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Fundamental Rights In Courts and Regulation

CASEBOOK

JUDICIAL PROTECTION OF HEALTH AS A FUNDAMENTAL RIGHT

UNIVERSITY OF TRENTO

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Introduction: A Brief Guide to the Casebook

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

II. Cross-Project Methodology

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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[9] C-616/17, Blaise, 1 October 2019, ECLI:EU:C:2019:800, paras 42 and 43 (the case concerned the placing of plant protection products on the market as well as glyphosate).

[10] Directive 2004/33, implementing Directive 2002/98 of the European Parliament and of the Council with regardto certain technical requirements for blood and blood components.

[11] C-528/13, Léger, 29 April 2015, ECLI:EU:C:2015:288, paras 57-58.

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

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

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

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

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

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

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

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

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

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

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

[15] Thematic Report, Health-related issues in the case-law of the European Court of Human Rights, Council of Europe, June 2015, available at https://www.echr.coe.int/Documents/Research_report_health.pdf, 5

[16] See among all decisions, A, B and C v. Ireland, app. no. 25579/05, 16 December 2010, on abortion.

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

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

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

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

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

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[17] Oyal v. Turkey, app. no. 4864/05, 23 March 2010.

[18] Panaitescu v. Romania, app. no. 30909/06, 10 April 2012.

[19] Vo v. France, app. no. 53924/00, 8 July 2004.

[20] Kaçiu and Kotorri v. Albania, app. nos. 33192/07 and 33194/07, 25 June 2013; Gäfgen v. Germany, app. no. 22978/05, 1 June 2010. For more details on this see Thematic Report, Health-related issues in the case-law of the European Court of Human Rights, cited above, 5.

[21] M.S. v. the United Kingdom, app. no. 24527/08, 3 May 2012.

[22] Rappaz v. Switzerland, app. no. 73175/10, 26 March 2013; Nevmerzhitsky v. Ukraine, app. no. 54825/00, 5 April 2005; Ciorap v. Moldova, app. no. 12066/02, 19 June 2007.

[23] Mouisel V. France, app. no. 67263/01, 14 November 2002, concerning the State's failure to provide adequate medical care for a detainee with leukaemia; Kudla v. Poland, app. no. 30210/96, 26 October 2000, concerning the violation of the Convention for lack of adequate psychiatric treatment during detention. Similarly, and more recently, see also Strazimiri v. Albania, appl. no. 34602/16, 21 January 2020, concerning the lack of a special medical institution for the mentally ill deprived of their liberty on the basis of Court-ordered compulsory treatment. See also Venken and Others v. Belgium, appl. no. 46130/14, 9 April 2021, in which the Court found a violation of Art. 3 ECHR in relation to the long-term imprisonment in psychiatric wings of persons placed in compulsory confinement.

[24] Khokhlich v. Ukraine, app. No. 41707/98, 29 April 2003; Alver v. Estonia, app. no. 64812/01, 8 November 2005.

[25] Feilazoo v. Malta, application no. 6865/19, 11 March 2021.

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

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

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

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

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

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

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

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

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

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

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[30] Costa and Pavan v. Italy, app. no. 54270/10, 12 June 2014. See also S.H. v. Austria, appl. no. 57813/00, 3 November 2011.
[31] Tysiąc v. Poland, app. no. 5410/03, 20 March 2007; P. and S. v. Poland, app. no. 57375/08, 30 October 2010; A., B. and C. v. Ireland, app. no. 25579/05, 16 December 2010.
[32] S.H. v. Austria, app. no. 57813/00, 3 November 2011; Evans v. the United Kingdom, app. no. 6339/05, 10 April 2007; Dickson v. the United Kingdom, app. no. 44362/04, 4 December 2007.
[33] Vavřička and Others v. the Czech Republic, Applications no. 47621/13 and five others, 8 April 2021.
[34] Kiyutin v. Russia, app. no. 2700/10, 15 March 2011.
[35] A similar decision was adopted a few years later in Novruk and Others v. Russia, app. no. 31039/11, 16 March 2016.
[36] For some preliminary hints see the dedicated Factsheet – COVID-19 health crisis, available on the website of the Court: https://www.echr.coe.int/Documents/FS_Covid_ENG.pdf.
[37] Communauté genevoise d'action syndicale (CGAS) v. Switzerland, appl. no. 21881/20, 15 March 2022.
[38] For example, see the effects of Costa and Pavan v. Italy at a national level: after the ECtHR decision, the Italian Constitutional Court declared the prohibition of preimplantation genetic diagnosis void (decision n. 96 of 2015).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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[46] C. Newdick, The positive side of healthcare rights, in S.A.M. McLean (ed.), First do not harm, Ashgate, 2006, 579.
[47] C-372/04, Watts, 16 May 2006, ECLI:EU:C:2006:325.
[48] C. Newdick, The positive side of healthcare rights, cited above at C. Newdick, Healthcare rights and NHS rationing, cited above.
[49] See Léger, cited above.
[50] Austrian Constitutional Court, E137 / 2019, 6 November 2019.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[68] Communication from the commission to the European parliament, the Council, the European economic and social committee and the committee of the regions, Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats, Brussels, 11.11.2020, COM(2020) 724 final.
[69] See Communication from the Commission, Brussels, 26.04.2022, COVID-19 - Sustaining EU Preparedness and Response: Looking ahead, COM(2022) 190 final, available at https://ec.europa.eu/health/publications/covid-19-sustaining-eu-preparedness-and-response_en.