

FRI CoRe

Judicial Training Project

Fundamental Rights In Courts and Regulation

CASEBOOK

JUDICIAL PROTECTION OF HEALTH AS A FUNDAMENTAL RIGHT



UNIVERSITY
OF TRENTO



THIS PUBLICATION IS FUNDED
BY THE EUROPEAN UNION'S
JUSTICE PROGRAMME (2014-2020)

Judicial Protection of Health as a Fundamental Right

Edited by Paola Iamiceli, Fabrizio Cafaggi, Chiara Angiolini

Publisher: Scuola Superiore della Magistratura, Rome – 2022

ISBN 9791280600233

Published in the framework of the project:

Fundamental Rights In Courts and Regulation (FRICoRe)

Coordinating Partner:

University of Trento (*Italy*)

Partners:

Scuola Superiore della Magistratura (*Italy*)

Institute of Law Studies of the Polish Academy of Sciences (INP-PAN) (*Poland*)

University of Versailles Saint Quentin-en-Yvelines (*France*)

University of Groningen (*The Netherlands*)

Pompeu Fabra University (*Spain*)

University of Coimbra (*Portugal*)

Fondazione Bruno Kessler (*Italy*)

The content of this publication represents the views of the authors only and is their sole responsibility. The European Commission does not accept any responsibility for use that may be made of the information it contains.

Edition: May 2022

Scientific Coordinator of the FRICoRe Project:

Paola Iamiceli

Coordinators of the team of legal experts on Health Law:

Fabrizio Cafaggi - Paola Iamiceli

Project Manager:

Chiara Patera

Co-editors and Co-authors of this Casebook:

Co-editors: Paola Iamiceli (Project Coordinator), Fabrizio Cafaggi, Chiara Angiolini

Introduction: Fabrizio Cafaggi and Paola Iamiceli; sec. III: Lucia Busatta

Chapter 1: Lucia Busatta

Chapter 2: Lottie Lane and Tobias Nowak

Chapter 3: Matteo Ferrari and Gianmatteo Sabatino

Chapter 4: Chiara Angiolini

Chapter 5: Lottie Lane and Tobias Nowak

Chapter 6: Simone Penasa

Chapter 7: Chiara Angiolini

Note on national experts and contributors:

The FRICoRe team would like to thank all the judges, experts, and collaborators who contributed to the project and to this Casebook by suggesting national and European case law (*in alphabetical order*):

Maria Abbruzzese

Nicoletta Bezzi

Alexandr Biagioni

Līga Biksiniece-Martinova

Dominik Dworniczak

Sébastien Fassiaux

Benedicte Favarque Cosson

Alejandro Fernández

Maxence Fontaine

Franco Frattini

Annabelle Fröhlich

Alexia-Maria Giakkoupi

Inès Giauffret

Guillaume Halard

Mareike Hoffmann

Christopher Hristov

Nikoleta Kiralyova

Heike Koehler

Maria Laura Maddalena

Meron Mekonnen

Marita Miķelsone

Kate Murphy

Sonia Ramos

Donna Savolainen

Verena Schneider

Ana Beatriz Silva de Sa

John Sorabji

Markus Thoma

Patricia Vargová

Boštjan Zalar

Szimon Zaręba

Christina Zátka

Table of contents

<i>Introduction: A Brief Guide to the Casebook.....</i>	<i>8</i>
I. The Structure of the Casebook: Some Keys for Reading.....	11
II. Cross-Project Methodology.....	13
III. Health as a Fundamental Right: a European Union Law Perspective	14
III. 1. Health and Healthcare in the Charter of Fundamental Rights of the European Union	14
III. 2. The Right to Healthcare and the European Court of Human Rights	19
III. 3. The Right to Health, Rights to Healthcare, and Common Constitutional Traditions of Member States.....	24
III. 4. Health Law and the European Union, a Matter of Competences	28
III. 5. The Mainstream: Health in All Policies (HiAP).....	30
III. 6. The EU in the Fight Against the Pandemic Emergency	32
<i>1 Cross-Border Healthcare.....</i>	<i>34</i>
1.1 Cross-Border Healthcare: Its Definition and Importance in EU Health Law	34
Question 1 – List of Reimbursable Medical Treatments	36
1.2 Procedural Requirements	40
Question 2 – Undue Delay	41
1.3 The Impact of CJEU Caselaw on the Directive on Patient’s Rights in Cross-Border Healthcare	46
Question 3 – A Wide Interpretation of Undue Delay	47
1.4 Effectiveness of Remedies in Recent Times and New Issues	49
Question 4 - Cross-Border Healthcare and Non-Discrimination	50
1.5 Guidelines Emerging from the Analysis	53
<i>2 Health and Consumer Protection</i>	<i>55</i>
2.1 The Principle of Effectiveness and Complementarity between Health and Consumer Protection	55
Question 1 – Relationship between the Individual and Collective Dimensions of the Right to Health	56
Question 2 – Declaration of conformity of medical products with quality systems	61
Question 3 – Defective Products that Could Be Dangerous for Health	64
Question 4 – Risk of Defective Products and Damage to Health	72
2.2 Conflicts between Freedom to Conduct a Business, Freedom of Expression and the Protection of Health in its Collective Dimension with Consumer Law	77
2.2.1 The Role of the Precautionary Principle.....	77

Question 5 – The precautionary principle and risks to consumer health	78
2.2.2 The Role of the Proportionality Principle	82
Question 6 – Restrictive rules for E-cigarettes and freedom to conduct a business.....	83
Question 7 – Limits on the labelling and advertising of products	88
Question 8 - The role of proportionality in justifying restrictions on the licensing of gaming and betting activities	92
2.3. Guidelines emerging from the analysis.....	99
3 <i>Food Safety and Effective Protection of Health</i>	103
3.1 Introduction	103
3.2 Right to Health and Food Safety: the Role of the Precautionary Principle	104
Question 1 – Effective protection of health and the precautionary principle.....	105
Question 2 – The allocation of the burden of proof	111
Question 3 - Health Protection and Restrictions to the Free Movement of Goods	116
Question 4 – Health Protection and Restrictions on the Freedom of Expression and Freedom to Conduct a Business.....	119
3.3 Guidelines Emerging from the Analysis	124
4 <i>Health and Data Protection</i>	126
4.1. Health Data and their Regime under the GDPR.....	126
4.1.1. The Notion of Health Data and their Regime.....	126
4.1.2. Data Processing for Health-Related Purposes.....	127
Main question addressed	129
4.2. Health Data Processing between Individual and Collective Interests.....	129
Question 1 - Access to health data by health professionals, public institutions and the public in light of effective data protection	129
Question 2 – Cross border health care and MSs’ role with regard to health data: the eHealth Network	136
Question 3 – Principle of proportionality, the protection of collective and public health, and the processing of health data for purposes of public research.....	138
Question 4 – Looking forward: sharing health data in Health data spaces	141
Question 5 – Health data and COVID-19 Certificates.....	143
4.3. Guidelines Emerging from the Analysis	144
5 <i>Health and Non-Discrimination</i>.....	146
5.1 Complementarity with Other Fundamental Rights.....	146
Question 1a – Discrimination on the basis of illness.....	148
Question 1b – Discrimination on the basis of obesity.....	152

Question 1c – Discrimination on the basis of temporary incapacity.....	156
Question 2 – Personal scope of protection from discrimination based on health-related conditions	161
Question 3 - Non-discrimination and the definition of public health.....	166
5.2 Conflict Between Health and Other Fundamental Rights	168
Question 4 – Justifying discrimination on the basis of health-related issues.....	169
5.3 Guidelines Emerging from the Analysis	175
6 Migration, Asylum and Health.....	178
6.1 Migrants’ Health and Return Procedure: the Suspensive Effect of Appeals and Basic Healthcare Needs	179
Question 1 – The risk of a grave and irreversible deterioration in the state of health and the suspension of a return procedure.....	179
6.2 Subsidiary Protection and Migrant Health: the Requirement of the (Intentional) Deprivation of Healthcare in the Country of Origin	185
Question 2 – Intentional deprivation of healthcare and the right to subsidiary protection.....	185
6.3 The Dublin Transfer and Non-Refoulement Principle in Light of an Asylum Seeker’s Health	188
Question 3 – The risk to an asylum seeker’s health and suspension of a Dublin transfer.....	188
6.4 Migrant Health and Family Reunification: the Concept of Dependency under Directive 2003/86	193
Question 4 - Migrant health and family reunification: the concept of dependency under Directive 2003/86.....	193
6.5 Guidelines for Analysis.....	195
7 Health and COVID.....	197
7.1. Introduction	197
7.2. Access to Justice, Right to a Fair Trial and COVID-19	197
Question 1 - The role of Art. 47 and the principle of effectiveness in interpreting national procedural rules adopted due to the COVID-19 emergency.....	197
Question 2 – Restrictive procedural measures, Art. 47 and the right to be heard.....	200
Question 3 - COVID-19 outbreak and the renewal of procedural deadlines.....	207
Insights from the case law analysis	208
7.3. Healthcare Management: the Collective and Individual Dimensions of Health Protection	209
Question 4 - Collective and individual dimensions in the definition of vaccination strategy	209
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.....	209

Question 4b – Non-discriminatory access to vaccines against COVID-19, vulnerability, and risk of contagion.....	216
Question 5 – Proportionality and effectiveness of healthcare choices concerning medical and non-medical interventions against COVID-19.....	219
Insights from the case law analysis	221
7.4. Right to Health, Freedom of Information, and the Right to Be Informed	223
Question 6 – Access to information regarding the pandemic and the effectiveness of the right to information.....	223
Question 7 – Information management: the role of the freedom of information and of the right to be informed	224
Insights from the case law analysis	227
7.5. Restrictions on Freedom of Movement and their Proportionality and Necessity in Light of Health Protection.....	228
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	228
<i>Insights from the case law analysis</i>	234
7.6. Right to Health and Freedom to Conduct a Business: the Role of the Principle of Proportionality.....	235
Question 9 - The right to conduct a business and health protection in light of the principle of proportionality.....	235
Question 10 – The regulation of economic activities related to the satisfaction of primary needs and the exercise of fundamental rights during the emergency	239
Question 11 – Compensation and other remedies: the role of the principle of proportionality...	241
<i>Insights from the case law analysis</i>	242
7.7. Data and Health Protection in Light of the Principles of Proportionality, of Data Minimization, and of Art. 8 CFR	243
Question 12 – Data processed for purposes related to COVID-19.....	243
Question 13 – Enforcement of Health security rules concerning COVID-19 and data protection	248
Question 14 – Data transfers outside the EEA and COVID-19	250
<i>Insights from the case law analysis</i>	253

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 Certificate¹ 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.

7 Health and COVID¹¹³

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 *Delwigne*, C-650/13, 6 October 2015 §§ 25-27; *Torrallbo 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 is 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 *ERTC*-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; *CIT*, 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 *Uniq*a 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 movement**. 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 to 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, *Uniga*, 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 Vavříčka and Others v. the Czech Republic, of 8 April 2021

In the recent case Vavříčka 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 interference 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 2011), 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; *Furdik 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 significant 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 *Vavříčka 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 legislature 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 EMAM 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 *Vavříčka 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 been 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 *Vavříčka 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 Covid-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

The Constitutional Court of Slovenia, in decision No. U-I-83/20, 27th August 2020¹²⁸ 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, *Pešce*, 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 Court¹²⁹ 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^o 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 not 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 2020¹³⁷**, 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 Court¹³⁸** 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, **the 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 Facebook Ireland* case on national case law (e.g., French Council of State, decision n° 444937, of 13 October 2020).

