacrifice their personal health to preserve that of others without being granted just compensation for damage caused by medical treatment (see also, in this vein: Constitutional Court, judgement 268/2018).

c. With regard to the **relationship between access to educational services and mandatory vaccination**, the Italian Constitutional Court, in its abovementioned decision 5/2018, held that requiring a certificate for school enrolment and imposing fines were both reasonable measures.

d. With regard to the relationship between **mandatory vaccination and employment conditions**:

- **The Greek Council of State, in decision no. 133/2021, of 29 June 2021,** addressed a case concerning the issuance of an act titled "Vaccination of personnel serving in the Special Units for Disaster Response (EMAK)," issued on 5/18/201 by the Head of the Fire Service. According to the act, all personnel serving in EMAK were to be vaccinated against COVID-19, due to the need to safeguard the continuous operations of the service. According to the act, members of personnel not already vaccinated were given a deadline of June 11, 2021, to schedule a vaccination appointment, otherwise, they would be transferred to other units of the Fire Service. The Greek Council rejected the claim, weighing the compelling reasons of public interest that led to the issuance of the aforementioned act against the reasons put forward by the employees, considering that the act did not force applicants to be vaccinated, since they could opt to be transferred to another unit.

- **The Italian Council of State, in its decision of 20 October 2021, No. 7045**, addressed a case concerning the vaccination obligation imposed by law on health professionals and health care operators who perform their activities in public and private health, social and welfare structures, pharmacies, para pharmacies, and professional offices. The vaccination obligation and the sanction provided for by the law were challenged by some doctors and health professionals. The Council of State dismissed the claim stating that mandatory vaccination can be required according to the precautionary principle and the principle of solidarity enshrined in Art. 2 of the Italian Constitution. In particular, the Council of State balanced the right to self-determination and dignity of the individual professional operator with the right to public health in consideration of the duty of care that falls on health professionals; hence it considered the vaccination obligation to be proportionate and reasonable, as it related to vaccines that are sufficiently safe and approved by the competent authorities. The Council recalled the judgment of the ECHR *Vavřička and others v. the Czech Republic of 8 April 2021* issued by the Grand Chamber in ric. n. 47621/13, n. 3867/14, n. 73094/14, n. 19306/15, no. 19298/15 and n. 43883/1, on compulsory vaccinations, underlining how Art. 8 of the Convention allows public interference in the private and family sphere under precise strict conditions. In the case in question, the legislation pursued an aim in the public interest (i.e. containment of the contagion) for the protection of democratic society, the protection of the most fragile in the context of a global pandemic (of an airborne virus that is particularly dangerous for the most vulnerable individuals), and those suffering from other diseases or the elderly, through the administration of a vaccine whose efficacy and safety is recorded in the general consensus of the scientific community (on mandatory vaccination of health professional, see also Italian Council of State, 20 December 2021, no. 8454 concerning the assessment of the conformity of vaccination exemption certificate presented by a doctor).

- *National litigation concerning vaccination against COVID-19 of people with disabilities*

National litigation concerning vaccination against COVID-19 has already begun.

In a first group of cases the right to self-determination was weighed against the right to health of the individual eligible for vaccination. Not only the full capacity of the individual came into question but also the need for a prior protection of health compared with that of self-determination.

For example, in **three cases Spanish Courts** (Court of 1st Instance No. 17 of Seville, Resolution No. 47/2021 of 15 January; Court of 1st Instance No. 6 of Santiago de Compostela, Resolutions 55/2021 of 19 January and 60/2021 of 20 January) intervened in order to mandate that retirement homes administer

the Covid-19 vaccine to elderly individuals lacking legal capacity. In two of the cases, settled by the Court of 1st Instance No. 17 of Seville in Resolution No. 47/2021 of 15 January and by the Court of 1st Instance No. 6 of Santiago de Compostela in Resolution 55/2021 of 19 January, **the individual's children, who legally represented their parents, ordered their respective retirement homes not to administer the vaccine.** In the UK, a similar case was decided by the Court of protection (*E (Vaccine) [2021] EWCOP 7*, 20 January 2021). In the case settled by the Court of 1st Instance No. 6 of Santiago de Compostela in Resolution 60/2021 of 20 January an elderly person with limited capacity refused vaccination. As a result of these refusals regarding the vaccine, the managing department of the different retirement homes requested authorization from the Courts to administer the vaccine. The Courts granted authorization. The Courts stated that the effects on public health cannot be considered in these cases because vaccination is voluntary. In their assessment, the Courts applied **reasonableness** and took into account the fact that the individual in each case lacked legal capacity. **In this respect, the Court considered whether not vaccinating them may cause more harm than not, by respecting the free will of their legal representatives or of the individual refusing to be vaccinated, having limited capacity**. The Courts based their judgment on Article 6 of the Spanish Act 41/2002 regulating patient autonomy and the rights and obligations regarding clinical information and documentation, which establishes that in those cases in which consent is to be given by the legal representative or by family members or other closely related individuals, the decision must always be made in the **best interests of the patient's life or health**. The Courts considered that the arguments put forward by those refusing vaccination for their family member or to be vaccinated themselves were understandable and legitimate, but must be weighed against the safe nature of the Covid-19 vaccine, which had been approved by the European Medicines Agency, as well as the risk of contracting infection from coronavirus being greater and more serious than the risk of suffering any serious side effects from the vaccine. In particular, the Courts considered the age and health of the residents, who belonged to a Covid-19 risk-group and the especially harmful effects that the pandemic had on the residents of retirement homes.

Question 4b – Non-discriminatory access to vaccines against COVID-19, vulnerability, and risk of contagion

What is the role of the right to non-discrimination and of the principle of proportionality in establishing the vaccination schedule of different groups of the population?

Litigation concerning priorities in establishing access to vaccines began in MSs with several common features concerning the assessment of the risks related to COVID-19, including the relationship between the judicial and legislative assessment of such risks. A first group of cases concerns the definitions of risk groups in relation to the vulnerability of persons. Other issues addressed in the case law concerned the off-label use of vaccines, and the assessment of specific risks of contagion for prisoners.

- *The assessment of criteria for establishing priority groups for vaccination*

With regard to German case law, **the Administrative Court Frankfurt am Main**, in decision no. 5 L 219/21.F, of 12 February 2021,[114] addressed the issue of the criteria adopted for defining the vaccination strategy with regard to the vaccination schedule for different groups. At the time of the decision, vaccination appointments could be allocated only to persons aged 80 and above. An 8-year-old girl, with severe health and mental diseases, issued a claim with the Administrative Court of Frankfurt am Main in order to oblige the respondent to give priority to her in the next delivery of vaccines or, alternatively, to give priority to her proxies, who were also applicants, or, as an additional auxiliary request, alternatively, to oblige the respondent to consider her previous disease to submit an appropriate vaccination offer. The severe mental disability of the young girl was certified by a treating pediatrician, who also recommended immediate vaccination. The Court clarified that the applicant could not be given the vaccine together with the second prioritized category of people pursuant to §2 of the Corona Vaccination Ordinance, since, according to the provisions of this act, she fell into the third category of people entitled to prioritized vaccination pursuant to §3 of the abovementioned ordinance**. The Court highlighted that the examined provisions did not infringe her fundamental rights to health, life, and bodily integrity, as the claimant argued: according to the German Basic Law, the government has a certain margin of discretion when deciding how to fulfil its duty to protect the population's health, life, and bodily integrity and, thus, when deciding what protective measures are suitable and necessary to ensure effective health protection. This margin of discretion is exceeded only if the measures implemented by the government are manifestly unsuitable, unnecessary, or disproportionate**. **The duty of protection is completely disregarded, if no protective action is taken at all.** According to the Court, this was not the case. **The fact that the vaccination campaign had been organized by implementing a vaccination order based on the level of vulnerability of people was considered suitable, necessary, and proportionate by the Court, given the very scarce availability of vaccines at the time of the decision and the need for a fair and inclusive healthcare management.** For these reasons, a violation of the principle of equality before the law by the considered ordinance was not detectable. However, the Court admitted that, despite the very young age of the applicant (for which no vaccine was authorized) and according to certified medical reports, she fell into the third high priority-group pursuant §3 of the Ordinance and, thus, the local administration should

[114] The description of this case is partially based on a case summary made by Maria Abbruzzese and Heike Koehler.

decide (within its margin of discretion) about the applicant's request to be vaccinated, by taking her belonging to the third prioritized group into account.

A very similar case was decided by **the Administrative Court of Gelsenkirchen in its decision no. 20 L 182/21, of 18 February 2021.**[115] In that case, the applicant issued a claim with the Administrative Court of Gelsenkirchen to request, by injunctive relief, that the local health administration be obliged to upgrade the applicant from level §3 of the federal Corona Vaccination Ordinance (high priority) to level §2 (highest priority) due to severe and proven health diseases, in order to obtain a Covid-19 vaccination appointment without delay in order to protect his fundamental rights to life, health, and bodily integrity as well as equal treatment. After a summary balancing test, the Court concluded that the claim was unfounded and the applicant could not be granted an upgrade in the order of prioritization in the vaccination campaign, due to the scarce availability of vaccines, which made it absolutely necessary to stick to the established vaccination order to guarantee a fair vaccine distribution. In its reasoning, the Court stated that the compliance with the aforementioned order was absolutely necessary to guarantee the protection of the most vulnerable part of the population, and that since the applicant did not belong to this group no infringement of his right to equal treatment/non-discrimination could be detected by the Court.

Another interesting German case was decided by the **Administrative Court of Schleswig-Holstein** in **decision no. 1 B 12/21 of 17 February 2021.**[116] In that case, a man issued a claim, via injunctive relief, to request a derogation from the Federal "Corona Vaccination Ordinance," which established a list of categories of vulnerable people to be prioritized in the vaccination campaign. According to the applicant, a rejection of his request to be vaccinated immediately would infringe upon his fundamental rights to health, life, bodily integrity and equality before the law, since the claimant suffered from several severe health issues. In addition, his wife worked as a nurse and was therefore at greater risk of contracting Covid-19 at her place of employment. **According to the Court, the applicant did not sufficiently demonstrate that his risk of a severe or fatal Covid-19 infection was comparable to that of the prioritized categories of people.** Furthermore, according to the Court, the fact that the claimant's wife was exposed to a high infection risk due to her employment did not represent a circumstance that justified a derogation. The Court considered that the ordinance did not mention the possibility to also primarily vaccinate people who were close to people belonging to the highest risk category (such as the applicant's wife), while it explicitly did so in the second category on the vaccination list (people over 70, people with specific severe health disease, etc.): up to two close contacts of people belonging to this second category could be vaccinated with the same level of priority. The fact that it did not provide for such an extension in the first case represented, according to the Court, a conscious decision by the government in view of the scarce availability of vaccines. Thus the Court rejected the claim.

In Italy, an interesting case was decided by the **Regional Administrative Tribunal of Catania, in its decision of 13 February 2021, n. 102**. In this case, the claimants, although they were not included in the priority categories indicated by the National Strategic Plan of vaccination against Sars-Cov2/Covid-19, received the first dose of the vaccine produced by Pfizer-Biontech. The Health Department of the region

[115] The description of this case is partially based on a case summary drafted by Heike Koehler.
[116] The description of this case is partially based on a case summary drafted by Heike Koehler.

of Sicily then suspended administration of the second dose of the vaccine for all subjects who had access to the first dose without being entitled to. The applicants filed an action. The Court rejected the plaintiffs' claim as a precautionary measure, relying, *inter alia*, on the following arguments: i) there was no scientific evidence of any risks arising from the non-administration of the second dose, except for the possible ineffectiveness of the vaccine; ii) the need to ensure the regular continuation of the vaccination campaign with respect to those entitled to do so, taking into account the number of doses of the vaccine available.

- *Off-label use of vaccines*

The German **Administrative Court Frankfurt am Main**, in decision no. 5 L 219/21.F, of 12 February 2021,[117] stated that it was also **possible to administer the vaccine to children under the so-called off-label-use exemption, in exceptional cases where children suffer from high-risk diseases and their closest contacts do not belong to prioritized groups**. The Court concluded that the local healthcare administration was obliged to decide on the applicant's request and to arrange a suitable and reasonable vaccination appointment considering the applicant's conditions and the availability of the vaccines.

- *Risk of contagion and prisoner vaccination*

In France, a very interesting case concerned the **vaccination of prisoners in penitentiary institutions**. In this case, an association asked the interim relief judge of the Council of State to order the Prime Minister to modify the inter-ministerial instruction of December 15, 2020 which specified the first stage of the Covid-19 vaccination campaign, including all prisoners in penitentiary institutions. The **Council of State**, in **decision no. 449081 of 5 February 2021,**[118] noted that prisoners over 75 years of age or at high risk of developing serious or fatal forms of the disease were included in the first phase of the vaccination campaign which had begun for the rest of the population. **The judge did not consider it compulsory to vaccinate all prisoners as a priority, as the risk of developing a serious form of Covid-19 did not appear to be higher for prisoners than for the average population**. The Council of State considered that, despite the particular vigilance required by the situation in prisons, the decision not to include all detainees among the priority groups for the first phase of the vaccination campaign did not constitute a manifestly illegal infringement of a fundamental freedom. The Council of State analysed (i) whether there was **discrimination** between the general population and persons held in prisons with regard to the first stage of vaccination; and (ii) whether the inter-ministerial instruction of December 15, 2020 infringed the **right to health of prisoners**. First, the Council of State observed that i) those detained in prison who are part of the target groups of this first stage of vaccination are not excluded because of their detention situation; ii) surplus doses will be used for the vaccination of other prisoners, including those in later phases of the vaccination campaign; iii) the administration indicated that vaccination had already begun. **The Court then considered that the situation of persons held in prisons was considered on an equal footing with the rest of the population in the context of the vaccination campaign.** Furthermore, the Court also considered that while the applicant invoked the particular risks of the virus spreading in prisons in view of detention conditions, there was no certainty in the state of scientific knowledge as to the possible effectiveness of the vaccine against Covid-19 in reducing the risks

[117] The description of this case is partially based on a case summary drafted by Maria Abbruzzese and Heike Koehler.
[118] The description of this case is partially based on a case summary drafted by Sébastien Fassiaux.

of transmission of the disease. Therefore, although the situation of persons detained in prisons warranted particular vigilance, the decision not to include all of these persons among the priority groups likely to receive an injection from the first phase of the vaccination campaign did not reveal, in view of the priorities adopted for vaccination and the characteristics of these persons, a serious and manifestly unlawful failure to act that would justify ordering the measure requested by the interim relief judge. The Council of State therefore rejected the submissions for an injunction presented by the applicant. The judge thus rejected the association's request.

Question 5 – Proportionality and effectiveness of healthcare choices concerning medical and non-medical interventions against COVID-19

In a context of scarce resources and scientific uncertainty, how to ensure effective protection of the right to health with respect to choices concerning medical treatment of COVID-19?

- *Suggestions from national case law*

In order to answer this question three different decisions, which considered the following different aspects, are of particular interest:

- *The medical treatment of COVID-19 and the existing debates within the scientific medical community*

In Italy, in decision 7097 of 11 December 2020, the Council of State decided a case concerning the use of a specific drug, hydroxychloroquine, for the medical treatment of COVID-19.[119] In the first phase of the SARS-CoV-2 pandemic, the Italian Medicines Agency (AIFA), as well as other European and non-European national agencies, initially allowed, with resolution no. 258 of 2020, the off-label use of hydroxychloroquine and enabled its prescription within the National Health Service framework. Later, by a decision of May 26, 2020, the AIFA ordered the suspension of the authorization for the off-label use of hydroxychloroquine for the treatment of SARS-CoV-2, except in the context of controlled clinical trials, and provided its exclusion from reimbursement by the State within the National Health Service framework. Several doctors challenged this decision before the administrative tribunal of Lazio (Rome), which rejected the interim relief request (ordinance n. 7069/2020). In its decision the Council of State considered that: i) on the one hand, at that moment there was **no experimental evidence demonstrating the ineffectiveness of hydroxychloroquine for patients with mild or moderate symptoms**; ii) on the other hand, the use of the medicine was not dangerous. After considering these elements, **the Council concluded that the decision of the Agency invaded the field reserved for doctors, which, asking for a patient's informed consent, must be able to freely exercise their profession and prescribe the medicines considered most appropriate**. The Court applied the **reasonableness principle,** by stating that in case of doubt regarding the efficacy of a new therapy, the State has the duty to consent to the use of a medicine, if not dangerous to human health, under the control and responsibility of the doctor. Furthermore, the Court addressed the issue of an extension of judicial review of acts of the independent authority. The Council of State indicated that:

> "the scientific appreciations of AIFA are not exempt from the review of the administrative judge, not even during the precautionary phase and even less so in the current phase of epidemiological

[119] The description of this case is partially based on a case summary drafted by Maria Laura Maddalena.

emergency, due to the need, inherent in the very existence of administrative jurisdiction and enshrined in the Constitution, to protect subjective legal situations, starting with those that have a constitutional basis such as the **fundamental right to health**, in the face of the exercise of public power and, therefore, also of the so-called technical discretion by the competent authority in health matters. (…) Judicial review, aimed at ensuring **effective protection of legal situations**, even when it comes to the exercise of technical discretion of an independent authority, also implies an intrinsic control, including through the use of technical knowledge belonging to the same specialized science applied by the independent administration, on the reliability, consistency and correctness of the results" (unofficial translation).

Moreover, the Council of State pointed out that with regard to the exercise of the technical discretion of the independent authority, the administrative judge cannot replace a power already exercised, but must only establish whether the complex assessment made in the exercise of the power must be considered correct, both in terms of the technical rules applied, in the phase of contextualization of the rules adopted to protect health and in the phase of comparison between the facts established and the contextualized parameter. Moreover, the Council stated that on the technical side, **judicial review** is aimed at verifying whether the authority violated the principle of **technical reasonableness**, without the administrative judge being allowed, in line with the constitutional principle of the separation of powers, to replace the evaluations of the administration, even if questionable, with judicial ones. In other words, the administrative judge must be able to verify that the administration correctly applied the rules of specialized knowledge applicable to the sector of administrative activity subject to the exercise of regulatory power to the concrete case in accordance with the proper principles to the chosen scientific method.

- *The regulation of triage within the hospitals*

In **Germany**, the regulation of triage in hospitals was the subject of judicial review by the **Federal Constitutional Court in decision no. - 1 BvR 1541/20 of 16 July 2020.**[120] In particular, the complainants issued a claim with the Federal Constitutional Court challenging the inactivity of the Federal Government with regard to the regulation of triage in hospitals (in cases of overload due to severe Covid-19 infections), which was only subjected to non-binding recommendations. According to the claimants, who belonged to the at-risk group as a consequence of previous illnesses, the inaction of the government violated their right to life, health, human dignity and equal treatment (non-discrimination). The Court stated that the questions of whether and when legislative action can be required in fulfilment of a government's duty and of the scope of this action in regulating medical prioritisation, needed a detailed examination, which was not possible within an urgent proceeding. Moreover, the Court considered that given the incidence of infection and the intensive medical treatment capacities in Germany the occurrence of a situation of triage was very unlikely. Thus, according to the Court, no violation of their fundamental rights was likely to occur. Moreover, the Court considered that the implementation of a special Committee within the Federal Government would not significantly improve the complainants' situation,

[120] The description of this case is partially based on a case summary drafted by Heike Koehler.

because such a body would not have be legitimised to issue regulations with the binding force of a legislative act. The Court therefore rejected the claim.

- *The interaction between the medical treatment of COVID-19 and non-medical measures*

The French Council of State decision no. 439674 of March 22, 2020 shows the importance of the interaction and complementarity between medical and non-medical interventions (e.g., closure of shops, etc.) in the fight against COVID-19. In that case, the trade union *Jeunes Médecins* asked the Council of State to order the Government to declare a complete lockdown of the population and to take measures to ensure the industrial-scale production of screening tests and the screening of medical staff. The Council of State rejected the request for a complete lockdown, arguing that it could have serious implications for the health of the population and that the continuation of certain essential activities (e.g. distribution of food), implied the maintenance of other activities on which they depend (in particular public transport). The Council of State then stated that some derogations existing in current emergency measures concerning the lockdown could lead in certain cases to authorizing travel and behaviour contrary to the rationale of the lockdown. Consequently, the Council of State ordered the Government to take the following measures within 48 hours: i) specify the scope of the exemption from confinement for health reasons; re-examine, within the same time period, the maintenance of the derogation for "short journeys, close to the home" given the major public health issues and the confinement order; ii) assess the public health risks of keeping open-air markets open, taking their size and level of attendance into account. Finally, the Council of State considered that the authorities had arranged to increase testing capacity as quickly as possible. The judge affirmed that the limitation of tests to health personnel presenting symptoms of the virus only was the result of an insufficient availability of equipment.

Insights from the case law analysis

Within the case law, several issues related to health management were considered, namely those related to vaccination strategy and to the need to ensure effective protection of health in a context of scientific uncertainty and scarce resources.

The approach taken by some MS decisions is analysed with regard to two different aspects:

- *the relationship between medical self-determination and vaccination and the role of the principles of effectiveness and proportionality*

In this respect, the case law is twofold: i) the decisions concerning mandatory vaccination are obviously important, and ii) that concerning the vaccination of people with disabilities is of particular interest.

i) case law concerning mandatory vaccination

With regard to the first group of cases, the recent case *Vavřička and Others v. the Czech Republic*, decided by the ECtHR on April 8, 2021 provides some guidelines. The Court assessed the compatibility of legislation by examining: i) the existence of an interference with Art. 8 ECHR, considered proven in that case; ii) justification of the interference (in accordance with the law; necessity in a democratic society, proportionality test). In this respect, the Court stated that the interference was provided for by law, and focused on the assessment of **the necessity of the measure in a democratic society**. In its **proportionality assessment**, which is part of the necessity test, the Court considered several elements:

i) the general consensus of States on the effectiveness of vaccination as a mean of vital importance for protecting populations against diseases that may have severe effects on individual health, and that, in the case of serious outbreaks, may cause disruption to society**; ii)** the safety of vaccines and the risk of significant negative consequences, **iii)** the means of enforcement of mandatory vaccination in case of violations of that obligation **iv)** the possibility for the authorities to react with flexibility to the epidemiological situation and to developments in medical science and pharmacology; **v)** the transparency of decision making; **vi)** the existence of a conflict of interest by decision making authorities was not proven by applicants.

Furthermore, national **case law developed in recent years** is particularly interesting for the understanding of the judicial trends among European Countries, and of the role of the principles of **proportionality** in the definition of national vaccination strategy. In several Member States there is significant case law concerning the **provisions establishing mandatory vaccination**. In several cases, the Courts considered the lawfulness of mandatory vaccination relying on various arguments: i) that the legislature has the discretion to define a vaccination policy in order to protect the health of individuals and society at large, according to scientific developments (French Constitutional Council, decision no. 2015-458 QPC of 20 March 2015; Hungarian Constitutional Court of 20 June 2007, no. 39/2007); ii) that the protection of Health within the Constitution requires the necessary **balancing** of the individual's right to health with the coexisting and reciprocal right of each individual and with the health of the community (*inter alia*: Italian Constitutional Court, judgment no 307/1990 of 14 June 1990; judgement no. 258 of 23 June 1994); iii) the **precautionary principle** (Italian Constitutional Court, decision 5/2018).

With regard to **available remedies**, some Courts considered that the State should provide the possibility to challenge the vaccination order to granting the right to an **effective legal remedy**. In this vein, the Hungarian Constitutional Court stated that there should be the possibility to seek an action against a refusal of exemptions from compulsory vaccination (Hungarian Constitutional Court of 20 June 2007, no. 39/2007; in this vein see also: Slovenia, judgement U-I-127/01, of 12 February 2004). Furthermore, in Italy, with regard to **compensation**, since judgment no 307/1990 of 14 June 1990 the Constitutional Court determined that, as the risk of damage to an individual's health cannot be completely avoided, the legislature struck a balance, giving precedence to the collective aspect of health, but ensuring no one could be asked to sacrifice their personal health to preserve that of others without being granted just compensation for damage caused by medical treatment (see also, in this vein: Constitutional Court, judgement 268/2018).

ii) *case law concerning vaccination against COVID-19 of people with disabilities*

With regard to vaccination of people with disabilities, a Spanish Court balanced the protection of health of people with disabilities living in a retirement home with their representatives (Court of 1st Instance No. 17 of Seville, Resolution No. 47/2021 of 15 January; Court of 1st Instance No. 6 of Santiago de Compostela, Resolutions 55/2021) or with the will of the person with disabilities (Court of 1st Instance No. 6 of Santiago de Compostela in Resolution 55/2021 of 19 January). In these cases, the Courts granted authorisation for them to be vaccinated. The Courts stated that the effects on public health could not be considered in these cases since vaccination is voluntary; thus the best interests of the patient's health and

lives were considered. In their assessment, the Courts applied reasonableness, by taking into account the fact that the individual in each case was incapacitated, and the age and health of the residents, who belonged to a group at serious risk of Covid-19 and the especially harmful effects that the pandemic had on residents of retirement homes.

- *Non-discriminatory access to vaccines*

In several cases, national Courts dealt with the definition of priorities in defining groups with access to vaccines. In particular, German Courts assessed the criteria according to which risk groups were established (Administrative Court Frankfurt am Main, decision no. 5 L 219/21 F, of 12 February 2021; the Administrative Court of Gelsenkirchen in its decision no. 20 L 182/21, of 18 February 2021; Administrative Court of Schleswig-Holstein in its decision no. 1 B 12/21 of 17 February 2021) and a French Court assessed the issue of priority vaccination for prisoners in penitentiary institutions (Council of State, decision no. 449081 of 5 February 2021)

- *Medical interventions against Covid-19 and the fundamental right to health*

The case law shows the diversity of issues related to the effective protection of the right to health, and the starting of litigation concerning these aspects. As examples, scientific uncertainty led the **Council of State, in decision 7097 of 11 December 2020**, to decide on the possibility to use a specific drug, hydroxychloroquine, by evaluating scientific evidence and the importance of doctor's autonomy to determine, together with patients, the best treatment for the case. Moreover, the question of non-discriminatory access to treatments related to COVID-19 was also addressed by the German Federal Constitutional Court, in a case concerning triage within hospitals (**Federal Constitutional Court in decision no. - 1 BvR 1541/20 of 16 July 2020**). Moreover, the duty of public authorities to manage the COVID-19 crisis was at stake in French Council of State decision no. 439674 of March 22, 2020, concerning the State's test strategy.

7.4. Right to Health, Freedom of Information, and the Right to Be Informed

Question 6 – Access to information regarding the pandemic and the effectiveness of the right to information

In light of the principle of effectiveness, does the freedom of information (right to be informed) jointly with the right to health, allow individuals or associations to request access to information regarding the pandemic held by the public administration?

In the context of the pandemic, access to technical information and scientific reports relied upon by public decision-makers in adopting measures to protect public health is relevant both from the perspective of protecting health and balancing it with other rights. As for the former, analysis of the scientific documentation can serve to understand whether public decision-makers put in place the necessary measures to protect health with respect to the existing epidemiological context, and appropriately evaluated existing risks. In relation to balancing with other rights, access to information serves to understand whether measures restricting fundamental rights other than the right to health (e.g., freedom of movement) are appropriate and, for example, not disproportionate in light of the epidemiological context which is described from the documents to which access was requested.

The Italian case law is of particular interest on this issue, with special regard to a group of decisions adopted by the Courts. As for the facts, several individuals requested access to various minutes of the Scientific Technical Committee established for facing the COVID-19 emergency (hereinafter: STC), associated with the Italian Civil Protection Department. These minutes were preparatory acts for several Decrees of the President of the Council of Ministers (hereinafter: DPCM), with which the Government took measures to face the emergency. **The action sought by the applicants was the specific action referred to as "civic access," aimed at obtaining access to information held by the public administration, in order to allow the public widespread control of the legitimacy of the administrative action. This action permits anyone to request and obtain information.**

The Civil Protection Department rejected the request. The applicants sought action contesting the rejection of their request to access the abovementioned information held by the Public Administration. **In decision No. 8615/2020 of 22 July 2020, the Regional Administrative Tribunal of Lazio upheld the claim and annulled the contested measures. Consequently, the tribunal ordered the administration to grant access to the minutes subject to request.**

Then, the Council of State, in judgment 5426/2020 of 11 September 2020, declared a cessation of the existence of the dispute, because the Presidency of the Council of the Minister made the minutes available and provided the requested copies.

Question 7 – Information management: the role of the freedom of information and of the right to be informed

Could the need to manage the crisis and provide credible information to the public lead States to adopt guidelines or rules on the media regarding reporting on the COVID-19 outbreak? What is the role of the principles of effectiveness and proportionality in that regard, if any? Which could be the role of Social Media in this context?

In the context of the pandemic, characterized by the growing importance of scientific information and uncertainty as to its validity, the exercise of freedom of information, as well as the right to be informed acquire a peculiar value with regard to the evaluation of information that is credible and accredited from the scientific point of view. On the one hand, the right to be informed about the public health situation brings with it a reflection on the verification of the credibility of the information disseminated, also to allow each person to make choices that may affect his or her health and public health on the basis of effective knowledge. On the other hand, freedom of expression and the right to criticism demonstrate the importance of defining what is scientifically credible and what is not, with respect to the risk of censorship of critical or minority positions, which could have detrimental effects in the public and scientific debate that is the basis for making the most effective choices for the protection of individual and collective health.

In several countries **media and telecommunication authorities adopted decisions regulating the provision of information concerning the COVID-19 pandemic**.

For example, the **Italian information and communication Authority adopted decision No. 129/20/CONS on March 18, 2020** concerning the application of principles of fairness and transparency

of information with regard to COVID-19 related issues. The Authority invited audiovisual and radio media service providers to ensure adequate and comprehensive information coverage on the COVID-19 pandemic, making every effort to ensuring the testimony of scientific experts, in order to provide citizens with verified and well-founded information. Furthermore, according to the decision, providers of video sharing platforms should take appropriate measures to counteract the dissemination on the web (spec. social media) of coronavirus information that is incorrect or disseminated from sources that are not scientifically accredited. The Authority stated that these measures must also include effective systems for identifying and reporting offences and their perpetrators.

Moreover, in **decision n. 153/20/CONS of 7 -10 April 2020, the Italian Communication Authority** considered a TV program concerning Covid-19 as being in breach of the general principles of television communications and the commercial communications broadcast therein and, as a sanction, suspended the broadcasting of content by the audio-visual media service operating on the related channel for a period of six months. In its decision, the Authority considered, *inter alia*, that during the TV program: i) statements were made such as "low carb diet ... adequate physical activity … can do a lot against this virus"; ii) the standard indications for prevention issued by health authorities (frequent hand washing, safe distance from other subjects, distance from crowded places) were presented as measures characterized by backwardness, through the statement that quarantines were used in the Middle Ages; iii) it was hypothesized - basing this assertion on statistics and allegedly scientific reconstructions - that the negative effects of the Covid-19 virus were linked to deficiencies of the immune system due to unnecessary surgery or to a bad diet claiming: "a higher consumption of carbohydrates encourages the spread of the virus." Furthermore, the TV program provided information on the role of the diet in the treatment of COVID-19. This decision was challenged before the Regional Administrative Tribunal of Rome, which adopted its **decision on November 9, 2020, no. 12884**. **The tribunal stated that the Authority's detailed assessment, being exhaustively motivated as well as free from evident illogicality, irrationality, or error of fact**, is to be upheld, also with regard to the Authority's assessment concerning the TV program which was prejudicial to correct medical-scientific information and therefore to the protection of public health. Furthermore, the tribunal considered that the actual validity of the medical-scientific theories discussed in the transmission were relevant here, both because any judgment on that aspect would result in an inadmissible review of the merits of the administrative activity under scrutiny and because the same content and the particular method of communication applied there appeared in themselves, especially during an international health emergency, harmful to the principles of objectivity, completeness, fairness and impartiality of information. Furthermore, the tribunal found **the sanction to be disproportionate**, and quashed the administrative decision, on the grounds that the Authority's assessment was not sufficiently motivated. In particular, the tribunal considered that: i) the argument concerning the suitability of the period of suspension, in light of scientific forecasts on the course of the epidemic, was not sufficient nor was it based on the declaration of the state of health emergency referred to in the Prime Ministerial Decree of January 31, 2020; ii) comparison of the period of suspension (6 months) with the duration of the contested TV program (2 days).

In the **UK**, a decision concerning the provision of information related to COVID-19 was challenged before the **High Court of England and Wales**. In that case, the regulatory body for the communications industry (Ofcom) had issued two Guidance Notes to broadcasters concerning the

approach they should take when broadcasting information concerning the Covd-19 pandemic. The notes were challenged on the basis that they sought to limit the broadcast of material that challenged the 'official narrative' concerning the pandemic on the basis that it was harmful material. The challenge was based on: i) a claim that such material was not harmful and was thus outside the vires of the regulatory authority to issue such guidance; and ii) amounted to censorship contrary to the right to freedom of expression. The Court, in its decision ***Free Speech Union & Anor v Office of Communications (OFCOM [2020] EWHC 3390 (Admin)*, of 9 December 2020,**[121] held that the guidance was *intra vires*. The guidance sought to provide direction on the approach to take with respect to material that could cause harm in relation to the ongoing pandemic. The Court affirmed that it was entirely valid for the regulator to issue such guidance to broadcasters. Furthermore, the judge stated that **there was no basis on which it could be argued that the guidance infringed Article 10 of the European Convention on Human Rights, as the guidance sought to promote clarity by ensuring that misinformation concerning the pandemic was put in its proper context**. Accordingly, the Court stated that the guidance was both consistent with Article 10 and the guidance issued by the UN Special Rapporteur on Human Rights: see Report of the Special Rapporteur of the United Nations General Assembly Human Rights Council on "*Disease pandemics and the freedom of opinion and expression*" (a Report "on the promotion and protection of the right to freedom of opinion and expression" (A/HRC/44/49), dated 23 April 2020). Thus, the Court rejected both elements of the challenge.

In the Netherlands, the **District Court of Amsterdam,** in **decision No. C/13/689184 / KG ZA 20-783, of 13 October 2020,**[122] addressed the issue of the **role of social media in assessing the credibility of reporting concerning COVID-19**. In that case, the applicant, a society called "Smart Exit," challenged Facebook's removal of its pages called "Nee tegen 1,5 meter" (No to 1.5 metres) and "Viruswaanzin" (Virus Madness) to the District Court of Amsterdam, claiming that by doing so Facebook had infringed the company's freedom of expression. More specifically, the claimant argued that Facebook was acting with the consent of the government and the WHO frustrating a substantive debate by removing content that conflicted with prevailing opinion. The Court stated that freedom of expression is a fundamental right that is of great importance in a free democratic society, especially when it concerned expressions contrary to prevailing opinion. To summarize, **the Court stated that if freedom of expression is obstructed to such an extent that any effective exercise of that fundamental right is impossible, it is up to the State to intervene and to guarantee that the right be exercised.** Moreover, the Court stated that Facebook was indirectly obliged under Dutch Law to act in accordance with the standards of **reasonableness and fairness** when performing agreements and that **these standards do also include freedom of expression. However, the Court stated that in the present case there was not any evident and intolerable restriction of freedom of expression by Facebook, according to Article 10 ECHR.** In its assessment the Court considered that: i) after the removal of its page, the company still had the possibility to express its opinion through mass media, the press, and other online platforms; ii) **the right to freedom of expression can actually be restricted in order to protect other rights and interests such as public health.** In this respect, the Court affirmed that with its COVID-19 policy Facebook answered the call of central governments and international and

[121] The description of this case is partially based on a case summary drafted by J.Sorabji.
[122] The description of this case is partially based on a case summary drafted by H. Koehler.

supranational organizations to cooperate in the fight against the spread of incorrect information about COVID-19. That call was made in the interests of the protection of public health, which can count as a legitimate restriction, as explained above. Facebook had a social obligation to comply with governmental guidelines, unless these are obviously incorrect. This was not the case according to the Court, so the claim was thus rejected.

Insights from the case law analysis

With regard to the effectiveness of freedom of expression, within the case law the importance of the right to be informed arose; on the one hand, the right to be informed jointly with the principle of transparency were the basis for access requests to minutes of the Scientific Committee supporting the Government and to scientific documentation held by public authorities which were decided by Italian Courts (*e.g.*, Regional Administrative Tribunal of Lazio, decision No. 8615/2020 of 22 July 2020). On the other hand, the regulation of freedom of information during the COVID-19 outbreak called into question the right to be *correctly* informed, and the possible negative consequences of harmful information considering both the role of independent authorities (Regional Administrative Tribunal of Rome decision on 9 November 2020, no. 12884; High Court of England and Wales, *Free Speech Union & Anor v Office of Communications (OFCOM [2020] EWHC 3390 (Admin)*, of 9 December 2020) and social media (District Court of Amsterdam decision No. C/13/689184 / KG ZA 20-783, of 13 October 2020). On the basis of existing case law, further litigation developments may be expected, especially with regard to the identification of subjects legally in charge of defining the boundaries of "credible information," and the criteria according to which those boundaries are established, taking into account information pluralism, freedom of expression, and the right to be informed, as well as the principles of transparency and proportionality.

7.5. Restrictions on Freedom of Movement and their Proportionality and Necessity in Light of Health Protection

Question 8 – Criteria for establishing the lawfulness of restrictions on freedom of movement: the role of the principle of proportionality and of the necessity of health protection

What are the criteria for evaluating the lawfulness of restrictions on freedom of movement adopted due to the COVID-19 crisis? What is the role of the principle of proportionality? On what sources of law did the Court rely on?

Insights from EU documents and the Regulation 2021/953 on the EU Digital COVID Certificate

In the European legal framework, freedom of movement is primarily protected by Article 21 TFEU and public health rules are dictated by Article 168 TFEU. In addition, Art. 29 of dir. 2004/38 provides for limitations on the freedom of movement that Member States can adopt for reasons of public health, which are also related to diseases with epidemic potential defined by the World Health Organization. Several well-known limitations were adopted in the context of the Covid-19 pandemic declared on March 11, 2020 by the WHO.

Within this legal framework, EU institutions addressed the question of the limitation on freedom of movement in several documents. In particular, the **principle of proportionality** was considered important within the assessment of scientific data in the lifting of restrictions. In the Common European Roadmap towards the lifting of COVID-19 containment measures, dated April 17, 2020, the Commission emphasized the importance of applying the principle of proportionality and provided three sets of criteria to be used to assess the lifting of restrictive measures: epidemiological criteria, the capacity of health systems, and adequate monitoring capacity. In addition, on October 13, 2020, the Council adopted Recommendation 2020/1475, for a coordinated approach to restrictions on freedom of movement in response to the pandemic, which was later amended by Recommendation 2021/119, dated February 1, 2021. The Recommendation aimed to facilitate the application of the principles of EU law, proportionality and non-discrimination in particular, and defined some common criteria for the purpose of assessing the introduction of restrictions on freedom of movement by Member States. These criteria were identified in recommendation 1475/2020 in the cumulative rate of COVID-19 cases recorded within a 14-day span, in the rate of positive tests, and in the rate of tests being carried out. On the basis of these criteria, the Council provided for mapping risk zones (green, orange, red, grey, to which the racc. 2021/119 added dark red) and outlined a system of restrictions that varied according to the classification of the zones, and which foresaw the possibility of more significant restrictions following rec. 2021/119.

Subsequently, in the Communication "A united front to beat COVID-19" dated January 19, 2021, the Commission went into the merits of some measures, stating that "border closures or blanket travel bans and suspension of flights, land transport, and water crossings are not justified, as more targeted measures have sufficient impact and cause less disruption."

In addition, it should be recalled how the Commission adopted a proposal in November 2020 for a regulation that strengthened the role of the European Centre for Disease Prevention and Control (ECDC). With respect to the role of this body, in the Communication "A common path to safe and sustained re-opening" of March 17, 2021, accompanying the proposal for a regulation, the ECDC was expected to be strongly involved, in particular, in the construction of evidence-based decision-making processes based on robust epidemiological indicators defined by the Commission as a "key to opening at the right time – with the virus sufficiently under control to allow for relaxation, and to avoid restrictions lasting longer than necessary."

In this vein, on June 14, 2021 the EU Parliament and the Council adopted Regulation (EU) 2021/953 2021 on a framework for the issuance, verification, and acceptance of interoperable COVID-19 vaccination, test, and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic. According to Art. 11 of the Regulation, entitled 'Restrictions to free movement and information exchange':

> "without prejudice to Member States' competence to impose restrictions on grounds of public health, where Member States accept vaccination certificates, test certificates indicating a negative result or certificates of recovery, they shall refrain from imposing additional restrictions to free movement, such as additional travel-related testing for SARS-CoV-2 infection or travel-related quarantine or self-isolation, unless they are **necessary and proportionate** for the purpose of safeguarding public health in response to the COVID-19 pandemic, also taking into account available scientific evidence, including epidemiological data published by the ECDC on the basis of Recommendation (EU) 2020/1475."

Insights from the application of the ECHR within national legal systems

The Belgian Constitutional Court, in its decision of June 10, 2021, No. 88/2021, decided a case concerning a request for the suspension and annulment of the Flemish Community decree establishing the obligation to self-isolate for 7 to 10 days for persons travelling in high-risk areas, who presented an increased risk of COVID-19 contamination, or who were informed that they presented an increased risk of COVID-19 contamination. The applicants argued that the measure constituted an unjustified deprivation of liberty in the sense of **Article 5 of the European Convention on Human Rights, protecting "Right to liberty and security."** The Court first recalled the conditions for suspension of the contested measure: (i) the plaintiff must invoke serious means; and (ii) the immediate execution of the contested measure must be likely to cause serious harm that is difficult to repair — these conditions being cumulative. The Court analysed the second condition and held that the claimants could not demonstrate that the contested decree was likely to cause them serious harm that was difficult to repair. The judge then considered that the contested measure should be considered a restriction on the freedom of movement in the sense of Article 2 of Protocol No. 4 to the European Convention on Human Rights and not a deprivation of liberty under Art. 5 of the European Convention on Human Rights. In qualifying the measure, the Court considered the context in which it was made, its nature, its duration, its effects, and the manner of its execution. All in all, the Court recognized the undoubtedly intrusive nature of the contested measure which imposed isolation for seven to ten days on people who had no or had not yet shown any symptoms of illness.

Insights from national case law

In this context, national Courts applied various criteria, relying on various legal bases, for evaluating the lawfulness of restrictions on freedom of movement adopted by States for facing the COVID-19 crisis.

With regard to European sources of law applied by national Courts, both EU law and the ECHR are to be considered. For example, the **High Court of Ireland**, in decision no. IEHC 461, of October 2, 2020 concerning the lawfulness of Government guidance on cross-border trips and 14-day quarantines, **referred to Citizenship Directive 2004/38/EC** and considered that the guidance was consistent with EU law, and that it did not represent a breach to the right to freedom of movement, as the Irish State was entitled to derogate from EU law rights on the grounds of public health.

Moreover, in several cases **Courts referred to the ECHR and the related ECtHR case law** (Austrian Constitutional Court, in decision-363/2020, of 14 July 2020; Constitutional Court of the Republic of Croatia, decision No. U-II-3170/2020 et al., 14 September 2020, concerning the obligation to wear a mask in public transport; the Administrative Court of the Republic of Slovenia in judgment no. I U 1201/2020-37, 18 December 2020). As an example, in **decision-363/2020, of 14 July 2020**, also relying on Art. 2, par. 1 of prot. No. 4 ECHR protecting freedom of movement, the **Austrian Constitutional Court** assessed the lawfulness of limitations on this freedom. The Court stated that freedom of movement is a fundamental right that may be limited, and that restrictions must be provided for by law and must be necessary in a democratic society, *inter alia*, in order to protect health. Furthermore, the Court stated that limitations on free movement of persons is lawful only if they are provided by law for the purpose of legitimate public interests and are suitable, necessary, and proportionate (interpreting proportionality in the narrower sense). Applying these criteria, the Court declared the restrictions adopted in the Austrian legislation to be lawful.

The ECHR was also recalled by the **Administrative Court of the Republic of Slovenia** in **judgment no. I U 1201/2020-37, 18 December 2020**, where the Court balanced the right to freedom of movement of the plaintiff, which contested the measure of the mandatory quarantine for persons who entered the country from states classified as "red zones" with other rights protected by the ECHR. In particular, the Court referred to health care, human dignity, physical integrity and protection of life in accordance with Article 2(1), Protocol 6 and 13 of the ECHR.

Within the **assessment of the lawfulness of restrictions** to freedom of movement, national Courts considered several criteria:

a) The Principle of Proportionality. In applying this principle, Courts considered several aspects:

i) The role of scientific evidence in assessing, with the proportionality test, the necessity of the measure

For example, in assessing the lawfulness of a provision establishing mandatory quarantines for persons entering a country from a state classified as a red-zone, **the Administrative Court of the Republic of Slovenia in judgment no. I U 1201/2020-37, 18 December 2020**[123] applied a proportionality test that was slightly different compared with other cases of strict judicial scrutiny not related to COVID-19

[123] The following description of this case is partially based on a case summary drafted by B. Zalar.

measures. In this particular case, the Court stated that in assessing the necessity of the restrictive measure related to COVID-19, an element to be considered is that administrative decisions must be based on law which must inevitably be supported by scientific or medical expertise. Nevertheless, the Court considered that in case of scientific uncertainty (as, for example, in late August 2020), the Government holds political and democratic responsibility for adopting health care policy. In Germany, **the Federal Constitutional Court, in decision of 13 - 1 BvR 1021/20 -, Rn. 1-13, of 13 May 2020** considered that in adopting restrictive measures there is margin for balancing fundamental rights. According to the Court, in the evaluation of this margin of discretion, the uncertain scientific basis on which governmental decisions had to be taken and the existence of a procedure aimed at reassessing the measures for adapting them to the changes of the epidemiological situation were of particular importance. In France, **the Council of State, in decision n°448029 of 7 January 2021,**[124] assessed an urgent request for the establishment of a derogation to the curfew in order to permit leaving one's home (from 8:00pm to 6:00am) to take part in individual outdoor sports activities or to go for walks with members of the same household, within a limit of one hour and a one-kilometre radius around the home. In that case, the Council of State, recalling the health situation on which the decree was based, considered that given the current context of the pandemic marked by a high level of contamination and the persistence of strong pressure on the health system, the prohibition did not constitute a serious and manifestly illegal infringement on the freedom to come and go.

Moreover, the French Council of State decided a case where the children of a resident of an EHPAD (residence for the dependent elderly) requested that the interim relief judge of the Council of State suspend the ban by the Ministry of Health on EHPAD residents leaving their residences. The **Council of State, in decision no. 449759 of 3 March 2021**, found that the total ban was **disproportionate**, as the majority of residents had been vaccinated and the vaccination had demonstrated its positive effects. Appropriate measures could thus be made on a case-by-case basis by the directors of the establishment.

Furthermore, in its **decision of 1 April 2021, no. 450956, the French Council of State** decided a case where a vaccinated person asked to suspend the execution of a decree prescribing lock down measures in 16 departments without carving out any exemptions for vaccinated people. Having assessed the proportionality of the disputed measures with regard to the information on the effects of the vaccines, the judge rejected the claim. In particular, in assessing the proportionality of the measure, the Council of State considered that:

- although the risk was low, vaccination did not completely eliminate the possibility that vaccinated people might be carriers of the virus;

- consequently, given the acceleration of the epidemic across the territory, it was uncertain whether the observance of social distancing by vaccinated people carrying the virus (although low in number) would be sufficient to limit its circulation and the risk for vulnerable people who had not yet been vaccinated.

[124] The description of this case is partially based on a case summary drafted by G. Halard and S. Fassiaux.

- the Scientific Council clarified that the real effect of vaccination on the circulation of the virus would only be achieved with a sufficient threshold of vaccination among the entire population (95% approximately).

On these bases, the Council affirmed that the lockdown for vaccinated people was deemed necessary and appropriate, and thus proportionate to the objective of protecting public health, given the situation.

ii) The existence of exceptions to the limits on the freedom of movement

The **Constitutional Court of Slovenia, in decision No. U-I-83/20, 27th August 2020**, reviewed the proportionality of the temporary prohibition on movement outside municipalities in the country: the Court considered that the benefit brought by the measures outweighed its interference with the freedom of movement, taking into account, *inter alia*, that the legislation provided some exceptions to the prohibition on movement which took into accounts the possible needs of the population.

iii) The temporary nature of the measure

For example, the Constitutional Court of Slovenia, in abovementioned decision No. U-I-83/20, 27th August 2020, when assessing proportionality, considered that the measures were temporary and were thus not meant to impose an unlimited restriction on personal liberty, since the measures were linked to the evolution of the pandemic. (See also the Federal Constitutional Court decision no. 1 BvR 755/20 of 7 April 2020 described in the following paragraph).

iv) Balancing of fundamental rights at stake

The **German Federal Constitutional Court, in decision no. 1 BvR 755/20 of 7 April 2020**[125] balanced different fundamental rights in assessing the request for an interim suspension of several measures restricting social activities and personal freedom in order to curb the spread of Covid-19. In particular, the Court admitted that the challenged measures considerably restricted the fundamental rights of people residing in Bavaria. However, the Court considered that suspension of the challenged measures would significantly increase the risk of contracting the virus, of many people falling ill, of hospitals being overburdened and, in the worst case, of people dying. Thus, the Court considered that legislation may provide a temporary restriction on people's freedom of movement and of gatherings, in order to enable the greatest possible protection of public health and life, to which the state was also obliged under the German Constitution. Ultimately, the Federal Constitutional Court declared that the challenged measures, in the way they had been implemented, were **proportional to the emergency situation and to the need for protection of people's health and life**. Restriction on people's other fundamental rights and freedoms were thus legitimate and the claim was rejected.

Furthermore, the **German Federal Constitutional Court, in decision 13 - 1 BvR 1021/20 -, Rn. 1-13, of 13 May 2020** assessed the lawfulness of restrictive measures indiscriminately directed at the whole population, including the low-risk group represented by younger people. The Court in this respect considered that the government's scope of intervention according to the Constitution is not limited to the protection of people's health and life solely through restrictions to their own freedom, but rather, it

[125] The following description of this case is partially based on a case summary drafted by H. Koehler.

might also restrict the freedom of presumably healthier and less vulnerable people in order to ensure to the more vulnerable group a certain degree of social participation and freedom, instead of completely depriving this group of its freedom.

Moreover, the **High Administrative Court of Mecklenburg-Vorpommern, in decision no. 2 KM 281/20, of 9 April 2020**, assessed the request for a suspension of the prohibition on day-excursions within the Land during the Easter holiday and applied the **proportionality test.** Accordingly, the challenged measure was considered to be both **necessary and suitable** to the aim of limiting the population's freedom of movement in order to limit the opportunities for infection during Easter holidays and thus protecting public health. **However, the Court asserted that the manner in which the measure was implemented made it disproportionate and unreasonable and caused an unjustified infringement of the other fundamental rights involved in the decision: freedom of movement and free development of personality.**

v) Justification of the measure

In decision no. 788/2021 of 3 June 2021, the Spanish Supreme Court considered that the restrictive health measures in question (nighttime limitation on free movement and the limitation on gatherings), despite a proper legal basis (Organic Law 3/1986), had not been sufficiently justified. The Court expressly stated that the measures challenged did not meet the proportionality test and explained that neither the regional government nor the regional Court had properly justified the need to adopt the measures concerned in light of the health situation of the Autonomous Community. Only general appeals to caution were provided which were not enough to justify the proportionality of the restrictive measure.

On the contrary, in its decision of **19 November 2021, 1 BvR 781/21 Rn. 1-306**, the **German Federal Constitutional Court** considered that the restrictions on contacts were adequate to the legislative objective of protecting human life and health from the dangers of COVID-19, as well as of preventing the healthcare system from being overwhelmed.

b) Necessity of the measure in light of the epidemiological situation.

As an example, in Germany the **High Administrative Court of Saxony, in decision no. 3 B 26/21 of 4 March 2021**[126] adopted this criterion in assessing the lawfulness of a local government ordinance prohibiting outdoor sports in an area exceeding a 15 km radius from the residential area and imposing a curfew from 10 p.m. to 6 a.m. The Court stated that no urgent necessity of generally applicable exit restrictions could be inferred from the motivation of the ordinance. More specifically, the Court observed that the 7-day incidence rate of Covid-19 infections for the entire territory of Saxony was 81.2 out of 100,000 inhabitants at the time of the decision, while the local government, when issuing the challenged measures, referred to an incidence rate from January of over 300 cases per 100,000 inhabitants. **Thus, according to the Court, the application of the ordinance to the entire territory of Saxony was no longer justified and therefore unreasonable, even if it provided for the possibility of derogation from some restrictions for the areas that were less affected**. The fact that these kinds of restrictions were part of the measures agreed between the Prime Minister of Saxony and the Federal Chancellor in

[126] The following description of this case is partially based on a case summary drafted by H. Koehler.

December 2020 no longer justified the alleged special necessity of the measures, given the significantly reduced incidence rates since that time. Given the high probability of a declaration of the invalidity of the measures under consideration, the Court concluded that the applicant's personal interest in the protection of her freedom of movement outweighed the public interest in (overly) guaranteeing people's health and lives.

To the contrary, **the French Council of State, in decision No. 445430, of 23 October 2020**, rejected a request to suspend an administrative decision imposing a curfew, stating that the spread of the virus in the territory had increased during the period in question, that the sanitary situation was worsening in nine cities in particular in the counties concerned, and that scientific data suggested that contamination occurred mostly in private areas.

Moreover, in decision no. 7 Ob 151/20m, E129443, of 23 September 2020 **the Austrian Supreme Court of Justice**[127] assessed the lawfulness of the restriction on the freedom of movement of an elderly person affected by severe dementia who refused to wear a mask and maintain social distance and who was suspected of being infected with Covid-19. The Court applied the proportionality principle in order to balance the fundamental rights involved in the decision and considered the measures (which were restricting the freedom of movement) **proportional to the necessity** of protecting the health of a group of vulnerable people.

c) Reasonableness of the measure

T**he Constitutional Court of Slovenia, in decision No. U-I-83/20, 27th August 2020**[128] referred to reasonableness as a criterion for assessing the lawfulness of a Decree on the Temporary Prohibition of Movement outside Municipalities. The Court also highlighted that the specific measures in question appeared to be a reasonable choice in order to pursue the aims of public health in the context of COVID-19 and were also based on the scientific knowledge of the moment.

Insights from the case law analysis

The Courts applied various criteria relying on various legal bases for evaluating the lawfulness of restrictions on freedom of movement adopted in order to confront the COVID-19 crisis, relying mostly on national legislation, but also on the ECHR (Austrian Constitutional Court, in decision-363/2020, of 14 July 2020; Constitutional Court of the Republic of Croatia, decision No. U-II-3170/2020 et al., 14 September 2020; Administrative Court of the Republic of Slovenia in judgment no. I U 1201/2020-37, 18 December 2020; Belgian Constitutional Court, decision of 10 June 2021, No. 88/2021), and more rarely on EU law (High Court of Ireland decision, no. IEHC 461, of 2 October 2020)

Within the **assessment of the lawfulness of restrictions** on freedom of movement, national Courts considered several criteria:

a) The principle of proportionality. In applying this principle, Courts considered several aspects: i) The role of scientific evidence in assessing, within the proportionality test, the necessity of the measure (Administrative Court of the Republic of Slovenia, judgment no. I U 1201/2020-37, 18 December 2020;

[127] The following description of this case is partially based on a case summary drafted by H. Koehler.
[128] The following description of this case is partially based on a case summary drafted by G. Sabatino.

German Federal Constitutional Court, in its decision of 13 - 1 BvR 1021/20 -, Rn. 1-13, of 13 May 2020; French Council of State decision of 7 January 2021, n°448029 and decision no. 449759 of 3 March 2021; French Council of State, decision of 1 April 2021, no. 450956); ii) The existence of exceptions to the limits imposed on the freedom of movement (Constitutional Court of Slovenia, in its decision No. U-I-83/20, 27th August 2020); iii) The temporary nature of the measure (Constitutional Court of Slovenia, decision No. U-I-83/20, 27th August 2020, German Federal Constitutional Court, decision no. 1 BvR 755/20, of 7 April 2020); iv) the balancing of fundamental rights at stake (German Federal Constitutional Court, in its decision no. 1 BvR 755/20, of 7 April 2020 and decision of 13 - 1 BvR 1021/20 -, Rn. 1-13, of 13 May 2020; German High Administrative Court of Mecklenburg-Vorpommern, in decision no. 2 KM 281/20, of 9 April 2020; v) the justifications at the bases of the measure (Spanish Supreme Court decision of 3 June 2021, no. 788/2021).

b) Necessity of the measure in light of the epidemiological situation (German High Administrative Court of Saxony, in its decision of 4 March 2021, no. 3 B 26/21; French Council of State, in its decision No. 445430, of 23 October 2020; the Austrian Supreme Court of Justice)

c) Reasonableness of the measure (Constitutional Court of Slovenia, in its decision No. U-I-83/20, 27th August 2020).

In their conclusions, in a large number of cases, Courts stated that the protection of health justified restrictions on the freedom of movement (*e.g.*, German Federal Constitutional Court, in decision 13 - 1 BvR 1021/20 -, Rn. 1-13, of 13 May 2020; Constitutional Court of the Republic of Croatia, decision No. U-II-3170/2020 et al., 14 September 2020; French Council of State, in decision No. 445430, of 23 October 2020; Austrian Supreme Court of Justice, decision no. 7 Ob 151/20m, E129443, of 23 September 2020). In other cases, Courts considered that the limitations on freedom of movement were not justified, for example, for a lack of urgent necessity in the measure (German High Administrative Court of Saxony, in its decision of 4 March 2021, no. 3 B 26/21) or because the measures did not comply with the principle of proportionality (High Administrative Court of Mecklenburg-Vorpommern, in decision no. 2 KM 281/20, of 9 April 2020).

7.6. Right to Health and Freedom to Conduct a Business: the Role of the Principle of Proportionality

Within the EU legal framework the relationship between the right to health and the right to conduct a business, enshrined in Article 16 of the Charter of Fundamental Rights of the EU, was addressed as it emerged in the context of food safety (see Chapter 3) and consumer protection (see Chapter 2), as well as in other cases (e.g., CJEU *Érsekcsanádi*, C-56/13). In the context of the pandemic, national courts assessed government measures restricting the freedom to conduct business aimed at coping with the pandemic by using various criteria such as the essential character of economic activities at stake and the proportionality of restrictions.

Question 9 - The right to conduct a business and health protection in light of the principle of proportionality

How to balance the need to protect the health of individuals with the right to conduct a business? Is it legitimate and proportionate to provide for the closure of some business activities while others could

continue to exercise their business under some limitations? How is the principle of proportionality applied? (e.g., on the closing of nightclubs)

NB: in general, this section concerns economic activities that do not satisfy primary needs of the population.

Insights from national case law

The selection of businesses to be closed and the definition of the related criteria are particularly important issues **where the principle of proportionality plays a strong role in assessing the lawfulness of restrictions that limit the freedom to conduct a business** as MS case law shows. As an example of such importance, the **Belgian Council of State in its decision of November 13, 2020, No. 248918**, relying on Constitutional Court case-law, affirmed that the freedom to conduct a business was not absolute and that a restriction on that freedom would be found to be an infringement if such a measure were **disproportionate** to the objective pursued. In that specific case, the judge declared that *prima facie* there was no violation of that freedom. In another case, where the claimants asked to suspend a decision according to which the inside areas of establishments belonging to the event and cultural sector were closed to combat the spread of COVID-19 the Belgian Council of State, in its decision of 7 January 2022, no 252.586, rejected the claim. The Council affirmed that the principles of good administration and the principle of proportionality were not breached as the measure was necessary to stop the spread of COVID-19.

Nevertheless, the proportionality test and balancing techniques more generally were not the only legal instruments adopted. In some cases, Courts referred to the boundaries of economic rights such as the freedom to conduct a business. For example, the **Italian Council of State, in its decree of April 27, 2020, No. 2294**, relating to the lawfulness of a municipal order which restricted the sale of food and beverages through stores with vending machines, affirmed that the municipal ordinance did not infringe on the right to conduct a business, since such a freedom did not include the ability to conduct business when it is in conflict with security, personal freedom, and human dignity. Accordingly, the judge affirmed that the temporary prohibition of automatic food and beverage distribution was constitutional when this was necessary to fight against a health epidemic.

However, when Courts assess the proportionality of the provisions which limited the freedom to conduct a business, judges considered several elements, among them the following are of particular interest:

i) In some cases, the proportionality principle was applied considering **the necessity of closure, due to the impossibility of protecting public health through safety rules while maintaining normal business activity** (e.g., social distancing, wearing of face masks etc.). For example, in a French case concerning the opening of discotheques and dance rooms, the **Council of State, in decision Nos. 441449, 441552, 441771, of 13 July 2020**, estimated that the closure of these places was not a disproportionate measure within the context of the health policy and justified the closure of the premises, taking into account the nature of the physical activity (dancing) and the difficulty of ensuring social distancing and mask wearing was respected. Accordingly, the judge estimated that the harm these measures caused to the freedom of doing business, commerce, and industry was clearly not illegal. Moreover, the **French Council of State**, in its **decision of 16 October 2020, n°445102** concerning the

closure of sports halls, adopted similar reasoning based on the necessity of closure, due to the impossibility of protecting public health with safety rules.

ii) The assessment of scientific data within the application of the proportionality principle. In the abovementioned French decision of the **Council of State, No. 445102 of October 16, 2020**, the judge **relied on scientific data,** citing the High Council for Public Health in warning that physical activities "contribute to a high risk of respiratory transmission through sustained ventilation (cycling, jogging)" and that "during physical activities, droplet emissions are particularly high and at risk of transmission." Moreover, the judge affirmed that the available scientific data showed that, despite the health protocols in place, sports halls were among the places where the virus was actively spread. The importance of **scientific data** was confirmed in decisions from other Member States, such as the decision of the **Austrian Constitutional Court**, **n. V405/2020 and V429/2020 of October 1, 2020** concerning governmental bans on entry to any kind of restaurant-establishment. In that specific case, the Court held such bans to be unlawful due to a lack of sufficient documentation as the basis for the decision. Moreover, lack of scientific evidence was a key argument in the decision of the **Austrian Constitutional Court V411/2020, V395/2020 et.al., V 396/2020 et.al. July 14, 2020**, where the Court stated that it was not apparent from the legislative measure which circumstances concerning the possible developments of Covid-19 had led the administration to set the conditions for entry to trading establishments (with regard to the obligation to wear masks and maintain a distance of at least 1 meter from others in public places see also: Constitutional Court, V463-467/2020, 1 October 2020).

iii) **The necessity of the measure for preserving the functioning of the healthcare system**. This was an argument adopted, for example, by the German **Federal Constitutional Court in its** Decision of the 3rd Chamber of the First Senate of November 11, 2020, concerning the closure of cinemas and restaurants within the Region of Bavaria.

Furthermore, the advice of the **Italian Council of State, no. 850/21, of April 28, 2021**, was of particular interest, as it applied both the principles of proportionality and precaution. The Council, assessing the lawfulness of governmental measures establishing the closure of restaurants and bars from 6:00 PM to 5:00 AM, considered that these measures were not illogical or irrational but adequately based on sufficient technical and scientific investigation. Furthermore, the Council of State indicated that they were both proportionate and reasonable according to the **precautionary principle** and offered the best protection of public health. In this respect, the Council, relying also on CJEU case law (CJEU, *Pesce*, 9 June 2016, C-78/2016,) stated that the **precautionary principle must be reconciled with that of proportionality**. However, the Council affirmed that **the test of proportionality and the strict necessity of limiting measures must be compared with the level of risk - and therefore to the proportional level of protection deemed necessary - caused by the extraordinary virulence and diffusivity of the pandemic**. The Council stated that the prevalence of the precautionary principle was therefore reasonably motivated in relation to the context of a health emergency characterized by contagion from a virus for which the scientific community had few certainties. Accordingly, the Council of State considered that the action of the public authorities can and must result in prevention even before the consolidation of scientific knowledge to protect the primary value of health. The precautionary principle was also applied by the **German Federal Constitutional Court, in its decision of May 20, 2021, No. 1 BvR 968/21**. In this decision the Court applied the balancing test and the **proportionality principle** when

considering that restrictions and prohibition on conducting a business were limited in time (the time necessary for the rate of infection to drop. However, the main reasoning of the sentence was more focused on the **precautionary principle** and the obligation of the State to protect the health and physical integrity of its inhabitants.

Moreover, a group of cases concerned the **role of proportionality** in assessing the justification of **legislation which provided for different restrictions on the freedom to conduct a business with regard to several activities**. Two examples were decision n. **V392/2020, October 1, 2020 of the Austrian Constitutional Court**, and the abovementioned decision of the **Latvian Constitutional Court, No. 2020-26-0106, of December 11, 2020**.

Decision n. V392/2020, October 1, 2020 of the Austrian Constitutional Court[129] concerned a ban on entering business premises with the exception (inter alia) of gas-stations and 'attached' car-wash-plants (the ban comprised stand-alone car-wash-plants not attached to a gas-station). The Court stated that it was not clear which circumstances led the administration to differentiate the opening regulation, considering that this regulation intervened intensively in the sphere of the fundamental rights of car-wash-plant entrepreneurs, which were still subject to a ban on entry. The Court concluded that the ban, for public health reasons, on entry to stand-alone car-wash-plants and car-wash-plants not attached to a gas station violated the **principle of equality**.

A decision of the **Latvian Constitutional Court, No. 2020-26-0106, of 11 December 2020**[130] instead concerned legislation related to COVID-19 which provided that Lotteries and Gambling Supervisory Inspection was to suspend all licences for operating gambling both in physical locations and in online environments for the period in which the legislation remained in force. The Constitutional Court held that restrictions on face-to-face gambling set during the COVID-19 emergency situation complied with the Constitution, but restrictions on interactive gambling (which was not face to face) violated the freedom to conduct a business. In particular, the Court pointed out with regard to the first measure that the risk of contagion of visitors to gambling establishments justified the restrictive measure. With regard to interactive gambling, the Court considered that the prohibition on online gambling for every person, regardless of their psychological or financial situation was not justifiable for pursuing the legitimate goals of protecting people from wasteful spending and deterioration of their financial situation, as well as to protect human health in the context of interactive gambling. In its assessment of the restrictions, the Constitutional Court applied the principles of proportionality, necessity, and reasonableness.

Furthermore, the Courts considered **the existence of measures of economic restoration or compensation for the consequences of the measure restricting the freedom to conduct a business**. In **Italy**, the Regional Administrative Tribunal of Rome in decision no. 5408, of August 19, 2020, rejecting a request for the interim suspension of a government measure providing for the closure of several economic activities, considered that the measure in question referred to the need to immediately open a round table between government actors and trade associations in order to identify national economic support measures for the sector affected by the restrictions. In the same vein, the **Italian Council of State, in its decree of May 11, 2021 no. 2493**, assessing a request for the interim suspension of a governmental measure prohibiting catering services for private facilities, stated that in

[129] The following description of this case is partially based on a case summary drafted by H. Thoma.

[130] The following description of this case is partially based on a case summary drafted by Līga Biksiniece-Martinova, Marita Miķelsone.

the presence of enormous damages suffered by multiple economic sectors during the pandemic, **the damage to the catering sector, limited to those forms carried out at private facilities** (e.g., a villa or a rented farmhouse), **did not assume the character of irreparability, since it was economic damage.** Accordingly, the Council of State rejected the claim.

Furthermore, in the decision of the abovementioned **Latvian** Constitutional Court, No. 2020-26-0106, of December 11, 2020, concerning the prohibition on gambling, in assessing the lawfulness of the restrictive provision the Court considered the existence of compensation and of mechanisms aimed at mitigating the consequences of the restrictions imposed in an emergency. In **France**, the Council of State, in its ordinance of April 1, 2020 n. 439762 in a case concerning the closure of food markets, considered the existence of support measures, in particular the solidarity fund for companies particularly affected by the economic, financial, and social consequences of the spread of the Covid-19 epidemic.

Question 10 – The regulation of economic activities related to the satisfaction of primary needs and the exercise of fundamental rights during the emergency

How should the proportionality of legislative and regulatory measures that provide for the closing or for a scheduled opening of economic activities that satisfy primary needs (e.g. opening hours and days of markets and supermarkets) and fundamental rights (e.g. bookshops) be assessed?

In several Member States, one criterion for selecting which activities should be closed and which could remain open was the essential nature of those activities for the satisfaction of basic needs (access to food) or fundamental rights (e.g. freedom of information). The application of this criterion sometimes gave rise to litigation, where the principle of proportionality as well as other balancing techniques were applied.

For example, **in France,** at the beginning of the pandemic, the closure of markets was challenged and later the opening of bookshops after the Government categorized them as "non-essential businesses" (Government decree of October 29).[131] In particular, with regard to the closure of markets, the Council of State, in its ordinance of April 1, 2020 n. 439762, considered that in the state of a health emergency, it is the responsibility of the various competent authorities, in particular the Prime Minister, to take all measures likely to prevent or limit the effects of the epidemic in order to safeguard the health of the population. According to the Council of State, **these measures, which may limit the exercise of fundamental rights and freedoms such as the freedom to conduct a business, must be necessary, appropriate, and proportionate to the objective of safeguarding public health which they pursue.** The Council of State, in judging the lawfulness of the measure closing food markets, considered: i) the impossibility of respecting health protection measures due to a lack of organization; ii) the possibility of exceptions in case the opening of food markets served to satisfy a supply need of the population and that the organization and the controls provided allowed the rules of health security to be respected in order to ensure the protection of the population and workers. The Council of State concluded that the provisions in dispute provided a fair balance between the need to protect public health and the satisfaction of the population's need for food supply. **Therefore, according to the Council of State,**

[131] The following description of this case is partially based on a case summary drafted by Līga Biksiniece-Martinova, Marita Miķelsone.

the measures were strictly proportionate to the health risks involved and appropriate to the circumstances of time and place.

As for the **closure of bookshops**, several applicants sought a decision from the French Council of State. The judge, in decision nn. 445883, 445886, 445899, of November 13, 2020,[132] pointed out that bookshops contributed to the effective exercise of freedom of speech and to the free communication of ideas and opinions, and that books – although not first necessity goods like food products – have an essential character which must be taken into consideration by the government in the context of confinement or deconfinement measures. The judge observed that the decision to close bookshops and other businesses was in accordance **with the necessity**, in the health situation, to limit interactions between people as much as possible which was the principal occasion for the virus to spread. The Council of State also indicated that bookshops were allowed to stay open for delivery or pick up and collect activities (more than a third of independent libraries already offered online shopping possibilities), **and that they also benefited from general and complementary financial support measures.** Finally, the judge noted that book selling in supermarkets was forbidden and that the administration had committed to giving a particular attention to bookshops during confinement measures as well as to recurrent evaluation. **On these grounds, the Council of State estimated that the closure of bookshops to the public did not seriously and clearly harm the freedom to conduct a business, free competition, the principle of equality, or the right to non-discrimination.**

[132] The following description of this case is partially based on a case summary drafted by B. Favarque Cosson.

Question 11 – Compensation and other remedies: the role of the principle of proportionality

Should the economic consequences arising from restrictions on the right of economic initiative be compensated or restored in some other way? What is the role of the principle of proportionality in choosing the remedy and in determining the amount?

In order to face the economic consequences of legislation restricting business activities, several Member States adopted indemnity and support measures. In some cases, as seen in question 4, the existence of such measures affected the assessment of the proportionality of the restrictions.

As for national law, the decision of the **Austrian Constitutional Court, of July 14, 2020, no. G202/2020**[133] concerned compensation in cases of lawful restriction to the freedom to conduct a business. In this decision, the Court affirmed that **providing compensation** in relation to restrictions on business activities in the context of the COVID-19 emergency **was not mandatory**. Accordingly, the Court affirmed that **there was not a disproportionate interference with the fundamental right to the integrity of property** caused by the non-compensation of property. In particular, the Court considered that the legislature was not obliged to provide compensation but must always consider whether the restriction of ownership in the specific case complies with the **principle of proportionality**. In that regard, relying on previous case law, the Court stated that compensation may be required in cases where an individual or group of persons is to be qualified as a factually unjustified 'special victim.' Furthermore, according to the Constitutional Court, serious, disproportionate restrictions on ownership in specific individual cases can also create liability for compensation. In relation to the present case, the Court considered that the legislature did not impose prohibition of entry as an isolated measure, but embedded it in a "package" of measures and rescues, which functionally aimed at mitigating the economic impact of the prohibition on companies affected by it or the consequences of the COVID- 19 pandemic in general.

Another example is **decision no. IV U 1195/20, of September 2, 2020, issued by the District Court in Olsztyn (Poland)**[134] concerning the conditions for access to national compensation measures provided in case of closures of economic activity. The Polish legislation established, as a condition for access to the compensation measure, a threshold of revenues in the months preceding the request. In that case, the Court upheld the appeal basing the criteria for access to compensation on the teleological interpretation of the legislative measure setting. Accordingly, the Court stated that the appellant was entitled to obtain compensation related to the closure of her activity even if she did not meet all the conditions literally specified in Article 15 of the Covid Act.

With regard to **selection of remedies**, in Italy, the **Regional Administrative Tribunal of Rome in decision no. 5408, of August 19, 2020**, rejected a request for an interim suspension of a government measure which closed several economic activities and held that the nature of the damages alleged in the complaint in principle permitted subsequent monetary compensation in the event that a judgment was favourable to the plaintiff.

[133] The following description of this case is partially based on a case summary drafted by M. Thoma.
[134] The following description of this case is partially based on a case summary drafted by Dominik Dworniczak.

Insights from the case law analysis

The case law concerning freedom to conduct a business demonstrates the importance of the principle of proportionality in assessing restrictions to that freedom provided for by Member States.

In particular, **Courts evaluated the proportionality and lawfulness of the selection of businesses to be closed and the definition of related criteria** (e.g., Belgian Council of State in its decision of November 13, 2020, No. 248918).

However, when Courts assess the **proportionality** of the provisions which limit the freedom to conduct a business, judges considered several elements; among them the following are of particular interest: i) **the necessity of closure** due to the impossibility of protecting public health with safety rules while maintaining the activity open for business (e.g., French Council of State, in decision Nos. 441449, 441552, 441771, of 13 July 2020, decision of 16 October 2020, n°445102); ii) **the assessment of scientific data** (French Council of State, decision no. 445102 of 16 October 2020, Austrian Constitutional Court, n. V405/2020 and V429/2020 of 1 October 2020; decision no. V411/2020, V395/2020 et.al., V 396/2020 et.al. 14 July 2020, no. V463-467/2020, 1 October 2020); iii) **the necessity of the measure to preserve the functioning of the healthcare system** (German Federal Const. Court, 11 November 2020).

Moreover, a group of cases concerned the **role of proportionality jointly with equality** (Austrian Constitutional Court, V392/2020, 1 October 2020) or with necessity and reasonableness (Latvian Constitutional Court, decision No. 2020-26-0106, of 11 December 2020) in assessing the justification of **legislation which provided different restrictions on the freedom to conduct a business with regard to different activities.**

However, the proportionality test and balancing techniques more generally were not the only legal instruments adopted. In some cases, Courts referred to the boundaries of economic rights such as the freedom to conduct a business. This was the case of the Italian Council of State which, in its decree of April 27, 2020, No. 2294, resolved a case interpreting Art. 41 of the Italian Constitution, according to which private economic enterprise is free and may not be carried out against the common good or in such a manner that could damage safety, liberty, and human dignity.

Furthermore, in several Member States one element considered for selecting which activities should be closed and which should remain open was the essential nature of those activities for the satisfaction of basic needs (access to food; French Council of State, ordinance of 1° April 2020 n. 439762) or fundamental rights (e.g., freedom of information; French Council of State decision nn. 445883, 445886, 445899, of 13 November 2020). The application of this criterion sometimes gave rise to litigation, where the principle of proportionality as well as other balancing techniques were applied.

Moreover, Courts also considered **the existence of measures of economic restoration or compensation for the consequences of measures restricting the freedom to conduct a business** as an element for assessing the lawfulness of restrictions (Italy, Regional Administrative Tribunal of Rome, decision no. 5408, of 19 August 2020; **Latvian** Constitutional Court, No. 2020-26-0106, of 11 December 2020; **French** Council of State, decision of 1 April 2020 n. 439762). Indeed, the possibility of

ex-post compensation was considered in balancing the fundamental right to health, strengthening the latter.

With regard to **compensation or other remedies concerning the economic consequences arising from restrictions**, the **Austrian Constitutional Court in decision no. G202/2020 of July 14, 2020** considered compensation in case of lawful restrictions to the freedom to conduct a business. In this decision, the Court affirmed that **providing compensation** in relation to the restrictions to business activities provided in the context of the COVID-19 emergency **was not mandatory**, but that limitation on the right to property should be proportionate. With regard to the **selection of remedies**, in Italy, the **Regional Administrative Tribunal of Rome in decision no. 5408, of August 19, 2020**, rejected a request for an interim suspension of a government measure closing several economic activities and held that the nature of the damages alleged in the complaint in principle permitted their subsequent monetary compensation in the event that a judgment was favourable to the plaintiff.

With regard to the outcomes of Courts' reasoning, in a large number of cases Courts affirmed that health protection justified limitations on the freedom to conduct a business (*e.g.*, Belgian Council of State, decision of 13 November 2020, No. 248918; French Council of State, 16 October 2020, n°445102; French Council of State, decision Nos. 441449, 441552, 441771, of 13 July 2020). In some cases where the claim concerned the lawfulness of restrictions in comparison with other economic activity which was not subject to such restrictions, Courts considered the restrictions to be unlawful, as they violated the principle of equality (Austrian Constitutional Court, of 14 July 2020, no. G202/2020) or the principle of proportionality (Austrian Constitutional Court decision n. V392/2020, 1 October 2020).

7.7. Data and Health Protection in Light of the Principles of Proportionality, of Data Minimization, and of Art. 8 CFR

Question 12 – Data processed for purposes related to COVID-19

What is the impact of the principles of proportionality, data minimisation, and the right to data protection (Art. 8 CFR) on the assessment concerning the lawfulness of personal data processing for purposes related to COVID-19, including scientific research?

Suggestions from EU data protection authorities: examples of contact tracing and of Regulation 2019/953 on the EU Digital COVID certificate

EU institutions addressed the issues related to the balancing between public health and data protection in cases of data processing related to COVID-19 on several occasions (e.g. *Commission Recommendation (EU) 2020/518 of 8 April 2020 on a common Union toolbox for the use of technology and data to combat and exit from the COVID-19 crisis, in particular concerning mobile applications and the use of anonymised mobility data; Communication from the Commission Guidance on Apps supporting the fight against the COVID-19 pandemic in relation to data protection, 2020/C 124 I/01*).

For the purposes of this casebook the documents issued by EU Data protection authorities are of particular interest. These authorities analysed several hypotheses where personal data was processed for purposes related to the COVID-19 crisis, such as contact tracing, for scientific research purposes, and processing within the context of Regulation 2021/953 on the EU Digital COVID Certificate.

With regard to contact tracing, and more specifically contact tracing apps, in guidelines 4/2020 on the use of location data and contact tracing tools in the context of the COVID-19 outbreak, the **European Data Protection Board (EDPB) reiterated that the general principles of effectiveness, necessity, and proportionality must guide any measure adopted by Member States or EU institutions that involve processing of personal data to fight COVID-19** (See also EDPB, *Statement on the data protection impact of the interoperability of contact tracing apps*, adopted on June 16, 2020 § 22). For example, with regard to contact tracing applications, the EDPB affirmed that according to the principle of purpose limitation, the purposes must be specific enough to exclude further processing for purposes unrelated to the management of the COVID- 19 health crisis (e.g., commercial or law enforcement purposes), and that once the objective has been clearly defined, it will be necessary to ensure that the use of **personal data is adequate, necessary, and proportionate**. Furthermore, with regard to data retention, the EDPB stated "*the current health crisis should not be used as an opportunity to establish disproportionate data retention mandates*" and therefore that storage limitation should consider true needs and medical relevance (this may include epidemiology-motivated considerations like incubation period, etc.). Furthermore, the EDPB stated that personal data should be retained only for the duration of the COVID-19 crisis (afterwards, as a general rule, all personal data should be erased or anonymized). The EDPB stated that in accordance with the application of data minimisation principles within contact tracing apps and data protection **by design**, the data processed by centralized server should be limited to a minimum.

Moreover, the Commission implementing decision (EU) 2020/1023 of 15 July 2020 amending Implementing Decision (EU) 2019/1765 with regard to the cross-border exchange of data between national contact tracing and warning mobile applications for combatting the COVID-19 pandemic, introduced Art. 7a, titled "Cross-border exchange of data between national contact tracing and warning mobile applications through the federation gateway," according to which:

> 1. Where personal data is exchanged through the federation gateway, the processing shall be limited to the purposes of facilitating the interoperability of national contact tracing and warning mobile applications within the federation gateway and the continuity of contact tracing in a cross-border context. (…)
>
> 6. The effectiveness of the technical and organizational measures for ensuring the security of processing of personal data within the federation gateway shall be regularly tested, assessed, and evaluated by the Commission and by the national authorities authorized to access the federation gateway. (…)"

The **data minimisation principle** was mentioned by the EDPB in its *Guidelines 03/2020 on the processing of data concerning health for the purpose of scientific research in the context of the COVID-19 outbreak*, adopted on April 21, 2020, where the authority stated that in scientific research, data minimisation can be achieved through the requirement of specifying research questions and assessing the type and amount of data necessary to properly answer such questions (§46). In these guidelines the EDPB also referred to the principle of **proportionality** with regard to the definition of the data storage period for example (§ 47).

With regard to data processing related to the use of the EU Digital COVID certificate and to the managing of cross-border travellers, the EDPB *Statement on the processing of personal data in the context of reopening borders following the COVID-19 outbreak*, adopted on June 16, 2020, and the EDPB-EDPS *Joint Opinion 04/2021 on the Proposal for a Regulation of the European Parliament and of the Council on a framework for the issuance, verification, and acceptance of interoperable certificates on vaccination, testing, and recovery*, adopted on

March 31, 2021 are of particular interest. In the first document, the EDPB emphasised that personal data processing for dealing with the pandemic must be **necessary and proportionate** (and therefore that measures should be based on scientific evidence) and that the principle of **data minimisation** should be respected. Moreover, in their recent joint opinion 4/2021 the EDPB and the EDPS, recalling **Art. 52 CFR** and the principle of **proportionality,** stated that the regulation of the EU Digital COVID Certificate should achieve a fair balance between the objectives of general interest pursued by the EU Digital COVID Certificate and the individual interest in self-determination, as well as respect for her/his fundamental rights to privacy, data protection, and non-discrimination, as well as other fundamental freedoms. Moreover, the two authorities, assessing the possibility of uses of the EU Digital COVID Certificate beyond what was foreseen in the proposal presented by the Commission, stated that Member States must respect Articles 7 and 8 CFR, and they must provide regulation in compliance with the GDPR, and that therefore they must comply **with the principles of effectiveness, necessity, and proportionality** (§24).

Suggestions from national case law and national DPA decisions

With regard to contact tracing, in decision no. **2020/800 of May 21, 2020** the **French Constitutional Council** assessed the Constitutional legitimacy of several provisions concerning the information system designed for contact tracing of persons affected by Covid-19. After recalling previous case law, the Constitutional Council stated for the first time that when personal data of a medical nature is processed, particular vigilance must be observed in processing operations and the determination of their terms. **In order to assess the adequacy and proportionality of contested provisions with regard to the objective pursued**, the Council considered, *inter alia*, that i) the collection, processing, and sharing of the aforementioned personal data could only be implemented to the extent strictly necessary for four specific purposes; ii) the scope of personal health data that may be collected, processed, and shared was restricted by the legislature to data relating to the virological or serological status of individuals with regard to Covid-19 or to clinical diagnostic and medical imaging evidence specified by decree in the Council of State after consulting the High Council for Public Health.

With regard to data processing for purposes related to COVID-19, the **French Council of State, in decision no. 440916 of 19 June 2020,**[135] addressed several issues concerning the collection and further processing of personal data within the "Health Data Hub," in connection with the Minister of Health's authorization that the platform collect and manage pseudonymised health data to conduct projects of public interest in relation to the Covid-19 pandemic and only during the state of the health emergency. The Council of State affirmed that the collection of data as specified by the decree **followed legitimate objectives and was proportionate to reaching them**, considering that: i) the Minister of Health authorised the platform to collect and manage pseudonymised **health data to carry out projects of public interest in relation to the Covid-19 pandemic and only during the state of the health emergency**; ii) **use of the platform must be justified by the emergency of the project and the absence of alternative solutions relevant for such a project to be conducted in due time**; iii) projects were, when relevant, submitted to authorization by the French data protection authority (*CNIL*). The Council of State also addressed the issue of **platform security**, considering that the latter was

[135] The following description of this case is partially based on a case summary drafted by B. Fauvarque-Cosson

homologated to the current reference system. It was submitted to an external inspection by an enterprise in November 2019 and will be audited again by a service provider qualified by the National agency for the security of information systems. However, the judge highlighted that the **French data protection authority**, when consulted on the project of the decree in question, had no time to check whether the concrete measures adopted by the platform were sufficient. As a consequence, the judge ordered the platform to communicate all the elements concerning the processes of pseudonymisation used to the CNIL, in less than five days, for the authority to assess them.

With regard to the application of **the principle of proportionality,** two Spanish decisions are of particular interest. First, in **decision no. 1103 of August 28, 2021 the Spanish Supreme Court** decided a case concerning the authorization or ratification of health measures restrictive of fundamental rights, which introduced the requirement to show the EU digital Covid-19 certificate or a negative antigen or PCR test taken within the last 72 hours before entering catering establishments or nightclubs with music (Order 405/2021). The Supreme Court addressed the proportionality of the concerned measure which essentially restricted the right to privacy (Art.18 SC). After reviewing the proportionality test applied by the Regional Court, it stated that the limitation provided for was neither an adequate measure for avoiding contagion nor necessary considering its extension and intensity. Accordingly, the measure was not ratified. Second, in **decision No. 1412/2021 of December 1, 2021 the Spanish Administrative Chamber of the Supreme Court**, upheld a cassation appeal lodged by the Basque Country government against an order of the High Court of the Basque Country which did not ratify the need to display a Covid certificate for entering certain leisure establishments in the region due to a lack of proportionality. The Supreme Court, after examining the legal basis and the proportionality of the health measure concerned, considered that it did not infringe upon the right to privacy nor the right to equality, and thus proceeded to ratify it. The Supreme Court first explained that the relative ebb of the pandemic at that moment and reduced hospital occupation did not justify a lack of health measures aimed at avoiding such critical moments. Moreover, the high number of vaccinated persons was still not preventing the spread of the virus and there was still a large percentage of unvaccinated people, which facilitated its further spread. Furthermore, the Court explained that it was also reasonable to impose the measure across the entire Autonomous Community. Contrary to what occurred in September, there was a significant increase in contagion, which was particularly noteworthy in the Basque Country, and the Covid certificate was also being required in other parts of Spain and abroad.

In the same vein, the **French Council of State, in decision no. 453505, of July 6, 2021**, decided a case where an association defending the fundamental right to data protection and privacy requested suspension of the "health pass" device (QR Code requiring the processing of data related to marital status and health) introduced by Decree of June 7, 2021, alleging that it was a serious and manifestly illegal infringement of the right to privacy and the right to protection of personal data. The judge rejected the request, considering the data necessary for the effectiveness of the system, the Government's choice to implement such a system, and the objective of protecting public health. In applying the data minimization principle, the judge utilised a proportionality test, considering the strict necessity within the framework of the "health pass" system. The principle of proportionality was applied by the **French Constitutional Court in its decision no. 2022-83521, of 21 January 2022,** where the Court rejected the claims against the provision establishing mandatory certificate of vaccination for entering different kinds of places.

Furthermore, in relation to the application of the principle of proportionality, the **Norwegian DPA of August 17, 2020 concerning a contact-tracing app** was of particular interest. The Authority considered that the app collected large amounts of personal data about the people using it, including continuous registration of movements and information about users' contact with others, for several purposes related to COVID-19. In its decision, the Norwegian Data Protection Authority temporarily banned the processing of personal data using the contact tracing mobile application, affirming that the **app cannot be considered a proportionate intervention on users' fundamental right to data protection**. The DPA considered that: i) the Norwegian Institute of Public Health (NIPH) did not document the **benefit of the app** and considering the technical solutions chosen, the low level of adoption (approx. 14% of the population aged 16 or above), and the spread of the infection in the population; ii) **the lack of evidence by the NIPH on the necessity of using location data** from GPS when contact tracing, which the DPA found to be in conflict with the principle of **data minimization**; iii) the fact that users did not have the option of choosing to share personal data for just one or several of the purposes (the purposes must be separated).

Moreover, the **French Constitutional Council, in its decision of May 31, 2021, No. 2021-819**, carried out a constitutional review of Act n° 2021-689, May 31, 2021, on the management of the health crisis, which introduced measures for dealing with Covid-19 concerning the collection of health data.

The Council rejected the claim, stating that the right to family life had not been violated. The decision was based on the following arguments: (I) the aim of the measure was none other than reinforcing the fight against Covid-19 in the long term, (II) the data collected could only be used for certain purposes provided for by law (III) they could not be used for products or medication marketing/promotion. Second, it underlined how the national health data system could n ot omit personal information (names, surnames, addresses or ID card numbers…), which should also include phone and email data. Third, access to the health data collected in the national system should be made through a process instituted by the French data protection authority, which entails certain guarantees. Last, people whose health data was collected receive individual information in that regard.

Question 13 – Enforcement of Health security rules concerning COVID-19 and data protection

What is the role of the principles of proportionality, effectiveness, and data minimization in defining the criteria for evaluating the lawfulness of data processing aimed at ensuring the enforcement of health security rules established for dealing with the COVID-19 pandemic?

The case law of Member States on this issue addressed cases where data was processed by public and private entities.

With regard to cases in which **public entities were responsible for processing data**, the French case law is of particular interest. A first group of cases concerned the use of drones for patrolling restrictions on the freedom of movement adopted in the context of COVID-19. In a first case, the association Quadrature du Net and the Human Rights League asked the Paris Administrative Court to order the police prefecture to cease drone surveillance set up to enforce lockdown measures. Their request was rejected by the Court, and the associations appealed to the Council of State. **The Council of State, in its decision of May 18, 2020, nn. 440442, 440445, ordered the State to immediately cease drone surveillance concerning compliance with the health regulations in force during the lockdown**. The Police Prefecture of Paris indicated that the drones were not used to identify individuals, but only to detect public gatherings in Paris that were contrary to the health measures in force, and thus be able to disperse the gathering or evacuate the premises. However, the Council of State considered that the drones were equipped with optical zoom and could fly below 80 meters, which made it possible to collect identifying data. It observed that the drones were not equipped with any technical device to ensure that the information collected could not lead to the identification of persons being filmed, and this, for a use other than the identification of public gatherings.

Consequently, the judge stated that the use of drones involved the processing of personal data and must respect the framework of the French Data Protection Act. The Council of State found that there was a violation of this act and ordered the State to cease using drones. Furthermore, the Council of State decided that the surveillance through the use of the drones may restart if i) after the opinion of the CNIL a regulatory text authorizing the creation of a personal data processing system in compliance with the law of January 6, 1978 was approved applicable to processing falling within the scope of dir. EU 680/2016; or ii) the drones are equipped with technical devices which make it impossible, whatever the uses made of them, to identify persons filmed. In its reasoning, the Council of State mentioned the **principle of proportionality**, affirming that the measures taken by public authorities in order to fight the epidemic, which may limit the exercise of fundamental rights and freedoms, must, to that extent, be necessary, appropriate, and proportionate to the objective of safeguarding public health which they pursue.

After some time, a new proceeding was initiated, where the applicant provided documents attesting to the police prefecture's continued use of drones for such purposes. The applicant requested the Council of State suspend the decision of the police prefect of Paris to use drones in public spaces and to charge the State the sum of 4,096 euros. The **Council of State**, in its **decision of December 22, 2020, n°446155**[136] stated that it was apparent from other documents in the case file that the prefecture, after the decision of May 18, 2020, set up a system combining the tool for capturing images without recording

[136] The following description of this case is partially based on a case summary drafted by S. Fassiaux.

them by drones with software for automatically blurring personal data. This system nevertheless constituted processing of personal data even if the image that arrived in the command room was blurred, and such processing required authorization by means of a legal text. **The Council of State therefore suspended the decision of the police prefect of Paris to use such drones in public spaces.**

Another French case concerned the use of a fixed thermal camera placed at the entrance of a municipal building of the city of Lisses and of mobile thermal cameras in schools and school-related buildings of the municipality. In this case, the **Council of State, in decision no. 441065 of 26 June 2020**[137], ordered the municipality to put an end to the use of thermal cameras in schools. In its reasoning, the Council of State considered that: i) collection of health data can be considered automated personal data treatment in the sense of the general data protection regulation (GDPR), and that in the absence of a text justifying the use of such cameras on public health grounds and in the absence of students and employees' consent, the conditions were not fulfilled to allow such data treatment; ii) students, teachers, and other employees must comply with this temperature taking to enter the establishment and an abnormal result led to an obligation to leave the premises. Accordingly, the Council of State indicated that the municipality of Lisses was responsible for a clearly illegal infringement of the right to private life of students and employees, which included the right to personal data protection and freedom of movement. Furthermore, with regard to the fixed camera within municipal premises, the Council of State pointed out that people entering such buildings have the choice of stepping into the spot in which a temperature check is performed, and that choosing not to did not restrict access to the premises. It was also highlighted that the temperature check did not imply any data collection, and that no municipal employee could manipulate the camera or obtain access to results. **On these grounds, the urgent application judge determined that the use of such cameras did not lead to personal data treatment in the sense of the GDPR and so rejected the appeal to put an end to their use.**

With regard to cases where **private entities processed data**, the Austrian case law is noteworthy. In particular, in **decision no. V 573/2020 of March 10, 2021 the Austrian Constitutional Court**[138] decided a case concerning the introduction of a provision according to which local administrative authorities could stipulate by ordinance that catering establishments and hospitals were obliged to collect personal data of people who have stayed at the places in question for more than 15 minutes and to transmit this data to the local administrative authority upon request, but only to the extent and as long as this was absolutely necessary and proportionate for dealing with the Covid-19 pandemic. In assessing the Constitutionality of this provision, the Constitutional Court held that **when adopting such ordinances, the local authorities should balance the fundamental interests involved and introduce this kind of provision only if actually necessary and proportionate to the objective of limiting the spread of Covid-19**. In this context, **the documentation attached to such ordinances should report the aforementioned assessments of necessity and proportionality in order to ensure the legality of the local administrative act.** Given this, it was not clear to the Court on the basis of which concrete circumstances the city administration of Vienna considered the challenged provisions to be necessary and proportionate. Thus, the provisions were declared formally unconstitutional for violating the principle of legality and it was unnecessary to analyse the other parts of the claim. **The Court partially upheld the**

[137] The following description of this case is partially based on a case summary drafted by B. Fauvarque-Cosson
[138] The following description of this case is partially based on a case summary drafted by H. Koheler.

claim and quashed the challenged provisions as far as they were not compliant with the principle of legality, as the city ordinance did not sufficiently justify the issuance of the act through a necessity and proportionality assessment, which was required by the underlying national law.

Question 14 – Data transfers outside the EEA and COVID-19

In light of CJEU case law, Art. 47 and 8 CFR and the principles of effectiveness, what are the legal grounds according to which personal data concerning COVID-19 can be transferred outside the EEA?

- *Suggestions from EU case law*

With regard to data transfers, two very important CJEU cases are *Schrems*, C-362/14, 6 October 2015 and *Schrems Facebook Ireland,* C- 311/20, 16 July 2020. It is beyond the scope of this chapter to deeply analyse these judgements which were addressed within the FRICoRe Data Protection Casebook. For our purposes, it should be reiterated that in *Schrems Facebook Ireland,* (C- 311/20) the CJEU, relying on *Schrems* (C-362/14) stated that:

i) in light of the principle of **proportionality**, of Art. 52 CFR, and of Art. 45 GDPR, the Commission Implementing Decision (EU) 2016/1250 of 12 July 2016 on the adequacy of the protection provided by the *EU-US Privacy Shield* was invalid;

ii) in the application of Article 46(1) and Article 46(2)(c) GDPR, concerning data transfers to third countries or international organisations which are subject to appropriate safeguards, data subjects whose personal data are transferred to a third country pursuant to standard data protection clauses must be afforded a level of protection essentially equivalent to that guaranteed within the European Union **by the GDPR, read in light of the CFR**. To that end, the assessment of the level of protection afforded in the context of such a transfer must take into consideration both the contractual clauses agreed between the controller or processor established in the European Union and the recipient of the transfer established in the third country concerned and, with regard to any access by the public authorities of that third country to the personal data transferred, the relevant aspects of the legal system of that third country, in particular those set out, in a non-exhaustive manner, in Article 45(2) GDPR.

- *Suggestions from national case law*

French case law addressed issues related to the transfer of personal data outside the EEA.

The impact of the *Facebook Schrems* case (C-311/18) also in litigation related to COVID-19 is clear from French case law concerning the subcontracting of the hosting of the "Health data hub" created by French authorities. **In a first decision, no. 440916, of 19 June 2020, prior to *Facebook Schrems* case (C-311/18),** the Council of State, with regard to the data hosting, considered that Microsoft hosts data in Europe (in Netherlands) in hubs that are labelled as "data health host" in accordance with the Code of public health. Moreover, the Council observed that Microsoft submitted to the requirements of French regulation on health data hosting as specified in the contracts it signed and must respect the GDPR rules regarding the transfer of personal data to a third country. Furthermore, **the Council of State stated that, concerning possible data transfers to the United States for maintenance needs, such transfers fit in the regulatory framework authorized by a decision of the European commission in 2016 as permitted by the GDPR**.

In a second decision on the same topic, the Council of State, in **decision n°444937 of 13 October 2020**[139], considered that given the possibility of data being transferred to the United States, either in application of the contract concluded with Microsoft Ireland Operations Limited, or because of requests that would be addressed to this company outside of the transfers contractually agreed by the Health Data Platform, the Council of State distinguished between (i) the risk of data transfers due to the application of the contract with Microsoft; and (ii) the risk of other types of data transfers (extraterritoriality of US law). With regard to the first risk, t**he Council of State recalled that, as a result of the ruling of the CJEU of 16 July 2020 (C-311/18, *Schrems Facebook Ireland*) no transfer of personal data to the United States can take place on the basis of Article 45 of the EU General Data Protection Regulation (GDPR). If a transfer remains possible on the basis of Article 46, it is on the condition that appropriate safeguards are provided and that the data subjects have enforceable rights and effective remedies.** However, it follows from the same judgment that, in the event that the US authorities have access, on the basis of surveillance programs, to personal data transferred from the EU, the data subjects do not have rights that can be enforced against the US authorities before the Courts. Thus, the Council of State found that no appropriate safeguards existed to remedy this. **Under these conditions, any transfer of personal data to the United States by a company that may be subject to requests from the US authorities on the above-mentioned grounds is likely to contravene Articles 44 et seq. of the GDPR, unless it can be justified under Article 49, which contains exemptions for a number of specific situations.** The Council of State considered that in this case, the data processed by the Health Data Hub is hosted by Microsoft in data centres in the Netherlands and both parties agreed contractually that Microsoft will not process the Hub's data outside the geographical area specified without the Hub's approval and that, in the event that access to the data is required for the purposes of the operations of online services and incident resolution carried out by Microsoft, from a location outside that area, it will be subject to the Platform's prior approval. However, it appears that such data would only be limited to telemetry data, to monitor the proper functioning of the services offered by Microsoft, and billing data. Thus, it did not appear from the investigation that the Health Data Hub could be forced, for technical reasons, to agree to a transfer of personal health data. Moreover, the French Health Minister adopted a decree on October 9, 2020 prohibiting any transfer of personal data from its health system outside the EU. Therefore, it did not appear that personal data from the health system may be transferred outside the EU pursuant to the contract concluded between the Health Data Hub and Microsoft. Consequently, the Council of State declared that there was not the risk of a serious and manifestly unlawful interference with the right to respect for private life, including the right to protection of personal data. With regard to **the second risk (extraterritoriality of US law),** the applicants claimed that Microsoft Corporation, being a US company, and Microsoft Ireland Operations Limited, by virtue of being a subsidiary of a US company, may be subject to requests for access to certain health data by US authorities, in the context of surveillance programs, even though this data is hosted in the EU and the terms of the contract concluded between the Health Data Hub and Microsoft would prevent this. The Council of State affirmed that, applying the criteria adopted by the CJEU to the relationship between controller and processor, the level of protection provided during the processing of the data must be verified by considering the contractual provisions and the relevant elements of the legal system of the third country where the data would be transferred. Although the contract mentions that

[139] The following description of this case is partially based on a case summary drafted by S. Fassiaux.

Microsoft would not disclose data to public authorities except when required by law, the French data protection regulator (CNIL) considered that the risk of such requests could not be excluded. **Also, it could not be totally ruled out, from a technical point of view, that Microsoft could be led to comply with a request from the US authorities**. However, the Council of State explained, first, that the CJEU only ruled, in its judgment of 16 July 2020, on the conditions under which transfers of personal data to the US can take place and not on the conditions under which such data can be processed, within the territory of the EU, by companies governed by US law or their subsidiaries as processors, or even controllers. Second, the applicants only mentioned the risk of violation of the GDPR in the event that Microsoft would not be able to reject a request of the US authorities, and even though the data in question is anonymized by French public authorities and encrypted by Microsoft. **Third, the Council of State considered that there was strong public interest in allowing the continued use of health data for the purposes of health emergency management in the context of the pandemic**. **The Council of State refused to suspend the Health Data Hub, but did require special precautions to be taken, under the supervision of the French data protection regulator (CNIL), for example to verify that projects of the Health Data Hub pursued a public interest purpose in relation to the Covid-19 epidemic and that use of the platform was necessary and proportionate to the health risks.** The Council of State also ordered the Health Data Hub to provide evidence that it concluded a new addendum to the contract with Microsoft to specify that the applicable law referred to in the addendum of September 3, 2020 was that of the law of the Union or the law of the Member State to which the company is subject, and that the amendments that this addendum made to the addendum on data protection for Microsoft online services apply to all the services provided by Microsoft that may be used for the processing of personal data of the health system.

A similar case was decided by the French Council of State in **decision no. n°450163, of March 12, 2021**[140] where associations and trade unions asked the interim relief judge of the Council of State to suspend the partnership between the Ministry of Health and Doctolib, arguing that the hosting of vaccination appointment data by the subsidiary of a US company (Amazon Web Services) entailed risks with regard to access requests by US authorities. **The Council of State, applying the criteria applied by the CJUE in its judgment *Schrems Facebook Ireland* (C-311/18)of July 16, 2020** to the relationship between controller and processor, considered that the level of protection provided during the processing of data should be verified by taking into account not only the contractual stipulations agreed between the controller and his processor, but also, in the event of the processor being subject to the law of a third country, the relevant elements of the legal system of that country. However, the Council of State found that the data at issue included personal identification data as well as data relating to appointments, but no health data on the possible medical reasons for eligibility for vaccination. The persons concerned simply self-certified, when making the appointment, that they fell within the relevant vaccination priority group. This data was deleted by the end of a period of three months from the date of the appointment, and each person concerned who created an account on the platform for the purposes of vaccination may delete it directly online. Moreover, the Council of State considered that Doctolib and AWS concluded a complementary addendum on data processing establishing a specific procedure in the event of requests for access by a public authority to data processed on behalf of Doctolib, providing in

[140] The following description of this case is partially based on a case summary drafted by S. Fassiaux.

particular for the contestation of any general request or one that does not comply with European regulations. Furthermore, the judge considered that Doctolib also set up a security system for data hosted by AWS through an encryption procedure based on a trusted third party located in France in order to prevent the reading of data by third parties. With regard to those safeguards and to the data concerned, the Council of State found that the level of protection of the data relating to appointments made in the context of the Covid-19 vaccination campaign could not be regarded as manifestly inadequate in light of the risk of infringement of the GDPR invoked by the applicants. Therefore, the Council of State held the decision by the Minister of Solidarity and Health to entrust the company Doctolib, among other possible ways of booking appointments, with the management of Covid-19 vaccination appointments did not seriously and manifestly illegally infringe upon the right to respect for private life and the right to protection of personal data.

Insights from the case law analysis

During the pandemic, data processing operations were conducted in relation to COVID-19 for several purposes. Within the case law, documents, and decisions of data protection authorities, the following issues emerge, among others:

i) the impact of the principles of proportionality, of data minimization, of the right to data protection on the assessment concerning the lawfulness of processing personal data for purposes related to COVID-19, such as processing for contact tracing purposes (e.g., EDPB, *Guidelines 4/2020 on the use of location data and contact tracing tools in the context of the COVID-19 outbreak*; with regard to the application of proportionality, see the decision of the French Constitutional Council no. 2020/800 of 21 May 2020 and decision no. 2020/800 of 21 May 2020; Norwegian DPA of 17 August 2020), for scientific research purposes (see EDPB *Guidelines 03/2020 on the processing of data concerning health for the purpose of scientific research in the context of the COVID-19 outbreak*, adopted on 21 April 2020), or for monitoring the pandemic (French Council of State, decision no. 440916 of 19 June 2020) and the establishment of a system of certificates concerning medical events such as vaccination or recovery (e.g., EDPB-EDPS *Joint Opinion 04/2021 on the Proposal for a Regulation of the European Parliament and of the Council on a framework for the issuance, verification, and acceptance of interoperable certificates on vaccination, testing, and recovery*, adopted on March 31, 2021).

ii) the role of the abovementioned principles in defining the criteria for evaluating the lawfulness of data processing aimed at ensuring the enforcement of health security rules established for facing the COVID-19 pandemic (e.g., on data processing through drones see Council of State, decision of 18 May 20220, nn. 440442, 440445; Council of State, in its decision of 22 December 2020, n°446155; on the mandatory collection of contact details for catering establishments see Austrian Constitutional Court, decision no. V 573/2020, of 10 March 2021).

iii) the need to ensure effective data protection in relation to data transfers outside the EEA for purposes related to COVID-19, also considering the impact of the *Schrems Facebbok Ireland* case on national case law (e.g., French Council of State, decision n° 444937, of 13 October 2020).