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Health and Healthcare in the European Union

The need for greater harmonisation and coordination of European Union health policies and systems

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Introduction

Health can be considered as the most important component of everyone's life.

It consists of the enjoyment of the highest attainable standard of physical and mental health, and it is inevitably connected with the provision of medical assistance, i.e. healthcare.

The protection of health and the provision of medical assistance have been recognised as fundamentally important, and a right to health and to healthcare has been recognised at the international, European and, in some cases, even national level.

A full realisation of the right to health and to healthcare is inevitably linked to the existence of an adequate and effective health system, able to guarantee a good state of health of the population.

However, although health systems are all roughly structured in the same way, they differ considerably among each other and can be classified into different typologies. Health systems mainly present differences with respect to funding, providing and governing healthcare, differences that make them able to protect and ensure the realisation of the right to health and to healthcare in different ways and to different degrees.

This is also the case in the European Union, which does not have a unique health system, and is rather characterized by the coexistence of 27 separate and different national health systems, all built on a set of common values and principles, but with considerable differences among each other.

The heterogeneity of health systems within the European Union matches the differences in the state of health of the various Member States. Indeed, even though the state of health is generally good in the whole European Union, there are major health and healthcare gaps and inequalities across Member States with respect to health status, accessibility and coverage, with some

countries clearly still lagging behind in the process of ensuring a full realisation of the right to health and to healthcare.

The differences in the state of health and health systems can be linked to the fact that health and healthcare are primarily a national issue and are dealt with by each of the 27 Member States in a fairly independent and autonomous way. Indeed, European Union law clearly establishes that the definition of health policy and the organisation and delivery of health services and medical care are responsibilities of the individual Member States, and the European Union is mostly relegated to a role of coordination, support and completion of national health policies and actions.

However, the European Union still covers an important role in the field of health and healthcare, and some convergence and harmonisation have taken place, especially with regards to those areas in which health and healthcare trespass national boundaries and involve more than one Member States, such as cross-border healthcare and serious cross-border threats to health.

Cross-border healthcare in the European Union is characterised by the existence of a still not perfectly harmonised dual system, based on social security coordination on the one hand, and the internal market on the other, but in allowing patients to receive treatment in another Member State, it contributes to greater integration and harmonisation of European health systems and helps improving the full realisation of the right to health and to healthcare.

Serious cross-border threats to health inevitably require coordination at European Union level as they spread or entail a significant risk of spreading across the national borders of the Member States. Although the responsibility to manage public health crises at national level lies with each Member State, it is necessary to ensure coordination among the various national measures to guarantee that such measures do not negatively affect other Member States and that a high level of human health is protected. The European Union has been recently called to act with respect to its role in serious cross-border threats to health in the event of the COVID-19 pandemic. With regard to the pandemic, a common coordinated European response has not

come about immediately, and, especially at the beginning, Member States have reacted selfishly and chaotically, adopting different and sometimes conflicting responses and approaches, looking out for themselves and giving an 'only for me' response. However, the European Union has adopted measures in a variety of fields, sustaining and helping Member States, coordinating their responses and providing practical advice and guidance, and its action has proven fundamental.

My work will be divided into four chapters, in which I will address the abovementioned issues with a view to point out that, in order to ensure a full realisation of the right to health and to healthcare, greater harmonisation and coordination of European Union health policies are needed.

The first chapter will address the right health and to healthcare and health systems. I will discuss how the right to health and to healthcare has been acknowledged under international law, and the relation between international law and the European Union with regard to health and healthcare; how the right to health and to healthcare are protected under European law itself; and how and whether the right to health and to healthcare are acknowledged in European national Constitutions. I will then present how health systems are structured, how they differ from each other and how they can be classified, especially with regard to the European Union's health systems.

The second chapter will focus on the state of health in the European Union through the analysis of a set of indicators, including health status, health expenditure and financing, health accessibility and health coverage.

The third and fourth chapters will be dedicated to European health policy, and in particular to cross-border healthcare and serious cross-border threats to health.

The third chapter will address cross-border healthcare, outlining its development ~~a~~nd presenting the relative legislation, i.e. Regulation (EC) No 883/2004 on the coordination of social security systems and Directive 2011/24/EU on the application of patients' rights in cross-border health

care. The chapter will address the relation between these two legal instruments, outlining their main differences, and highlighting the existence of a not perfectly harmonised dual system, which however still represents an important area of integration and coordination of European health systems.

The fourth and last chapter will instead address the role of the European Union with respect to serious cross-border threats to health, presenting the relative legislation, i.e. Decision No 1082/2013/EU on serious cross-border threats to health, and analysing how the COVID-19 pandemic has been dealt with as an example of how serious cross-border threats to health are actually dealt with in the European Union. I will initially outline the main events and data, and then move on to discuss the measures undertaken by the individual Member States, showing how such measures have been undertaken uncoordinatedly and selfishly. I will subsequently analyse the European Union's response to the COVID-19 pandemic, presenting the main measures and actions, and highlighting the importance of working together in a coordinated manner when faced with issues that trespass national borders and affect all Member States.

Chapter 1 – The right to health and health systems typologies in the European Union

Introduction

Health is a fundamental component of everyone's life, and it can be considered as the most basic and essential asset of every human being[1]. It has been defined by the World Health Organization as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity"[2]. From this definition, it appears clear that the concept of health does not coincide with that of being healthy. Rather, it is a more comprehensive and inclusive concept related to the idea of enjoying "the highest attainable standard of physical and mental health"[3]. Health has been recognized as "one of the fundamental rights of every human being"[4], as "a fundamental human right indispensable for the exercise of other human rights"[5], and it is therefore inalienable and "inherent to all human beings, regardless of race, sex, nationality, ethnicity, language, religion, or any other status"[6], and therefore it has to be enjoyed by "every human being, without distinction of race, religion, political belief, economic or social condition"[7].

[1] United Nations Office of the High Commissioner for Human Rights (OHCHR), *Fact Sheet No. 31, The Right to Health*, June 2008, No. 31, Introduction.
[2] World Health Organization (WHO), *Constitution of the World Health Organization*, Bulletin of the World Health Organization, 80 (12), 983 – 984, 22 July 1946, Preamble.
[3] United Nations (UN) General Assembly, *International Covenant on Economic, Social and Cultural Rights*, art. 12(1), United Nations, Treaty Series, vol. 993, p. 3, 16 December 1966.
[4] WHO, *Constitution*, Preamble, *op. cit.*
[5] United Nations Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12 of the Covenant)*, Vol. E/C. 12/2000/4, Par. 1, 11 August 2000.
[6] United Nations (UN), *Human Rights*, available at https://www.un.org/en/sections/issues-depth/human-rights/.
[7] WHO, *Constitution*, Preamble, *op. cit.*

The right to health and to healthcare have been recognised at the international level, as well as at the European one, and in some cases also at the National level.

The two rights are strictly intertwined, and when a right to healthcare is not explicitly mentioned, the related right to health is often intended as also including healthcare. Indeed, as affirmed in the United Nations Office of the High Commissioner for Human Rights' *Fact Sheet No. 31, The Right to Health*, the right to health refers also to the right to the enjoyment of those goods, facilities, services and conditions that are necessary for its realization[8].

Notwithstanding the acknowledged importance of these rights, their realization is still far from being a reality, and this is often linked to the lack of an adequate and effective health system. All the health systems across the world are more or less structured in the same way, even though they show wide differences among each other. Indeed, even though all health systems have the same building blocks, they can be classified in different ways and there are many different health system types, each based on a different conception of the right to health and of the role of the state. Interestingly, the European Union does not have a unique health system, but is rather characterized by the coexistence of 27 separate and different national health systems.

1.1 The right to health and to healthcare

The right to health and to healthcare have been recognised in international law, in the European Union and in some national constitutions.

1.1.1 The European Union and the right to health under international law

[8] OHCHR, *Fact Sheet No. 31, The Right to Health*, *op. cit*.

The right to health and to healthcare: an international perspective

At the international level, the right to health is included in the Universal Declaration of Human Rights, whose Article 25 states that "everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services"[9].

The right to health is also recognized in the 1966 International Covenant on Economic, Social and Cultural Rights, whose Article 12 affirms that "the States Parties to the (…) Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health"[10].

The implementation of this Covenant is delegated to the United Nations Committee on Economic, Social, and Cultural Rights, which in 2000 issued the *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12)* providing an authoritative guidance on how the States Parties to the Covenant have to implement the obligations arising from Article 12[11].

General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12)

The General Comment enlarges the scope of the right to health, claiming that it "embraces a wide range of socio-economic factors that promote conditions in which people can lead a healthy life, and extends to the underlying determinants of health, such as food and nutrition, housing, access to safe and potable water and adequate sanitation, safe and healthy working conditions, and a healthy environment" [12].

[9] United Nations (UN) General Assembly, *Universal Declaration of Human Rights*, Art. 25, 217 A (III), 10 December 1948.
[10] UN General Assembly, I*nternational Covenant on Economic, Social and Cultural Rights*, Art. 12(1).
[11] Davidson, L., *The Routledge Handbook of International Development, Mental Health and Wellbeing,* Routledge, 2019.
[12] CESCR, *General Comment No. 14*, par.4.

The Comment also claims that "the right to health contains (…) the right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health"[13] and that it has to "be understood as a right to the enjoyment of a variety of facilities, goods, services and conditions necessary for the realization of the highest attainable standard of health"[14].

In the General Comment, the Committee recognises the right to health as being composed by four fundamental elements, i.e. availability, accessibility, acceptability and quality. Therefore, health facilities, goods, services and programmes have to be available in sufficient quantity and to include the underlying determinants of health[15]; physically and economically accessible to everyone without discrimination[16]; respectful of medical ethics, culturally appropriate, sensitive to specific requirements and aimed at improving the health status of those concerned[17]; and of good quality as well as scientifically and medically appropriate[18].

The Committee also defines a series of obligations States have towards the right to health. Under these obligations, States are required to guarantee the exercise of the right to health without discrimination, and to take deliberate, concrete and targeted steps towards its full realization[19]. They have the obligations to respect and to protect the right to health, by preventing third parties from interfering with its enjoyment and refraining from doing so themselves[20]; to fulfil the right to health by adopting the measures necessary to achieve its full realization[21]; and to facilitate, provide and promote it by enabling and facilitating its enjoyment, by providing it when individuals or a group are unable to realize it themselves, and by creating,

[13] *Ivi*, par. 8.
[14] *Ivi*, par. 9.
[15] *Ivi*, par. 12 (a).
[16] *Ivi*, par. 12 (b).
[17] *Ivi*, par. 12 (c).
[18] *Ivi*, par. 12 (d).
[19] *Ivi,* par.30.
[20] *Ivi,* par.33.
[21] *Ibidem.*

maintaining and restoring the health of the population[22]. States are further obliged to ensure access to health facilities, goods and services to everyone on a non-discriminatory basis[23], and to ensure their equitable distribution[24]. They are also required to guarantee access to the minimum essential food[25], to an adequate supply of potable water, and to basic shelter, housing and sanitation[26], as well as to provide essential drugs[27]. Moreover, States shall adopt and implement a national public health strategy and plan of action which shall be based on epidemiological evidence and shall take into consideration the health concerns of the whole population[28]. Finally, States have an obligation to ensure reproductive, maternal and child health care[29], to provide immunization against the major infectious diseases[30], to take measures to prevent, treat and control epidemic and endemic diseases[31], to provide education and access to information concerning the main health problems in the community[32], and to provide appropriate training for health personnel[33].

The Committee also identifies some obligations States have towards the right to health at the international level, including the respect of the enjoyment of the right to health in other countries, and the prevention, through legal or political means, of its violation[34].

In the second paragraph of Article 12 of the International Covenant on Economic, Social and Cultural Rights, four main areas in which States need to take action in order to achieve the full realization of the right to health are listed[35]. For each of these four areas, the General Comment

[22] *Ivi,* par.37.
[23] *Ivi,* par.43(a).
[24] *Ivi*, par.43(e).
[25] *Ivi,* par.43(b).
[26] *Ivi,* par.43(c).
[27] *Ivi,* par.43(d).
[28] *Ivi,* par.43(f).
[29] *Ivi,* par.44(a).
[30] *Ivi,* par.44(b).
[31] *Ivi,* par.44(c).
[32] *Ivi,* par.44(d).
[33] *Ivi,* par.44(e).
[34] *Ivi,* par.39.
[35] UN General Assembly, I*nternational Covenant on Economic, Social and Cultural Rights*, Art. 12(2).

individuates a related right and specifies which steps States will have to undertake. The first area is the reduction of stillbirth-rate and of infant mortality and the healthy development of the child. The Committee links it to the right to maternal, child and reproductive health, and requires States to adopt measures aimed at the improvement of child and maternal health, and of sexual and reproductive health services, such as emergency obstetric services, pre- and post-natal care, and family planning[36]. The second area is the improvement of environmental and industrial hygiene, associated with the right to healthy natural and workplace environments. For this area, States are compelled to adopt preventive measures concerning occupational accidents and diseases, the reduction of the population's exposure to harmful substances or other environmental conditions negatively affecting human health, and the reduction of the causes of health hazards in the working environment. States are also required to guarantee an adequate supply of safe and potable water and of food and proper nutrition, as well as to ensure basic sanitation, adequate housing and safe and hygienic working conditions[37]. For the third area, i.e. the prevention, treatment and control of epidemic, endemic, occupational and other diseases, which the Committee relates to the right to prevention, treatment and control of diseases, States have to establish education programmes for behaviour-related health concerns, and to promote the social determinants of good health, such as education and gender equity; to create a system of urgent medical care in cases of epidemics, occupational accidents and other health hazards, and to deliver disaster relief and humanitarian assistance in the case of emergency; and to collaborate in order to make available relevant technologies for epidemiological surveillance, the control of infectious diseases, and the implementation or amelioration of immunization programmes[38]. The last area in which States are required to take action is the creation of the conditions necessary for ensuring medical services to all in case of

[36] CESCR, *General Comment No. 14*, par. 14.
[37] *Ivi*, par.15.
[38] *Ivi*, par.16.

sickness. The Committee relates this area to the right to health facilities, goods and services, and requires States to ensure the provision of equal and timely access to all health services and to health education. In particular, States are required to guarantee screening programmes, the treatment of diseases, illnesses, injuries and disabilities, appropriate mental health treatment and care, and the provision of essential drugs. States are also required to increase the participation of the population in the provision of health services and in the political decisions concerning the right to health[39].

In the General Comment, the Committee acknowledges that the most appropriate and feasible measures to implement the right to health will differ significantly between States and, therefore, recognizes to each State a margin of discretion in choosing which measures to take[40].

However, it requires States to take all the measures necessary to ensure the enjoyment of the highest attainable standard of physical and mental health for everyone, which will require guaranteeing access to health facilities, goods and services, the implementation of adequate policies, and the adoption of an appropriate national health strategy and plan of actions[41]. Such national health strategies and plans of action should be based on the principles of non-discrimination and people's participation[42] as well as on the principles of accountability, transparency and independence of the judiciary[43].

The Committee suggests that States should also adopt a framework law establishing mechanisms for monitoring the implementation of the national health strategies and plans of action and the progress towards the realization of the right to health[44].

The international right to health as applying to specific issues or groups

[39] *Ivi*, par.17.
[40] *Ivi*, par.53.
[41] *Ibidem.*
[42] *Ivi*, par.54.
[43] *Ivi*, par.55.
[44] *Ivi,* par.56.

The right to health is also acknowledged in some international documents which focus on more specific issues or groups, such as children, women or people affected by disabilities[45].

Among these documents, it is important to mention the Convention on the Rights of the Child, the Convention on the Elimination of All Forms of Racial Discrimination, the Convention on the Elimination of All Forms of Discrimination Against Women, the Convention on the Rights of Persons with Disabilities, and the International Convention on the Protection of the Rights of All Migrant Workers and Members of Their Families[46].

The European right to health under international law

The European Union can in some cases be considered bound by international human rights obligations. Indeed, in so far as human rights standards are part of Customary International Law, the European Union is directly bound to guarantee their protection[47].

All the European Member States are party to the majority of the main international human rights treaties[48], and in particular to the Charter of the United Nations, whose obligations are binding both on them and on the European Union.

This has been further stressed in the *Kadi* case[49], where it has been affirmed that "the Community must be considered to be bound by the obligations under the Charter of the United Nations in the same way as its Member States"[50].

However, the Charter of the United Nations does not directly address human rights, although it underlines their importance by setting the achievement of international co-operation in the

[45] Potts, H., and Hunt, P. H., *Accountability and the right to the highest attainable standard of health*, University of Essex, 2008.

[46] Agenzia Italiana del Farmaco (AIFA), *International Treaties and the Right to Health,* available at http://www.agenziafarmaco.gov.it/en/content/international-treaties-and-right-health.

[47] United Nations Office of the High Commissioner for Human Rights (OHCHR), Europe Regional Office, *The European Union and International Human Rights Law*, United Nations Office of the High Commissioner for Human Rights, Europe Regional Office, 2008, p. 23.

[48] *Ivi*, p. 7.

[49] Court of First Instance, *Case T-315/01, Kadi v. Council and Commission*, 2005.

[50] *Ivi,* par.193.

promotion and encouragement of respect for human rights for all without distinction of race, sex, language, or religion as one of the purposes of the United Nations[51].

The Charter further affirms the importance of human rights in Article 55, where it is reiterated that the United Nations shall promote universal respect for, and observance of, human rights for all[52], and in Article 56, in which it is stated that all Members pledge themselves to take action for the achievement of the purposes set forth in Article 55[53], thus including the promotion of respect and observance of human rights.

Human rights at the international level are more specifically dealt with in the Universal Declaration of Human Rights, which, however, is not legally binding. Nonetheless, the reference to human rights in the Charter of the United Nations has been interpreted by the United Nations General Assembly to also include the Universal Declaration of Human Rights. Therefore, Member States can be considered as having an obligation to respect and implement the human rights included in the Universal Declaration of Human Rights[54].

As previously discussed, the right to health is more explicitly considered in the International Covenant on Economic, Social and Cultural Rights, which has been ratified by all the European Member States[55]. Consequently, the European Union can be claimed to be bound to respect and promote the rights included in the Covenant, and thus also the right to health.

The fact that the European Union can be considered bound by international human rights obligations can be also found in European Law itself[56], and more precisely in Article 3(5) of the Treaty on the European Union, which affirms that the Union shall, among other things, contribute to the protection of human rights, and to the development and compliance of

[51] United Nations (UN), *Charter of the United Nations*, 1 UNTS XVI, 24 October 1945, art. 1(1).
[52] *Ivi*, art. 55(c).
[53] *Ivi*, art. 56.
[54] OHCHR, Europe Regional Office, *The European Union and International Human Rights Law*, p. 7.
[55] UN General Assembly, *International Covenant on Economic, Social and Cultural Rights*, *op. cit.*
[56] OHCHR, Europe Regional Office, *The European Union and International Human Rights Law*, p. 6.

international law[57], and in Article 351 of the Treaty on the Functioning of the European Union, which states that the rights and obligations resulting from agreements concluded before the Treaties entered into force, or anyway before the date of accession, shall not be affected by the provisions of such Treaties[58].

The Court of Justice of the European Union has considered Article 351 of the Treaty on the Functioning of the European Union as having two main consequences: it allows European Member States to accord priority to previous obligations over European Union Law[59], and it implies that the European Union has to refrain from interfering with the implementation of such agreements by the Member States[60].

Moreover, the General Court has affirmed that, to the extent that the European Union has assumed powers previously exercised by the Member States in the area regulated by the Charter of the United Nations, the provisions of the Charter have to be considered as binding the European Union[61].

The Court of Justice of the European Union has specified that the obligations arising under the Charter of the United Nations can take effect in the European Union in so far as they are consistent with primary law, and especially with the general principles, including fundamental rights[62].

Even though the standards arising from the Charter of the United Nations and the UN human rights treaties go beyond those explicitly acknowledged in European Union Law, they do not

[57] European Union (EU), *Consolidated version of the Treaty on European Union (TEU)*, OJ C 326, 26.10.2012, p. 13–390, 13 December 2007, art. 3(5).
[58] European Union (EU), *Consolidated version of the Treaty on the Functioning of the European Union (TFEU)*, OJ C 326, 26.10.2012, p. 47–390, 13 December 2007, art. 351.
[59] OHCHR, Europe Regional Office, *The European Union and International Human Rights Law*, p. 24. Taken from Case C-158/91, Levy [1993] ECR I-4287, para. 17.
[60] *Ibidem*. Taken from Case 812/79, Burgoa [1980] ECR 2787, paras. 9-11.
[61] *Ibidem*. Taken from General Court Case T-315/01, Kadi [2005] ECR II-3649, para. 203. Case T-306/01, Yusuf [2005] ECR II-3533, para. 253.
[62] *Ibidem*. Taken from CJEU Joined Cases C-402/05 P and C-415/05 P, Kadi [2008] ECR I-6351, para. 308.

conflict with it, and can therefore be considered consistent with European primary law, general principles, and fundamental rights[63].

1.1.2 The right to health and to healthcare in the European Union

The right to health and to healthcare has also been specifically recognised at the European Union level itself.

As stated in Article 2 of the Treaty on the European Union, respect for human rights is considered as one of the founding principles of the European Union[64].

Although the Treaty on the European Union does not explicitly address the protection of a right to health or to healthcare, its Article 3 affirms that one of the Union's aim is to promote the well-being of its peoples[65].

The same is also affirmed in the Treaty on the Functioning of the European Union, which in Article 168 affirms that the protection of health shall be ensured in all the policies and activities of the Union[66].

Human rights at the European level have been explicitly addressed for the first time in the European Convention on Human Rights, which, however, does not include a right to healthcare or a right to be healthy[67].

Like other socio-economic rights, these rights are instead addressed in the European Social Charter[68].

[63] *Ivi*, p. 25. Taken from Case C-540/03, Parliament v Council [2006] ECR I-5769, para. 37.
[64] EU, *TEU,* art. 2.
[65] *Ivi*, art. 3.
[66] EU, *TFEU*, art. 168.1.
[67] European Court of Human Rights (ECHR), *Thematic Report: Health-related issues in the case-law of the European Court of Human Rights*, Introduction, 2015.
[68] *Ibidem*.

A right to healthcare is also included in the Charter of Fundamental Rights of the European Union, whose Article 35 recognizes to everyone the right to access to preventive health care and to benefit from medical treatment, and requires that a high level of human health protection be ensured in the definition and implementation of all Union policies and activities[69].

The right to health and to healthcare have recently been reaffirmed at the European level at the 2017 Social Summit for Fair Jobs and Growth, where the European Parliament, the Council and the Commission proclaimed the European Pillar of Social Rights setting out 20 key social principles and rights[70]. The European Pillar of Social Rights restresses the fundamental importance of health in the Preamble, where it claims that the European Union, in defining and implementing its policies and activities, shall take into consideration the protection of human health[71]. The Pillar also reaffirms the right to healthcare in its Article 16, where it recognizes that "everyone has the right to timely access to affordable, preventive and curative health care of good quality"[72].

The European Social Charter

As mentioned above, the right to health and the right to healthcare are specifically addressed in the European Social Charter[73], a Council of Europe treaty adopted in 1961 and revised in 1996[74]. The European Social Charter provides the most extensive and complete protection of fundamental social and economic rights, and guarantees the enjoyment of rights such as health, social protection and welfare to everyone without discrimination[75].

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[69] European Union (EU), *Charter of Fundamental Rights of the European Union*, OJ C 326, 26.10.2012, p. 391–407, 26 October 2012, art. 35.

[70] European Commission (EC), *Delivering on the European Pillar of Social Rights*, in Employment, Social Affairs & Inclusion, available at https://ec.europa.eu/social/main.jsp?catId=1226&langId=en.

[71] European Parliament (EP), European Council and European Commission (EC), *European Pillar of Social Rights*, Preamble, 2017.

[72] *Ivi,* art. 16.

[73] ECHR, *Thematic Report: Health-related issues in the case-law of the European Court of Human Rights*, *op. cit*.

[74] Council of Europe (CoE), *European Social Charter (Revised)*, European Treaty Series No. 163, 3 May 1996.

[75] *Ibidem*.

In the Charter, the States Parties have declared to accept as the purpose of their policies the realization of the conditions allowing, inter alia, for the effective realization of everyone's right to enjoy the highest possible standard of health attainable, as well as to benefit from social welfare services and from social and medical assistance[76].

It is interesting to notice that the wording of the European Social Charter concerning the right to health ("everyone has the right to benefit from any measures enabling him to enjoy the highest possible standard of health attainable"[77]) is almost the same as the wording of the International Covenant on Economic, Social and Cultural Rights ("the States Parties to the (…) Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health"[78]).

It is important to stress the fact that the European Social Charter does not only recognize a right to the enjoyment of physical, mental and social well-being, but also a right to social and medical assistance, i.e. a right to healthcare.

The European Social Charter specifically deals with health and healthcare in Articles 11 and 13 respectively.

Article 11 regards the right to the protection of health, and affirms that the States Parties undertake to adopt adequate measures aimed at the removal of the causes of ill-health, at the provision of facilities for the promotion of health, and at the prevention of accidents and diseases, including epidemic and endemic diseases[79].

Article 13 concerns the right to social and medical assistance, and affirms that the States Parties undertake to ensure adequate assistance and necessary care to any person who is without adequate resources and who is unable to secure them, to guarantee that such assistance does not entail a diminution of the political or social rights of the assisted, and to ensure the provision

[76] *Ivi*, part I.
[77] *Ivi*, part I (11).
[78] UN General Assembly, *International Covenant on Economic, Social and Cultural Rights*, art. 12(1).
[79] CoE, *European Social Charter*, art. 11.

of appropriate public or private services such advice and personal help necessary to prevent, to remove, or to alleviate personal or family want [80]. The provision under Article 13 have to be applied by the States Parties on an equal footing with their nationals to nationals of other States Parties lawfully within their territories[81].

Signatures, ratification and reservations

Even though the majority of the European Member States are bound by the Charter, that there are some exceptions.

Romania and Slovenia have signed the Charter but not ratified it, and Bulgaria, Estonia and Lithuania have neither signed nor ratified it[82].

Moreover, most States have made some declarations thereby not accepting the Charter in its entirety[83]. Only Belgium, Italy and Spain have accepted all the undertakings arising from it[84]. Concerning Articles 11 and 13, there are 14 European Member States other than Belgium, Italy and Spain that consider themselves bound by both Articles in their entirety: Austria, Croatia, Czech Republic, Denmark, Finland, Germany, Greece, Hungary, Latvia, Luxemburg, Malta, Netherlands, Portugal, and Sweden. Regarding the remaining countries, Cyprus has accepted Article 11 in its entirety, but not Article 13; Ireland has accepted Article 13 in its entirety, but only paragraph 3 of Article 11; and France, Poland and Slovakia have accepted Article 11 in its entirety but only some paragraphs of Article 13 (1, 3, and 4 France; 2 and 3 Poland; 1, 2 and 3 Slovakia)[85].

[80] *Ivi*, art. 13.
[81] *Ivi*, art. 13(4).
[82] Council of Europe (CoE), *Chart of signatures and ratifications of Treaty 035 (European Social Charter)*, status as of 28/03/2020, available at https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/035/signatures.
[83] Council of Europe (CoE), *Reservations and Declarations for Treaty 035 - European Social Charter*, status as of 28/03/2020, available at https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/035/declarations?p_auth=1w8L7mTZ.
[84] *Ibidem*.
[85] *Ibidem.*

The European Committee of Social Rights' interpretation of the European Social Charter

States' compliances with the European Social Charter is monitored by the European Committee of Social Rights, which is composed by 15 independent and impartial members elected by the Council of Europe's Committee of Ministers every six years[86].

Compliance with the Charter is monitored through two complementary mechanisms: a collective complaints procedure and a (national) reporting system[87]. Under these monitoring mechanisms, the Committee adopts decisions and conclusions which have to be respected by the States concerned, and, even if they are not directly enforceable in the national legal systems, they can provide the basis for positive developments in social rights through national legislation and case-law[88].

The European Committee of Social Rights presents its interpretation of the articles of the European Social Charter, and the principles on which this interpretation is based, in the Digest, whose current version dates 2018[89]. Here, the Committee underlines that the European Social Charter is a human rights treaty aimed at the application of the Universal Declaration of Human Rights in Europe, as an addition to the European Convention on Human Rights[90].

The Committee acknowledges the diversity of national traditions of the European Member States and affirms the importance of their respect, but it also underlines that it is important to consolidate adhesion to the shared values and to individuate the principle that guarantee that the rights embodied in the European Social Chart are applied equally effectively in all the European Member States[91].

[86] Council of Europe (CoE), *European Committee of Social Rights*, available at https://www.coe.int/en/web/european-social-charter/european-committee-of-social-rights.
[87] *Ibidem*.
[88] *Ibidem*.
[89] *Ibidem*.
[90] European Committee of Social Rights (ECSR), *Digest of the Case Law of the European Committee of Social Rights*, 2018, part II (iii).
[91] *Ibidem*

Additionally, the Committee affirms that as a human rights protection instrument, the Charter's aim is to protect rights theoretically as well as in fact. As a consequence, in order to give full effect to the rights recognised in the Charter, States have to take legal and practical actions, making the necessary resources available and introducing the required operational procedures[92].

In Part III of the Digest, the European Committee of Social Rights presents its interpretation of the different provisions of the European Social Charter, including Articles 11 and 13.

With regard to Article 11 granting everyone the right to benefit from any measures enabling him to enjoy the highest possible standard of health attainable[93], the Committee affirms the fundamental importance of healthcare as a prerequisite for the preservation of human dignity, the fundamental value and the core of positive European human rights law[94], and underlines that the right to the protection of health includes respect for physical and psychological integrity[95].

The Committee also sustains that Article 11 enshrines both the right to the highest possible standard of health and the right of access to healthcare[96]. Concerning the right to the highest possible standard of health, the Committee maintains that Article 11 imposes a series of obligations on States, such as undertaking positive and proactive measures enabling the enjoyment of the highest possible standard of health attainable, as well as refraining from interfering with the enjoyment of the right to health[97]. Regarding the right of access to healthcare, the Committee affirms that healthcare systems have to be accessible to everyone[98],

[92] *Ivi*, part II (iv).
[93] CoE, *European Social Charter,* part I (11).
[94] ECSR, *Digest of the Case Law*, part III, art, 11. Taken from International Federation of Human Rights Leagues (FIDH) v. France, Complaint No. 14/2003, Decision on the merits of 3 November 2004, par. 31.
[95] *Ibidem.* Taken from Transgender Europe and ILGA Europe v. Czech Republic, Complaint No. 117/2014, Decision on the merits of 15 May 2018, par. 74.
[96] *Ivi,* part III, art. 11(1).
[97] *Ibidem.*
[98] *Ibidem*.

and requires States to provide adequate and timely care on a non-discriminatory basis[99]. It moreover underlines that the realization of the right of access also requires the cost of healthcare to be at least partially borne by the whole community[100] and not to represent an excessive burden for the individual, meaning inter alia that out-of-pocket payments should not be the main source of funding of the health system[101]. Moreover, access has to be provided without unnecessary delays[102] and the number of health care professionals, equipment and hospital beds must be adequate[103].

Article 11 also requires advisory and educational facilities for the promotion of health and the encouragement of individual responsibility in matters of health to be provided, thus imposing on States two obligations: education and awareness raising, and doctor's consultations and screening[104].

Moreover, under Article 11 States are required to take appropriate measures designed, inter alia, to prevent as far as possible epidemic, endemic and other diseases, as well as accidents, through the adoption of preventive measures based on the precautionary principle[105]; to guarantee a healthy environment; and to adopt measures against the use of tobacco, alcohol and drugs, undertake largely accessible immunisation programmes, maintaining high coverage rates, and take steps to prevent accidents[106].

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[99] *Ibidem.* Taken from International Planned Parenthood Federation – European Network (IPPF EN) v. Italy, complaint No. 87/2012, decision on the merits of 10 September 2013, par. 66.

[100] *Ibidem.* Taken from Conclusions I (1969), Statement of Interpretation on Article 11.

[101] *Ibidem.* Taken from Conclusions 2013, Georgia.

[102] *Ibidem.* Taken from Conclusions XV-2 (2001), United Kingdom; Conclusions 2013, Poland; and Recommendation No. (99)21 of the Committee of Ministers of the Council of Europe on criteria for the management of waiting lists and waiting times in health care.

[103] *Ibidem.* Taken from Conclusions XV-2 (2001), Addendum, Turkey and Conclusions XV-2 (2001), Denmark.

[104] *Ivi*, part III, article 11(2).

[105] The precautionary principle establishes that in the event of a preliminary scientific evaluation showing the existence of reasonable grounds for concern about potentially dangerous effects on human health, States are required to take precautionary measures to prevent such effects.

[106] ECSR, *Digest of the Case Law*, part III, art, 11(2).

With regard to Article 13 granting anyone without adequate resources the right to social and medical assistance[107], the Committee underlines how the European Social Charter breaks with the traditional concept of assistance linked to the moral duty of charity as States no longer grant assistance only as they think fit, but they are now under an obligation to grant assistance, and they may be called on in court to honour such obligation[108].

The Committee specifies that social assistance concerns those benefits based on individual need as the main criterion for eligibility, without any requirement of affiliation to a social security scheme aimed to cover a particular risk, or any requirement of professional activity or payment of contributions[109]. Such benefits are payable to any person on the sole ground that of need, and the system of assistance has to be universal[110].

Article 13 guarantees the right to two types of assistance: social and medical. Concerning social assistance, the Article does not specify what form it should take, and therefore it can consist in benefits in cash as well as in kind[111]. However, it has to be appropriate[112], and it has to be provided without time-limits for as long as the situation of need persists[113]. Entitlement to social assistance is conditional only on the criterion of necessity, and that the availability of adequate resources is the only ground on which assistance can be denied, suspended or reduced[114]. For what concerns medical assistance, the Article is more exhaustive, as it specifies that everyone who lacks adequate resources has the right to obtain free of charge the necessary medical care,

[107] CoE, *European Social Charter,* part I (13).
[108] ECSR, *Digest of the Case Law*, part III, article 13(1). Taken from Conclusions I (1969), Statement of Interpretation on Article 13.
[109] *Ibidem.* Taken from Conclusions XIII-4 (1996), Statement of Interpretation on Articles 12 and 13.
[110] *Ibidem.* Taken from Finnish Society for Social Rights v. Finland, Complaint No 88/2013, decision on the merits of 9 September 2014, par. 110.
[111] *Ibidem.*
[112] *Ibidem.*
[113] *Ibidem.* Taken from European Roma Rights Centre (ERRC) v. Bulgaria, complaint No. 48/2008, Decision on the merits of 18 February 2009, par. 39.
[114] *Ibidem.* Taken from Conclusions XVIII-1 (2006), Spain.

with medical care including free or subsidised healthcare or payments to allow to pay for the necessary medical care[115].

Importantly, Article 13 has to be applied by States Parties on an equal footing with their nationals to nationals of other States Parties lawfully within their territories[116].

1.1.3 The Right to Health and to Healthcare in European National Constitutions

Human rights principles and rights, in some cases also specifically addressing health and healthcare, are given remarkable protection also at the national level[117]. Indeed, all the European Member States have their own human rights legislation and, in some cases, they also specifically commit to the protection of the right to health and/or to healthcare[118]. Some have also adopted specific patients' rights legislation, while others include such rights in the general health legislation[119].

Like many other countries around the world, all the European Member States except Austria, Cyprus, Denmark, France, Germany, Ireland, Malta and Sweden, acknowledge and protect the right to health and/or to healthcare in their constitutions. A 2008 study[120] on national constitutions has shown that of the 186 analysed constitutions, 135 (73%) encompassed some form of health provisions, 95 (51%) included the rights to health facilities, good and services, and only 4 (2%) incorporated essential medicines in the health rights. Interestingly, from this

[115] *Ibidem.* Taken from European Roma Rights Centre (ERRC) v. Bulgaria, complaint No. 46/2007, Decision on the merits of 3 December 2008, par. 44.

[116] *Ivi*, part III, Article 13(4). Taken from Conclusions XIV-1 (1998), Statement of Interpretation on Article 13.4 and Conclusions VII (1981), Statement of Interpretation on Article 13.4.

[117] McHale, J., *Fundamental rights and health care*, in E. Mossialos, G. Permanand, R. Baeten, & T. Hervey (Eds.), Health Systems Governance in Europe: The Role of European Union Law and Policy (Health Economics, Policy and Management, pp. 282-314), Cambridge University Press, p. 292, 2010.

[118] *Ibidem.*

[119] *Ivi,* p. 293.

[120] In 2008, all the European Member States had already adopted their national constitutions, with the exception of Hungary, which adopted The Fundamental Law of Hungary in 2011.

study it appeared that none of the European Member States is among the countries with the most comprehensive constitutions concerning the right to health, among the countries whose constitutions include the most binding health provisions, or among the countries whose constitutions include the greatest number of health rights and principles[121]. On the contrary, the strongest commitments to the right to health and healthcare can be found in the constitutions of poor countries with weak democracies[122]. However, it is important to stress that the existence of strong constitutional provisions does not always lead to an equivalent system in practice[123], and that many countries that dedicate extensive resources to health and healthcare appear to be among those with no specific constitutional provision[124].

1.2 Health systems

The realization of the right to health and to healthcare is still far from being a reality, and this is often linked to the lack of an adequate and effective health system. All the health systems across the world are more or less structured in the same way, even though they show wide differences among each other. Indeed, even though all health systems have the same building blocks, they can be classified in different ways and there are many different health system types, each based on a different conception of the right to health and of the role of the state. Interestingly, there is no common agreement on how to classify these various health systems, and this disagreement has led to the development of a variety of health system typologies. Also interesting is the fact that within the European Union we can witness the existence of a variety

[121] Perehudoff, S. K., *Health, human rights & national constitutions*, 2008.
[122] *Ibidem*, and Kinney, E. D. and Clark, B. A., *Provisions for Health and Health Care in the Constitutions of the Countries of the World*, Cornell Int'l LJ 37: 285, 2005.
[123] Kinney, E. D. and Clark, B. A., *Provisions for Health and Health Care in the Constitutions of the Countries of the World*, *op. cit.*
[124] *Ibidem.*

of health systems. Indeed, the European Union does not have a unique health system, but is rather characterized by the coexistence of 27 separate national health systems. These systems are all built on a set of common values and principles, such as universality, access to good quality care, equity and solidarity[125], but they differ considerably among each other and can be classified in different health system typologies.

1.2.1 The building blocks of health systems

A health system has been defined by the World Health Organization as consisting of all the activities whose primary purpose is to promote, restore or maintain health[126]. It consists of a formal structure for a defined population, whose finance, management, scope and content are defined by law and regulations, which provides for services to be delivered to people to contribute to their health and healthcare in defined settings, and which may affect the physical and psychosocial environment[127].

The fundamental objectives and the essential functions of a health system

In *The world health report 2000: health systems: improving performance*[128], the World Health Organization identified three fundamental objectives and four essential functions of a health system. The fundamental goals of a health system are better health, fairness in financial contribution and responsiveness to people's expectations in regard to non-health matters. The main functions of a health system are stewardship (acting as the overall stewards of the

[125] European Commission (EC), *Communication from the Commission on effective, accessible and resilient health systems*, COM(2014) 215 final, Brussels, 4 April 2014.
[126] World Health Organization (WHO), *The world health report 2000: health systems: improving performance*, World Health Organization, 2000.
[127] Roberts, J. L., and World Health Organization (WHO), *Terminology: a glossary of technical terms on the economics and finance of health services*, No. EUR/ICP/CARE 94 01/CN01, Copenhagen: World Health Organization Regional Office for Europe, 1998.
[128] WHO, *The world health report 2000: health systems: improving performance, op. cit.*

resources, powers and expectations entrusted to it), creating resources (investing in people, buildings and equipment), delivering services (provision of personal and non-personal health services), and financing (raising, pooling and allocating the revenues to purchase health services)[129].

The fundamental building blocks of a health system

Health system's functions have been broken down into a set of six fundamental building blocks that make up a health system. These building blocks have been defined by the World Health Organization in its 2007 *Everybody business: strengthening health systems to improve health outcomes: WHO's framework for action*, and are: service delivery; health workforce; information; medical products, vaccines and technologies; financing; and leadership and governance[130].

It is important to underline that a health system is a set of inter-connected parts that have to function together in order to be effective, and therefore interaction among the building blocks is vital for achieving better health outcomes[131].

Service delivery

The first building block, i.e. service delivery, concerns the organization and management of inputs and services aimed at ensuring access, quality, safety and continuity of care. Good health services are characterized by the delivery of effective, safe and quality health interventions to the individuals who need them, when and where they need them, with the minimum waste of resources possible[132].

[129] *Ibidem.*
[130] World Health Organization (WHO), *Everybody business: strengthening health systems to improve health outcomes: WHO's framework for action,* World Health Organization, Geneva, 2007.
[131] *Ibidem.*
[132] *Ibidem.*

Health workforce

The second building block, i.e. health workforce, refers to health service providers and health management and support worker, to all the people involved in activities related to the protection and improvement of health. A well-performing health workforce has to be competent, responsive and productive, and has to work fairly and efficiently with the aim of achieving the best health outcomes possible[133].

Information

The third building block, i.e. information, concerns the development of health information and surveillance systems, as well as of standardized tools and instruments, and the gathering and publication of international health statistics. A well-functioning health information system is thus characterized by the production, analysis, diffusion and utilization of reliable and timely information on health determinants, health systems performance and health status[134].

Medical products, vaccines and technologies

The fourth building block, i.e. medical products, vaccines and technologies, concerns access to and use of essential medical products, vaccines and technologies, as well as their quality and safety. A well-functioning health system is one that guarantees equitable access to essential medical products, vaccines and technologies of assured quality, safety, efficacy and cost-effectiveness, as well as their scientifically valid and cost-effective use[135].

Financing

[133] *Ibidem.*
[134] *Ibidem.*
[135] *Ibidem.*

The fifth building block, i.e. financing, concerns the collection of revenues; the pooling of pre-paid revenues so as to allow for risk sharing; and the purchasing of services. An effective, efficient and equitable health financing system is one that raises adequate funds for health, so as to ensure that people can use needed services without risking to incur into financial catastrophe or impoverishment associated with the cost of healthcare[136].

Leadership and governance

The sixth building block, i.e. leadership and governance, concerns the role of the government in the health sector and its relation to other actors whose activities have an impact on health. It involves guaranteeing the existence of strategic policy frameworks, together with effective oversight, coalition-building, the provision of appropriate regulations and incentives, attention to system-design, and accountability[137].

1.2.2 The context of health systems

Even though every health system is characterized by the same building blocks, there are no two exactly identical health systems. This is because health systems are deeply embedded in the social, cultural, political and economic context of their country, they are connected to the political and legal institutions and practices of their country, as well as to the cultural and historical setting from which they originated, and their shaping is influenced by the size of the population, its ethnic, racial and religious composition, and the level of economic equality.

Country-specific factors

[136] *Ibidem.*
[137] *Ibidem.*

Therefore, each health system presents some peculiar characteristics that are the product of a multitude of country-specific factors[138].

Goals, objectives and priorities

Among these country-specific factors, a particularly important one concerns the goals, objectives and priorities each nation sets for its health system, and how much emphasis it puts on each of them[139].

Culture, history and system of values

Another important for the shaping of a health system are the specific culture, history and system of values of each country.

Of particular relevance is whether the right to healthcare is conceptualised as a negative or a positive right. Healthcare as a negative right allows people to use their personal resources as they see fit, and imposes an obligation on governments to simply refrain from interfering with people's exercise of their right, without providing for further obligations on the state to take positive action to guarantee an effective exercise of the right to healthcare. On the contrary, healthcare as a positive right imposes an obligation to ensure that everyone has the goods and services necessary to exercise his or her right to healthcare, therefore imposing on governments an obligation to take positive action to guarantee an effective exercise of the right to healthcare. How the right to healthcare is conceptualised, and the type of obligations linked to it, can be generally related to the dominant culture of a country. Indeed, while countries characterized by an egalitarian culture tend to emphasize the right to healthcare and the social commitment to provide it, those countries that are characterized by a communitarian culture tend to organize

[138] Blank, R., Burau, V., and Kuhlmann, E., *Comparative health policy*, 5th edition, Macmillan International Higher Education, 2018.
[139] *Ibidem*.

their health system as to guarantee the interests of the various groupings and communities, and the countries with a prevailing individualistic culture tend to place emphasis on healthcare as an individual right located above the welfare of the community[140].

Moreover, as previously mentioned, sometimes the right to health and/or to healthcare is not even acknowledged in the constitution of a country, as it is the case in Austria, Cyprus, Denmark, France, Germany, Ireland, Malta and Sweden. Additionally, even when a right to health and/or to healthcare is included, it is not always particularly comprehensive[141].

Institutional setup

Another important element that influences the shaping of a health system is the specific institutional setup of a country, and whether a country presents a unitary system where political power tends to be centralized and decisions concerning the health system and its management are dealt with at the national level, or a federal or semi-federal system where political power rather tends to be dispersed and decisions concerning the health system and its management are mainly dealt with at the regional or local level[142].

Demographics and wealth

The differences among health systems can also be explained from a functionalist/structuralist perspective, based on quantitative features such as demographics and wealth. Indeed, the differences in size, age and ethnic variety of populations lead countries to face different health issues. Countries with a small, highly concentrated population deal with different health needs compared to countries with a large, diverse population, in the same way as countries with a large old age cohort are confronted with different health needs than countries with an averagely

[140] *Ibidem*.
[141] Perehudoff, S. K., *Health, human rights & national constitutions*, *op. cit.*.
[142] Blank, R., Burau, V., and Kuhlmann, E., *Comparative health policy*, *op. cit.*.

younger population and a small old age cohort. Additionally, different cultures and religions might have very different views and ideas concerning health and healthcare, and consequently countries with a highly heterogeneous population have to confront their health systems with a vaster variety of health needs. Similarly, also the wealth of a country affects its health system, with wealthier countries having more resources at their disposal to fund their health systems. However, wealth itself does not ensure good health, nor an equitable and effective health system. The health status of a population is not affected only by the overall wealth of its country, but also by the degree of inequality in social and economic conditions of its population. Indeed, regardless of their overall wealth and health expenditure, countries with greater inequalities are generally characterized by a poorer health status. Even though their extent varies, in all countries inequalities in health status tend to be related to factors such as age, ethnicity, socio-economic status and education. Socio-economic status is probably the main influencer of health status, with lower socio-economic classes being consistently characterized by a generally worse health status. Such health status inequalities related to socio-economic status can be attributed to a variety of factors that can be broadly explained by three theories. The natural and social selection theory sees health status as one of the main determinants of social class, and argues that people with poorer health are generally more disadvantaged and therefore naturally tend to concentrate in the lower social classes. The structuralist theory relates health status inequalities to structural factors such as wealth, as people with a lower socio-economic status tend to concentrate in less healthy home and work environments. The last theory is a cultural and behavioural one and links health status inequalities to personal behaviour, which is in turn linked to socio-economic status. According to this last theory, people from lower socio-economic classes tend to engage in high-risk behaviours which lead to a poorer health status[143].

[143] *Ibidem*.

1.2.3 Health systems typologies

Even though health systems vary from country to country, various typologies have been developed in order to classify them[144].

Health system typologies are often constructed around different models of funding, providing and governing healthcare. Funding concerns the processes of raising financial resources, e.g. through taxes, social insurance contributions, private insurance premiums and out-of-pocket payments, and allocating them to the providers of healthcare. Provision of healthcare refers to the delivery of health services, and can be made by public or private providers, or a mix of them. Finally, governance of healthcare concerns the coordination of health systems and their various actors.

The classification of health systems is also often related to what Bambra defined as health decommodification, i.e. the extent to which an individual's access to healthcare and health services depends on his or her market position and the extent to which a country's provision of healthcare and health services depends on the market or is independent from it[145].

Most health systems typologies tend to assume that certain models of funding are always linked to certain models of provision, e.g. funding from taxes is usually assumed to go hand in hand with public provision[146]. Even though this is the case in some countries, in the majority of cases health systems present a combination of characteristics taken from different typologies. Indeed, health system typologies generally represent ideal types of health systems, and can be defined as approximations of real health systems[147].

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[144] *Ibidem.*

[145] Bambra, C., *Worlds of Welfare and the Health Care Discrepancy*, Social Policy & Society 4 (1): 31–41, 2005.

[146] Blank, R., Burau, V., and Kuhlmann, E., *Comparative health policy*, *op. cit.*

[147] *Ibidem.*

Nonetheless, it is important to provide an overview of the main typologies of health systems, as they are useful to better understand how health systems actually differ from each other.

OECD typology

A relatively old but still among the most influential health systems typologies has been developed in 1987 by the Organisation for Economic Co-operation and Development (OECD) and distinguishes health system based on variations in the funding and provision of healthcare and on the degree of state intervention[148].

This typology identifies three main health system models: the national health service model, the social insurance model, and the private insurance model.

The national health service model, also called the Beveridge model, is mostly funded out of general taxation and is characterized by universal coverage.

The social insurance model, also called the Bismarck model, is based on the principle of social solidarity and is a sort of hybrid as it combines public and private features. It is characterized by universal coverage ensured through compulsory publicly mandated insurance funded through employer and individual contributions.

The third health system model of the OECD typology is the private insurance model, also called consumer sovereignty model, and is characterized by a predominance of the market, with very little state involvement. In this model, individuals purchase their own private health insurance and healthcare services are mainly provided privately.

Moran's typology

[148] Judge, K., *Financing and Delivering Health Care. A Comparative Analysis of OECD Countries*, Social Policy Studies No. 4, OECD, Paris, 1987.

Another influential health system typology has been developed in 2000 by Moran, who based his classification of health systems on the governance of consumption, provision, and technology, the three main governing arenas of 'the healthcare state'[149].

He termed health systems healthcare states to denote the symbiotic relation between states and healthcare institutions, and identified four main families of healthcare states based on the type and degree of state intervention in the three governing arenas.

These four main types of healthcare states are: the entrenched command and control state; the supply state; the corporatist state; and the insecure command and control state.

In the first type of healthcare state, the entrenched command and control one, the state has an important role in all the governing arenas. This type of healthcare states is characterized by broad public access to health services and public control of resource allocation.

In the second type of healthcare state, the supply one, the situation is completely reversed, with providers covering the main role in all the governing arena. Here, both access to healthcare and public control of costs are limited and subject to providers' interests, and healthcare is mainly funded through private insurance.

In the third type of healthcare state, the corporatist one, public law bodies and doctors' associations are the leading figures in the governing arenas, access to health services is public and healthcare is mainly funded through social insurance contributions, with limited public control over costs.

Finally, in insecure command and control healthcare states, the state has a relevant role and healthcare provision is legally universal, although the state lacks the administrative capacities for ensuring universal coverage and equal access[150].

[149] Moran, M., *Understanding the Welfare State: The Case of Health Care*, The British Journal of Politics and International Relations 2.2: 135–60, 2000.

[150] *Ibidem.*

Wendt, Frisina and Rothgang's typology

A third important health systems typology has been developed in 2009 by Wendt, Frisina and Rothgang[151].

This typology is based on the three main dimensions of health systems, i.e. financing, provision and regulation, and on who among the state, non-governmental actors and the market is responsible for them.

These authors developed their health system typology by connecting these three actors with the three health system dimensions, arriving at 27 possible combinations. Of these, only three are ideal types with all the three dimensions are dominated by the same actor. All the others cases consist of mixed types.

When the financing, provision and regulation dimensions are all dominated by state actors and institutions, we have the state healthcare system; when they are dominated by societal actors, it is the case of the societal healthcare system; and finally, when all three dimensions are dominated by market actors, we have the private healthcare system.

Alongside each ideal healthcare system type, Wendt Frisina and Rothgang identified six combinations of mixed-types in which the same actor dominates two of the three dimensions, thus approximating an ideal type. Alongside the state healthcare system, they individuated six state-based mixed types with a predominance of state actors; alongside the societal healthcare system, they individuated six societal-based mixed-types with a dominance of societal actors; and alongside the private healthcare system, they individuated six private-based mixed types with a predominance of private market actors.

[151] Wendt, C., Frisina, L. and Rothgang, H., *Healthcare System Types: A Conceptual Framework for Comparison*, Social Policy & Administration 43.1: 70–90, 2009.

The authors also found six combinations of mixed-types where each of the three dimensions is characterized by the domination of a different actor. These six healthcare system types are referred to as pure mixed-types and do not approximate any ideal type[152].

1.2.4 The European Union health systems

As previously mentioned, within the European Union we can witness the coexistence of various health systems, as the European Union does not have a unique health system, but it is rather characterized by 27 separate national health systems.

The health systems of the European Union are recognized as being a fundamental component of the European social protection and justice systems, as well as a fundamental element of European cohesion and integration[153].

As acknowledged by the back then 25 Health Ministers of the European Union in the 2006 *Council Conclusions on Common values and principles in European Union Health Systems*[154], and subsequently by the European Commission in its 2014 *Communication from the Commission on effective, accessible and resilient health systems*[155], the European systems are all built on a set of common values and principles, but they differ considerably among each other in respect to funding, providing and governing.

The common values shared by all European health systems are universality, access to good quality care, equity, and solidarity, and beneath them there are the operating principles of good quality care, patient safety, evidence and ethics-based care, patient involvement, right to redress, privacy and confidentiality[156].

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[152] *Ibidem.*

[153] Council of the European Union (Council of the EU), *Council Conclusions on Common values and principles in European Union Health Systems*, Official Journal of the European Union, 2006.

[154] *Ibidem.*

[155] EC, *Communication from the Commission on effective, accessible and resilient health systems*, *op. cit*.

[156] Council of the EU, *Council Conclusions on Common values and principles in European Union Health Systems*, *op. cit*.

Although they share these common values and principles, the various European Member States put them in practice and realize them in significantly different ways[157] as to reflect their different societal choices[158]. In particular, even though they are all committed to universal coverage of health services, each Member State organises its health system and deals with health coverage in very different ways[159], providing different baskets of services on different basis to different population groups, and often not achieving a real universal coverage.

Moreover, in line with Article 168 of the Treaty on the Functioning of the European Union, the definition of health policy and the organisation and delivery of health services and medical care are responsibilities of the individual Member States[160], and the role of the European Union is to merely complement national health policies and actions[161] and encourage cooperation between Member States in the field of health and healthcare[162].

The classification of European health systems

As a 2014 study by Wendt has shown, European health systems do not form a European healthcare model[163].

In his study, Wendt analysed and clustered 32 OECD health systems, and verified whether European health systems present more similarities compared with other countries. The results of this analysis have clearly shown that European countries do not share common features more than do health systems of other countries, and are indeed clustered in different typologies, thus not forming a European healthcare model[164].

Therefore, as Wendt's study has shown, a unique European health system does not exist.

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[157] *Ibidem*.
[158] EC, *Communication from the Commission on effective, accessible and resilient health systems*, *op. cit*.
[159] Mackenbach, J.P., Karanikolos, M., and McKee, M., *The unequal health of Europeans: successes and failures of policies*, The Lancet, 381.9872: 1125-1134, 2013.
[160] EU, *TFEU*, art. 168.7.
[161] *Ivi,* art. 168.1.
[162] *Ivi*, art. 168.2.
[163] Wendt, C., *Changing healthcare system types*, Social policy & administration, 48.7: 864-882, 2014.
[164] *Ibidem*.

Nonetheless, there have been some efforts in clustering European health systems into health system typologies.

Wendt's classification

One of these European health systems classifications has been proposed by Wendt in 2009[165]. In his study, Wendt analysed 15 European countries and clustered them into three typologies based on expenditures, financing, provision and access to healthcare. More specifically, he based his classification on total healthcare expenditure, the public-private financing mix, the amount of out-of-pocket payments, out-patient and in-patient healthcare provision, entitlement to healthcare, remuneration of medical professionals, and patients' access to healthcare providers.

The first health system typology identified by Wendt is a 'health service provision-oriented type', characterized by a high number of healthcare providers and free access for patients to medical doctors. This health system type was found in Austria, Belgium, France, Germany, and Luxembourg.

The second health system typology is a ''universal coverage-controlled access type', in which healthcare is recognized as a social citizenship right and equal access to healthcare is considered as more important than freedom of choice. This health system type was found in Denmark, Italy, Ireland, and Sweden.

The third health system typology developed by Wendt is a 'low budget-restricted access type', which is characterized by limited financial resources for healthcare and in which patients' access to healthcare is limited by high private out-of-pocket payments and the regulation that

[165] Wendt, C., *Mapping European Healthcare Systems. A comparative analysis of Financing, Service Provision and Access to Healthcare*, Journal of European Social Policy 19.5: 432-45, 2009.

patients have to sign up on a general practitioner's list for a longer period of time. This health system type was found in Finland, Portugal, and Spain[166].

Reibling's classification

Another interesting classification of European health systems has been provided for by Reibling in 2010[167], who classified them into four clusters based on healthcare access.

The first cluster consists of the 'financial incentive states', where the state has no or very little gatekeeping features, access is mostly regulated through cost sharing, and there generally is a high availability of medical personnel and technology. This cluster is composed by Austria, Belgium, France and Sweden.

The second cluster is composed by the 'weakly regulated and high supply states', which present a very low level of access regulation, with almost no gatekeeping characteristics and no use of cost sharing as an access regulation tool. These countries are characterised by the highest number of doctors, and especially of specialists, and this cluster consists of the Czech Republic, Germany and Greece.

The third cluster consists of 'strong gatekeeping and low supply states', where access to care is highly regulated through extensive gatekeeping arrangements, there are no cost sharing measures and a low number of doctors and medical technology, with the exception of nurses. This cluster is composed by Denmark, the Netherlands, Poland, and Spain.

The fourth and last cluster identified by Riebling is a 'mixed regulation type' that combines strong gatekeeping characteristics with institutionalized cost sharing measures. In the countries belonging to this cluster, the number of doctors is higher than in the strong gatekeeping and low supply states, but lower than in the financial incentive states and the weakly regulated and

[166] *Ibidem*.

[167] Reibling, N., *Healthcare systems in Europe: towards an incorporation of patient access*, Journal of European Social Policy 20.1: 5-18, 2010.

high supply states, while the availability of medical technology is the highest. This cluster consists of Finland, Italy and Portugal[168].

Baeten, Spasova, Vanhercke and Coster's classification

A third relevant classification of European health systems has been developed in a 2018 study by Baeten, Spasova, Vanhercke and Coster of the European Social Policy Network (ESPN)[169], in which European health systems have been classified according to their funding mechanisms into three typologies, similar to the OECD typologies[170] discussed before.

The typologies identified by these authors are National Health Service systems, Social Health Insurance systems and Private Health Insurance systems[171].

National Health Service systems are funded through general taxation and can be found in Cyprus (in transition towards a SHI system), Denmark, Spain, Ireland, Italy, Latvia (in transition towards a SHI system), Malta, Portugal, and Sweden.

Social Health Insurance systems are funded through a combination of general taxation and social contributions, and are found in Austria, Belgium, Bulgaria, Czech Republic, Estonia, France, Croatia, Hungary, Lithuania, Luxembourg, Poland, Romania, Slovenia and Slovakia.

Private Health Insurance systems are funded through premiums directly paid by the insured to the insurance company on an individual basis, or paid by the employer and subtracted from the employee's pay. This system can only be found in The Netherlands.

Baeten, Spasova, Vanhercke and Coster also identified some mixed systems in the cases of Germany, Finland and Greece. Germany is classified as a Social Health Insurance system, with a compulsory Private Health Insurance for some groups. Finland and Greece are classified as a

[168] *Ibidem*.
[169] Baeten, R., Spasova, S., Vanhercke, B., and Coster, S., *Inequalities in access to healthcare. A study of national policies*, European Social Policy Network (ESPN), European Commission, Brussels, 2018.
[170] Judge, K., *Financing and Delivering Health Care. A Comparative Analysis of OECD Countries*, *op. cit.*
[171] Baeten, R., Spasova, S., Vanhercke, B., and Coster, S., *Inequalities in access to healthcare. A study of national policies*, *op. cit.*

tax funded National Health Service system combined with compulsory Social Health Insurance[172].

Conclusion

This chapter has shown how health and healthcare have been recognised a fundamental importance, at the international level, as well as the European and national ones.

The European Union has indeed explicitly recognised a right to the enjoyment of physical, mental and social well-being, i.e. a right to health, as well as a right to social and medical assistance, i.e. a right to healthcare, and most European Member States have acknowledged and protect the right to health and to healthcare in their national constitutions, even though none of them has a particularly strong commitments to these rights compared to other countries.

Notwithstanding the acknowledged importance of these rights, their realization is still far from being a reality, and this is often linked to the lack of an adequate and effective health system.

All the health systems are more or less structured in the same way, based on the same building blocks, but they differ considerably due to the context they are in.

This is also the case in the European Union, where it is possible to identify a variety of health systems which, although are all built on a set of common values and principles, present noticeable differences in various respects. Indeed, the European Union health systems do not form a European healthcare model, as they do not share common features more than do health systems of other countries, and are clustered in different typologies.

[172] *Ibidem*.

The existence of a European right to health and to healthcare clashes with the existence of so many different European health systems, where health is conceptualised and healthcare is provided in very different and sometimes conflicting ways.

Chapter 2 – The state of health in the European Union

Introduction

Notwithstanding its acknowledged importance, the realization of the right to health and healthcare is still far from being a reality within the European Union, as there are still people lacking access to health services and without a proper health coverage. Moreover, there are major health and healthcare gaps and inequalities across countries, even though the state of health is generally good, especially if considered on the base of indicators such as health status, expenditure, financing, accessibility and coverage.

The data presented are mostly taken from the 2018 edition of *Health at a Glance: Europe*[173], a report developed by the Organization for Economic Co-operation and Development (OECD) in cooperation with the European Commission assessing the state of health of European citizens and the performance of European health systems and designed to assist the European Member States in improving the health of their citizens and the performance of their health systems[174].

The report analyses 35 European countries, including the currently 27 Member States, the United Kingdom, 5 candidate countries, i.e. Albania, FYR of Macedonia, Montenegro, Serbia and Turkey, and 3 European Free Trade Association (EFTA) countries, i.e. Iceland, Liechtenstein, Norway and Switzerland[175]. For the purpose of my work, I have decided to focus on the 27 European Union Member States.

[173] Organization for Economic Co-operation and Development (OECD) / European Union (EU), *Health at a Glance: Europe 2018: State of Health in the EU Cycle*, OECD Publishing, Paris/European Union, Brussels, 2018.

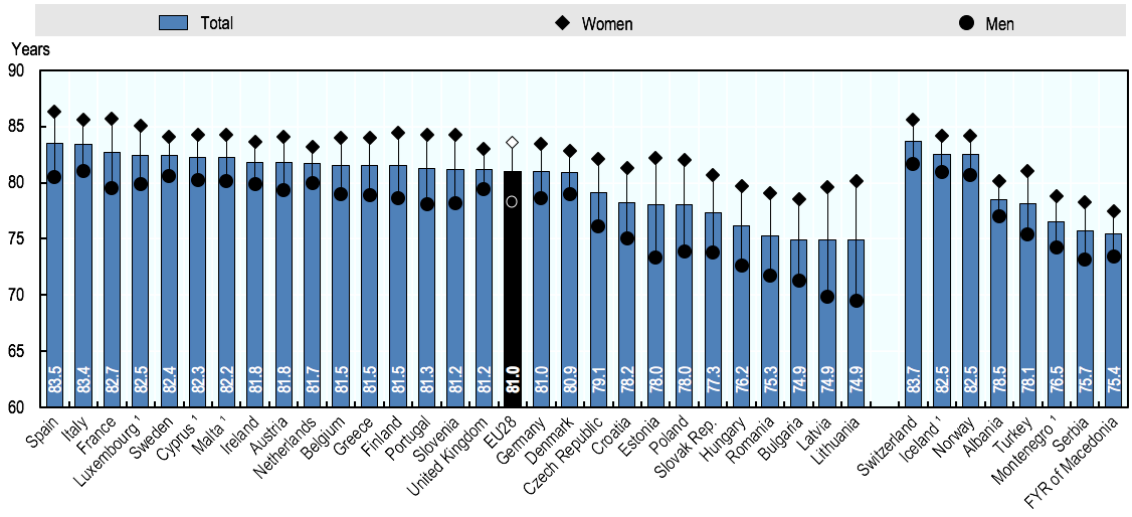
[174] European Commission (EC), *Health at a Glance: Europe*, in State of Health in the EU, available at https://ec.europa.eu/health/state/glance_en.

[175] *Ibidem*.

2.1 Health status

Overall, the European Union presents a fairly good health status of its population, with the average life expectancy at birth being 81 years[176]. Life expectancy ranges from around 75 years in Bulgaria, Latvia, Lithuania and Romania, to over 83 years in Italy and Spain, with women having a higher life expectancy than men in all the European countries[177]. Life expectancy presents some differences based on socioeconomic status, regardless of whether this is measured by education level, income or occupational group, with the groups with the highest socioeconomic status being characterized by a higher life expectancy. Life expectancy across the European Union has been rising almost constantly over the past decades, although this increase has slowed down since 2010. In some years, life expectancy has also witnessed a decrease, especially due to excess mortality especially among older people related to bad flu seasons and the increased mortality from cardiovascular diseases[178].

Life expectancy at birth, by gender, 2016

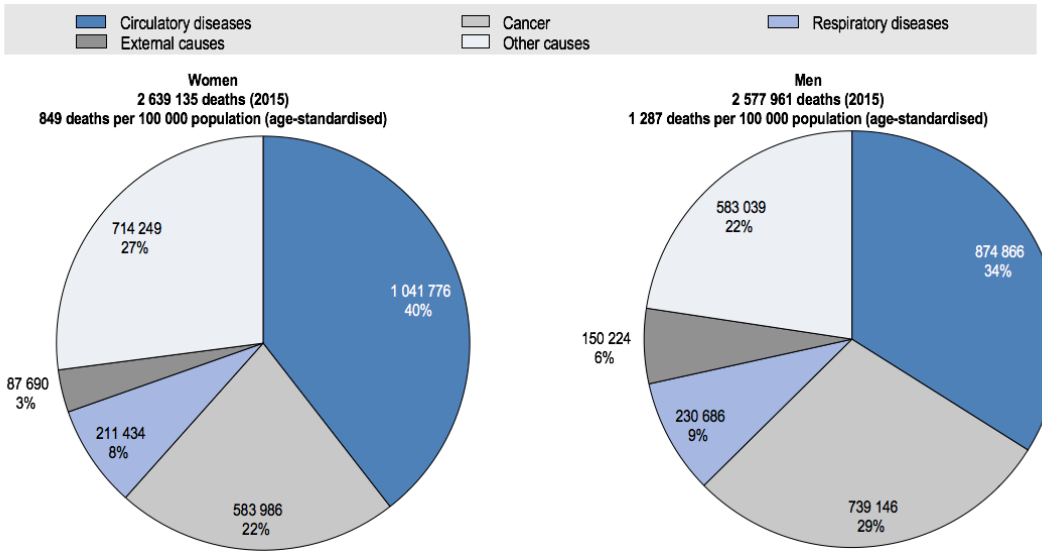


Source: OECD/EU, Health at a Glance: Europe 2018: State of Health in the EU Cycle, 2018.

[176] OECD/EU, *Health at a Glance: Europe 2018: State of Health in the EU Cycle*, *op. cit.*
[177] *Ibidem*.
[178] *Ibidem*.

In 2015, the main causes of death across European countries were circulatory diseases and cancer, accounting together for over 60% of all deaths[179]. More precisely, circulatory diseases accounted for 37% of all deaths (40% among women and 34% among men), and cancer accounted for 25% of all deaths (22% among women and 29% among men). After circulatory diseases and cancer, respiratory diseases were the third main cause of death across Europe, accounting for 8% of all death among women and 9% among men. In the same year, 3% of all deaths among women and 6% of deaths among men were due to external causes of death, such as accidents, suicides, homicides and other violent causes of death[180].

Main causes of mortality among women and men in EU countries, 2015



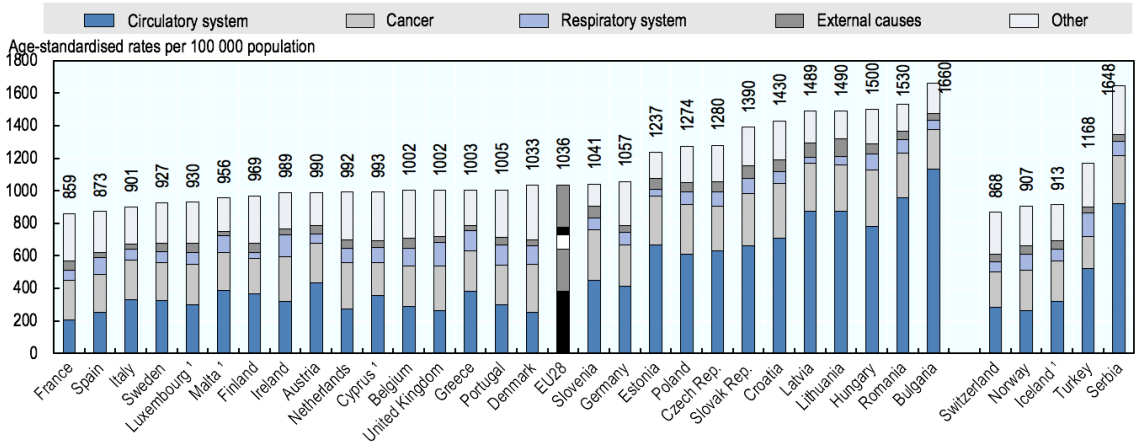
Source: OECD/EU, Health at a Glance: Europe 2018: State of Health in the EU Cycle, 2018.

However, there are some differences in mortality rates across European countries. They are lowest in France, Italy and Spain, while they are highest in Bulgaria, Hungary and Romania. These differences in mortality rates are mainly due to relatively low mortality rates from circulatory diseases in France, Italy and Spain, relatively high mortality rates from circulatory

[179] *Ibidem*.
[180] *Ibidem*.

diseases in Bulgaria and Romania, and relatively high mortality rates from cancer in Hungary[181].

Main causes of mortality by country, 2015

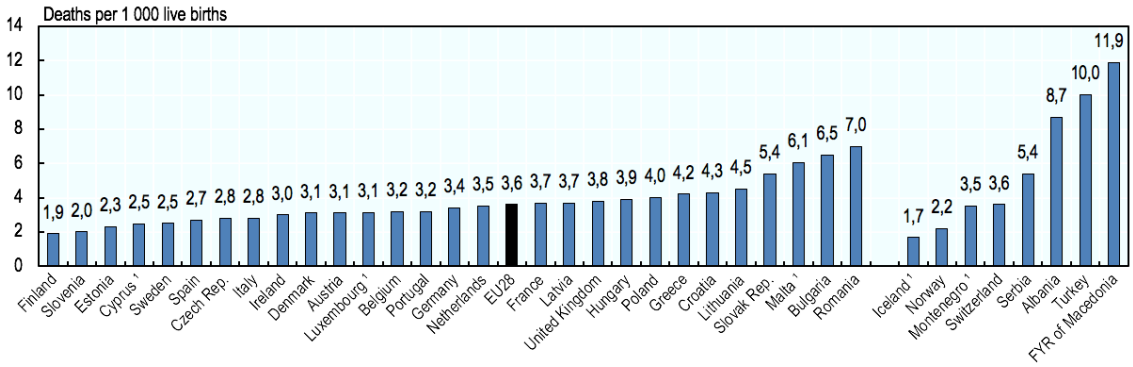


Source: OECD/EU, Health at a Glance: Europe 2018: State of Health in the EU Cycle, 2018.

An important indicator of a country's overall health status can be identified in infant health, and more specifically in infant mortality[182]. Indeed, infant mortality reflects the effect of socioeconomic conditions on the health of mothers and new-borns, and the effectiveness of the health system. Overall, across the European Union infant mortality rates are generally low, averaging 3.6 deaths per 1000 live births[183]. However, there are still wide differences across the various European Member States, ranging from 1.9 deaths per 1000 live births in Finland, to 7.0 deaths per 1000 live births in Romania[184]. In the last decades, the European Union has witnessed remarkable progresses in the reduction of infant mortality rates, which have decreased from an average of 10 deaths per 1000 live births in 1990 to an average of only 3.6 deaths in 2016. Notwithstanding these notable improvements, this trend in infant mortality rates has recently witnessed a slowdown across the European Union[185].

[181] *Ibidem*.
[182] *Ibidem*.
[183] *Ibidem*.
[184] *Ibidem*.
[185] *Ibidem*.

Infant mortality, 2016



Source: OECD/EU, Health at a Glance: Europe 2018: State of Health in the EU Cycle, 2018.

2.2 Health expenditure and health financing

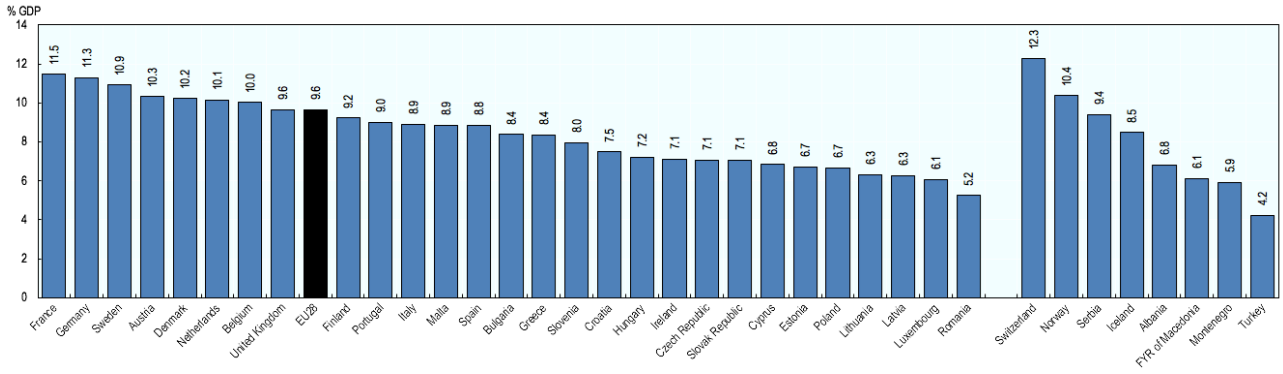
2.2.1 Health expenditure

How much a country spends on healthcare is usually related to the size of its economy as a whole, with higher income countries generally spending a higher proportion of their income on healthcare[186].

In the last years, and also during and after the 2008 economic and financial crisis, the share of GDP spent on healthcare has generally increased across the whole European Union, with the exception of Greece, Hungary, Ireland, Luxembourg and Romania[187]. Overall, in 2017 the European Union spent 9.6% of GDP on healthcare. This proportion ranged from 11.5% in France and 11.3% in Germany, to 5.2% in Romania, 6.1% in Luxemburg, and 6.3% in Latvia and Lithuania[188].

[186] *Ibidem*.
[187] *Ibidem*.
[188] *Ibidem*.

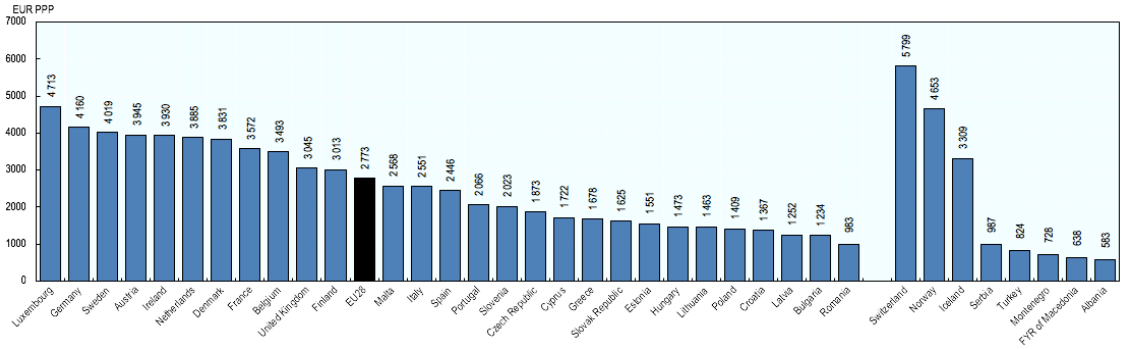
Health expenditure as a share of GDP, 2017



Source: OECD/EU, Health at a Glance: Europe 2018: State of Health in the EU Cycle, 2018.

The main healthcare spender per person in 2017 was Luxembourg (EUR 4.713), followed by Germany (EUR 4.160), Sweden (EUR 4.019) and Austria (EUR 3.945). The countries that in 2017 spent less on healthcare per person were Romania (EUR 983) and Bulgaria (EUR 1.234). Per capita health spending in the European Union as a whole in 2017 was EUR 2.773[189].

Health expenditure per capita, 2017



Source: OECD/EU, Health at a Glance: Europe 2018: State of Health in the EU Cycle, 2018.

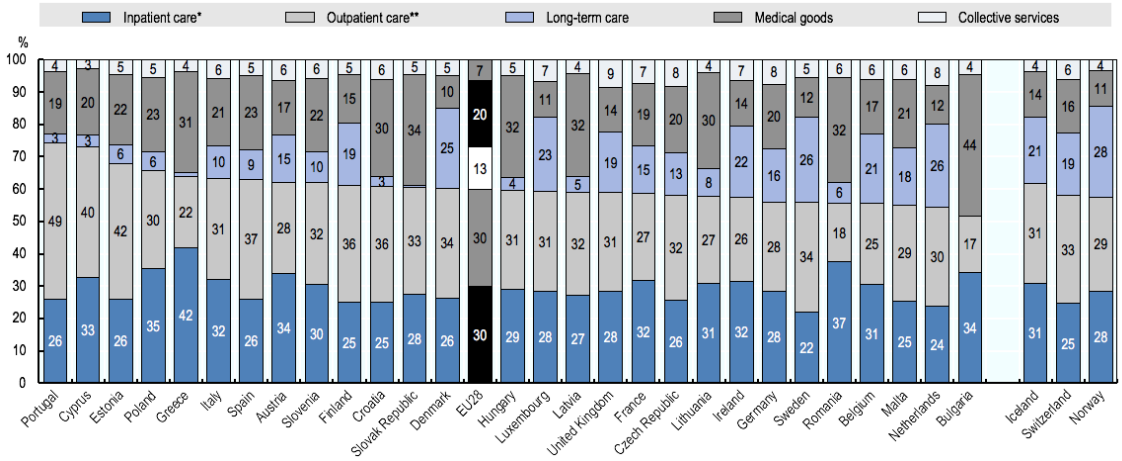
It is interesting to notice that some countries with relatively high health expenditure per capita have relatively low health spending to GDP ratios, and vice versa. This is for example the case of Luxembourg, which has one of the lowest health spending to GDP ratio, but the highest per

[189] *Ibidem*.

capita spending of the whole European Union, as well as the case of Bulgaria and Slovenia, which have a similar health spending to GDP ratio but a very different per capita spending[190]. In 2016, across the European Union, the majority of health expenditure was on curative and rehabilitative care services (60%), followed by medical goods (mainly pharmaceuticals) (20%), health-related long-term care (13%), and finally collective services, such as prevention, public health and the governance and administration of health care systems (7%)[191]. More specifically, spending on inpatient care and spending on outpatient care averaged 30% of total health expenditure each, ranging from 22% in Sweden to 42% in Greece for inpatient care expenditure, and from 17% in Bulgaria to 49% in Portugal for outpatient care expenditure[192]. Spending on medical goods averaged 20% of total health expenditure across the European Union, and it was particularly high in Southern and Central European countries and particularly low in Western European and Scandinavian countries, ranging from 10% in Denmark to 44% in Bulgaria[193]. Concerning health-related long-term care, it accounted for averagely 13% of total health spending, ranging from less than 3% in Bulgaria, Greece and the Slovak Republic to 26% in Sweden and the Netherlands[194]. Finally, spending on collective services across the European Union averaged 7% of total health expenditure, ranging from 3% in Cyprus to 8% in the Czech Republic, Germany and the Netherlands[195].

[190] *Ibidem*.
[191] *Ibidem*.
[192] *Ibidem*.
[193] *Ibidem*.
[194] *Ibidem*.
[195] *Ibidem*.

Health expenditure by function, 2016

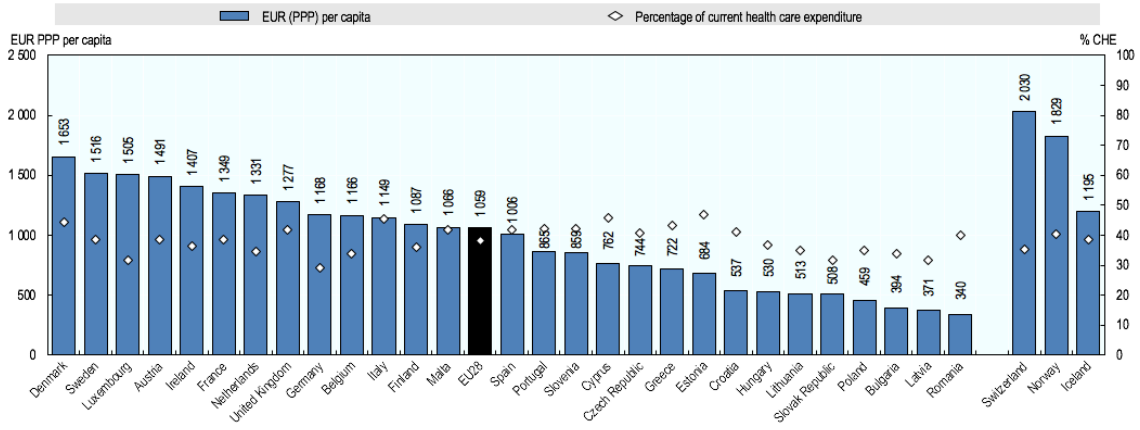


Source: OECD/EU, Health at a Glance: Europe 2018: State of Health in the EU Cycle, 2018.

In 2016, around 40% of total health expenditure across Europe came from health services in hospitals, which represented the largest spending category for most European countries[196]. This proportion ranged from almost 50% in Cyprus, Estonia and Italy to less than 30% in Germany, where health services are largely provided for in ambulatory settings. In 2016, across the European Union hospital spending was EUR 1.059, and as for total health spending, it was generally higher in high-income countries[197]. The European country that in 2016 spent the most per person on hospitals was Denmark (EUR 1.653), followed by Luxembourg and Sweden (more than EUR 1.500), while the countries that spent the less were Bulgaria, Latvia, Poland and Romania (less than EUR 400)[198].

[196] *Ibidem*.
[197] *Ibidem*.
[198] *Ibidem*.

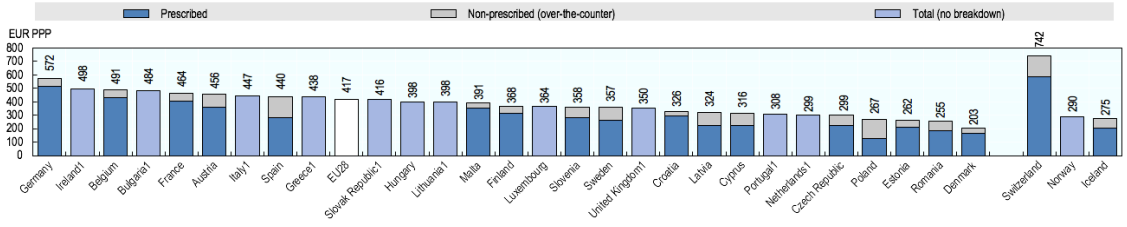
Hospital spending in per capita terms and as a share of health spending, 2016



Source: OECD/EU, Health at a Glance: Europe 2018: State of Health in the EU Cycle, 2018.

Over 15% of total health expenditure in 2016 across the European Union was accounted for by pharmaceuticals[199]. The spending on pharmaceuticals per capita was highest in Germany (EUR 572), followed by Ireland (EUR 498) and Belgium (EUR 491), while it was lowest in Denmark (EUR 203), Romania (EUR 255), Estonia (EUR 262) and Poland (EUR 267)[200].

Expenditure on retail pharmaceuticals per capita, 2016



Source: OECD/EU, Health at a Glance: Europe 2018: State of Health in the EU Cycle, 2018.

2.2.2 Health financing

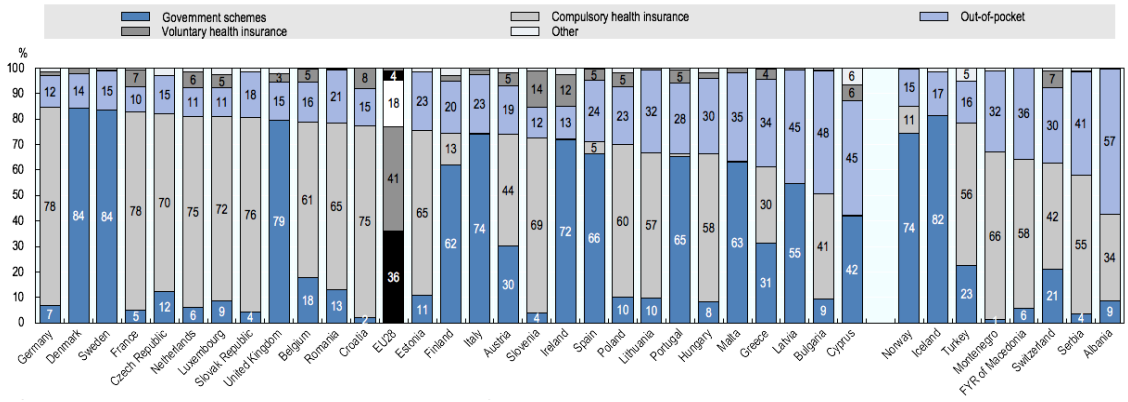
The 27 European national health systems are characterised by a variety of financing methods. Healthcare financing can be analysed considering financing schemes, i.e. the ways in which health services are paid for and obtained by people, which include government schemes,

[199] *Ibidem*.
[200] *Ibidem*.

compulsory health insurance (either public/social or private), voluntary health insurance and out-of-pocket payments (which can be individual payments or part of a co-payment arrangement)[201]. In 2016, across the whole European Union 41% of total health expenditure was financed through compulsory health insurance, 36% through government schemes, 18% through out-of-pocket payments and 4% through voluntary health insurance[202]. The share of total health expenditure that was financed through each of these financing schemes varied considerably across the European Union. Concerning government schemes, it financed from only 2% of total health expenditure in Croatia to 84% in Denmark and Sweden. Similarly, the share of total health expenditure financed through compulsory health insurance ranged from 78% in France and Germany to 5% or less in Cyprus, Denmark, Ireland, Italy, Latvia, Malta, Portugal, Spain and Sweden. Interestingly, Cyprus was the only European country where less than 50% of total health expenditure was financed through government schemes and compulsory health insurance, accounting respectively for 42% and 1%, compared to a European average of 77%[203]. Wide differences existed also in the share of total health expenditure financed through out-of-pocket spending, which ranged from 45% or more in Bulgaria, Cyprus and Latvia, to 16% or less in Belgium, Croatia, Czech Republic, Denmark, France, Germany, Ireland, Luxemburg, The Netherlands, Slovenia and Sweden[204].

[201] *Ibidem*.
[202] *Ibidem*.
[203] *Ibidem*.
[204] *Ibidem*.

Health expenditure by type of financing, 2016



Source: OECD/EU, Health at a Glance: Europe 2018: State of Health in the EU Cycle, 2018.

2.3 Healthcare accessibility

Healthcare accessibility is an extremely important indicator of health systems performance, and it is a fundamental component of the right to health and to healthcare. It can be found in article 35 of the Charter of Fundamental Rights of the European Union explicitly acknowledging the right of access to healthcare and medical treatment[205], in Article 11 of the European Social Charter, interpreted by the European Committee of Social Rights as enshrining the right of access to healthcare, and thus as requiring health systems to be accessible to everyone[206], and in Article 16 of the European Pillar of Social Rights affirming the right to timely access to affordable, preventive and curative health care of good quality[207]. It is important to notice that at the European level the right of access to healthcare is intended as requiring health facilities, goods and services to be within physical reach as well as economically affordable, meaning that the cost of healthcare has to be at least partially borne by the whole community and not to

[205] EU, *Charter of Fundamental Rights of the European Union,* art. 35.
[206] ECSR, *Digest of the Case Law*, part III, art, 11.
[207] EP, European Council and EC, *European Pillar of Social Rights*, art. 16.

represent an excessive burden for the individual, and therefore that out-of-pocket payments shall not be the main source of funding of the health system[208].

Other than being a fundamental part of the right to health and to healthcare, and one of the values and principles underpinning European health systems, accessibility is a vital, multi-dimensional aspect of health system performance[209] and a fundamental element in any health system. If access to healthcare is limited, this might result in poorer health outcomes and greater health inequalities[210], which in turn have important economic and distributional impacts. Indeed, good health improves educational performance and attainments, enables the accumulation of human capital, increases earnings opportunities, and raises individual productivity and income[211]. Therefore, reducing gaps in access to healthcare, and consequently health inequalities, promotes improvement in the well-being of the whole population, which in turn leads to economic growth, greater labour force participation and higher productivity[212].

Although accessibility and the right to timely access to affordable, preventive and curative healthcare of good quality are among the common values and principles underpinning the 27 European national health systems, gaps in healthcare accessibility are still a reality in the European Union.

Healthcare accessibility can be assessed considering unmet healthcare needs, affordability of services, availability of medical personnel, hospital beds and technologies, waiting times, and distance to health facilities.

2.3.1 Unmet needs

[208] ECSR, *Digest of the Case Law*, *op. cit*.

[209] European Commission's Directorate-General of Health and Food Safety (DG SANTE), *State of Health in the EU Companion Report 2019,* Luxembourg: Publications Office of the European Union, 2019.

[210] OECD/EU, *Health at a Glance: Europe 2018: State of Health in the EU Cycle*, *op. cit*.

[211] World Bank Group, *Poverty and Shared Prosperity 2016: Taking on Inequality*, World Bank Publications, 2016.

[212] Expert Panel on effective ways of investing in health (EXPH), *Report on access to health services in the European Union*, 2016.

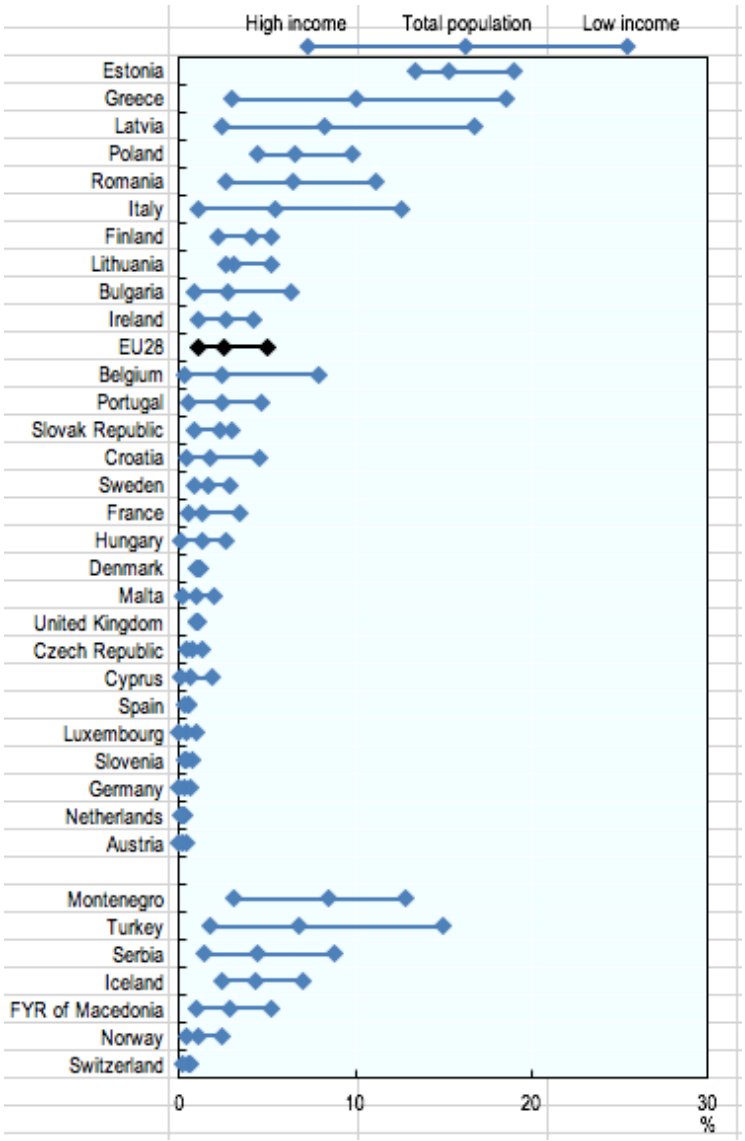
One of the most used measures of accessibility is unmet healthcare needs[213].

On average, the number of European citizens reporting unmet healthcare needs is generally low, totalling only 2.5% of the population in 2016[214]. However, there are significant variations across European countries, as the share of the population reporting some unmet healthcare needs ranges from 0.2% in Austria and the Netherlands, to 15.3% in Estonia[215].

Substantial disparities exist also within countries, and are mainly related to income level, gender, residence status and ethnicity[216]. Overall, women tend to face more difficulties in access to healthcare than men, and Roma populations are among the most vulnerable with regard to access to healthcare[217]. Disparities are also related to age, education and employment, with rates of unmet healthcare needs being considerably higher among people aged over 65, the less educated and the unemployed[218]. Concerning disparities in access to healthcare services by income level, low-income households facing significantly higher levels of unmet medical needs. On average, in 2016 (2017 for Greece) across the European Union 5% of low-income households reported unmet medical needs, compared to 1,1% of high-income households[219]. Most strikingly, in Greece 18.6% of low-income households reported unmet medical needs compared to only 3% of high-income households, and in Latvia 16.8% of low-income households reported unmet medical needs compared to only 2.4% of high-income households[220].

[213] OECD/EU, *Health at a Glance: Europe 2018: State of Health in the EU Cycle*, *op. cit.*
[214] Baeten, R., Spasova, S., Vanhercke, B. and Coster, S, *Inequalities in access to healthcare. A study of national policies*, *op. cit,*
[215] OECD/EU, *Health at a Glance: Europe 2018: State of Health in the EU Cycle*, *op. cit.*
[216] Baeten, R., Spasova, S., Vanhercke, B. and Coster, S, *Inequalities in access, a study of national policies, op. cit.*
[217] *Ibidem.*
[218] Expert Panel on effective ways of investing in health (EXPH), *Opinion on benchmarking access to healthcare in the EU*, 2017.
[219] OECD/EU, *Health at a Glance: Europe 2018: State of Health in the EU Cycle*, *op. cit.*
[220] *Ibidem.*

Unmet needs for medical examination for financial, geographical or waiting times reasons, by income quintile, 2016



Source: OECD/EU, Health at a Glance: Europe 2018: State of Health in the EU Cycle, 2018.

2.3.2 Affordability

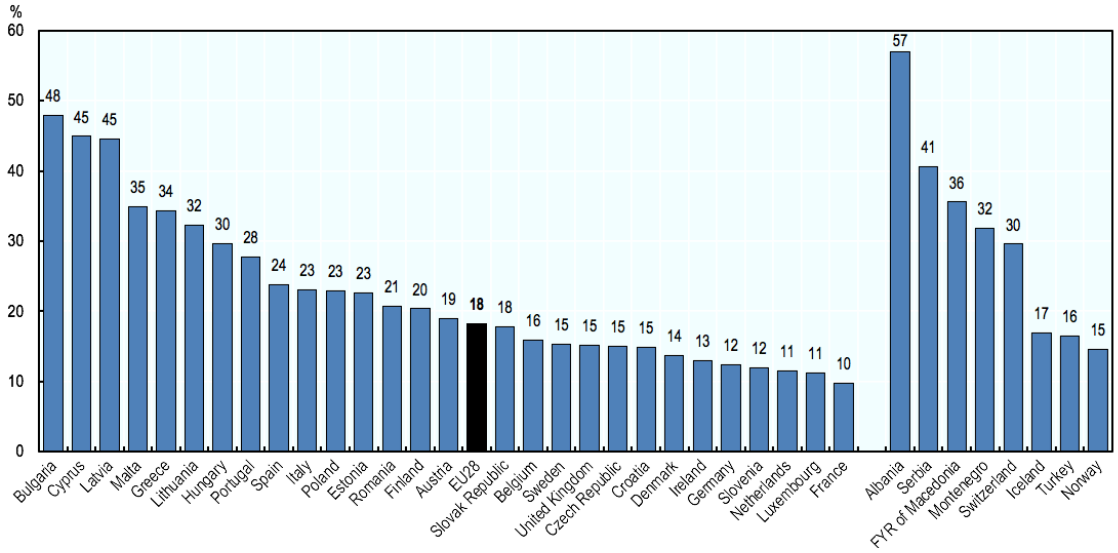
One of the main reasons for unmet healthcare needs across the European Union is financial barriers, with 4.2% of Europeans experiencing great difficulty in affording healthcare services, 8.4% experiencing moderate difficulties and 16.2% some difficulties. Particularly marked

difficulties are experienced in Bulgaria, Cyprus, Greece, Hungary, Ireland, and Latvia[221]. Such financial barriers are usually linked to excessive out-of-pocket payments, whose extent depends on the health system financing model: where the health system is mainly publicly financed, gaps in access and unmet need tend to be lower, while they tend to be higher in those system with a higher reliance on out-of-pockets or private financing.

Out-of-pocket payments are defined as health expenditures borne directly by a patient[222], and a certain degree of out-of-pocket payments exists in all the European health systems.

At an aggregate level, across the European Union 18% of all health spending consists in out-of-pocket payments, with significant variations across countries, ranging from 10% in France, Luxembourg and the Netherlands to over 40% in Bulgaria, Latvia and Cyprus[223].

Share of total health spending financed by out-of-pocket payments, 2016



Source: OECD/EU, Health at a Glance: Europe 2018: State of Health in the EU Cycle, 2018.

The problem with out-of-pocket payments is that they may lead to financial hardship, especially for poor households and for those who have to pay for long-term treatments. Financial hardship associated with out-of-pocket payments is usually measured through the incidence of

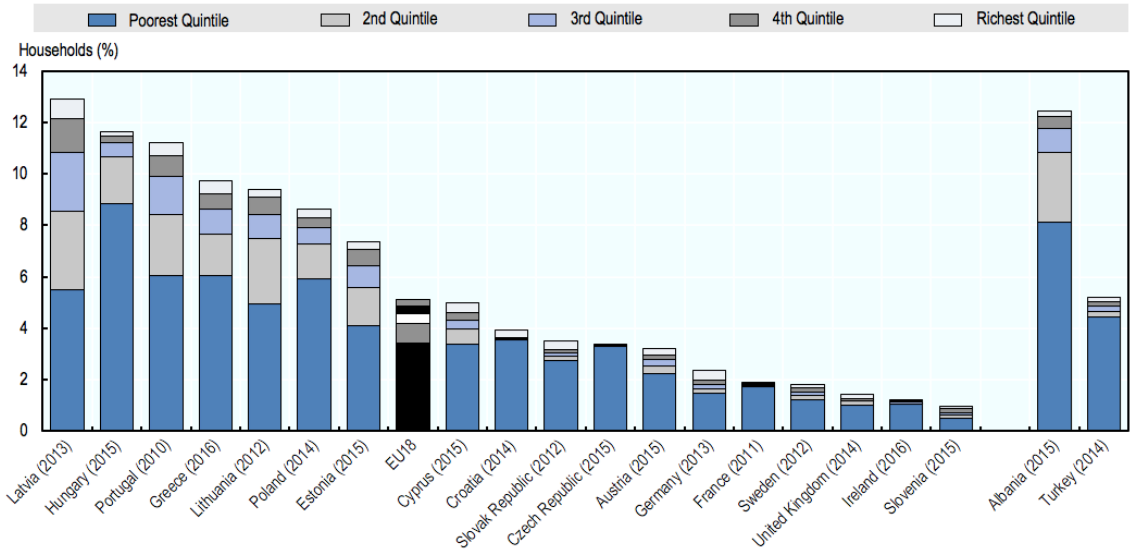
[221] DG SANTE *State of Health in the EU Companion Report 2019, op. cit.*

[222] OECD/EU, *Health at a Glance: Europe 2018: State of Health in the EU Cycle*, *op. cit.*

[223] *Ibidem.*

catastrophic health spending, defined as out-of-pocket payments that exceed 40% of a household's ability to pay for health care[224]. The incidence of catastrophic health spending across European countries ranges from around 2% in France, Ireland, Slovenia and Sweden, to around 8% in Greece, Hungary, Latvia, Lithuania, Poland and Portugal, with poor household more likely to experience it. Generally, those countries with relatively high levels of public spending on health and low levels of out-of-pocket payments tend to have a lower incidence of catastrophic health spending, while high levels of out-of-pocket payments are generally associated with high shares of households incurring catastrophic spending, with poorer households, people with certain clinical characteristics (e.g. older patients suffering from diabetes mellitus and cardiovascular diseases) and other disadvantaged groups, such as minorities, being most affected. In many countries catastrophic expenditure is concentrated among the poorest quintile and among people aged over 60 years, while in Germany it is concentrated mainly among people receiving social benefits or dependent on income from spouses, and in Croatia and Lithuania among households without children[225].

Share of households with catastrophic spending on health by consumption quintile, latest year available



Source: OECD/EU, Health at a Glance: Europe 2018: State of Health in the EU Cycle, 2018.

[224] *Ibidem.*
[225] *Ibidem.*

2.3.3 Availability

Another widely used measure of healthcare accessibility consists in healthcare availability[226]. Healthcare availability refers to the number of medical personnel, i.e. doctors and nurses, of hospital beds and of medical technologies available.

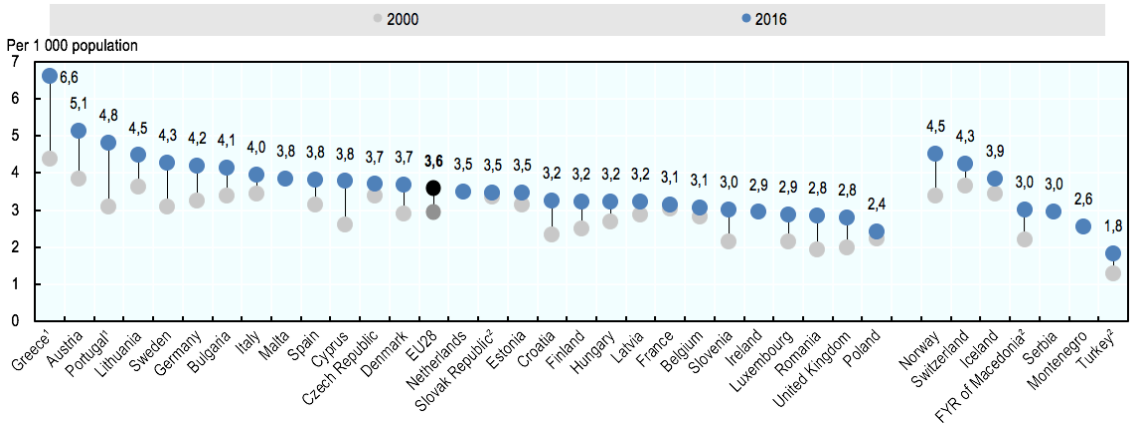
Availability of medical personnel

In 2016, across the European Union there were averagely 3.6 doctors per 1000 population[227]. However, this value changes considerably across European countries, ranging from only 2.4 doctors per 1000 population in Poland, to 6.6 doctors per 1000 population in Greece, followed by Austria with 5.1 doctors per 1000 population, and Portugal with 4.8 doctors per 1000 population. However, in Greece and Portugal the number of doctors per population is an overestimation as it includes all the doctors who are entitled to practice, and thus also retired physicians and those who have emigrated[228].

From 2000 to 2016, the overall number of doctors per 1000 population has increased from 2.9 to 3.6. This increase happened in almost all European countries, with the exception of France, Poland and the Slovak Republic, where the number of doctors per capita has remained stable[229].

[226] *Ibidem.*
[227] *Ibidem.*
[228] *Ibidem.*
[229] *Ibidem.*

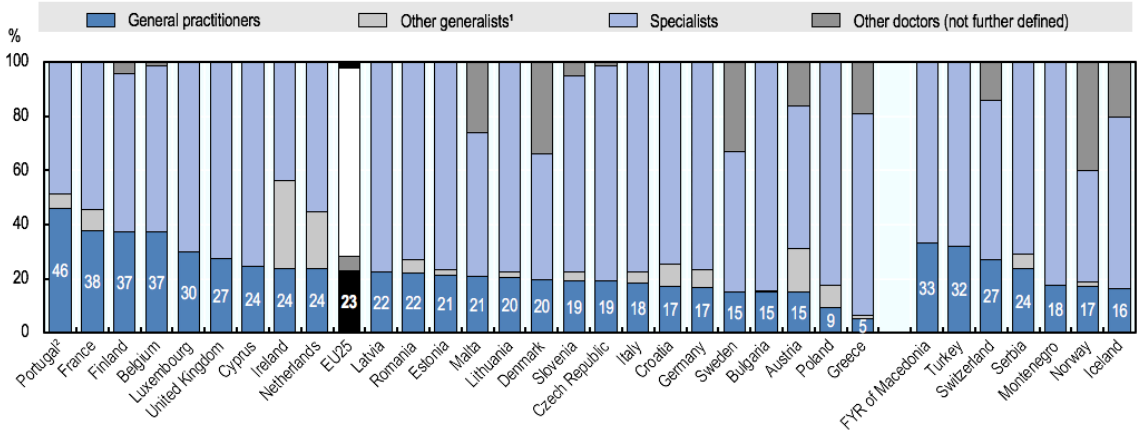
Practising doctors per 1 000 population, 2000 and 2016



Source: OECD/EU, Health at a Glance: Europe 2018: State of Health in the EU Cycle, 2018.

Despite this increase in the overall number of doctors per capita, most countries have witnessed a decrease in the share of general practitioners (GPs), which in 2016 accounted for less than 25% of all physicians, ranging from 5% in Greece and 9% in Poland, to 46% in Portugal[230].

Share of different categories of doctors, 2016



Source: OECD/EU, Health at a Glance: Europe 2018: State of Health in the EU Cycle, 2018.

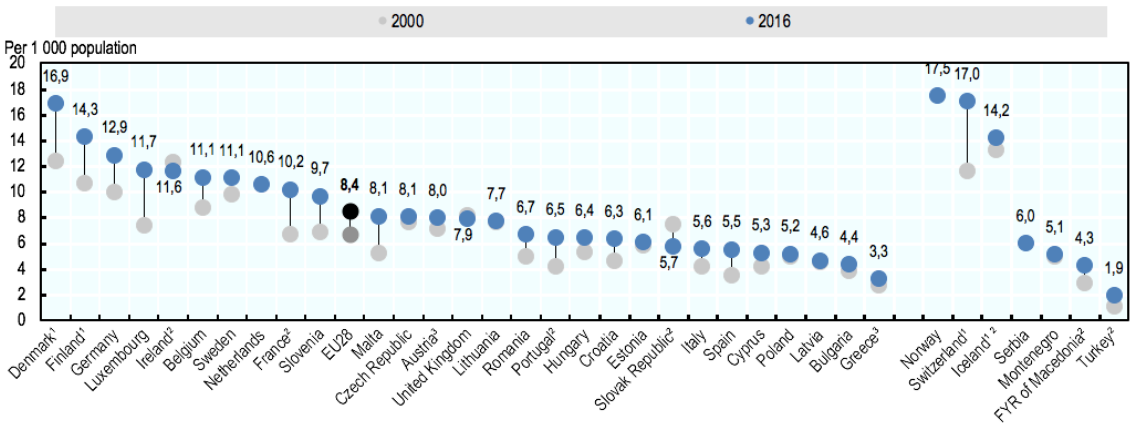
In most European countries, nurses largely outnumber doctors, with an average ration of roughly 3 nurses per doctor[231].

[230] *Ibidem.*
[231] *Ibidem.*

In 2016, the European Union had an average of 8.4 nurses per 1000 population. This value ranged from 16.9 nurses per 1000 population in Denmark, to 3.3 nurses per 1000 population in Greece (data only include nurses working in hospital) and 4.4 nurses per 1000 population in Bulgaria[232].

From 2000 to 2016, the overall number of nurses per 1000 population has increased from 6.7 to 8.4. This increase happened in almost all European countries, with the exception of the Netherlands, Poland, and the three Baltic countries, i.e. Estonia, Latvia and Lithuania, where the number of nurses per capita has remained almost unchanged, and the exception of Ireland and the Slovak Republic, where the number of nurses per capita has witnessed a decrease. The rise in the number of nurses per capita has been especially large in Denmark, Finland, France, Germany, Luxembourg, and Malta, followed by Belgium, Portugal and Slovenia[233].

Practising nurses per 1 000 population, 2000 and 2016



Source: OECD/EU, Health at a Glance: Europe 2018: State of Health in the EU Cycle, 2018.

It is important to underline that the abovementioned data do not always account for the difference between the overall number of medical personnel and the number of medical personnel working in the public system[234], and the numbers of medical personnel are sometimes

[232] *Ibidem.*
[233] *Ibidem.*
[234] Baeten, R., Spasova, S., Vanhercke, B. and Coster, S, *Inequalities in access to healthcare. A study of national policies*, *op. cit.*

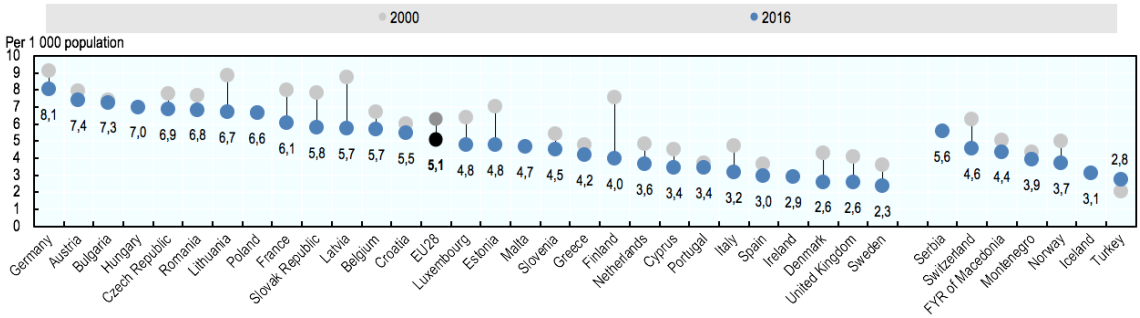
accounted for in different ways, for example sometimes also including doctors and nurses employed in administrative, management, academic and research roles[235].

Hospital beds

In 2016, across the European Union there were averagely 5.1 hospital beds per 1000 population, ranging from 2.3 in Sweden to 8.1 in Germany[236].

From 2000 to 2016, the overall number of hospital beds per capita has decreased in almost all the European Member States, with an average decrease of almost 20%[237]. The reduction of hospital beds per capita has been especially noticeable in Estonia, Finland, France, Latvia, Lithuania and the Slovak Republic, while it has been almost inexistent in Bulgaria, Hungary, Ireland, Malta and Poland[238]. In some cases, the decrease in the number of hospital beds per capita has gone hand in hand with a decrease in the number of hospital admissions and in the average length of stay[239].

Hospital beds per 1 000 population, 2000 and 2016



Source: OECD/EU, Health at a Glance: Europe 2018: State of Health in the EU Cycle, 2018.

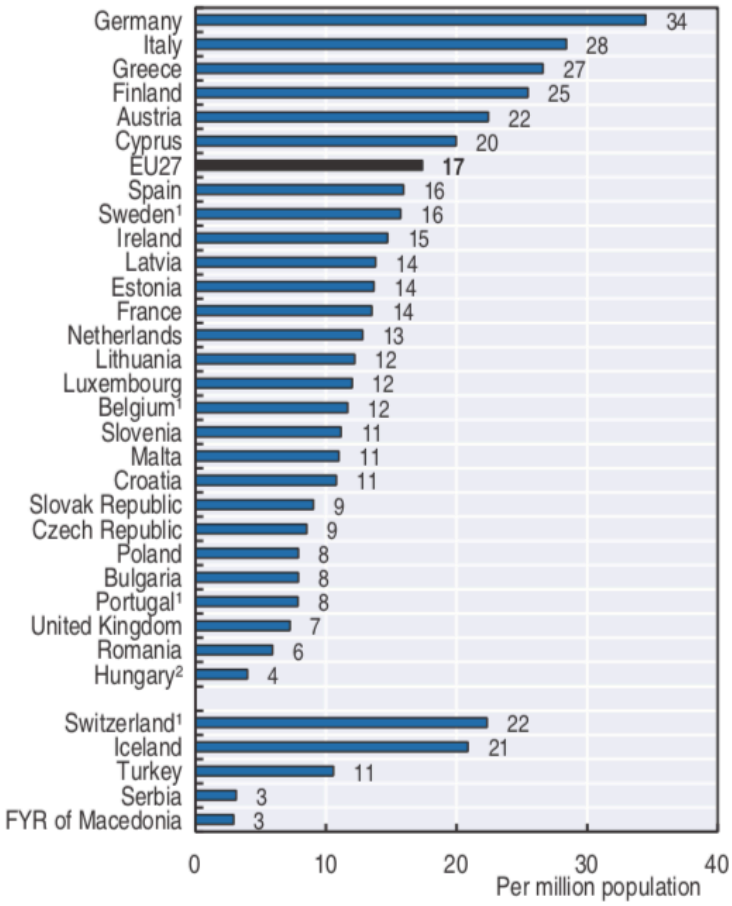
Medical technologies

[235] OECD/EU, *Health at a Glance: Europe 2018: State of Health in the EU Cycle*, *op. cit.*
[236] *Ibidem.*
[237] *Ibidem.*
[238] *Ibidem.*
[239] *Ibidem.*

The availability of medical technologies is another important component of healthcare availability. Medical technologies include a variety of machines and instruments, including diagnostic imaging technologies such as magnetic resonance imaging units.

The availability and use of magnetic resonance imaging units have witnessed a considerable increase across the European Union, with averagely 17 magnetic resonance imaging units per million population[240]. Nonetheless, there still exist large difference among countries, with the number of magnetic resonance imaging units per million population ranging from 34 in Germany, followed by Italy (28) and Greece (27), to only 4 in Hungary and 6 in Romania[241].

MRI units, 2016



Source: OECD/EU, Health at a Glance: Europe 2018: State of Health in the EU Cycle, 2018.

[240] *Ibidem.*

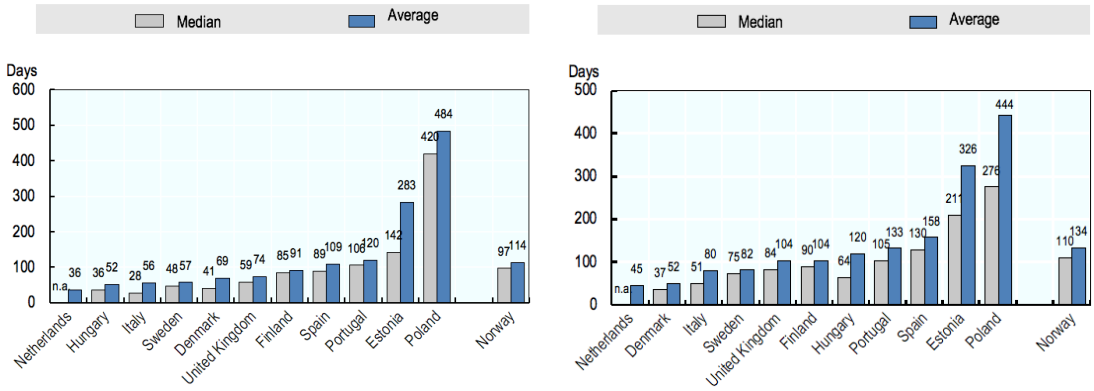
[241] *Ibidem.*

2.3.4 Waiting times

Together with financial barriers, waiting times are the main cause of unmet health needs in the Europe Union, especially in Estonia, Finland, Ireland, Poland, Slovenia and the Slovak Republic[242]. In some countries, waiting times and waiting lists are a problem affecting the whole health system, while in other countries they are an issue only for some types of care[243]. Long waiting times are frequently an issue in the case of elective (non-emergency) surgery, such as cataract surgery and hip replacement[244]. In 2016, the average waiting time for cataract surgery ranged from 36 days in the Netherlands, to 3-4 months in Finland, Portugal and Spain, roughly 9 months in Estonia, and well over a year in Poland (484 days). Similarly, in the same year the average waiting time for hip replacement ranged from 45 days in the Netherlands, to 4-5 months in Hungary, Portugal and Spain, almost 11 months in Estonia and well over a year in Poland (444 days)[245]. Interestingly, Poland shows the longest waiting times for both cataract surgery and hip replacement, due to a low number of doctors and medical equipment, coupled with a highly uneven geographical distribution of medical facilities and services[246].

[242] DG SANTE *State of Health in the EU Companion Report 2019, op. cit.*
[243] Baeten, R., Spasova, S., Vanhercke, B. and Coster, S, *Inequalities in access, a study of national policies, op. cit.*
[244] OECD/EU, *Health at a Glance: Europe 2018: State of Health in the EU Cycle*, *op. cit.*
[245] *Ibidem.*
[246] *Ibidem.*

Waiting times of patients for cataract surgery (left) and hip replacement (right), 2016



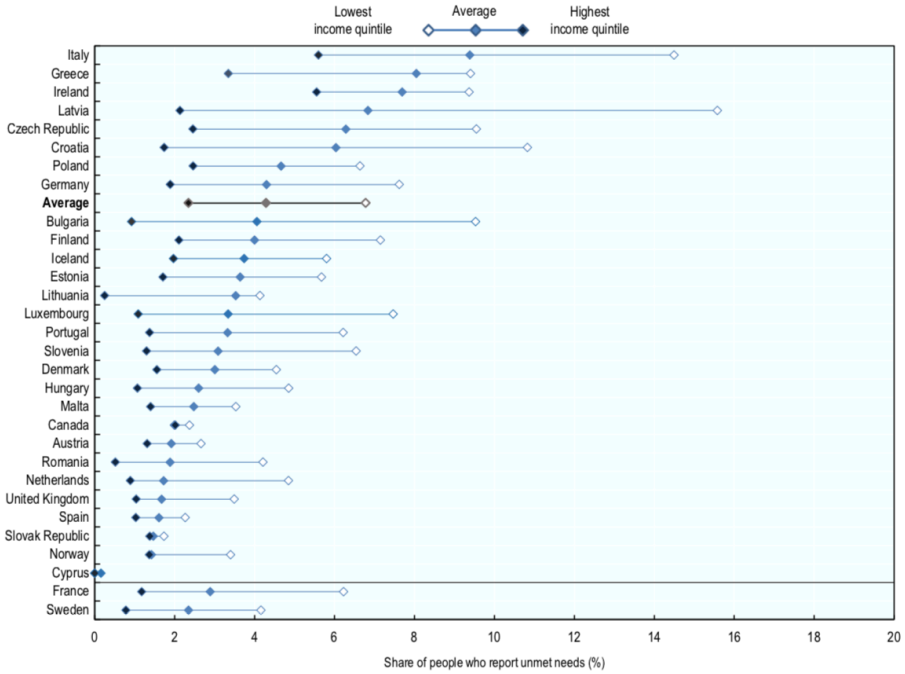
Source: OECD/EU, Health at a Glance: Europe 2018: State of Health in the EU Cycle, 2018.

2.3.5 Distance

Distance from health services and facilities is another important issue in healthcare accessibility. Overall, in the European Union roughly 4% of adults report having delayed or unmet healthcare needs due to distance or transport, ranging from almost 0% in Cyprus to 9% in Italy[247]. The share of people incurring in unmet healthcare needs due to distance or transport problems is generally higher in the lowest income quintile. In the European Union, approximately 7% of low-income people experience unmet healthcare needs due to distance or transport problems, compared to barely more than 2% of high-income people. This gap is more pronounced in Bulgaria, Croatia, Italy and Latvia, while it is almost inexistent in Cyprus and the Slovak Republic[248].

[247] Organization for Economic Co-operation and Development (OECD), *Health for Everyone?: Social Inequalities in Health and Health Systems*, OECD Health Policy Studies, OECD Publishing, Paris, 2019.
[248] *Ibidem.*

Unmet needs due to distance or transport problems, by income quintile

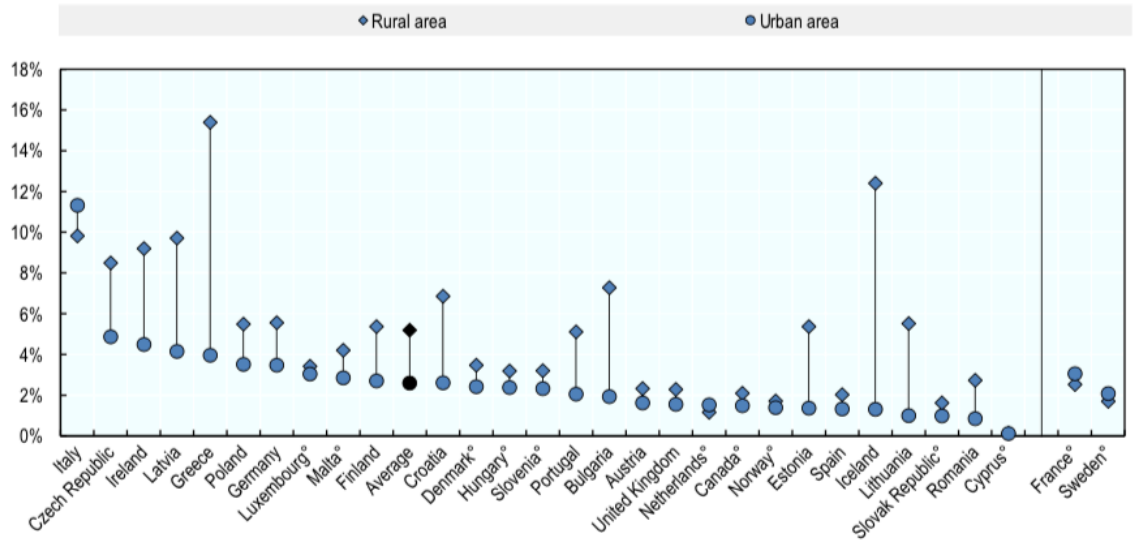


Source: OECD, Health for Everyone?: Social Inequalities in Health and Health Systems, 2019.

The share of people incurring in unmet healthcare needs due to distance or transport problems is also generally higher for people living in rural areas. In the European Union, on average 5% of people living in rural areas incur in unmet healthcare needs due to distance or transport problems, compared to 2% for people living in urban areas. This gap is particularly large in Greece (15% and 4% respectively), while it is almost inexistent in Austria, Luxemburg, the Netherlands, Spain and the Slovak Republic. Interestingly, in Italy unmet healthcare needs due to distance and transport problems are higher for people living in urban areas than for people living in rural areas[249].

[249] *Ibidem.*

Unmet needs due to distance or transport problems, by degree of urbanisation



Source: OECD, Health for Everyone?: Social Inequalities in Health and Health Systems, 2019.

2.4 Health coverage

Universality is one of the common values underpinning European health systems[250], and it characterizes the majority of European Member States health systems, which thus have universal or almost universal health coverage[251]. However, the services covered and the degree of cost-sharing is varied, and there are still some countries with sizeable groups of the population excluded from coverage[252].

Healthcare coverage is made up of three dimensions: population coverage, benefit package and user charges[253]. Population coverage refers to the share of the population entitled to health services; benefit package refers to the range of health goods and services covered; user charges

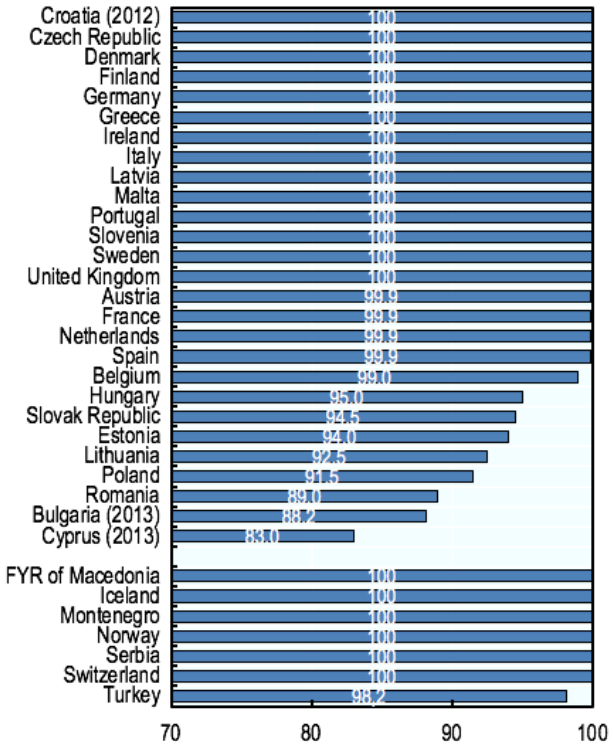
[250] EC, *Communication from the Commission on effective, accessible and resilient health systems*, *op. cit.*
[251] OECD/EU, *Health at a Glance: Europe 2018: State of Health in the EU Cycle*, *op. cit.*
[252] *Ibidem.*
[253] *Ibidem.*

refers to the proportion of costs covered and the extent to which people have to pay for health services at the point of use[254].

2.4.1 Population coverage

Overall in the European Union, population coverage, i.e. the share of the population entitled to health services, is very high, and in many cases universal or nearly universal[255]. Nonetheless, some countries still have more than 5% of the population excluded from coverage, a share that goes up to over 10% in Bulgaria (11.8%), Cyprus (17%) and Romania (11%)[256].

Population coverage for a core set of services, 2016



Source: OECD/EU, Health at a Glance: Europe 2018: State of Health in the EU Cycle, 2018.

[254] Baeten, R., Spasova, S., Vanhercke, B. and Coster, S, *Inequalities in access, a study of national policies, op. cit.*

[255] OECD/EU, *Health at a Glance: Europe 2018: State of Health in the EU Cycle*, *op. cit.*

[256] *Ibidem.*

However, even in countries with an almost universal population coverage, some population groups might still be excluded from coverage[257].

The most frequently excluded groups are irregular residents, asylum seekers, homeless people and Roma people[258]. In some countries, other groups excluded from coverage are non-active people of working age without entitlement to cash social protection benefits, some self-employed or employed in non-standard and precarious jobs people, and people who have not contributed a sufficient number of years[259]. For example, in Romania, the share of uninsured population is mainly composed of unemployed or self-employed people not registered for benefits, agricultural workers, and Roma people[260]; Germany and Austria show a relatively high share of self-employed individuals being uninsured[261]; and in Poland persons having some kinds of civil law contracts are uninsured[262].

Coverage gaps can also be linked to age, as in Croatia and Greece, where older persons experience more unmet needs, or in Denmark, where young persons are those experiencing more unmet needs, and specific diseases, as in Austria, Estonia, Croatia, Latvia, Poland, Malta and the Netherlands for patients with rare diseases, or in Austria, Poland and Malta for children with mental health problems[263].

Entitlement to coverage

Entitlement to healthcare coverage can be conditional on residence status, employment status, payment of contributions or citizenship.

[257] Baeten, R., Spasova, S., Vanhercke, B. and Coster, S, *Inequalities in access, a study of national policies, op. cit.*

[258] DG SANTE, *State of Health in the EU Companion Report 2019, op. cit.*

[259] Baeten, R., Spasova, S., Vanhercke, B. and Coster, S, *Inequalities in access, a study of national policies, op. cit.*

[260] OECD/EU, *Health at a Glance: Europe 2018: State of Health in the EU Cycle*, *op. cit.*

[261] DG SANTE, *State of Health in the EU Companion Report 2019, op. cit.*

[262] *Ibidem.*

[263] *Ibidem.*

Entitlement to healthcare coverage is usually linked to residence status in countries providing universal population coverage through a tax-funded national health service system, such as Denmark, Italy, Latvia, Malta, Portugal, Spain and Sweden[264]. An exception is Cyprus, a national health service system where entitlement is based on household income[265].

Entitlement to healthcare coverage is usually linked to employment status or payment of contributions in countries with a social health insurance system[266]. These countries tend to show lower shares of population coverage and a higher incidence of catastrophic out-of-pocket payment[267], since those without entitlement to healthcare coverage usually are poorer people[268]. However, social health insurance systems usually provide coverage also for non-contributing groups such as dependent family members, pensioners, unemployed people, and disable people[269]. Interestingly, some social health insurance systems such as France and the Czech Republic, base entitlement to healthcare coverage on permanent residence status[270].

2.4.2 Benefit package

Other than the share of the population covered, it is also necessary to look at the range of health goods and services covered, i.e. included in a benefit package.

[264] Baeten, R., Spasova, S., Vanhercke, B., and Coster, S., *Inequalities in access to healthcare. A study of national policies*, *op. cit.*
[265] Thomson, S., Jonathan, C., and Tamás, E., *Can people afford to pay for health care? New evidence on financial protection in Europe*, Eurohealth 25.3: 41-46, 2019.
[266] Baeten, R., Spasova, S., Vanhercke, B., and Coster, S., *Inequalities in access to healthcare. A study of national policies*, *op. cit.*
[267] Thomson, S., Jonathan, C., and Tamás, E., *Can people afford to pay for health care? New evidence on financial protection in Europe*, *op. cit.*
[268] EXPH, *Report on access to health services in the European Union*, *op. cit.*
[269] Baeten, R., Spasova, S., Vanhercke, B., and Coster, S., *Inequalities in access to healthcare. A study of national policies*, *op. cit.*
[270] *Ibidem.*

Benefit packages tend to be relatively comprehensive across the European Union, even though there are some variations across countries[271] in the content of the benefits package[272]. European countries guarantee coverage for some essential healthcare goods and services, publicly financing them through government schemes or compulsory health insurance schemes[273], also to groups not covered by the statutory system[274]. These essential healthcare goods and services are usually meant as including urgently necessary healthcare, some kinds of preventive care, e.g. for infectious diseases, and pregnancy and maternity care[275].

The most frequent exceptions to benefit packages include dental care, physiotherapy, eye treatments, mental care, therapeutic and hearing aids, dietary supplements, over-the-counter drugs, non-compulsory vaccinations, cosmetic surgery, home nursing, speech therapy, rehabilitation programmes for alcoholics and drug addicts, and accidents related to extreme sports[276].

Across the European Union, hospital care, i.e. inpatient curative and rehabilitative care in hospitals, is the most comprehensively covered type of care, and 93% of all these expenses are borne by government or compulsory insurance schemes[277]. This share goes up to almost 100% in Estonia (98%), Romania (98%) and Sweden (99%), followed by Italy (96%) and Germany (96%). Cyprus (67%), Greece (67%) and Ireland (69%) are the only European countries where the financial coverage for costs of hospital care is below 70%[278]. These three countries are among those that present the highest share of hospital care expenses covered by voluntary health insurance[279].

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[271] DG SANTE, *State of Health in the EU Companion Report 2019, op. cit.*
[272] EXPH, *Report on access to health services in the European Union*, *op. cit.*
[273] OECD, *Health for Everyone?: Social Inequalities in Health and Health Systems*, *op. cit.*
[274] Baeten, R., Spasova, S., Vanhercke, B., and Coster, S., *Inequalities in access to healthcare. A study of national policies*, *op. cit.*
[275] *Ibidem.*
[276] DG SANTE, *State of Health in the EU Companion Report 2019, op. cit.*
[277] OECD/EU, *Health at a Glance: Europe 2018: State of Health in the EU Cycle*, *op. cit.*
[278] *Ibidem.*
[279] OECD, *Health for Everyone?: Social Inequalities in Health and Health Systems*, *op. cit.*

Concerning outpatient medical care, i.e. outpatient curative and rehabilitative care excluding dental care, across the European Union 77% of it is covered through government and compulsory health financing schemes[280]. This share goes up to 90% or above in the Czech Republic (90%), Denmark (92%), Germany (90%) and the Slovak Republic (95%). Bulgaria (46%) and Cyprus (37%) are the only European countries where the financial coverage for costs of outpatient medical care is below 50%, followed by Latvia at 51%[281]. In some countries, outpatient primary and specialist care might be free at the point of use, but there could be some user charges for specific services or if providers outside the public sector are consulted, as it is the case for visits to psychologists and physiotherapists in Denmark[282]. Furthermore, in some countries, outpatient psychological services (e.g. Belgium) and outpatient physiotherapy and rehabilitation services (e.g. Latvia, the Netherlands), may be completely excluded from the range of covered benefits[283].

Dental care coverage in the European Union is generally quite restricted, e.g. covered only for specific groups such as children or the chronically ill[284], and involves higher levels of cost-sharing[285]. Overall, only 30% of dental care expenses are covered through government and compulsory health financing schemes[286]. This share is above 50% only in Croatia (61%), Germany (68%), the Slovak Republic (56%) and Slovenia (51%). In some countries, such as Italy, dental care expenses for adults without any specific entitlement are not covered at all[287].

Coverage by government and compulsory schemes for pharmaceuticals, i.e. prescribed and over-the-counter medicines including medical non-durables, across the European Union is

[280] OECD/EU, *Health at a Glance: Europe 2018: State of Health in the EU Cycle*, *op. cit.*
[281] *Ibidem.*
[282] *Ibidem.*
[283] Baeten, R., Spasova, S., Vanhercke, B., and Coster, S., *Inequalities in access to healthcare. A study of national policies*, *op. cit.*
[284] *Ibidem.*
[285] OECD/EU, *Health at a Glance: Europe 2018: State of Health in the EU Cycle*, *op. cit.*
[286] *Ibidem.*
[287] *Ibidem.*

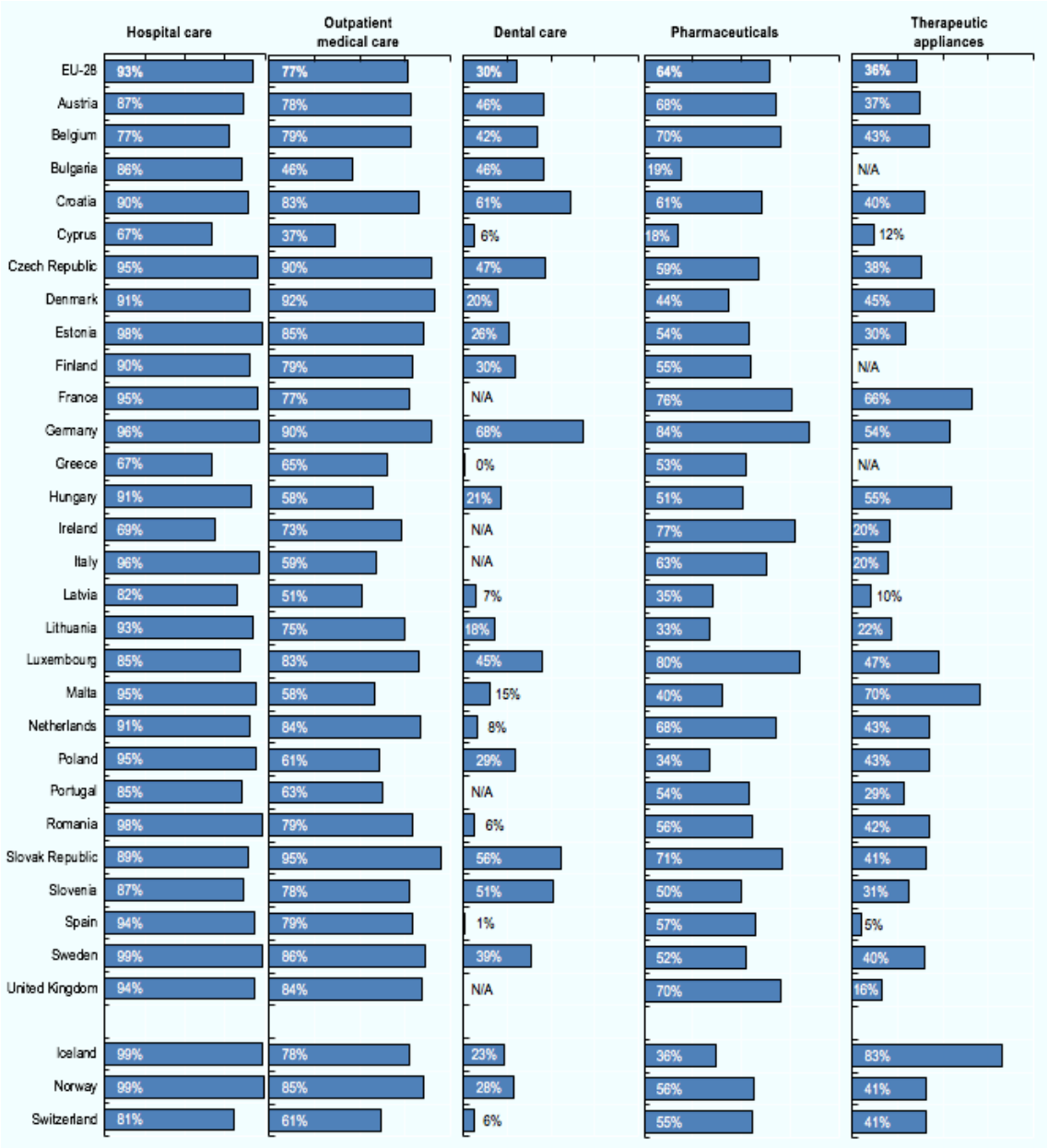
around 64%[288]. This proportion ranges from less than 20% in Bulgaria (19%) and Cyprus (18%) to 80% or above in Germany (84%) and Luxemburg (80%)[289]. In many countries, over-the-counter medicines are not covered by basic coverage schemes[290], and this is an important factor explaining low coverage shares e.g. in Poland, where half of total pharmaceutical expenditure is due to over-the-counter medicines[291]. Moreover, in some countries, patients have to pay the full cost of prescribed medicines, sometimes with the exception of some medications or with exemptions for some groups, e.g. the chronically ill[292].

Across the European Union, coverage by government and compulsory schemes for therapeutic appliances, such as eye products, hearing aids and other medical devices, is only 36%[293]. This share is above 50% only in France (66%), Germany (54%), Hungary (55%) and Malta (70%)[294]. Sometimes, some therapeutic appliances, such as prosthetics, orthodontics, eye products or hearing aids, may also be completely excluded from the statutory benefit package[295].

[288] *Ibidem.*
[289] *Ibidem.*
[290] *Ibidem.*
[291] OECD, *Health for Everyone?: Social Inequalities in Health and Health Systems*, *op. cit.*
[292] Baeten, R., Spasova, S., Vanhercke, B., and Coster, S., *Inequalities in access to healthcare. A study of national policies*, *op. cit.*
[293] OECD/EU, *Health at a Glance: Europe 2018: State of Health in the EU Cycle*, *op. cit.*
[294] *Ibidem.*
[295] Baeten, R., Spasova, S., Vanhercke, B., and Coster, S., *Inequalities in access to healthcare. A study of national policies*, *op. cit.*

Health care coverage for selected goods and services, 2016

Government and compulsory insurance spending as proportion of total health spending by type of service



Source: OECD/EU, Health at a Glance: Europe 2018: State of Health in the EU Cycle, 2018.

2.4.3 User charges

Basic health coverage leaves out of coverage some benefits and, in many cases, coverage

involves a certain degree of cost-sharing. All the European Member States have some formal user charges for health services, even though there are remarkable cross-country differences[296]. Co-payments usually apply for medicines provided in outpatient care, dental care, outpatient visits to psychologists, outpatient physiotherapy and/or rehabilitation, and some medical devices, such as prosthetics, orthodontics, glasses, hearing aids and health services[297].

In some countries, such as Austria, Belgium, Germany, Finland, Croatia, Ireland, Luxemburg, Latvia, Sweden and Slovenia, an annual cap on user charges, above which the patient does not pay any further, has been set, either per household or per insured person[298]. The level of the cap varies greatly between countries, going from €110 in Sweden to €569 in Latvia, and it also varies according to health status, age or income of the insured[299].

Some groups are sometimes exempted from cost sharing, pay lower user charges or are entitled to a broader benefit package[300]. Such exceptions usually apply to pregnant women, children, pensioners, recipients of certain social benefits, poor people, and patients with specific health conditions, such as chronic or infectious diseases[301].

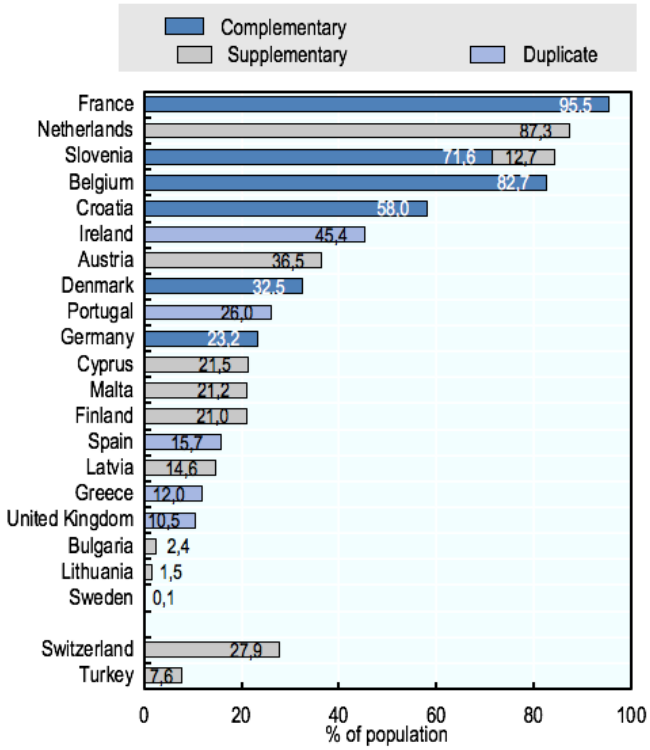
Additional private health insurance

In some countries private insurances providing for additional health coverage can be purchased. However, in the majority of the European Member States, private health insurances are not very common. In some countries, such as Bulgaria (2.4%), Lithuania (1.5%) and Sweden (0.1%), private health insurance plays virtually no role[302]. More than half of the population has an

[296] EXPH, *Report on access to health services in the European Union*, *op. cit.*
[297] Baeten, R., Spasova, S., Vanhercke, B., and Coster, S., *Inequalities in access to healthcare. A study of national policies*, *op. cit.*
[298] *Ibidem.*
[299] *Ibidem.*
[300] DG SANTE, *State of Health in the EU Companion Report 2019, op. cit.*
[301] *Ibidem.*
[302] OECD, *Health for Everyone?: Social Inequalities in Health and Health Systems*, *op. cit.*

additional private health insurance only in Belgium (82.7%), Croatia (58%), France (95.5%), the Netherlands (87.3%) and Slovenia (84.3%)[303].

Private health insurance coverage, 2016



Source: OECD/EU, Health at a Glance: Europe 2018: State of Health in the EU Cycle, 2018.

Additional private health insurance can be of three types: complementary insurance, covering for the cost-sharing left after basic coverage; supplementary insurance, adding further services; and duplicate insurance, providing for faster access or larger choice of providers[304]. Sometimes, additional private health insurance can also completely replace publicly financed coverage[305], thus having a substitutive role and being a person's only source of coverage[306].

[303] OECD/EU, *Health at a Glance: Europe 2018: State of Health in the EU Cycle*, *op. cit.*
[304] *Ibidem.*
[305] Baeten, R., Spasova, S., Vanhercke, B., and Coster, S., *Inequalities in access to healthcare. A study of national policies*, *op. cit.*
[306] EXPH, *Report on access to health services in the European Union*, *op. cit.*

Conclusion

As previously said, the European Union does not have a unique health system, but is rather characterized by the coexistence of 27 different national health systems that present considerable differences among each other. Additionally, notwithstanding its acknowledged importance, the realization of the right to health and healthcare is still far from being a reality within the European Union, as there are still people lacking access to health services and without a proper health coverage. Moreover, there are major health and healthcare gaps and inequalities across countries, even though the state of health is generally good, especially if considered on the base of indicators such as health status, expenditure, financing, accessibility and coverage.

Chapter 3 – Health policy and cross-border healthcare in the European Union

Introduction

Health and healthcare have always been a rather exclusive competence of European nation states, and the European Union has always been expected to almost abstain from interfering in the health systems of its Member States[307].

The Treaty on the Functioning of the European Union determines in Title I the categories and areas of Union competence. Relating to health and healthcare, it establishes that the European Union shall share competence with the Member States in regard to social policy[308], and shall have competence to support, coordinate or supplement the actions of the Member States in regard to the protection and improvement of human health[309].

The Treaty on the Functioning of the European Union more specifically determines in Article 168 that each European Union Member State is responsible for the definition of its national health policy and for the organisation and delivery of health services and medical care[310], even though it also requires Member States to coordinate among themselves their policies and programmes in the field of health and healthcare[311].

[307] Vollaard, H., and Martinsen, D. S., *The rise of a European healthcare union*, Comparative European Politics 15, 3, 337–351, 2017.
[308] EU, *TFEU*, art. 4.2 (b).
[309] *Ivi,* art. 6 (a).
[310] *Ivi*, art. 168.7.
[311] *Ivi*, art. 168.2.

Moreover, Article 168 TFEU establishes that the European Union's role is to merely complement Member States' national health policies and actions[312] and to encourage cooperation between Member States in the field of health and healthcare, especially in order to improve the complementarity of their health services in cross-border areas[313].

3.1 Health policy in the European Union

The European Union has adopted health legislation in areas such as patients' rights in cross-border healthcare; pharmaceuticals and medical devices; serious cross border health threats; tobacco; organs, blood, tissues and cells[314].

At the European Commission's level, the department responsible for European Union policy on food safety and health and for monitoring the implementation of related laws is the Directorate-General for Health and Food Safety (DG SANTE)[315].

Importantly, the European Union health policy is also often made under other guises, such as environmental, social and consumer protection policies. Therefore, also other Directorates-General play a role for health systems[316].

[312] *Ivi*, art. 168.1.
[313] *Ivi*, art. 168.2.
[314] European Commission (EC), *EU Healthy Policy – Overview,* available at https://ec.europa.eu/health/policies/overview_en.
[315] European Commission (EC), *Departments and agencies: Health and Food Safety,* in How the Commission is organised*,* available at https://ec.europa.eu/info/departments/health-and-food-safety_en.
[316] Greer, S. L., Fahy, N., Rozenblum, S., Jarman, H., Palm, W., Elliott, H. A., and Wismar, M., *Everything you always wanted to know about European Union health policies but were afraid to ask: Second*, Copenhagen (Denmark): European Observatory on Health Systems and Policies, 2019.

A clear and relevant example is the European Commission's Directorate-General for Employment, Social Affairs and Inclusion (DG EMPL), whose responsibilities include social security coordination, also in the field of cross-border healthcare[317].

3.1.1 Directorate-General for Health and Food Safety

The European Commission's Directorate-General for Health and Food Safety develops and carries out the Commission's policies on food safety and public health issues[318], and supports the Member States in protecting and improving the health of their citizens, as well as in guaranteeing the accessibility, effectiveness and resilience of their national health systems[319].
It carries out its role through various means, such as proposing legislation, offering financial aid, coordinating and easing the exchange of best practices, and carrying out health promotion activities[320].

Food safety

The first area the Directorate-General for Health and Food Safety has responsibility for is food safety.
In this regard, an integrated approach 'from farm to fork' covering all sectors of the food chain, i.e. feed production, primary production, food processing, storage, transport and retail sale, has been developed[321].

[317] European Commission (EC), *Departments and agencies: Employment, Social Affairs and Inclusion,* in How the Commission is organised, available at https://ec.europa.eu/info/departments/employment-social-affairs-and-inclusion_en.
[318] EC, *Departments and agencies: Health and Food Safety, op cit.*
[319] EC, *EU Healthy Policy – Overview, op. cit.*
[320] *Ibidem.*
[321] European Commission (EC), *Topics – Food safety,* available at https://ec.europa.eu/info/topics/food-safety_en.

The objectives of the Directorate-General for Health and Food Safety with regard to food safety are: ensuring a high level of protection of human life and health and the protection of consumers' interests, fair practices in food trade, animal health and welfare, plant health and the environment; guaranteeing the free movement of food and feed manufactured and marketed in the Union; and easing global trade of safe feed and safe, healthy food[322].

Food safety policy therefore aims at ensuring safe, nutritious food and animal feed, high standards of animal health and welfare and plant protection, and proper information on the origin, content, labelling and use of food[323].

Public health

The second area the Directorate-General for Health and Food Safety has responsibility for is public health.

The objectives of the Directorate-General for Health and Food Safety with regard to public health are: protecting citizens from serious cross-border health threats; contributing to efficient, accessible and resilient health systems; easing access to better and safer healthcare; promoting health, preventing diseases and fostering supportive environments for healthy lifestyles[324].

Relatedly, European public health policy primarily focuses on prevention, equal chances of good health and quality healthcare for all, tackling serious cross-border health threats, pooling health-related knowledge, and promoting a healthy lifestyle, with the ambition to ensure the accessibility, effectiveness and resilience of European health systems[325].

3.1.2 Directorate-General for Employment, Social Affairs and Inclusion

[322] *Ibidem*.
[323] European Commission (EC), *Strategy – Food safety,* available at https://ec.europa.eu/info/strategy/food-safety_en.
[324] European Commission (EC), *Topics – Public health,* available at https://ec.europa.eu/info/topics/public-health_en.
[325] *Ibidem.*

The Directorate-General for Employment, Social Affairs and Inclusion is responsible for European Union policy on social affairs as well as on employment, skills, labour mobility and the related funding programmes, and it develops and carries out the European Commission's policies on employment, social affairs, education and training[326].

Employment and social policy are primarily a national matter, and the European Union only supports and complements Member States' efforts, with the Commission coordinating and monitoring national policies and the implementation of European Union law and promoting the sharing of best practices[327].

The Directorate-General for Employment, Social Affairs and Inclusion is responsible for social affairs, thus including social security also in the field of healthcare, and its aim in this area is to coordinate and modernise social-security schemes[328].

3.2 Cross-border healthcare in the European Union: historical background

One of the main areas in which the European Union's role is more prominent is cross-border healthcare.

Cross-border healthcare in the European Union means that every person covered by the healthcare service of a Member State can receive medical treatment in all the other Member States[329]. It refers to those situations in which a patient is treated in a Member State different

[326] EC, *Departments and agencies: Employment, Social Affairs and Inclusion, op. cit.*

[327] European Commission (EC), *Policies: Employment and social Affairs,* available at https://ec.europa.eu/info/policies/employment-and-social-affairs_en.

[328] European Commission (EC), *Topics – Employment and social Affairs,* available at https://ec.europa.eu/info/topics/employment-and-social-affairs_en.

[329] Ministero della Salute, *Cross-border healthcare: what to know,* in Healthcare in European Union, available at http://www.salute.gov.it/portale/cureUE/dettaglioContenutiCureUE.jsp?lingua=english&id=3812&area=cureUnioneEuropea&menu=vuoto.

from the one in which he is insured, and applies to unexpected and emergency situations as well as planned care[330].

Nowadays, cross-border healthcare in the European Union is regulated by Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems [331] and Directive 2011/24/EU on the application of patients' rights in cross-border health care[332].

Before analysing Regulation No 883/2004 and Directive 2011/24, as well as their relation, it is necessary to provide an overview of the steps that led to the current situation, i.e. the European Convention on Social and Medical assistance, Regulation (EEC) No 1408/71 on the application of social security schemes to employed persons and their families moving within the Community, the 1998 European Court of Justice's rulings applying the principles of free movement to healthcare, and the failed 2004 service directive.

3.2.1 The European Convention on Social and Medical assistance

Initially, no proper European mechanism for cross-border healthcare was in place. The only instrument of co-ordination was the European Convention on Social and Medical assistance.

In 1950 the Council of Europe's Committee of Experts on social security questions proposed to draw up a European Convention on Social and Medical assistance in order to extend to all the members of the Council of Europe the provisions of a Convention on social and medical assistance concluded the year before between Belgium, France, Luxembourg, the Netherlands

[330] Čípová, I., *Patient's rights in cross-border health care in the European Union*, 2019.

[331] European Parliament (EP) and Council of the European Union (Council of the EU), *Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems,* OJ L 166, 30.4.2004, p. 1–123, 29 April 2004.

[332] European Parliament (EP) and Council of the European Union (Council of the EU), *Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare*, OJ L 88, 4.4.2011, p. 45–65, 9 March 2011.

and the United Kingdom[333]. The European Convention on Social and Medical assistance subsequently entered into force on 1 July 1954[334].

The aim of this Convention was for the members of the Council of Europe to extend their co-operation in the social field by establishing the principle of equal treatment for the nationals of each of them in the application of legislation providing for social and medical assistance[335].

Under the Convention, the Contracting Parties undertook to guarantee that nationals of the other Contracting Parties lawfully present in any part of their territory who were without sufficient resources, were entitled equally with their own nationals and on the same conditions to social and medical assistance[336]. The Convention also provided for the cost of assistance to be borne by the Contracting Party which granted the assistance[337].

However, the European Convention on Social and Medical assistance has only been ratified by 14 European Member States (Belgium, Denmark, Estonia, France, Germany, Greece, Ireland, Italy, Luxembourg, Malta, the Netherlands, Portugal, Spain and Sweden)[338].

3.2.2 Regulation (EEC) No 1408/71 on the application of social security schemes to employed persons and their families moving within the Community

The first proper European mechanism for cross-border healthcare was introduced in 1971, when the European Economic Community adopted a regulation on the application of social security schemes to employed persons and their families moving within the Community, i.e. Regulation

[333] Council of Europe (CoE), *Explanatory Report to the European Convention on Social and Medical Assistance and Protocol thereto*, European Treaty Series - Nos. 14 & 14A, Paris, 1953.
[334] *Ibidem*.
[335] Council of Europe (CoE), *European Convention on Social and Medical Assistance*, European Treaty Series - No. 14, Paris, 11 December 1953, Preamble.
[336] *Ivi,* art. 1.
[337] *Ivi*, art. 4.
[338] Council of Europe (CoE), *Chart of signatures and ratifications of Treaty 014 - European Convention on Social and Medical Assistance,* available at https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/014A/signatures.

(EEC) No 1408/71[339]. The following year, Regulation (EEC) No 574/72 fixing the procedure for implementing Regulation (EEC) No 1408/71[340] was issued.

Regulation (EEC) No 1408/71 established some mechanisms by which Community workers and their families could obtain healthcare in another Member State[341]. It granted a right to both acute treatment and planned treatment[342]. However, the access to planned treatment was subject to the principle of prior authorisation, meaning that, in order to obtain access to planned treatment, the patient needed prior authorization from his/her competent national institution to received planned treatment in another Member State[343].

Importantly, this Regulation only applied to workers who are subject to the legislation of a Member State and who are nationals of a Member State, as well as to the members of their families and their survivors[344], and to civil servants[345].

Since 1 May 2010, Council Regulation (EEC) No 1408/71 has been repealed by Regulation 883/2004[346], even though it remains in force and continues to have legal effects in Norway, Iceland, Liechtenstein and Switzerland until the current agreements with EEA and Switzerland are amended, and, until the European Council reaches an agreement on the extension of the

[339] Council of the European Communities, *Regulation (EEC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community*, OJ L 149, 05.07.1971, p. 2 – 50, 14 June 1971.

[340] Council of the European Communities, *Regulation (EEC) No 574/72 of the Council of 21 March 1972 fixing the procedure for implementing Regulation (EEC) No 1408/71 on the application of social security schemes to employed persons and their families moving within the Community*, OJ L 74, 27.3.1972, p. 1–83, 21 March 1972.

[341] Bertinato, L., Busse, R., Fahy, N., Legido-Quigley, H., McKee, M., Palm, W., Passarani, I., and Ronfini, F., *Policy brief: cross-border health care in Europe,* Technical Report, World Health Organization on behalf of the European Observatory on Health Systems and Policies, 2005.

[342] Martinsen, D. S., & Vasev, N. R., *Cross Border Healthcare in the European Union: EU Governance and National Responses in Healthcare*, in M. Hill (Ed.), Studying Public Policy: Bristol, UK: Policy Press, pp. 281-295, 2014.

[343] *Ibidem.*

[344] Council of the European Communities, *Regulation (EEC) No 1408/71*, art. 2.1.

[345] *Ivi*, art. 2.3.

[346] EP and Council of the EU, *Regulation (EC) No* 883*/2004*, *op. cit.*

new regulations, it also still applies to nationals of non-EU countries, legally resident in the European Union[347].

3.2.3 The European Court of Justice rulings of 1998: the Kohll and Decker cases

After Regulation (EEC) No 1408/71, the situation started evolving in 1998, with the Kohll[348] and Decker[349] rulings of the European Court of Justice.

In the Kohll case, the Union des Caisses de Maladie rejected the request of its insured Mr. Kohll, a Luxembourg national, to receive authorisation for his daughter, a minor, to receive treatment from an orthodontist in Germany. The Union des Caisses de Maladie refused to authorise such treatment on the ground that it was not an urgent treatment and that it could be provided in Luxembourg. The European Court of Justice ruled that reimbursement of the cost of dental care provided in another Member State is not subject to authorisation by the social security institution of the insured person, i.e. the Union des Caisses de Maladie[350].

In the Decker case, the Caisse de Maladie des Employés Privés refused to reimburse its insured Mr. Decker, a Luxembourg national, the cost of a pair of spectacles with corrective lenses purchased from an optician in Belgium with a prescription made by an ophthalmologist based in Luxembourg. The Caisse de Maladie des Employés Privés refused the reimbursement on the ground that the spectacles had been purchased abroad without its prior authorisation. The European Court of Justice ruled that the Caisse de Maladie des Employés Privés, being a social security institution of Luxemburg, i.e. a Member State, could not refuse to reimburse the

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[347] *Ivi,* art. 90.2, and European Commission, *Frequently asked questions – Regulations: Coordination of social security systems,* in Employment, Social Affairs & Inclusion, available at https://ec.europa.eu/social/main.jsp?catId=857&langId=en&intPageId=983.

[348] European Court of Justice (ECJ), Case C-158/96, *Raymond Kohll v Union des Caisses de Maladie*, 28 April 1998.

[349] European Court of Justice (ECJ), Case C-120/95, *Nicolas Decker v Caisse de Maladie des Employés Privés*, 28 April 1998.

[350] ECJ, C-158/96, *Raymond Kohll v Union des Caisses de Maladie*, *op. cit*.

insured person Mr. Decker on the ground that prior authorisation is required for the purchase of a medical product, in this case a pair of spectacles with corrective lenses, in another Member State[351].

In these two rulings, the European Court of Justice applied for the first time the principles of free movement of services and goods to healthcare, establishing that patients could use internal market provisions to access healthcare in other Member States and that imposing the need for prior authorization for treatment delivered in another Member State represented a hindrance to the principle of free movement[352]. Nevertheless, the European Court of Justice acknowledged the need to impose some barriers to free movement in order to allow Member States to maintain efficient, quality and accessible health systems, and therefore determined that access to healthcare services in another Member State could be subject to prior authorization. However, authorization could only be refused in a very limited amount of cases, i.e. if the same treatment, or an equivalent effective one, could be received at home without excessive delay[353].

3.2.4 The failed service directive

Since the Kohll and Decker cases, the European Court of Justice continued to apply the principles of free movement to healthcare through a series of other judgments[354].

It eventually became clear that there was a need to codify this body of case law[355], and the European Commission suggested to do so in 2004 by including healthcare in the proposal for a Directive on services in the internal market[356], and in particular in Article 23 dealing with the

[351] ECJ, C-120/95, *Nicolas Decker v Caisse de Maladie des Employés Privés*, *op. cit*.
[352] Bertinato, L., Busse, R., Fahy, N., Legido-Quigley, H., McKee, M., Palm, W., Passarani, I., and Ronfini, F., *Policy brief: cross-border health care in Europe, op. cit*.
[353] *Ibidem.*
[354] *Ibidem.*
[355] Footman, K., Knai, C., Baeten, R., Glonti, K., and McKee, M., *Cross-border health care in Europe*, Europe: World Health Organization, 2014.
[356] European Commission (EC), *Proposal for a Directive of the European Parliament and of the Council on services in the internal market*, [SEC(2004) 21], COM/2004/0002 final - COD 2004/0001, 5 March 2004.

assumption of healthcare costs[357]. By doing so, health would have been incorporated into the general European Union regime for the regulation of services[358]. However, it was contended that health services are different from commercial services[359], and health was eventually removed from the scope of application of the service directive, which was subsequently approved in 2006[360].

3.2.5 Cross-border healthcare nowadays

Nowadays, cross-border healthcare in the European Union is regulated by Regulation (EC) No 883/2004 on the coordination of social security systems[361] and Directive 2011/24/EU on the application of patients' rights in cross-border health care[362].

Healthcare may be provided in another Member State also under parallel cross-border care agreements between Member States[363]. Several Member States have adopted bi-lateral and multi-lateral parallel procedures to deal with cross-border healthcare, and in some Member States such procedures account for a larger patient flows abroad than under Directive 2011/24 or Regulation No 883/2004[364]. However, there currently is no uniform reporting covering all the existing schemes and it is therefore not possible to have a complete assessment of the share of cross-border patient mobility covered by parallel agreements[365].

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[357] *Ivi,* art. 23.
[358] Footman, K., Knai, C., Baeten, R., Glonti, K., and McKee, M., *Cross-border health care in Europe*, *op. cit.*
[359] *Ibidem.*
[360] European Parliament (EP) and Council of the European Union (Council of the EU), *Directive 2006/123 of the European Parliament and of the Council of 12 December 2006 on services in the internal market,* OJ L 376, 27.12.2006, p. 36–68 ,12 December 2006.
[361] EP and Council of the EU, *Regulation (EC) No* 883*/2004*, *op. cit.*
[362] EP and Council of the EU, *Directive 2011/24/EU, op. cit*
[363] Wilson, P., Andoulsi, I., and Wilson, C., *Member State Data on cross-border patient healthcare following Directive2011/24/EU. Year 2018*, 2019.
[364] *Ibidem*.
[365] *Ibidem*.

3.3 Regulation (EC) No 883/2004 on the coordination of social security systems

Regulation (EC) No 883/2004 on the coordination of social security systems was issued in 2004 by the European Parliament and the Council with the aim of simplifying and clarifying the rules on the coordination of social security systems[366]. It entered into force only on 1 May 2010, when Regulation (EC) No 987/2009[367] laying down the procedures for its implementation became applicable as well[368]. As previously said, and in line with its Article 90, since its entry into force on 1 May 2010, Regulation 883/2004 repealed Council Regulation (EEC) No 1408/71[369].

Regulation (EC) No 883/2004 ensures that insured persons, and mainly workers, do not lose their social protection when moving to another Member State. It covers all areas of social security, including inter alia the provision of medically necessary and urgent healthcare treatments during a temporary stay outside the competent Member State and the possibility of receiving planned healthcare treatments in a Member State other than the competent one[370].

3.3.1 General provisions

Definitions

[366] EUR-Lex, *Social security schemes and free movement of persons: Basic Regulation,* available at https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=LEGISSUM%3Ac10516.

[367] European Parliament (EP) and Council of the European Union (Council of the EU), *Regulation (EC) No 987/2009 of the European Parliament and of the Council of 16 September 2009 laying down the procedure for implementing Regulation (EC) No 883/2004 on the coordination of social security systems,* OJ L 284, 30.10.2009, p. 1–42, 16 September 2009.

[368] EUR-Lex, *Coordination of social security systems,* available at available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:c10521.

[369] EP and Council of the EU, *Regulation (EC) No* 883*/2004,* art. 90.1.

[370] Ministero della Salute, *FAQ - Scope of the Directive and the Regulation*, available at http://www.salute.gov.it/portale/p5_1_1.jsp?id=178.

Article 1 of Regulation (EC) No 883/2004 provides a series of definitions[371]. Among them: "insured person" means any person satisfying the conditions required under the legislation of the competent Member State to have the right to benefits[372]; "frontier worker" refers to any person pursuing an activity as an employed or self-employed person in a Member State and who resides in another Member State to which he returns as a rule daily or at least once a week[373]; "residence" denotes the place where a person habitually resides[374]; "stay" denotes a temporary residence[375]; "competent authority" refers to the authority responsible for social security schemes[376]; "institution" denotes the authority responsible for applying the legislation[377]; "competent institution" is the institution with which the person concerned is insured at the time of the application for benefit[378]; "institution of the place of residence" means the institution which is competent to provide benefits in the place where the person concerned resides[379]; "institution of the place of stay" denotes the institution which is competent to provide benefits in the place where the person concerned is staying[380]; "competent Member State" denotes the Member State in which the competent institution is situated[381].

Persons covered and equality of treatment

The personal scope of Regulation (EC) No 883/2004 is defined in Article 2[382]. Differently from Regulation (EEC) No 1408/71 which only applied to employed persons and their families, Regulation (EC) No 883/2004 is applicable to all the nationals of a European Member State,

[371] EP and Council of the EU, *Regulation (EC) No* 883*/2004,* art. 1.
[372] *Ivi,* art. 1 (c).
[373] *Ivi,* art. 1 (f).
[374] *Ivi,* art. 1 (j).
[375] *Ivi,* art. 1 (k).
[376] *Ivi,* art. 1 (m).
[377] *Ivi,* art. 1 (p).
[378] *Ivi,* art. 1 (q).
[379] *Ivi,* art. 1 (r).
[380] *Ibidem*.
[381] *Ivi,* art. 1 (s).
[382] *Ivi,* art. 2.

stateless persons and refugees residing in a Member State who are or have been subject to the legislation of one or more Member States, as well as to the members of their families and to their survivors[383]. It also applies to the survivors of persons who have been subject to the legislation of one or more Member States, irrespective of the nationality of such persons, where their survivors are nationals of a Member State, stateless persons or refugees residing in one of the Member States[384]. Moreover, Regulation (EC) No 883/2004 establishes in Article 4 that, unless otherwise provided for by the Regulation itself, the persons to whom the Regulation applies shall enjoy the same benefits and be subject to the same obligations under the legislation of any Member State as the nationals thereof[385].

Matters covered

Regulation (EC) No 883/2004 applies to some branches of social security, which are listed in Article 3[386]. These are: sickness, maternity and equivalent paternity benefits; benefits in respect of accidents at work and occupational diseases; death grants; invalidity benefits; old-age and survivors' pensions; unemployment benefits; pre-retirement benefits; and family benefits[387]. Title III is dedicated to special provisions concerning these various categories of benefits.

3.3.2 Sickness benefits

Chapter 1 of Title III deals with sickness, maternity and equivalent paternity benefits, and is the relevant one in the field of cross-border healthcare.

[383] *Ivi,* art. 2.1.
[384] *Ivi,* art. 2.2.
[385] *Ivi,* art. 4.
[386] *Ivi,* art. 3.
[387] *Ibidem*.

It includes articles 17 to 35 and is divided into three sections. Section 1 includes articles 17 to 22 and applies to insured persons and members of their families, except pensioners and members of their families; Section 2 includes articles 23 to 30 and pertains to pensioners and members of their families; and Section 3 includes articles 31 to 35 and presents some common provisions.

Insured persons and members of their families, except pensioners and members of their families

Section 1 includes articles 17 to 22, and applies to insured persons and members of their families, except pensioners and members of their families.

Article 17 pertains to the provision of benefits in kind to an insured person or members of his family who reside in a Member State other than the competent one. The person in question shall receive, in the Member State of residence, benefits in kind provided by the institution of the place of residence on behalf of the competent institution, in accordance with the legislation applicable for the insured persons of that Member State[388].

Article 18 concerns the case of an insured person and the members of his family staying in the competent Member State when residence is in another Member State. The person in question shall receive benefits in kinds provided by the competent institution and at its own expense, in accordance with the legislation it applies, and as if he resided in that Member State[389].

Article 19 deals with the case of an insured person and the members of his family staying in a Member State other than the competent Member State. In this case, the person concerned shall be provided the medically necessary benefits in kinds by the institution of the place of stay on

[388] *Ivi,* art. 17.
[389] *Ivi,* art. 18.

behalf of the competent institution, in accordance with the legislation applicable for the insured persons of that Member State[390].

Article 20 deals with the case of an insured person or a member of his family[391] travelling to another Member State with the purpose of receiving benefits in kind, i.e. appropriate treatment. It establishes that, in order to receive such treatment, the person in question shall seek authorisation from the competent institution[392]. If such authorisation is given, he shall receive the benefits in kind provided by the institution of the place of stay on behalf of the competent institution, in accordance with the legislation applicable for the insured persons of that Member State. Authorisation shall be accorded when the treatment concerned is among those provided for by the legislation in the Member State where the person resides, and when such treatment cannot be provided within a medically justifiable time-limit[393].

Article 21 pertains to the entitlement to benefits in cash of an insured person and members of his family residing or staying in a Member State other than the competent Member State. It stipulates that such benefits in cash shall be provided to the insured person and members of his family by the competent institution in accordance with its legislation. If agreed so by the competent institution and the institution of the place of residence or stay, the benefits in cash might also be provided by the institution of the place of residence or stay at the expense of the competent institution in accordance with the legislation of the competent Member State[394].

Article 22 deals with the case of an insured person who, on making a claim for a pension, or during its investigation, ceases to be entitled to benefits in kind under the legislation of the Member State last competent. In this case, such person shall remain entitled to benefits in kind under the legislation of the Member State in which he resides. The right to benefits in kind in

[390] *Ivi,* art. 19.
[391] *Ivi,* art. 20.3.
[392] *Ivi,* art. 20.1.
[393] *Ivi,* art. 20.2.
[394] *Ivi,* art. 21.1.

the Member State of residence shall also apply to the members of the family of the pension claimant[395].

Pensioners and members of their families

Section 2 includes articles 23 to 30 and pertains to pensioners and members of their families.

Article 23 concerns the case of a person who receives a pension or pensions under the legislation of two or more Member States, one of which is the Member State of residence, and who is entitled to benefits in kind under the legislation of that Member State. Such person and the members of his family shall receive the benefits in kind from and at the expense of the institution of the place of residence, as if he was a pensioner whose pension was payable only under the legislation of that Member State[396].

Article 24 deals with the case of a person who receives a pension or pensions under the legislation of one or more Member States and who is not entitled to benefits in kind under the legislation of the Member State of residence. The pensioner and the member of his family shall still receive the benefits in kind, as long as the pensioner would be entitled to them under the legislation of the Member State, or of at least one of the Member States, competent for his pensions, if he resided in that Member State. The benefits in kind shall be provided by the institution of the place of residence, as if the person concerned was entitled to a pension and benefits in kind under the legislation of that Member State[397]. If the pensioner is entitled to benefits in kind under the legislation of a single Member State, the cost shall be borne by the competent institution of that Member State[398]. If instead the pensioner is entitled to benefits in kind under the legislation of two or more Member States, the cost shall be borne by the competent institution of the Member State to whose legislation the pensioner has been subject

[395] *Ivi,* art. 22.
[396] *Ivi,* art. 23.
[397] *Ivi,* art. 24.
[398] *Ivi,* art. 24.2 (a).

for the longest period of time; if this does not allow to determine a single responsible institution, the cost shall be borne by the institution applying the legislation to which the person was last subject[399].

Article 25 pertains to situations in which the person receiving a pension or pensions under the legislation of one or more Member States resides in a Member State under whose legislation the right to receive benefits in kind is not subject to conditions of insurance, or of activity as an employed or self-employed person, and no pension is received from that Member State. In these situations, the cost of benefits in kind provided to the pensioner and to members of his family shall be borne by the institution of one of the Member States competent in respect of his pensions determined in accordance with Article 24, to the extent that the pensioner and the members of his family would be entitled to such benefits if they resided in that Member State[400].

Article 26 concerns the case of members of the family of a person receiving a pension or pensions under the legislation of one or more Member States who reside in a Member State other than the one in which the pensioner resides. As long as the pensioner is entitled to benefits in kind under the legislation of a Member State, the members of his family shall receive benefits in kind from the institution of the place of their residence in accordance with the legislation it applies. The cost of such benefits in kind shall be borne by the competent institution responsible for the costs of the benefits in kind provided to the pensioner in his Member State of residence[401].

Article 27 determines that Article 19 shall apply mutatis mutandis to a person receiving a pension or pensions under the legislation of one or more Member States and entitled to benefits in kind under the legislation of one of the Member States which provide his pension(s) or to the members of his family who are staying in a Member State other than the one in which they

[399] *Ivi,* art. 24.2 (b).
[400] *Ivi,* art. 25.
[401] *Ivi,* art. 26.

reside[402]. It further establishes that also Article 18(1) shall apply mutatis mutandis to such persons when they stay in the Member State in which the competent institution responsible for the cost of the benefits in kind provided to the pensioner in his Member State of residence is situated[403]. The article additionally determines that also Article 20 shall apply mutatis mutandis to a pensioner and/or the members of his family who are staying in a Member State other than the one in which they reside with the purpose of receiving there the treatment appropriate to their condition[404]. Concerning the cost of the benefits in kind, Article 27 determines that if the pensioner or of the members of his family reside in a Member State which has opted for reimbursement on the basis of fixed amounts, the cost shall be borne by the institution of their place of residence[405]. Otherwise, the cost of the benefits in kind shall be borne by the competent institution responsible for the cost of benefits in kind provided to the pensioner in his Member State of residence[406].

Article 28 establishes some special rules for retired frontier workers. It determines that, in case of sickness, a frontier worker who retires is entitled to continue to receive benefits in kind in the Member State where he last pursued his activity, as long as this is a continuation of treatment which began in that Member State[407]. The cost of the benefits in kind shall be borne by the competent institution responsible for the cost of benefits in kind provided to the pensioner in his Member States of residence[408].

Article 29 stipulates that a person receiving a pension or pensions under the legislation of one or more Member States, as well as the members of his family[409], shall be paid cash benefits by the competent institution of the Member State in which the competent institution responsible

[402] *Ivi,* art. 27.1.
[403] *Ivi,* art. 27.2.
[404] *Ivi,* art. 27.3
[405] *Ivi,* art. 27.5.
[406] *Ivi,* art. 27.4.
[407] *Ivi,* art. 28.1.
[408] *Ivi,* art. 28.5.
[409] *Ivi,* art. 29.2.

for the cost of benefits in kind provided to the pensioner in his Member State of residence is situated[410].

Article 30 states that the institution of a Member State which is responsible under its legislation for making deductions in respect of contributions for sickness, maternity and equivalent paternity benefits, can request and recover such deductions only insofar as the cost of the benefits is to be borne by an institution of that Member State[411].

Common provisions

Section 3 includes articles 31 to 35 and presents some common provisions.

Article 31 instructs that a pensioner or the members of his family who are entitled to benefits under the legislation of a Member State on the basis of an activity as an employed or self-employed person shall be subject to Articles 17 to 21, rather than to Articles 23 to 30[412].

Article 32 establishes that an independent right to benefits in kind shall take priority over a derivative right to benefits for members of a family, unless such independent right in the Member State of residence exists directly and solely on the basis of the residence of the person concerned in that Member State[413].

Article 33 refers to situations in which an insured person or a member of his family has had a right to a prosthesis, a major appliance or other substantial benefits in kind recognised by the institution of a Member State before he became insured under the legislation applied by the institution of another Member State. In these situations, the said benefits shall be provided at the expense of the first institution, even if they are awarded after the person has become insured under the legislation applied by the second institution[414].

[410] *Ivi,* art. 29.1.
[411] *Ivi,* art. 30.1.
[412] *Ivi,* art. 31.
[413] *Ivi,* art. 32.1.
[414] *Ivi,* art. 33.1.

Article 34 determines that if a recipient of long-term care benefits in cash is also entitled to claim benefits in kind intended for the same purpose from the institution of the place of residence or stay in another Member State, and an institution in the first Member State is also required to reimburse the cost of these benefits in kind, the general provision on prevention of overlapping of benefits laid down in Article 10 (i.e. no right to several benefits of the same kind for one and the same period of compulsory insurance is conferred or maintained under the Regulation) shall be applicable. However, if the person concerned claims and receives the benefit in kind, the amount of the benefit in cash shall be reduced by the amount of the benefit in kind which is or could be claimed from the institution of the first Member State required to reimburse the cost[415].

Article 35 deals with reimbursements between institutions. It stipulates that the benefits in kind provided by the institution of a Member State on behalf of the institution of another Member State shall give rise to full reimbursement[416]. Such reimbursement shall be determined and made in accordance with the arrangements set out in the Implementing Regulation (i.e. Regulation No 987/2009) on production of proof of actual expenditure. In the case of Member States whose legal or administrative structures are such that the use of reimbursement on the basis of actual expenditure would not be appropriate, reimbursement shall be determined and made on the basis of fixed amounts[417].

3.3.3 The Administrative Commission

In the Preamble, the European Commission acknowledges the necessity to establish an Administrative Commission charged with dealing with all the administrative and interpretation

[415] *Ivi,* art. 34.1.
[416] *Ivi,* art. 35.1.
[417] *Ivi,* art. 35.2.

questions on the Regulation, and with promoting further cooperation between the Member States[418].

Regulation 883/2004/EC therefore establishes an Administrative Commission for the Coordination of Social Security Systems, which shall be composed of a government representative from each of the Member States, eventually assisted by expert advisers[419]. The meetings of the Administrative Commission shall be also attended by a representative of the Commission of the European Communities in an advisory role[420].

The Administrative Commission is principally charged with dealing with all the administrative and interpretation questions on the Regulation or the Implementing Regulation[421]; facilitating the uniform application of Community law[422]; fostering and developing cooperation between Member States in social security matters[423]; facilitating the realisation of actions of cross-border cooperation activities[424]; and encouraging the use of new technologies with a view to facilitate the free movement of persons[425].

Attached to the Administrative Commission, there are a Technical Commission for Data Processing, charged with proposing to the Administrative Commission common architecture rules for the operation of data-processing services[426], and an Audit Board, charged inter alia with verifying the method of determining and calculating the annual average costs presented by Member States[427]; and collecting the necessary data and carry out the calculations required for establishing the annual statement of claims of each Member State[428].

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[418] *Ivi,* Preamble (38).
[419] *Ivi,* art. 71.1.
[420] *Ibidem.*
[421] *Ivi,* art. 72 (a).
[422] *Ivi,* art. 72 (b).
[423] *Ivi,* art. 72 (c).
[424] *Ibidem*.
[425] *Ivi,* art. 72 (d).
[426] *Ivi,* art. 73.1.
[427] *Ivi,* art. 74.1 (a).
[428] *Ivi,* art. 74.1 (b).

3.3.4 The European Health Insurance Card

Regulation 883/2004 applies to planned treatment for which prior authorisation is need, as well as to emergency, urgent or medically necessary treatment. In the case of emergency, urgent or medically necessary treatment, access is ensured by the European Health Insurance Card or its replacement certificate[429].

The European Health Insurance Card is a free card issued by the national health insurance provider that gives access to emergency, urgent or medically necessary state-provided healthcare during a temporary stay in any of the 27 European Union Member States[430]. The Card is proof that a person is an "insured person" within the meaning of Regulation (EC) No 883/2004 and entitles such person to receive treatment in the Member State of stay under the same conditions and at the same cost as people insured in that country[431]. With the European Health Insurance Card, the treatment is provided directly at no cost, with the exception of eventual co-payments which are charged to the patient and are not refundable[432]. The European Health Insurance Card has substituted the forms E110, E111, E119 and E128[433], and its length of validity varies from one country to another[434].

Historical background

The decision to introduce the European Health Insurance Card was taken at the Barcelona European Council of March 2002. There, the European Council decided that a European Health

[429] Ministero della Salute, *Cross-border healthcare: what to know, op. cit.*
[430] European Commission (EC), *European Health Insurance Card,* in Employment, Social Affairs & Inclusion, available at https://ec.europa.eu/social/main.jsp?catId=559.
[431] Pacolet, J. and De Wispelaere, F., *The European Health Insurance Card - Reference year 2015,* June 2016.
[432] Ministero della Salute, *European Health Insurance Card - EHIC,* in Healthcare in European Union, available at http://www.salute.gov.it/portale/cureUE/dettaglioContenutiCureUE.jsp?lingua=english&id=5272&area=cureUnioneEuropea&menu=vuoto.
[433] *Ibidem.*
[434] European Commission (EC), *European Health Insurance Card - Applying for a card,* in Employment, Social Affairs & Inclusion, available at https://ec.europa.eu/social/main.jsp?catId=563&langId=en.

Insurance Card was to be adopted to replace the current paper forms needed for health treatment in another Member State[435].

The following year, the Administrative Commission of the European Communities on social security for migrant workers issued Decision No 189 aimed at introducing a European health insurance card[436], where it established that the European health insurance card shall progressively replace the existing forms giving entitlement to reimbursement of healthcare costs during a temporary stay in another Member State[437].

The European Health Insurance Card was introduced progressively from 1 June 2004, and since 1 January 2006 it has been issued and is recognised in all the European Member States[438].

Decision S1 of 12 June 2009 concerning the European Health Insurance Card

In June 2009, the Administrative Commission for the coordination of social security systems issued Decision S1 concerning the European Health Insurance Card, which came into force on 1 May 2010[439].

Decision S1 establishes that the European Health Insurance Card certifies the entitlement of an insured person staying in a Member State other than the competent Member State to medically necessary benefits in kind[440]. It also establishes that the European Health Insurance Card shall be individual and made out in the name of the card holder[441], that its period of validity be

[435] European Council, *Barcelona European Council, 15–16 March 2002. Presidency Conclusions*, 2002.
[436] Administrative Commission of the European Communities on social security for migrant workers, *Decision No 189 of 18 June 2003 aimed at introducing a European health insurance card to replace the forms necessary for the application of Council Regulations (EEC) No 1408/71 and (EEC) No 574/72 as regards access to health care during a temporary stay in a Member State other than the competent State or the State of residence*, OJ L 276, 27.10.2003, p. 1–3, 18 June 2003.
[437] *Ivi,* art. 1.
[438] European Commission (EC), *Frequently asked questions - The European Health Insurance Card*, in Employment, Social Affairs & Inclusion, available at https://ec.europa.eu/social/main.jsp?catId=857&intPageId=1304&langId=en.
[439] Administrative Commission for the coordination of social security systems, *Decision S1 of 12 June 2009 concerning the European Health Insurance Card*, OJ C 106, 24.4.2010, p. 23–25, 12 June 2009.
[440] *Ivi,* 1.
[441] *Ivi,* 2.

determined by the issuing institution[442], and that when exceptional circumstances prevent its issuing, a provisional replacement certificate with a limited validity period shall be issued by the competent institution[443].

Decision S1 further determines that the European Health Insurance Card can be used in any situation of temporary stay to receive medically necessary benefits in kind under the same procedures and tariffs as person covered by the sickness insurance scheme of that State[444] regardless of the reasons of the stay[445], unless it is to receive medical treatment[446].

When a person ceases to be entitled to sickness benefits in kind on behalf of a Member State and becomes entitled on behalf of another Member State, Decision S1 establishes that those Member States should cooperate in order to avoid the insured person making inappropriate use of the European Health Insurance Card[447].

Decision S1 establishes that the data contained in the European Health Insurance Card shall be "eye-readable"[448]. Such data shall be name, surname, personal identification number and date of birth of the card holder; expiry date and logical number of the card; ISO code of the Member State issuing the card; and identification number and acronym of the competent institution[449].

The technical specifications of the European Health Insurance Card are laid out in Annex I to Decision S2 of the Administrative Commission for the coordination of social security systems[450].

Coverage

[442] *Ivi,* 3.
[443] *Ivi,* 5.
[444] *Ivi,* 11.
[445] *Ivi,* 8.
[446] *Ivi,* 10.
[447] *Ivi,* 12.
[448] *Ivi,* Preamble (2).
[449] *Ivi,* 7.
[450] Administrative Commission for the coordination of social security systems, *Decision S2 of 12 June 2009 concerning the technical specifications of the European Health Insurance Card*, OJ C 106, 24.4.2010, p. 26–39, 12 June 2009.

In 2015, approximately 40% of the total number of insured persons living in a Member State had a valid European Health Insurance Card[451]. This proportion ranged from over 90% in Italy (about 100%), Malta (98%), the Czech Republic (96%), the Netherlands (95%) and Austria (94%), to 10% or less in Latvia (10%), France (10%), Spain (8%), Croatia (7%), Poland (6%), Bulgaria (5%), Greece (2%) and Romania (1%)[452].

These significant differences in the share of insured persons with a valid European Health Insurance Card between Member States are mainly due to the different application and issuing procedures. Indeed, some Member States issue the European Health Insurance Card automatically, while in others it is issued on request[453].

Coverage rates are also influenced by the validity period, which ranges from a few months to 10 years, the mobility of insured persons and their awareness of their cross-border healthcare rights[454].

3.4 Directive 2011/24/EU on the application of patients' rights in cross-border healthcare

In 2011, the European Parliament and Council adopted Directive 2011/24/EU on the application of patients' rights in cross-border health care[455].

[451] Pacolet, J. and De Wispelaere, F., *The European Health Insurance Card - Reference year 2015, op. cit*.
[452] *Ibidem.*
[453] De Wispelaere, F., De Smedt, L., and Pacolet, J., *Coordination of social security systems at a glance. 2019 Statistical Report*, Luxembourg: Publications Office of the European Union, 2019.
[454] *Ibidem.*
[455] EP and Council of the EU, *Directive 2011/24/EU, op. cit.*

Under this directive, European citizens can obtain health services in another European Member State and be reimbursed for the costs incurred as long as the treatment and the costs involved would be covered in their own national health system[456].

Moreover, Directive 2011/24/EU establishes the patients' right to freely choose their healthcare provider, and it sets out rules to ensure that patients receive all the information necessary to exercise their rights and benefit from safe and high-quality healthcare in every Member State, and to establish efficient cooperation between the Member States' health systems[457].

3.4.1 Background and development

As previously said, in 2004 the European Commission proposed to include healthcare in the Directive on services in the internal market[458], but health was eventually excluded from the scope of application of the directive, which was approved in 2006[459].

After exclusion of healthcare from the Directive on services in the internal market, and with the objective to clearly identify the problems in the field of cross-border healthcare and to receive input concerning objectives and policy options[460], in September 2006 the Commission launched a consultation regarding Community action on health services, inviting all relevant stakeholders to contribute[461].

Moreover, an impact assessment report was issued in order to consider the need for and the potential impact of different options for Community action in the field of cross-border

[456] Kamel, N., *European reference networks: moving towards a tangible outcome of the European Union's cross-border healthcare directive?,* European Respiratory Journal 2016 48: 1564-1568, 2016.
[457] Ministero della Salute, *FAQ - Scope of the Directive and the Regulation*, *op. cit*.
[458] EC, *Proposal for a Directive of the European Parliament and of the Council on services in the internal market*, *op. cit.*
[459] EP and Council of the EU *Directive 2006/123, op. cit.*
[460] European Commission (EC), *Commission Staff working document. Accompanying document to the Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare. Summary of the impact assessment*, COM(2008) 414 final, SEC(2008) 2163, 2 July 2008.
[461] European Commission (EC), *Consultation regarding Community action on health services*, SEC (2006) 1195/4, 26 September 2006.

healthcare[462]. The impact assessment report presented some options for Community action on health services. These options were: taking no further action at the Community level; providing guidance at Community level but without any additional binding legal measure; establishing a Community general legal framework for health services through a directive on health services; and establishing detailed legal rules at the Community level[463].

In July 2008, the European Commission finally issued a proposal for a Directive on the application of patients' rights in cross-border healthcare[464]. The aim of the proposed Directive was to establish a general framework for the provision of safe, high quality and efficient cross-border healthcare in the European Union[465], as well as to guarantee patients mobility and freedom to provide healthcare and high level of protection of health, while respecting the responsibilities of the Member States for the definition of social security benefits linked to health and the organisation and provision of healthcare and medical care and social security benefits[466]. The draft Directive encountered several objections from the Member States, worried that an excessive and unrestricted freedom of movement for patients and health services would have led them to incur in a loss of control over their national health budgets[467].

Notwithstanding these objections, the Directive on the application of patients' rights in cross-border health care was eventually adopted on 9 March 2011, and entered into force on 24 April 2011[468]. European Union Member States had to incorporate it into their national law by 25 October 2013[469].

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[462] EC, *Commission Staff working document. Accompanying document to the Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare. Summary of the impact assessment*, *op. cit.*

[463] *Ibidem.*

[464] European Commission (EC)*, Proposal for a Directive of the European Parliament and the Council on the application of patients' rights in cross-border healthcare,* COM (2008) 414 final, 2008/0142 (COD), 2 July 2008.

[465] *Ivi*, art. 1.

[466] *Ivi*, (8).

[467] Čípová, I, *Patient's rights in cross-border health care in the European Union*, *op. cit*.

[468] EUR-Lex, *Healthcare in other EU countries – patients' rights,* available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM%3Asp0002.

[469] EP and Council of the EU, *Directive 2011/24/EU,* art. 21.1.

3.4.2 General provisions

Aim

The aim of Directive 2011/24 on the application of patients' rights in cross-border health care is to improve the functioning of the internal market and the free movement of goods, persons and services[470]. More precisely, its aim is to ensure patient mobility through the establishment of rules for easing the access to safe and high-quality cross-border healthcare in the European Union, and to promote cooperation on healthcare between Member States, while entirely respecting the national competencies and responsibilities of the Member States for the definition of social security benefits relating to health and for the organisation and delivery of healthcare and medical care and social security benefits[471].

Scope

Directive 2011/24 applies to the provision of healthcare, regardless of how it is organised, delivered and financed[472]. However, there are some exceptions. It does not apply to long-term care services aimed at supporting people in need of assistance in carrying out routine, daily tasks[473]; to the allocation of and access to organs for organ transplants[474]; and to public vaccination programmes against infectious diseases aimed at protecting the health of the population in a specific Member State[475].

Definitions

[470] *Ivi,* Preamble (2).
[471] *Ivi,* Preamble (10).
[472] *Ivi,* art. 1.2.
[473] *Ivi,* art. 1.3 (a).
[474] *Ivi,* art. 1.3 (b).
[475] *Ivi,* art. 1.3 (c).

Article 3 of Directive 2011/24 provides a series of definitions[476]. Among them: "healthcare" refers to health services provided by health professionals to patients with the aim to assess, maintain or restore their state of health[477]; "insured person" means a person covered by Regulation (EC) No 883/2004 and who is insured within the meaning of that Regulation[478]; "Member State of affiliation" denotes the Member State competent to award to the insured person a prior authorisation to receive appropriate treatment outside his Member State of residence[479]; "Member State of treatment" refers to the Member State where healthcare is provided to the patient[480]; "cross-border healthcare" means healthcare provided or prescribed in a Member State other than the Member State of affiliation[481]; "healthcare provider" denotes a natural or legal person or another entity lawfully providing healthcare within a Member State[482]; "patient" denotes a natural person who receives or seeks to receive healthcare in a Member State[483].

3.4.3 Responsibilities of Member States and cooperation

Responsibilities of Member States

Directive 2011/24 defines a series of responsibilities Member States have with regard to cross-border healthcare.

In article 4, the Directive lays out the responsibilities of the Member State of treatment, which is required to inter alia guarantee that relevant information is provided to patients from the

[476] *Ivi,* art. 3.
[477] *Ivi,* art. 3 (a).
[478] *Ivi,* art. 3 (b.i).
[479] *Ivi,* art. 3 (c.i).
[480] *Ivi,* art. 3 (d).
[481] *Ivi,* art. 3 (e).
[482] *Ivi,* art. 3 (g).
[483] *Ivi,* art. 3 (f).

national contact point[484] and healthcare providers[485]; that transparent complaints procedures and mechanisms for patients are in place[486]; that the principle of non-discrimination regarding nationality is applied to patients from other Member States[487]; and that healthcare providers apply the same fees for healthcare for patients from other Member States, as for domestic patients[488].

The responsibilities of the Member State of affiliation are listed in Article 5. These include ensuring that the cost of cross-border healthcare is reimbursed in accordance with the Directive[489]; that mechanisms to provide patients with information on their rights and entitlements and procedures for accessing and determining those entitlements and for appeal and redress are in place[490]; that necessary medical follow-up is available as if healthcare had been provided on its territory[491]; and that patients have access to their medical records[492].

Moreover, Directive 2011/24 establishes that Each Member State shall designate at least one national contact point for cross-border healthcare[493], which shall facilitate the exchange of information[494] and provide patients with information concerning inter alia healthcare providers, their rights, complaints procedures and mechanisms for seeking remedies[495].

Cooperation in healthcare

Directive 2011/24 invites Member States to enhance and ease cooperation between their healthcare providers, purchasers and regulators in order to guarantee safe, high-quality and

[484] *Ivi,* art. 4.2 (a).
[485] *Ivi,* art. 4.2 (b).
[486] *Ivi,* art. 4.2 (c).
[487] *Ivi,* art. 4.3.
[488] *Ivi,* art. 4.4.
[489] *Ivi,* art. 5 (a).
[490] *Ivi,* art. 5 (b).
[491] *Ivi,* art. 5 (c).
[492] *Ivi,* art. 5 (d).
[493] *Ivi,* art. 6.1.
[494] *Ivi,* art. 6.2.
[495] *Ivi,* art. 6.3.

efficient cross-border healthcare[496]. It requires them to render the necessary mutual assistance, including cooperation on standards and guidelines on quality and safety and the exchange of information[497]. It also requires the Commission to encourage Member States, and especially neighbouring countries, to conclude agreements among themselves, and to cooperate in cross-border healthcare provision in border regions[498].

Cooperation among Member States is particularly required in the development of diagnosis and treatment capacity of rare diseases[499], and the Directive provides for the development of European reference networks between healthcare providers and centres of expertise in the Member States, especially in the area of rare diseases[500].

Moreover, the Directive determines that Member States shall guarantee that prescriptions issued for a medicinal product in another Member State for a certain patient can be dispensed on their territory, as long as such product is authorised to be marketed on their territory[501]. Restrictions on the recognition of individual prescriptions are prohibited unless they are non-discriminatory and limited to what is necessary and proportionate to safeguard human health[502], or based on legitimate and justified doubts concerning the prescription[503].

3.4.4 Reimbursement of costs of cross-border healthcare and prior authorisation

In Chapter III, Directive 2011/24 deals with reimbursement of costs of cross-border healthcare and prior authorisation.

[496] *Ivi,* Preamble (50).
[497] *Ivi,* art. 10.1.
[498] *Ivi,* art. 10.3.
[499] *Ivi,* art. 13.
[500] *Ivi,* art. 12.
[501] *Ivi,* art. 11.1.
[502] *Ivi,* art. 11.1 (a).
[503] *Ivi,* art. 11.1 (b).

Reimbursement of costs

Article 7 establishes that the Member State of affiliation shall guarantee that the costs incurred by an insured person who receives cross-border healthcare are reimbursed, as long as the healthcare received is among the benefits to which the insured person is entitled in the Member State of affiliation[504].

The Directive covers also the reimbursement for the prescription, dispensation and provision of medicinal products and medical devices provided in the context of a health service[505].

The Member State of affiliation shall reimburse or pay directly the costs of cross-border healthcare up to the level of costs that it would have assumed if that healthcare had been provided in its territory[506].

The Member State of affiliation can impose on an insured person requesting reimbursement the conditions, criteria of eligibility and regulatory and administrative formalities as it would impose if the healthcare was provided in its territory[507]. However, the Member State of affiliation can only limit the reimbursement of cross-border healthcare for overriding reasons of general interest[508], and it cannot make the reimbursement of costs of cross-border healthcare subject to prior authorisation, except in the cases explicitly set out in Article 8 of the Directive[509].

Prior authorisation

In Directive 2011/24, it is explicitly acknowledged that making the reimbursement of costs of cross-border healthcare provided in another Member State subject to prior authorisation is a restriction to the free movement of services[510]. However, it is also acknowledged that making

[504] *Ivi,* art. 7.1.
[505] *Ivi,* Preamble (16).
[506] *Ivi,* art. 7.4.
[507] *Ivi,* art. 7.7.
[508] *Ivi,* art. 7.9.
[509] *Ivi,* art. 7.8.
[510] *Ivi,* Preamble (38).

the reimbursement of costs of hospital care provided in another Member State subject to prior authorisation might be necessary and reasonable in order to ensure that there is sufficient and permanent access to a balanced array of high-quality hospital treatment, to control costs and to prevent wastage of resources[511].

Article 8 concedes that the Member State of affiliation can provide for a system of prior authorisation for reimbursement of costs of cross-border healthcare[512], but it specifies that such system shall be limited to what is necessary and proportionate to the objective to be achieved[513]. Article 8 determines that healthcare can be subject to prior authorisation only in three circumstances: (1) when it is subject to planning requirements in order to ensure sufficient and permanent access to a balanced array of high-quality treatments or to the wish to control costs and avoid waste of financial, technical and human resources, and it involves either overnight hospital accommodation of the patient or the use of highly specialised and cost-intensive medical infrastructure or equipment[514]; (2) when it involves treatments that may constitute a risk for the patient or the population[515]; and (3) when it is provided by a healthcare provider that might generate serious and specific concerns about the quality or safety of the care[516].

Article 8 further regulates that when the patient is entitled to the healthcare in question and when this healthcare cannot be provided on its territory within a medically justifiable time limit, the Member State of affiliation cannot refuse to grant prior authorisation[517]. It can refuse to grant it only in four cases: (1) if the patient would be exposed to an unacceptable risk[518]; (2) if the general public would be exposed to a considerable safety hazard[519]; (3) if the healthcare provider that would provide the healthcare in question raises serious and specific concerns

[511] *Ivi,* Preamble (40).
[512] *Ivi,* art. 8.1.
[513] *Ibidem.*
[514] *Ivi,* art. 8.a (a).
[515] *Ivi,* art. 8.1 (b).
[516] *Ivi,* art. 8.1 (c).
[517] *Ivi,* art. 8.5.
[518] *Ivi,* art. 8.6 (a).
[519] *Ivi,* art. 8.6 (b).

about the respect of standards and guidelines on quality of care and patient safety[520]; or (4) if the healthcare in question can be provided on its territory within a medically justifiable time limit[521].

3.4.5 Patient mobility under Directive 2011/24/EU

In 2018 the total amount of patient mobility in the European Union under Directive 2011/24 was 278,844, with a total spending on all reimbursement of approximately 73.2M€. In the previous year, the total amount of patient mobility was 205,417 with a total spending of approximately 49.9M€. Around 70% of all the patient mobility cases is between neighbouring countries[522].

The Directive provides for patient mobility both with and without prior authorisation. Of the 278,844 cases of patient mobility, 7,279 were with prior authorisation, while 271,565 were without it[523].

Concerning the 7,279 requests for patient mobility with prior authorisation, the majority of Member States reported less than 100 such requests. The total spending was 16,806,793€, with almost all the Member States having a total spend on healthcare with prior authorisation under 300,000€, but e.g. Ireland having a total spend of 11,622,453€[524].

The 271,565 cases of patient mobility without prior authorisation refer to those situations in which citizens travel to another Member State to receive healthcare without prior authorisation and then seek reimbursement upon their return. Of the 271,565 requests for reimbursement,

[520] *Ivi,* art. 8.6 (c).
[521] *Ivi,* art. 8.6 (d).
[522] Wilson, P., Andoulsi, I., and Wilson, C., *Member State Data on cross-border patient healthcare following Directive2011/24/EU. Year 2018*, *op. cit*.
[523] *Ibidem.*
[524] *Ibidem.*

84% of them were accepted. The total spend was roughly 56M€, ranging from 13M€ in France to 6,740€ in Spain[525].

3.5 The relation between Regulation 883/2004/EC and Directive 2011/24/EU

Before the adoption of Directive 2011/24 on the application of patients' rights in cross-border health care, cross-border healthcare was regulated by Regulation (EC) No 883/2004 on the coordination of social security systems and by the rulings of the European Court of Justice.
When Directive 2011/24 came into force and codified the European Court of Justice's rulings, Regulation (EC) No 883/2004 remained in place, leading to a dual system of cross-border healthcare.
Moreover, patients have the freedom to choose whichever system they want to use, whether they want to access cross-border healthcare under Regulation (EC) 883/2004 or Directive 2011/24/EU. When a patient decides to access cross-border healthcare under the Directive, he leaves the framework of social security coordination and enters the framework of internal market, thus moving from being a socially insured person to an economic subject[526].

3.5.1 The relation under the Directive

In the Preamble of Directive 2011/24, it is affirmed that the Directive should not affect an insured person's rights in respect of the assumption of the costs of cross-border healthcare under

[525] *Ibidem.*
[526] Strban, G., *Patient mobility in the European Union: between social security coordination and free movement of services*, ERA Forum (Vol. 14, No. 3, pp. 391-407), Springer Berlin Heidelberg, 2013.

Regulation (EC) No 883/2004, nor his right to be granted an authorisation for treatment in another Member State under Regulation (EC) No 883/2004[527].

It is also declared that the two systems should be coherent, meaning that either Directive 2011/24 applies or Regulation (EC) No 883/2004 applies[528]. This is further specified in Article 2 of the Directive, where it is affirmed that the Directive shall apply without prejudice to Regulation (EC) No 883/2004[529].

Directive 2011/24 also explicitly states that one of its aims is exactly to clarify its relationship with Regulation (EC) No 883/2004[530].

Concerning reimbursement of costs of cross-border healthcare, Directive 2011/24 establishes that the Member State of affiliation shall guarantee that such costs are reimbursed, without prejudice to Regulation (EC) No 883/2004[531].

With regard to requests for prior authorisation, it regulates that the Member State of affiliation shall ascertain whether the conditions laid down in Regulation (EC) No 883/2004 have been met, and that where such conditions are met, the prior authorisation shall be granted pursuant to the Regulation, unless the patient requests otherwise[532].

3.5.2 The main differences between Regulation 883/2004/EC and Directive 2011/24/EU

Regulation (EC) No 883/2004 and Directive 2011/24/EU differ mainly with regard to reimbursement of costs, prior authorisation, treatment that can be obtained abroad, and healthcare providers[533].

[527] EP and Council of the EU, *Directive 2011/24/EU,* Preamble (28).
[528] *Ivi,* Preamble (30).
[529] *Ivi,* art. 2 (m).
[530] *Ivi,* art. 1.1.
[531] *Ivi,* art. 7.1.
[532] *Ivi,* art. 8.3.
[533] Ministero della Salute, *FAQ - Scope of the Directive and the Regulation*, *op. cit.*

Reimbursement of costs

Concerning reimbursement of costs, Regulation (EC) No 883/2004 and Directive 2011/24/EU differ in that the first is mainly based on direct healthcare, while the latter is mainly based on indirect healthcare[534].

The fact that Regulation (EC) No 883/2004 is mainly based on direct healthcare means that the health service provided is paid directly by the competent health system, except for co-payments. The health service is provided under the same conditions as for persons insured in the country of treatment by public or affiliated private health facilities or professionals[535].

Conversely, the fact that Directive 2011/24/EU is mainly based on indirect healthcare means that the patient pays upfront for the treatment abroad, and subsequently claims reimbursement from his national health system. Such reimbursement is usually equal to the cost of that same treatment in the patient's country, however without exceeding the actual costs of the treatment received[536].

Prior authorisation

With regard to prior authorisation for schedule treatments, both Regulation (EC) 883/2004 and Directive 2011/24/EU acknowledge its possibility, but while under the Regulation prior authorisation is the rule, under the Directive it is the exception[537].

Indeed, under Article 20 of the Regulation, an insured person or a member of his family willing to travel to another Member State with the purpose of receiving treatment, shall always first seek authorisation to receive such treatment from his competent institution[538].

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[534] *Ibidem.*
[535] *Ibidem.*
[536] *Ibidem.*
[537] Strban, G., *Patient mobility in the European Union: between social security coordination and free movement of services*, *op. cit*.
[538] EP and Council of the EU, *Regulation (EC) No* 883*/2004,* art. 20.

On the contrary, Directive 2011/24 considers making the reimbursement of costs of cross-border healthcare subject to prior authorisation as a restriction to the free movement of services[539], and it allows Member States to make reimbursement of costs of cross-border healthcare subject to prior authorisation only in a very limited number of specific cases[540].

Treatment that can be obtained abroad

Regulation (EC) No 883/2004 and Directive 2011/24/EU also differ in regard to the types of treatment that can be obtained in another Member State[541].

Indeed, under Regulation (EC) No 883/2004 an insured person can obtain, in one of the European Union Member States, necessary and urgent treatment during temporary stays, as well as treatment appropriate to his condition, as long as he has received prior authorisation by his competent institution and as long as such treatment is among the benefits provided for by the legislation in the Member State where the person resides and it cannot be provided within a medically justifiable time limit[542].

Differently, under Directive 2011/24/EU an insured person can obtain, in one of the European Union Member States, any treatment provided by his health system, with the exception of long-term services, allocation of and access to organs for the purpose of organ transplants and public vaccination programmes[543].

Healthcare providers

Finally, Regulation (EC) No 883/2004 and Directive 2011/24/EU also differ with regard to healthcare providers[544].

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[539] EP and Council of the EU, *Directive 2011/24/EU,* Preamble (38).
[540] *Ivi,* art. 8.1.
[541] Ministero della Salute, *FAQ - Scope of the Directive and the Regulation*, *op. cit.*
[542] *Ibidem.*
[543] *Ibidem.*
[544] *Ibidem.*

Indeed, while under Regulation (EC) No 883/2004 the health services for which costs are covered are only those delivered by public or private health facilities or professionals affiliated with the health system of the country of treatment, under Directive 2011/24/EU the health services for which reimbursement of costs is available are those provided by public and private healthcare providers, even if not affiliated with the health system of the country of treatment[545].

Conclusion

Although the definition of national health policy and the organisation and delivery of health services and medical care are a responsibility of each Member State, the European Union still has its own role in the field of health and healthcare, even if it is mainly to complement and coordinate Member States' policies and actions.

Moreover, most health legislation in the European Union is made under other guises, even though there are some exceptions, such as cross-border healthcare.

However, with regard to cross-border healthcare, the existence of Regulation (EC) No 883/2004 and Directive (EU) 2011/24 as two distinct mechanisms has led to the creation of a dual system, which puts patient mobility in the European Union between social security coordination on one hand, and the economic freedoms of free movement of goods and services on the other.

[545] *Ibidem.*

Chapter 4 – Serious cross-border threats to health and the COVID-19 pandemic in the European Union

Introduction

Another health-related area in which the European Union has adopted health legislation is serious cross-border health threats[546].

More precisely, under Article 168 of the Treaty on the Functioning of the European Union the European Union is required to take action in the monitoring, early warning of and combating serious cross-border threats to health[547].

The logical justification for European Union's action with regard to serious cross-border threats to health is that an increasingly integrated European Union means population movements and supply chains, which make it easier for infectious diseases to trespass national borders[548].

An example of the application of these provisions can be found in the COVID-19 pandemic.

4.1 COVID-19: timeline and numbers

COVID-19 is an infectious disease caused by the Severe Acute Respiratory Syndrome

[546] EC, *EU Healthy Policy – Overview, op. cit.*

[547] EU, *TFEU*, art. 168.1.

[548] Greer, S. L., Fahy, N., Rozenblum, S., Jarman, H., Palm, W., Elliott, H. A., and Wismar, M., *Everything you always wanted to know about European Union health policies but were afraid to ask: Second, op. cit.*

Coronavirus-2 (SARS-CoV-2)[549].

It was first identified in the Chinese municipality of Wuhan in December 2019[550], and has since then spread to other regions of China and the world[551], affecting many countries globally[552]. It has been officially declared a global pandemic by the World Health Organization on 11 March 2020[553], and as of 23 September 2020, 31 658 573 cases and 971 869 deaths of COVID-19 have been reported worldwide[554].

4.1.1 Timeline

On 31 December 2019, some pneumonia cases of unknown aetiology were reported in the Chinese municipality of Wuhan[555]. The virus was subsequently identified as a novel coronavirus (SARS-CoV-2), and made its first victim on 9 January 2020[556].

On the same day, the European Commission's Directorate-General for Health and Food Safety opened an alert notification on the Early Warning and Response System[557].

[549] European Centre for Disease Prevention and Control (ECDC), *Q & A on COVID-19: Basic facts*, available at https://www.ecdc.europa.eu/en/all-topics-z/coronavirus/threats-and-outbreaks/covid-19/facts/q-covid-19/q-covid-19-basic-facts.

[550] European Council and Council of the European Union, *Timeline - Council actions on COVID-19*, available at https://www.consilium.europa.eu/en/policies/coronavirus/timeline/.

[551] *Ibidem.*

[552] World Health Organization (WHO), *Q&A on coronaviruses (COVID-19)*, available at https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/q-a-detail/q-a-coronaviruses.

[553] World Health Organization (WHO), *WHO Director-General's opening remarks at the media briefing on COVID-19 - 11 March 2020*, available at https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020.

[554] European Centre for Disease Prevention and Control (ECDC), *COVID-19 situation update worldwide, as of 23 September 2020*, available at https://www.ecdc.europa.eu/en/geographical-distribution-2019-ncov-cases.

[555] European Centre for Disease Prevention and Control (ECDC), *Event background COVID-19*, available at https://www.ecdc.europa.eu/en/novel-coronavirus/event-background-2019.

[556] CNN, *Coronavirus Outbreak Timeline Fast Facts*, in CNN health, 24 August 2020, available at https://edition.cnn.com/2020/02/06/health/wuhan-coronavirus-timeline-fast-facts/index.html.

[557] European Commission (EC), *Timeline of EU action*, in Coronavirus response, available at https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/timeline-eu-action_en.

As of 20 January 2020, there were 282 cases worldwide, 278 of which in China, and the other 4 in Thailand (2), Japan (1) and the Republic of Korea (1)[558].

On the following day, the first case on US soil was reported[559], and on 24 January also the European Union reported its first COVID-19 case in France[560].

On 28 January the European Union Civil Protection Mechanism was activated[561], and on 13 February, the Council of the European Union adopted conclusions on COVID-19, calling for more cooperation at European Union level[562].

On 28 February, the European Union and the Member States launched together a joint procurement of personal protective equipment[563], and on 2 March**,** the European Commission set up a coronavirus response team to coordinate the European response to the pandemic[564].

On 9 March 2020 Italy became the first European Union Member State to be put under a national lockdown[565], and on the following day the European Council held a video conference on how to coordinate European Union efforts to respond to the COVID-19 outbreak, emphasising the need to work together and for a joint European approach[566].

[558] World Health Organization (WHO), *Novel Coronavirus (2019-nCoV), Situation Report - 1,* World Health, 251, 21 January 2020.
[559] CNN, *Coronavirus Outbreak Timeline Fast Facts*, *op. cit.*
[560] EC, *Timeline of EU action*, *op. cit.*
[561] *Ibidem.*
[562] Council of the European Union (Council of the EU), *Council Conclusions on COVID-19 (13 February 2020),* 6038/20, Brussels, 2020.
[563] EC, *Timeline of EU action*, *op. cit.*
[564] *Ibidem.*
[565] CNN, *Coronavirus Outbreak Timeline Fast Facts*, *op. cit.*
[566] European Council, *Conclusions by the President of the European Council following the video conference on COVID-19*, in Press releases, 10 March 2020, available at https://www.consilium.europa.eu/en/press/press-releases/2020/03/10/statement-by-the-president-of-the-european-council-following-the-video-conference-on-covid-19/.

On 11 March 2020, with more than 118 000 cases reported in 114 countries, and 4291 deaths recorded, the World Health Organization declared the outbreak a pandemic[567]. On the same day, the United States suspended all travel from Europe to the United States for 30 days[568].

By mid-March 2020, Europe had become the epicentre of the COVID-19 pandemic, reporting over 40% of globally confirmed cases[569].

On 16 March the European Commission presented guidelines to Member States for border management measures[570] and recommended a temporary restriction on non-essential travel from third countries to the European Union for 30 days [571].

On 19 March the European Commission created a strategic RescEU stockpile of medical equipment and adopted a Temporary Framework for State aid measures to support the economy[572].

Between 23 March and 3 April, the European Commission presented advice and issued guidance to ensure the flow of goods and the movement of workers across the European Union and to support cross-border healthcare cooperation between Member States[573].

[567] World Health Organization (WHO) Regional Office for Europe, *Coronavirus disease (COVID-19) pandemic*, available at https://www.euro.who.int/en/health-topics/health-emergencies/coronavirus-covid-19/novel-coronavirus-2019-ncov.

[568] CNN, *READ: Trump's Oval Office speech on the coronavirus outbreak*, in CNN politics, 12 March 2020, available at https://edition.cnn.com/2020/03/11/politics/read-trump-coronavirus-address/index.html.

[569] WHO Regional Office for Europe, *Coronavirus disease (COVID-19) pandemic*, *op. cit.*

[570] European Commission (EC), *Guidelines for border management measures to protect health and ensure the availability of goods and essential services,* C(2020) 1753 final, Brussels, 16 March 2020.

[571] European Commission (EC), *Communication from the Commission to the European Parliament, the European Council and the Council. COVID-19: Temporary restriction on non-essential travel to the EU*, COM(2020) 115 final, Brussels, 16 March 2020.

[572] EC, *Timeline of EU action*, *op. cit.*

[573] *Ibidem.*

On 8 April 2020, the European Commission invited Member States to prolong the temporary restriction on non-essential travel to the European Union until 15 May 2020[574], and on 8 May 2020, it invited Member States to further prolong them again until 15 June 2020[575].

On 15 April 2020 the European Commission put forward a Joint European Roadmap towards lifting COVID-19 containment measures[576], and on 13 May, it presented guidelines and recommendations[577] to help Member States gradually lift travel restrictions[578], restore freedom of movement and lift internal border controls[579].

On 19 May, a solidarity instrument to help workers keep their incomes and help businesses stay afloat, called SURE, was set up[580].

On 11 June 2020, the European Commission encouraged Member States to finalise the lifting the internal border controls and restrictions to free movement within the European Union[581]. It also recommended to further extend the temporary restriction on non-essential travel to the European Union until 30 June 2020[582], day on which the Council of the European Union

[574] European Commission (EC), *Communication from the Commission to the European Parliament, the European Council and the Council on the assessment of the application of the temporary restriction on non-essential travel to the EU,* COM(2020) 148 final, Brussels, 8 April 2020.

[575] European Commission (EC), *Communication from the Commission to the European Parliament, the European Council and the Council on the second assessment of the application of the temporary restriction on non-essential travel to the EU,* COM(2020) 222 final, Brussels, 8 May 2020.

[576] European Commission (EC), *Joint European Roadmap towards lifting COVID-19 containment measures*, Official Journal of the European Union, C 126/1, 2020.

[577] European Commission (EC), *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. Tourism and transport in 2020 and beyond,* COM(2020) 550 final, Brussels, 13 May 2020.

[578] European Commission (EC), *Travel during the coronavirus pandemic: Safely resuming travel*, in Coronavirus response, available at https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/travel-and-transportation-during-coronavirus-pandemic_en#safely-resuming-travel.

[579] European Commission (EC), *Communication from the Commission, COVID-19, Towards a phased and coordinated approach for restoring freedom of movement and lifting internal border controls*, C(2020) 3250 final, Brussels, 13 May 2020.

[580] EC, *Timeline of EU action*, *op. cit.*

[581] European Commission (EC), *Communication from the Commission to the European Parliament, the European Council and the Council on the third assessment of the application of the temporary restriction on non-essential travel to the EU*, COM/2020/399 final, Brussels, 11 June 2020.

[582] *Ibidem.*

recommended to gradually start lifting them as from 1 July 2020 in a coordinated manner with regard to the residents of selected third countries[583].

On 17 June 2020, the European Commission proposed a European Union strategy to accelerate the development, manufacturing, and deployment of vaccines against COVID-19[584], and on 14 July 2020, the Council adopted a regulation on the conduct of clinical trials with and supply of medicinal products containing or consisting of genetically modified organisms intended to treat or prevent COVID-19[585].

On 15 July 2020, the European Commission put forward some measures to ensure European Union health preparedness in case of potential future COVID-19 outbreaks[586], and on 17-21 July 2020, the European Council agreed on a recovery package and the 2021-2027 European budget[587].

On 14 August 2020, the European Commission reached an agreement with the pharmaceutical company AstraZeneca to purchase a potential vaccine against COVID-19[588], and on 27 August 2020, the contract the European Commission negotiated on behalf of the European Union Member States with the pharmaceutical company AstraZeneca entered into force[589].

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[583] Council of the European Union (Council of the EU), *Council Recommendation on the temporary restriction on non-essential travel into the EU and the possible lifting of such restriction*, 2020/0134 (NLE), Brussels, 30 June 2020.

[584] European Commission (EC), *Communication from the Commission to the European Parliament, the European Council, the Council and the European Investment Bank. EU Strategy for COVID-19 vaccines,* COM(2020) 245 final, Brussels, 17 June 2020.

[585] Council of the European Union, *Vaccine against COVID-19: Council adopts measures to facilitate swift development*, in Press releases, 14 July 2020, available at https://www.consilium.europa.eu/en/press/press-releases/2020/07/14/vaccine-against-covid-19-council-adopts-measures-to-facilitate-swift-development/.

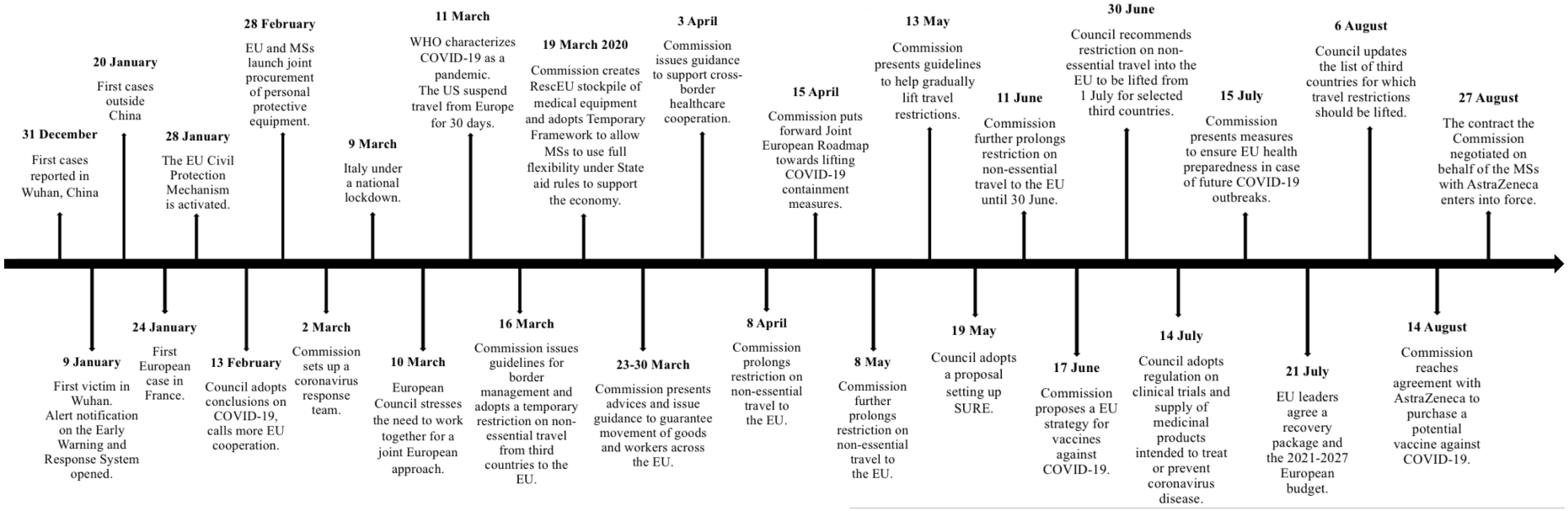
[586] European Commission (EC), *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. Short-term EU health preparedness for COVID-19 outbreaks,* COM(2020) 318 final, Brussels, 15 July 2020.

[587] European Council, *Special European Council, 17-21 July 2020*, in Meetings, available at https://www.consilium.europa.eu/en/meetings/european-council/2020/07/17-21/.

[588] European Commission (EC), *Coronavirus: Commission reaches first agreement on a potential vaccine*, in Press release, 14 August 2020, available at https://ec.europa.eu/commission/presscorner/detail/en/ip_20_1438.

[589] EC, *Timeline of EU action*, *op. cit.*

Timeline COVID-19 outbreak and developments in the European Union

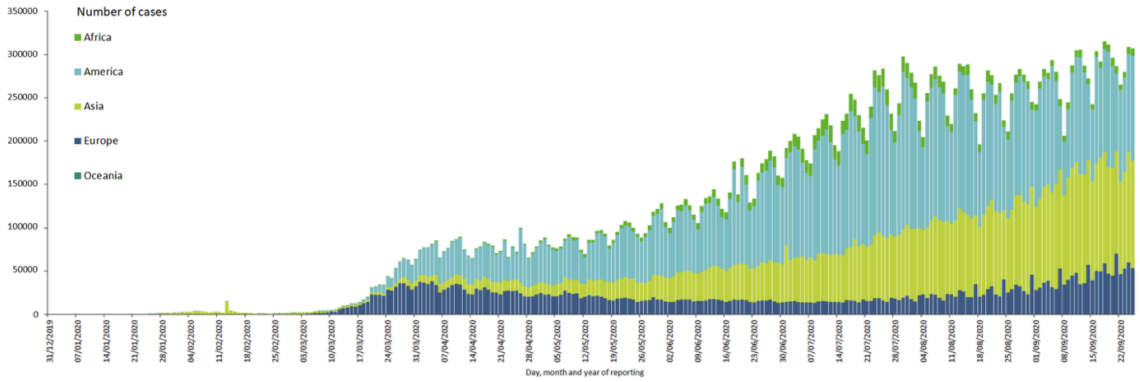


4.1.2 Numbers

Since 31 December 2019 and as of 23 September 2020, 31 658 573 cases of COVID-19 have been reported worldwide, and 971 869 deaths[590].

Of all the COVID-19 cases, 2 547 342 have been in the European Union[591].

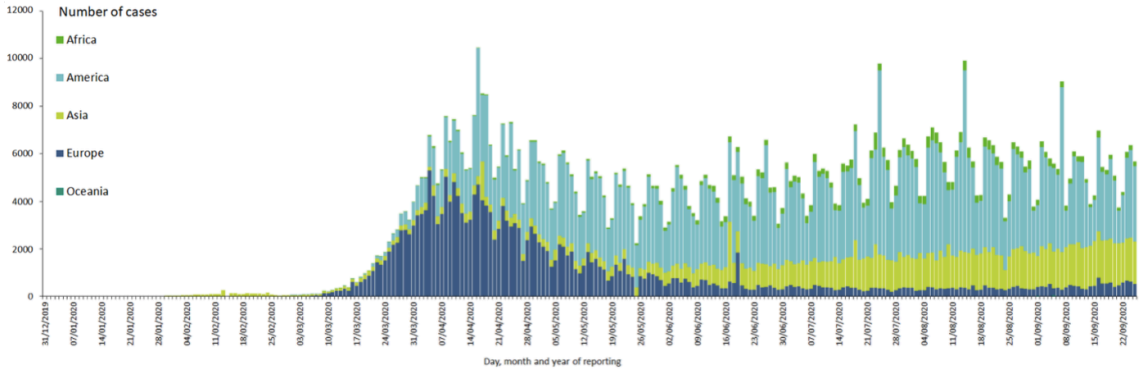
Distribution of COVID-19 cases worldwide, as of 23 September 2020



Source: ECDC, COVID-19 situation update worldwide, as of 23 September 2020

Of all the COVID-19 deaths, 144 999 have been in the European Union[592].

Distribution of COVID-19 deaths worldwide, as of 23 September 2020

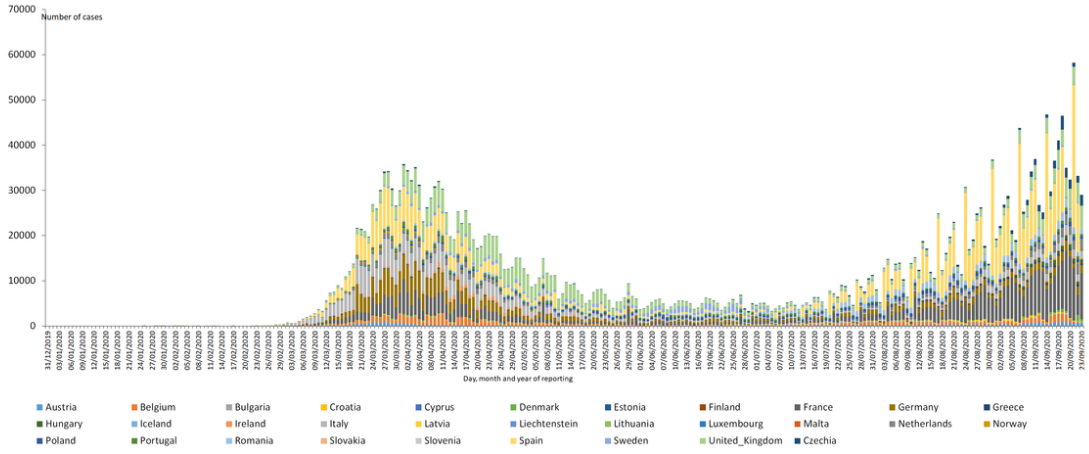


Source: ECDC, COVID-19 situation update worldwide, as of 23 September 2020

[590] ECDC, *COVID-19 situation update worldwide, as of 23 September 2020*, *op. cit*.
[591] European Centre for Disease Prevention and Control (ECDC), *COVID-19 situation update for the EU/EEA and the UK, as of 23 September 2020*, available at https://www.ecdc.europa.eu/en/cases-2019-ncov-eueea.
[592] *Ibidem*.

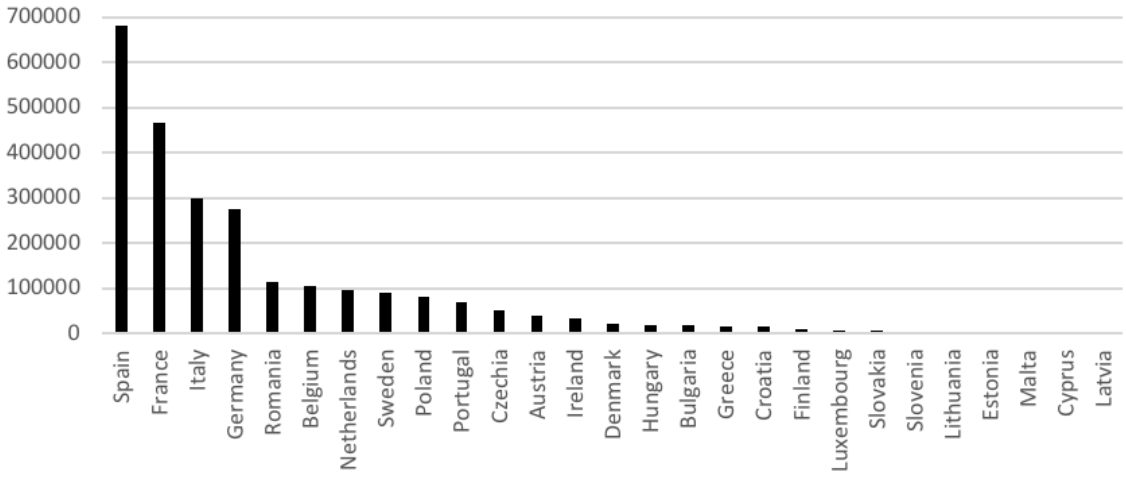
The COVID-19 cases in the European Union have been so distributed among Member States: Spain (682 267), France (468 069), Italy (300 897), Germany (275 927), Romania (114 648), Belgium (105 132), Netherlands (98 142), Sweden (89 436), Poland (80 699), Portugal (69 663), Czechia (53 158), Austria (39 897), Ireland (33 444), Denmark (23 799), Hungary (20 450), Bulgaria (19 123), Greece (15 928), Croatia (15 136), Finland (9 195), Luxembourg (8 016), Slovakia (6 931), Slovenia (4 558), Lithuania (3 859), Estonia (2 976), Malta (2 814), Cyprus (1 618), Latvia (1 560)[593].

Historical of distribution of laboratory confirmed cases of COVID-19 in the European Union



Source: ECDC, COVID-19 situation update for the EU/EEA and the UK, as of 23 September 2020

Distribution of COVID-19 case in the European Union, as of 23 September 2020

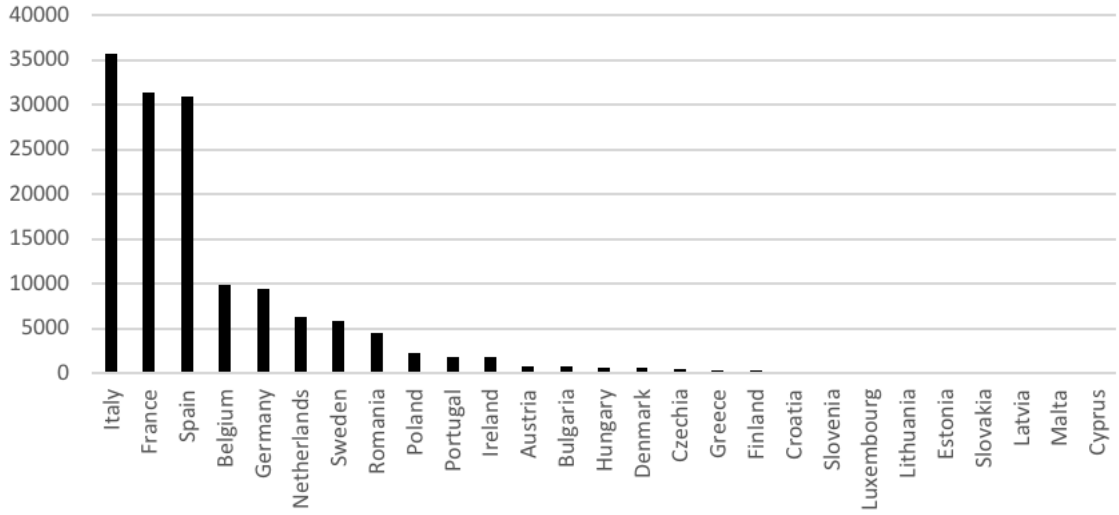


Source: ECDC, COVID-19 situation update for the EU/EEA and the UK, as of 23 September 2020

[593] *Ibidem.*

The COVID-19 deaths in the European Union have been so distributed among Member States: Italy (35 738), France (31 416), Spain (30 904), Belgium (9 955), Germany (9 409), Netherlands (6 282), Sweden (5 870), Romania (4 503), Poland (2 316), Portugal (1 925), Ireland (1 792), Austria (771), Bulgaria (767), Hungary (702), Denmark (641), Czechia (531), Greece (352), Finland (341), Croatia (255), Slovenia (133), Luxembourg (124), Lithuania (87), Estonia (64), Slovakia (40), Latvia (36), Malta (23), Cyprus (22)[594].

Distribution of COVID-19 deaths in the European Union, as of 23 September 2020



Source: ECDC, COVID-19 situation update for the EU/EEA and the UK, as of 23 September 2020

4.2 Member States responses

The crisis brought about by the diffusion of coronavirus has been dealt with in the European Union at a communitarian level as well as at the national levels.

Across the European Union, the severity and timing of the measures taken in response to the COVID-19 pandemic varied from country to country[595], and especially at the beginning and

[594] *Ibidem.*

[595] Hirsch, C., *Europe's coronavirus lockdown measures compared*, in Politico, 31 March 2020, updated on 15 April 2020, available at https://www.politico.eu/article/europes-coronavirus-lockdown-measures-compared/.

despite their pledge to an ever-closer union, European Union Member States have reacted selfishly and chaotically[596], taking gradual, sparse and inconsistent steps[597] and adopting unilateral measures[598], without a proper and effective European coordinated action.

Some European Union Member States have imposed a national lockdown, while others have limited their response to the introduction of differently sever restrictions; and some have reintroduced border controls or even decided to shut their borders[599].

However, most Member States have adopted relatively similar measures, including recommended or enforced "stay-at-home" policies, physical distancing measures, the limitation or cancellation of mass gatherings, and the closure of educational institutions and public spaces[600].

4.2.1 The restoration of border controls and border closure within the European Union

To contain the spread of COVID-19, some European Union Member States have reintroduced border controls, introduced travel bans and restrictions, and even closed their borders completely[601].

During March 2020, Austria reintroduced road and rail border controls with Italy and suspended flights to and from Italy, Spain and France; Cyprus shut its borders to all except Cypriots, Europeans working on the island and people with special permits; the Czech Republic closed its borders to all tourists and banned travels to high-risk countries; Denmark closed its borders

[596] Herszenhorn, D. and Wheaton, S., *How Europe failed the coronavirus test,* in Politico, 7 April 2020, updated on 10 April 2020, available at https://www.politico.eu/article/coronavirus-europe-failed-the-test/.
[597] Renda, A., and Castro, R., *Towards stronger EU governance of health threats after the COVID-19 pandemic,* European Journal of Risk Regulation: 1-10, 2020.
[598] Hasselbach, C., *Coronavirus and the EU: The nation versus the union?*, in Deutsche Welle, 19 March 2020, available at https://www.dw.com/en/coronavirus-and-the-eu-the-nation-versus-the-union/a-52848640.
[599] Hasselbach, C., *Coronavirus and the EU: The nation versus the union?, op. cit.*
[600] European Centre for Disease Prevention and Control (ECDC), *Q & A on COVID-19: What is the current situation in the EU regarding COVID-19?*, available at https://www.ecdc.europa.eu/en/covid-19/facts/questions-answers-eu-situation.
[601] Hasselbach, C., *Coronavirus and the EU: The nation versus the union?, op. cit.*

to all tourists but its citizens and resident foreigners[602]; Germany introduced border controls with Austria, Denmark, France and Luxembourg, allowing through only residents, cross-border commuters and delivery drivers[603]; Greece suspended flights to and from Italy; Hungary strengthened its borders, blocked entry to travelers from Italy[604] and closed its land borders with Austria and Slovenia[605]; Malta shut down its borders to travelers from Italy, Germany, France and Spain; the Netherlands banned flights with Italy; Poland closed its borders to tourists and set up health checks at borders with Germany and the Czech Republic; Slovakia shut its borders to foreigners; and Spain blocked all direct flights from Italy[606] and closed its land borders with France and Portugal, allowing only Spanish nationals, residents and cross-border workers to enter the country[607].

Under the Schengen rules, in case of a serious threat to public policy or internal security European Union Member States have the power to temporarily reintroduce border controls at their internal borders. However, the reintroduction of border controls at the internal borders must be an exception, must respect the principle of proportionality and should only be used as a measure of last resort[608].

4.2.2 Bans, closures and limitations

[602] Thiessen, T., *Coronavirus: Some Of These 24 European Countries Have Closed Their Borders To Tourists*, in Forbes, 14 March 2020, available at https://www.forbes.com/sites/tamarathiessen/2020/03/14/coronavirus-europe-closes-borders-tourists/#3a3f9d112765.

[603] Henley, J., Willsher, K., and Kassam, A., *Coronavirus: France imposes lockdown as EU calls for 30-day travel ban*, in The Guardian, 16 March 2020, available at https://www.theguardian.com/world/2020/mar/16/coronavirus-spain-takes-over-private-healthcare-amid-more-european-lockdowns.

[604] BBC News, *Coronavirus: European Union seals borders to most outsiders*, in Europe, 17 March 2020, available at https://www.bbc.com/news/world-europe-51927790.

[605] BBC News, *Coronavirus: Europe now epicentre of the pandemic, says WHO*, in Europe, 13 March 2020, available at https://www.bbc.com/news/world-europe-51876784.

[606] Thiessen, T., *Coronavirus: Some Of These 24 European Countries Have Closed Their Borders To Tourists*, *op. cit*.

[607] BBC News, *Coronavirus: European Union seals borders to most outsiders*, *op. cit*.

[608] European Commission (EC), *Temporary Reintroduction of Border Control*, in Migration and Home Affairs, available at https://ec.europa.eu/home-affairs/what-we-do/policies/borders-and-visas/schengen/reintroduction-border-control_en.

Gatherings and events

A measure largely implemented across the European Union to halt the spreading of COVID-19 has been the banning of events. This measure has been implemented in several Member States, including Austria, Belgium, Croatia, Cyprus, Czech Republic, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia and Spain[609].

Another measure adopted by several European Union Member States has been the limitation or banning of gatherings. Some countries like Italy imposed a total ban on all gatherings, while others allowed some forms of gathering but imposed a limit on the number of people. Such limit ranged from 2 people in Finland, Latvia, Lithuania and Luxemburg, 4 in Ireland and Malta, and 5 in Austria, to 10 people in Denmark and Estonia, and 50 people in Sweden[610].

Schools

A measure implemented in all the European Union Member States has been the total or partial closure of schools.

Schools started being shut down across European Union countries at the beginning of March, when Italy imposed the nationwide closure of schools on 5 March[611]. The other Member State followed, implementing school closures at different times, e.g. Greece on 10 March, the Czech Republic on 11 March, Spain, Belgium, Germany and Austria on 15 March, France, Poland, Portugal and Hungary on 16 March[612].

Moreover, some Member State implemented nationwide school closures, while others only partial/regional ones[613].

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[609] Hirsch, C., *Europe's coronavirus lockdown measures compared*, *op. cit*.
[610] *Ibidem.*
[611] *Ibidem.*
[612] *Ibidem.*
[613] Guardian Staff, *How do coronavirus containment measures vary across Europe?*, in The Guardian,16 March 2020, available at https://www.theguardian.com/world/2020/mar/12/how-do-coronavirus-containment-measures-vary-across-europe.

By 12 March, of the 16 European Union Member State that had implemented school closures, the Czech Republic, Denmark, Greece, Ireland, Italy, Lithuania, Malta, Poland, Romania and Slovenia had opted for a full nationwide closure, while Austria, Croatia, France, Portugal, Slovakia and Spain had deployed partial/regional closures[614].

Even though with different timings, by 17 March, all the European Union Member State had implemented a full nationwide closure of schools, with the only exception of Sweden, which had only deployed a partial closure[615]. Concerning school closure, Sweden has indeed been a unique case in the European Union, as it has been the only country to never shut down schools. The country has kept its schools for under-16s open throughout the whole COVID-19 outbreak, only recommending schools for over-16s and universities to close and switch to distance learning[616].

Museums, bars, restaurants and non-essential shops

Even if with different timings and some differences, most European Union Member States also decided to shut down museums, bars, restaurants and non-essential shops, only leaving allowing shops like supermarkets and pharmacies to stay open.

For example, in Austria, all non-essential shops, museums, theatres, concert halls and bars were closed, while restaurants and food retailers were initially allowed to stay open[617]. The Czech Republic closed all gyms, swimming pools, clubs and libraries, limited restaurant opening hours and only left open food stores, pharmacies and petrol stations[618]. Denmark shut down its cultural institutions, libraries and leisure facilities, allowing restaurants and shops to stay

[614] *Ibidem.*
[615] *Ibidem.*
[616] The Local, *How Sweden's schools are adapting to the coronavirus outbreak*, 11 March 2020, available at https://www.thelocal.se/20200511/how-swedens-schools-have-adapted-to-the-coronavirus.
[617] Thiessen, T., *Coronavirus: Some Of These 24 European Countries Have Closed Their Borders To Tourists*, *op. cit*.
[618] *Ibidem.*

open[619]. France shut down cafes, restaurants and all businesses except the essential ones, such as grocery stores, banks, gas stations[620] and pharmacies; the country also saw its entertainment facilities such as ski resorts[621], cinemas and theatres, along with its museums and cultural institutions, including the Louvre, the Palace of Versailles and the Eiffel Tower, closing their doors[622]. Germany shut down almost all shops except food stores, banks, pharmacies and petrol stations, and ordered the closure of hotels[623], clubs, bars, leisure facilities, zoos and playgrounds[624]. Greece ordered the closure of bars, cafes, shopping malls, theatres, cinemas, playgrounds and gyms, as well as museums and archaeological sites[625]. Italy shut down all shops, except for essential ones such as supermarkets, pharmacies, banks and post offices[626]. In the Netherlands, all non-essential shops, bars and restaurants were shut[627], along with many cultural venues and museums, including the Rijksmuseum national gallery and the Van Gogh museum[628]. Portugal closed all nightclubs and left open all shops, shopping malls and restaurants but with strict limits on the numbers of people allowed to enter[629]. Slovakia ordered the closure of all leisure facilities, ski resorts, wellness centres, bars and clubs, while it left open hotels, restaurants, shops and shopping malls, but the only stores allowed to stay open on

[619] *Ibidem.*
[620] Nossiter, A., Minder, R. and Peltier, E., *Shutdowns Spread Across Europe as Spain and France Order Broad Restrictions*, in The New York Times, 14 March 2020, available at https://www.nytimes.com/2020/03/14/world/europe/france-coronavirus.html?action=click&module=RelatedLinks&pgtype=Article.
[621] Sky News, *Coronavirus: Spain going into lockdown as France closes all 'non-essential' shops,* 15 March 2020, available at https://news.sky.com/story/coronavirus-jet2-cancels-all-flights-to-spain-including-ibiza-and-tenerife-11957450?dcmp=snt-sf-twitter.
[622] Thiessen, T., *Coronavirus: Some Of These 24 European Countries Have Closed Their Borders To Tourists*, *op. cit*.
[623] Henley, J., Willsher, K., and Kassam, A., *Coronavirus: France imposes lockdown as EU calls for 30-day travel ban*, *op. cit*.
[624] BBC News, *Coronavirus: European Union seals borders to most outsiders*, *op. cit*.
[625] Thiessen, T., *Coronavirus: Some Of These 24 European Countries Have Closed Their Borders To Tourists*, *op. cit*.
[626] *Ibidem.*
[627] Henley, J., Willsher, K., and Kassam, A., *Coronavirus: France imposes lockdown as EU calls for 30-day travel ban*, *op. cit*.
[628] Thiessen, T., *Coronavirus: Some Of These 24 European Countries Have Closed Their Borders To Tourists*, *op. cit*.
[629] *Ibidem.*

weekends were food stores and pharmacies[630]. Spain only allowed stores providing basic services, like supermarkets and gas stations, to stay open[631], and ordered hotels[632], restaurants, bars, cafes, cinemas and gyms to close[633]. Sweden allowed all pubs and restaurants to remain open[634], and allowed nightclubs to open until the end of March[635].

4.2.3 From the Italian, Spanish and French lockdowns to the Swedish approach

In response to the COVID-19 pandemic, European Member States have responded in very different ways, ranging from total lockdowns to very bland restrictions.

Lockdowns

Some European Member States, notably Italy, Spain and France, have responded to the COVID-19 pandemic with the imposition of a national lockdown.

The first European Union Member State to impose a national lockdown was Italy on 9 March[636]. The first measure taken by the Italian government was the imposition of public health measures such as social distancing throughout the national territory, and travel, events, shops and gathering restrictions on the Lombardy region and 14 other northern provinces on 8 March. On the following day, the restrictions were extended to the entire national territory[637]: people were

[630] *Ibidem.*
[631] Nossiter, A., Minder, R. and Peltier, E., *Shutdowns Spread Across Europe as Spain and France Order Broad Restrictions*, *op. cit.*
[632] Sky News, *Coronavirus: Spain going into lockdown as France closes all 'non-essential' shops, op. cit*.
[633] Thiessen, T., *Coronavirus: Some Of These 24 European Countries Have Closed Their Borders To Tourists*, *op. cit*.
[634] BBC News, *Coronavirus: The unusual ways countries are managing lockdowns*, 1 April 2020, available at https://www.bbc.com/news/world-52109792.
[635] Savage, M., *Lockdown, what lockdown? Sweden's unusual response to coronavirus*, in BBC News, 29 March 2020, available at https://www.bbc.com/news/world-europe-52076293.
[636] Tondo, L., *Coronavirus Italy: PM extends lockdown to entire country*, in The Guardian, 10 March 2020, available at https://www.theguardian.com/world/2020/mar/09/coronavirus-italy-prime-minister-country-lockdown?utm_term=Autofeed&CMP=twt_gu&utm_medium&utm_source=Twitter#Echobox=1583793579.
[637] *Ibidem.*

asked to avoid all unnecessary travel and to stay as home, except for essential reasons regarding work and health and to buy provisions; gatherings in public places were banned, bars and restaurants were required to close by 6pm and sporting events were not allowed; schools, universities, theatres, cinemas and museums had already been closed[638]. On 11 March, the Italian government ramped up the severity of the national lockdown, ordering the closure of all restaurants, bars and all commercial activities except for supermarkets and pharmacies[639], and on 20 March, the lockdown was tightened even more with a closure of parks and playgrounds and a ban on any outdoor activity, including running or walking far from the place of residence[640]. On 21 March, the Italian government established the closure of all the nonessential productive activities, only ensuring the functioning of all essential services such as public transport and the openness of supermarkets, groceries, pharmacies, banks, post offices and insurance offices[641]. People were only permitted to leave the house for work or health reasons, going grocery shopping, solitary exercise close to home or walking the dog, and when going out, they were required to bring with them a certificate declaring their reason for leaving the house[642]. Those who violated the lockdown could face fines between €400 to €3,000 or up to three months in jail[643].

[638] Redazione ANSA, *Factbox: Italy's lockdown measures,* in ANSA English, 10 March 2020, available at https://www.ansa.it/english/newswire/english_service/2020/03/10/factbox-italys-lockdown-measures_1f46e4d0-84ca-4368-b91b-506cf6585d46.html.

[639] Harlan, C. and Morris, L., *Italy ramps up coronavirus lockdown, Merkel warns virus could infect two-thirds of Germany*, in The Washington Post, 11 March 2020, available at https://www.washingtonpost.com/world/europe/merkel-coronavirus-germany/2020/03/11/e276252a-6399-11ea-8a8e-5c5336b32760_story.html.

[640] Horowitz, J., Bubola, E. and Povoledo, E., *Italy, Pandemic's New Epicenter, Has Lessons for the World,* in The New York Times, 21 March 2020, available at https://www.nytimes.com/2020/03/21/world/europe/italy-coronavirus-center-lessons.html.

[641] Leali, G., *Italy closes all nonessential factories to halt spread of coronavirus,* in Politico, 22 March 2020, available at https://www.politico.eu/article/italy-closes-all-nonessential-factories-to-halt-spread-of-coronavirus-giuseppe-conte/.

[642] Deutsche Welle, *Coronavirus: What are the lockdown measures across Europe?*, 14 April 2020, available at https://www.dw.com/en/coronavirus-what-are-the-lockdown-measures-across-europe/a-52905137.

[643] *Ibidem.*

After Italy, also Spain imposed a national lockdown on 14 March[644]. On 13 March, the Spanish government declared that it was implementing a state of alarm[645], and from the following day the country was put under a national lockdown for a period of 15 days[646]. People were only allowed to circulate to purchase provisions, pharmaceuticals and essential items, attend health facilities, go to work or provide employment services, and assist and care for seniors, minors, dependants, the disabled, or vulnerable people; all the stores that carried out public-facing activity were closed, with the exception of those distributing provisions and essential items; cafés and restaurants were only allowed to deliver; cinemas, theatres and museums were shut; all sporting events and local fiestas and marches were suspended; civil and religious ceremonies were allowed only if a distance of one meter between people was maintained[647]. On 28 March, the Spanish government tightened up the national lockdown and ordered all non-essential workers to remain at home for the following two weeks[648].

After Italy and Spain, also France imposed a national lockdown on 17 March[649]. Initially, the French government only imposed the closure of museums, cultural institutions, public theatres, libraries and concert halls on 13 March[650], followed on 14 March by restaurants, cafes, cinemas and nightclubs as well as non-essential businesses, only allowing food shops, chemists, banks,

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[644] Nossiter, A., Minder, R. and Peltier, E., *Shutdowns Spread Across Europe as Spain and France Order Broad Restrictions*, *op. cit.*

[645] CuÉ, C. E., PÉrez, C., De Blas, E. G., *Spanish government declares state of alarm*, in EL PAÍS English edition, 13 March 2020, available at https://english.elpais.com/politics/2020-03-13/spanish-government-declares-state-of-alarm-in-bid-to-combat-coronavirus-spread.html.

[646] Zafra, M., Galocha, A. and Alonso, A., *Spain's state of alarm: the key measures that are now in place*, in EL PAÍS English edition, 15 March 2020, available at https://english.elpais.com/society/2020-03-15/spains-state-of-alarm-the-key-measures-that-are-now-in-place.html.

[647] *Ibidem.*

[648] Jones, S., *Spain orders non-essential workers stay home for two weeks*, in The Guardian, 28 March 2020, available at https://www.theguardian.com/world/2020/mar/28/covid-19-may-be-peaking-in-parts-of-spain-says-official.

[649] *Ibidem.*

[650] FRANCE 24, *Louvre, Versailles and Eiffel Tower close over coronavirus crisis,* 13 March 2020, available at https://www.france24.com/en/20200313-france-s-louvre-museum-and-versailles-palace-to-shut-over-coronavirus-crisis.

tobacco shops and petrol stations to remain open[651]. On 16 March, the French government announced a 15-day lockdown beginning on the following day[652]: people were only allowed to go out to go to supermarkets, pharmacies and places of work[653], to practice outdoor physical activities alone for 1 hour once a day and walk the dog[654]. When going out people were required to fill out a form stating their reason for leaving the house, and those breaching lockdown rules could face fines between €135 to €3,700 as well as up to six months in prison for multiple violations[655].

Restrictions without a national lockdown

Other countries have implemented strict restrictions, but without imposing a national lockdown. These countries have usually banned or limited events, imposed a limit on the number of people allowed to gather, shut down or limited the functioning and opening hours of bars, restaurants and non-essential stores.

This approach to the containment of COVID-19 has been adopted in countries such as Denmark, Germany, Luxemburg and Malta.

In Denmark, people were never banned from going out[656], even if they were urged to stay at home and limit use of public transport[657]. Gathering and events with less than 10 people were

[651] BBC News, *Coronavirus: Spain and France announce sweeping restrictions*, 15 March 2020, available at https://www.bbc.com/news/world-europe-51892477.

[652] Cuthbertson, A., *Coronavirus: France imposes 15-day lockdown and mobilises 100,000 police to enforce restrictions,* in Independent, 16 March 2020, available at https://www.independent.co.uk/news/world/europe/coronavirus-france-lockdown-cases-update-covid-19-macron-a9405136.html.

[653] *Ibidem.*

[654] Jones, S., *Spain orders non-essential workers stay home for two weeks*, *op. cit*.

[655] *Ibidem.*

[656] Baker, S., *Denmark rushed to lock down before almost every other country. Now its response is so far ahead that it's starting to remove restrictions,* in Business Insider, 10 April 2020, available at https://www.businessinsider.com/coronavirus-how-denmark-reached-stage-of-easing-lockdown-restrictions-2020-4?IR=T.

[657] Thiessen, T., *Coronavirus: Some Of These 24 European Countries Have Closed Their Borders To Tourists*, *op. cit*.

allowed[658], while schools, cultural institutions, libraries and leisure facilities[659], as well as restaurant and many shops, were closed[660].

Germany never banned people from going out and instead opted for strict social distancing measures[661]. The federal government banned public gatherings of more than two people, with the exception of families and people living together[662], ordered the closure of hotels and most shops, except food stores, banks, pharmacies and petrol stations, banned religious gatherings and restricted visits to hospitals and care homes[663]. The implemented measures slightly varied from state to state[664].

Luxembourg banned gatherings of more than two people[665] and strongly recommended people aged over 65 and vulnerable people to stay at home and only go out when strictly necessary[666]. Home working was advised and non-essential shops were closed[667], with only stores selling food products, pharmacies, petrol stations, financial and insurance institutions, and funeral services allowed to stay open[668]. All cultural, social, festive, sporting and recreational activities were suspended; museums, cinemas, libraries, swimming pools and sports halls remained closed; and bars, restaurants and cafés were only allowed to work with take-aways, drive ins and home delivery services[669].

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[658] Baker, S., *Denmark rushed to lock down before almost every other country. Now its response is so far ahead that it's starting to remove restrictions, op. cit.*

[659] Thiessen, T., *Coronavirus: Some Of These 24 European Countries Have Closed Their Borders To Tourists*, *op. cit*.

[660] Hirsch, C., *Europe's coronavirus lockdown measures compared, op. cit.*

[661] Deutsche Welle, *Coronavirus: What are the lockdown measures across Europe?*, *op. cit*.

[662] *Ibidem*.

[663] Henley, J., Willsher, K., and Kassam, A., *Coronavirus: France imposes lockdown as EU calls for 30-day travel ban*, *op. cit.*

[664] Reality Check team, *Coronavirus: What measures are countries taking to stop it?,* in BBC News, 1 April 2020, available at https://www.bbc.com/news/world-51737226.

[665] Hirsch, C., *Europe's coronavirus lockdown measures compared, op. cit.*

[666] The Luxemburg Government, *Government Council - New measures taken in response to the Coronavirus*, 15 March 2020, available at https://gouvernement.lu/en/actualites/toutes_actualites/communiques/2020/03-mars/15-nouvelles-mesures-coronavirus.html.

[667] Hirsch, C., *Europe's coronavirus lockdown measures compared, op. cit.*

[668] The Luxemburg Government, *Government Council - New measures taken in response to the Coronavirus*, *op. cit.*

[669] *Ibidem*.

Malta banned gatherings of more than four people[670], and encouraged medically vulnerable people and those aged over 65 to remain home and only go out for essential reasons such as food and medical services[671]. Schools, educational institutions, and childcare centers were closed[672], along with all cultural sites, including museums, theatres and libraries[673]. Clubs, gymnasiums and cinemas were closed as well, while bars and restaurants were allowed to stay open only for take-aways and deliveries[674]. Non-essential shops such as lottery outlets, jewellery stores, cosmetic stores, souvenir shops, florists, furniture shops, hairdressers and beauticians were shut[675].

Sweden: a unique response to COVID-19

A unique case within the European Union has been Sweden.

Even though it implemented some social distancing measures[676], the Scandinavian country took a relatively relaxed attitude[677] and deployed fewer restrictions than any other European Union Member States[678], mainly issuing guidelines rather than strict rules, focusing on staying home if sick or old, washing hands, avoiding any non-essential travel, and working from home where possible[679].

Sweden was the European Union Member State allowing for the highest number of people to gather, as it only banned gatherings of more than 50 people[680]. It allowed all pubs and

[670] Hirsch, C., *Europe's coronavirus lockdown measures compared, op. cit.*

[671] GardaWorld, *Malta: Authorities begin partial easing of COVID-19 restrictions May 4 /update 6,* 04 May 2020, available at https://www.garda.com/crisis24/news-alerts/338911/malta-authorities-begin-partial-easing-of-covid-19-restrictions-may-4-update-6.

[672] *Ibidem*.

[673] Debattista, A. and Borg, N., *COVID-19 Country reports / Malta,* in Compendium of Cultural Policies & Trends, 17 April 2020, available at https://www.culturalpolicies.net/covid-19/country-reports/ma/.

[674] U.S. Embassy in Malta, *COVID-19 Health Alert*, 17 March 2020, available at https://mt.usembassy.gov/covid-19-health-alert-march-17-2020/.

[675] GardaWorld, *Malta: Authorities begin partial easing of COVID-19 restrictions May 4 /update 6, op. cit.*

[676] Deutsche Welle, *Coronavirus: What are the lockdown measures across Europe?*, *op. cit.*

[677] BBC News, *Coronavirus: The unusual ways countries are managing lockdowns*, *op. cit.*

[678] Reality Check team, *Coronavirus: What measures are countries taking to stop it?, op. cit.*

[679] Savage, M., *Lockdown, what lockdown? Sweden's unusual response to coronavirus*, *op. cit.*

[680] Hirsch, C., *Europe's coronavirus lockdown measures compared*, *op. cit*.

restaurants to remain open[681], and even allowed nightclubs to stay open until the end of March[682]. Furthermore, Sweden was the only European Union Member State not to implement a full nationwide closure of schools[683], keeping its schools for under-16s open throughout the whole COVID-19 outbreak, and only recommending schools for over-16s and universities to close and switch to distance learning[684].

4.3 European Union response

As shown, even though the severity and timing varied from country to country, most Member States have adopted similar measures, especially in regard to bans and limitations, but they have also adopted individual, sparse and inconsistent measures, with some imposing a national lockdown, reintroducing border controls or even completely shutting their European borders. However, although any attempt to coordinate action at the European level did not prevent Member States to undertake such individual measures, it is important to acknowledge that action at the Community level has been undertaken, in line with article 168 of the Treaty on the Functioning of the European Union establishing that European Union action shall, inter alia, cover monitoring, early warning of and combating serious cross-border threats to health[685]. The rules on epidemiological surveillance, monitoring, early warning of, and combating serious cross-border threats to health are laid down in Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health[686].

[681] BBC News, *Coronavirus: The unusual ways countries are managing lockdowns*, *op. cit*.
[682] Savage, M., *Lockdown, what lockdown? Sweden's unusual response to coronavirus*, *op. cit.*
[683] Guardian Staff, *How do coronavirus containment measures vary across Europe?*, *op. cit.*.
[684] The Local, *How Sweden's schools are adapting to the coronavirus outbreak*, *op. cit.*
[685] EU, *TFEU*, art. 168.1.
[686] European Parliament (EP) and Council of the European Union (Council of the EU), *Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border*

In a video conference on how to coordinate European Union efforts to respond to the COVID-19 outbreak held on 10 March, the members of the European Council emphasised the need to work together and acknowledged the need for a joint European approach[687]. In a subsequent video conference held on 17 March, the Members of the European Council reaffirmed the need to work together and identified four priorities of European Union's action in response to COVID-19: limiting the spread of the virus; ensuring the provision of medical equipment; promoting research for a vaccine; and tackling socio-economic consequences[688].

4.3.1 Decision No 1082/2013/EU on serious cross-border threats to health

Decision No 1082/2013/EU on serious cross-border threats to health lays down the rules on epidemiological surveillance, monitoring, early warning of, and combating serious cross-border threats to health[689].

The aim of this Decision is to support cooperation and coordination between Member States in order to improve the prevention and control of the spread of severe human diseases across the borders, and to combat other serious cross-border threats to health in order to contribute to a high level of public health protection in the European Union[690]. However, Member States still retain the right to maintain or introduce additional arrangements, procedures and measures for their national systems as long as they do not impair the application of this Decision[691].

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threats to health and repealing Decision No 2119/98/EC, OJ L 293, 5.11.2013, p. 1–15, 22 October 2013, art. 1.1.

[687] European Council, *Conclusions by the President of the European Council following the video conference on COVID-19*, *op. cit.*

[688] European Council, *Conclusions by the President of the European Council following the video conference with members of the European Council on COVID-19*, in Press releases, 17 March 2020, available at https://www.consilium.europa.eu/en/press/press-releases/2020/03/17/conclusions-by-the-president-of-the-european-council-following-the-video-conference-with-members-of-the-european-council-on-covid-19/.

[689] EP and Council of the EU, *Decision No 1082/2013/EU,* art. 1.1.

[690] *Ivi,* art. 1.2.

[691] *Ivi,* art. 2.6.

In article 3, Decision No 1082/2013/EU defines a serious cross-border threat to health as a life-threatening or otherwise serious hazard to health of a biological, chemical, environmental or unknown origin which spreads or entails a significant risk of spreading across the national borders of the Member States, and which may necessitate coordination at European Union level in order to ensure a high level of human health protection[692].

In the Preamble to the Decision, it is acknowledged that although the responsibility to manage public health crises at national level lies with each Member State, measures taken by individual Member States could damage the interests of other Member States if they are inconsistent with one another or based on different risk assessments, and therefore coordinating the response at Union level should aim to guaranteeing that measures taken at national level are proportionate and limited to public health risks related to serious cross-border threats to health[693].

Preparedness, response planning and joint procurement of medical countermeasures

Decision No 1082/2013/EU establishes that Member States and the Commission shall consult each other within the Health Security Committee[694] with a view to coordinating their efforts to develop, strengthen and maintain their capacities for the monitoring, early warning and assessment of, and response to, serious cross-border threats to health[695].

[692] *Ivi,* art. 3 (g).

[693] *Ivi,* Preamble (21).

[694] Established by Article 17 of Decision No 1082/2013/EU: "1. A Health Security Committee, composed of representatives of the Member States … is hereby established. / 2. The HSC shall have the following tasks: (a) supporting the exchange of information between the Member States and the Commission on the experience acquired with regard to the implementation of this Decision; (b) coordination in liaison with the Commission of the preparedness and response planning of the Member States…; (c) coordination in liaison with the Commission of the risk and crisis communication and responses of the Member States to serious cross-border threats to health… / 3. The HSC shall be chaired by a representative of the Commission. The HSC shall meet at regular intervals and whenever the situation requires, on a request from the Commission or a Member State. / 4. The secretariat shall be provided by the Commission."

[695] *Ivi,* art. 4.1.

It also establishes that the institutions of the European Union and any Member States may engage in a joint procurement procedure with a view to the advance purchase of medical countermeasures for serious cross-border threats to health[696].

Epidemiological surveillance and ad hoc monitoring

Decision No 1082/2013/EU establishes that, following an alert notified, Member States shall, in liaison with the Commission and on the basis of the available information from their monitoring systems, inform each other through the Early Warning and Response System[697] and, if so required by the urgency of the situation, through the Health Security Committee about their national developments of the threat concerned[698].

Early warning and alert notification

Decision No 1082/2013/EU determines that in the event of the emergence or development of a serious cross-border threat to health that is unusual or unexpected for the given place and time; causes or may cause significant morbidity or mortality in humans; it grows rapidly or may grow rapidly in scale; or exceeds or may exceed national response capacity; affects or may affect more than one Member State; and requires or may require a coordinated response at Union level, national competent authorities or the Commission shall notify an alert in the Early Warning and Response System[699].

Where an alert is notified, and where necessary for the coordination of the response at European Union level, the Commission is required to make promptly available to the national competent

[696] *Ivi,* art. 5.1.

[697] Established by Article 8.1 of Decision No 1082/2013/EU: "A rapid alert system for notifying at Union level alerts in relation to serious cross-border threats to health, an 'Early Warning and Response System' (EWRS), is hereby established. The EWRS shall enable the Commission and the competent authorities responsible at national level to be in permanent communication for the purposes of alerting, assessing public health risks and determining the measures that may be required to protect public health."

[698] *Ivi,* art. 7.1.

[699] *Ivi,* art. 9.1.

authorities and to the Health Security Committee, through the Early Warning and Response System, a risk assessment of the potential severity of the threat to public health[700].

Coordination of response

Following an alert notification, on a request from the Commission or a Member State and on the basis of the available information, Member States are required to consult each other within the Health Security Committee and in liaison with the Commission with a view to coordinating their national responses to the serious cross-border threat to health[701].

Where a Member State plans to adopt public health measures to combat a serious cross-border threat to health, it shall first inform and consult the other Member States and the Commission on the nature, purpose and scope of such measures[702].

If the need to protect public health is so urgent that the immediate adoption of the public health measures in response to the appearance or resurgence of a serious cross-border threat to health is necessary, the Member State shall immediately inform the other Member States and the Commission on the nature, purpose and scope of the urgently adopted measures[703].

4.3.2 Fighting disinformation on COVID-19

The COVID-19 pandemic has been accompanied by a massive wave of false and misleading information[704].

In this context, and in line with its commitment to protect societies, citizens and freedoms against misinformation and disinformation actions, the European Union has worked to raise

[700] *Ivi,* art. 10.1.
[701] *Ivi,* art. 11.1.
[702] *Ivi,* art. 11.2.
[703] *Ivi,* art. 11.3.
[704] European Commission (EC), *Tackling coronavirus disinformation*, in Coronavirus response > Fighting disinformation, available at https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/fighting-disinformation/tackling-coronavirus-disinformation_en.

awareness of dangers of disinformation, promoted the use of authoritative sources and encouraged online platforms to contribute to the fight against fake news and other misinformation attempts by removing illegal or false contents[705]. The European Union has exposed several disinformation narratives on the coronavirus, and on the European Commission's fighting coronavirus-disinformation page[706] it provides materials for myth busting and fact checking[707].

Moreover, on 10 June the European Commission and the High Representative for Foreign Affairs and Security Policy have issued a joint communication "Tackling COVID-19 disinformation - Getting the facts right"[708] in which they propose a series of concrete actions aimed at increasing the European Union's resilience against disinformation, such as stepping up European Union support to fact-checkers and researchers, strengthening its strategic communications capacities and enhancing cooperation with international partners[709].

4.3.3 Coordinating Member States' responses: the integrated political crisis response mechanism and the coronavirus response team

Integrated political crisis response mechanism

[705] European Council and Council of the European Union, *Fighting disinformation*, in COVID-19 coronavirus pandemic, available at https://www.consilium.europa.eu/en/policies/coronavirus/fighting-disinformation/.
[706] European Commission (EC), *Fighting disinformation*, in Coronavirus response, available at https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/fighting-disinformation_en.
[707] European Commission (EC), *Overview of the Commission's response: Fighting disinformation*, in Coronavirus response, available at https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/overview-commissions-response_en#fighting-disinformation.
[708] European Commission (EC) and High Representative of the Union for Foreign Affairs and Security Policy (HR/VP), *Joint Communication to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions. Tackling COVID-19 disinformation - Getting the facts right,* JOIN(2020) 8 final, Brussels, 10 June 2020.
[709] European Council and Council of the EU, *Fighting disinformation*, *op. cit*.

To respond to the COVID-19 outbreak, on 28 January 2020, the then Croatian presidency of the Council of the European Union decided to activate the European Union's integrated political crisis response mechanism in information sharing mode[710].

The integrated political crisis response mechanism is the European Union framework for coordination of cross-sectoral crises at the highest political level[711]. It supports rapid and coordinated decision-making at European Union political level by bringing together European Union institutions, affected Member States and other key actors[712]. In information sharing mode, the integrated political crisis response mechanism triggers the creation of analytical reports and the use of the web platform to better understand the situation and prepare for a possible escalation[713].

Due to the worsening of the situation, 2 March the Croatian presidency escaladed the integrated political crisis response mechanism's activation to full mode[714].

The full activation mode allows for the elaboration of concrete coordinated European Union response measures at presidency-led roundtables with the participation of the European Commission, the office of the President of the European Council, affected Member States, and relevant European Union agencies and experts. The full activation mode also involves the preparation of proposals for European Union action to be decided upon by the Council or European Council[715].

On 1 July, Germany took over presidency of the Council of the European Union, and it decided to maintain the integrated political crisis response mechanism activated in full mode[716].

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[710] European Council and Council of the European Union (Council of the EU), *Crisis coordination on the COVID-19 outbreak,* in COVID-19 coronavirus pandemic, available at https://www.consilium.europa.eu/en/policies/coronavirus/.

[711] *Ibidem.*

[712] European Council and Council of the European Union (Council of the EU), *The Council's response to crises (IPCR)*, available at https://www.consilium.europa.eu/en/policies/ipcr-response-to-crises/ .

[713] *Ibidem*.

[714] European Council and Council of the EU, *Crisis coordination on the COVID-19 outbreak, op. cit.*

[715] European Council and Council of the EU, *The Council's response to crises (IPCR)*, *op. cit.*

[716] European Council and Council of the EU, *Crisis coordination on the COVID-19 outbreak, op. cit.*

Coronavirus response team

In order to help Member States coordinate their response to the COVID-19 pandemic, on 2 March the European Commission's President Ursula von der Leyen launched a coronavirus response team[717]. This team brings together all the different strands of action and has three main pillars. The first pillar is the medical field, and it includes prevention, procurement, relief measures and foresight. The second pillar concerns mobility, and it deals with transportation, travel advice and Schengen-related questions. The third pillar covers the economy, and it includes various business sectors, such as tourism or transport, and trade, as well as value chains and macro-economy[718].

4.3.4 Cross-border cooperation in healthcare related to the COVID-19 crisis

Some overburdened Member States have asked for emergency cross-border healthcare assistance from the European Union and other Member States, and some regional initiatives of hospital cooperation to treat COVID-19 patients have consequently taken place, e.g. some German Länder and Luxembourg offering intensive care places and hospital treatment to Italian and French patients[719].

However, given the exceptional emergency situation created by the COVID-19 pandemic, the European Commission recognised that a more coordinated approach in cross-border healthcare was justified[720].

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[717] European Commission (EC), *Remarks by President von der Leyen at the joint press conference with Commissioners Lenarčič, Kyriakides, Johansson, Vălean and Gentiloni at the ERCC ECHO on the EU's response to COVID-19,* in Press corner > President von der Leyen on the EU's response to COVID-19, 2 March 2020, available at https://ec.europa.eu/commission/presscorner/detail/en/statement_20_368.

[718] European Commission (EC), *European Commission's coronavirus response team*, available at https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/european-commissions-action-coronavirus_en.

[719] European Commission (EC), *Communication from the Commission. Guidelines on EU Emergency Assistance on Cross-Border Cooperation in Healthcare related to the COVID-19 crisis,* C(2020) 2153 final, Brussels, 3 April 2020.

[720] *Ibidem.*

Article 168 of the Treaty on the Functioning of the European Union establishes that the European Union shall encourage cooperation between the Member States in combating serious cross-border threats to health, and the European Commission may take initiative to promote such coordination, through e.g. the establishment of guidelines[721].

In line with this, on 3 April, the European Commission issued a set of Guidelines on European Union Emergency Assistance on Cross-Border Cooperation in Healthcare related to the COVID-19 crisis providing some practical guidance to Member States[722].

The aim of the Guidelines is to facilitate the transfer of patients from one Member State to another, help qualified medical personnel to offer their assistance in other Member States and ease the pressure on overburdened national health systems[723].

In these Guidelines, the European Commission sets out a coordinated approach to cross-border cooperation on emergency healthcare[724] and provides for arrangements for patient mobility across borders, steps for the reimbursement of healthcare costs, and encourage national authorities to use existing bilateral and regional agreements[725].

Objective and Scope

With a view to alleviate overstretched healthcare facilities in Member States in need, in the Guidelines the European Commission invites Member States to use all the existing structures and mechanisms to work together to assist patients in need of critical care by offering available

[721] EU, *TFEU*, art. 168.2.

[722] EC, *Timeline of EU action*, *op. cit.*

[723] European Commission (EC), *Ensuring the availability of supplies and equipment: Supporting Member States in need and cross-border health cooperation*, in Coronavirus response > Public health, available at https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/public-health_en#ensuring-the-availability-of-supplies-and-equipment.

[724] European Commission (EC), *Coronavirus: Commission encourages and facilitates cross-border treatment of patients and deployment of medical staff*, in Press corner, 3 April 2020, available at https://ec.europa.eu/commission/presscorner/detail/en/ip_20_590.

[725] EC, *Ensuring the availability of supplies and equipment: Supporting Member States in need and cross-border health cooperation*, *op. cit.*.

hospital bed capacity, and all the available health professionals, enabling them to share expertise and skills working with health professionals across borders[726].

The European Commission commits to assisting health authorities, inter alia by coordinating the requests and offers of assistance; coordinating and co-funding emergency transports of patients and medical personnel; and providing clarity on the reimbursement of cross-border healthcare costs and on arrangements for patient mobility[727].

Coordinate cross-border assistance in healthcare

Member States can request for cross-border health care assistance relating to intensive care places, treatment and transfer of patients and appropriately qualified teams of medical personnel. In order to request such assistance, the Member State in need has to notify the Member States and the European Commission through the Early Warning and Response System. Member States able to offer the requested assistance can then respond through the same system, and the cooperating Member States will then coordinate the support directly with each other and with the hospitals[728].

Reimbursement of cross-border healthcare costs

The coverage of healthcare services received in a Member State other than the competent one is governed by Regulation (EC) No 883/2004. In line with this Regulation, patients who have to be transported to a hospital in another Member State to receive treatment should have received a prior authorisation from their competent social security institution.

However, the European Commission recognises that in an emergency situation, such as the one created by the COVID-19 pandemic, this system of prior authorisation is not practical.

[726] EC, *Communication from the Commission. Guidelines on EU Emergency Assistance on Cross-Border Cooperation in Healthcare related to the COVID-19 crisis, op. cit.*
[727] *Ibidem.*
[728] *Ibidem.*

Therefore, it invites the Member States to adopt a more pragmatic approach and recommends that it should be sufficient for the competent Member State to confirm that the patient has a document attesting that he is insured at the time of hospital admission[729].

Movement of patients and healthcare personnel

Concerning the free movement of patients across internal borders, the European Commission underlines that patients in need of urgent care in another Member State shall not be refused entry even if temporary controls at internal borders exist. Differently, patients travelling to another Member State to receive non-urgent care shall make sure that the Member State they are willing to travel to has in place border controls enabling them to travel[730].

The European Commission also stresses the fundamental importance of facilitating border crossing for health professionals, allowing them to unhinderedly access work in a healthcare facility in another Member State[731].

Cross-border healthcare cooperation in border regions

Through its Interreg programmes[732], the European Union supports cooperation and integration of health systems among border regions. There are several projects in Interreg regions specifically working for a more coordinated approach to the COVID-19 pandemic. These include the Euregio Meuse-Rhine between Belgium, Germany and The Netherlands, setting up a tri-lateral crisis management centre, i.e. Task Force Corona; and the Cerdanya Hospital

[729] *Ibidem.*
[730] *Ibidem.*
[731] *Ibidem.*
[732] "Interreg is one of the key instruments of the European Union (EU) supporting cooperation across borders through project funding. Its aim is to jointly tackle common challenges and find shared solutions in fields such as health, environment, research, education, transport, sustainable energy and more." Retrieved from Interreg, *About Interreg,* available at https://interreg.eu/about-interreg/.

between France and Spain cooperating with French hospitals to share intensive healthcare capacity and medical personnel[733].

Financial assistance for cross-border healthcare cooperation

For what concerns financial assistance for cross-border healthcare cooperation, the European Commission sustains that it shall be provided through the Emergency Support Instrument. Such financial assistance shall be made available in particular for the transport of patients in need to cross-border hospitals; the exchange of medical professionals; the hosting of foreign patients; or other types of mutual support and deployment of temporary health care facilities[734].

4.3.5 Joint European Roadmap towards lifting COVID-19 containment measures

On 15 April 2020, the European Commission, in cooperation with the President of the European Council, put forward a Joint European Roadmap towards lifting COVID-19 containment measures[735].

In the Roadmap, the European Commission acknowledges that the restrictive measures implemented by Member States have been necessary to slow down the spread of the virus, but it also recognises that such measures have seriously impacted the functioning of the Single Market, and triggered the need for public intervention to counterbalance the socio-economic impact, both at European Union and Member State levels[736].

The European Commission also affirms the need for a well-coordinated approach in the European Union and among all Member States for the phase when economic and social

[733] EC, *Communication from the Commission. Guidelines on EU Emergency Assistance on Cross-Border Cooperation in Healthcare related to the COVID-19 crisis, op. cit.*
[734] *Ibidem.*
[735] EC, *Joint European Roadmap towards lifting COVID-19 containment measures*, *op. cit*.
[736] *Ivi,* Introduction.

activities can be restarted, and in the Roadmap, it provides for such an approach by setting out recommendations to Member States, informing their actions and providing a frame for ensuring European Union-level and cross-border coordination[737].

Criteria and principles

The European Commission established three sets of criteria to assess whether the time has come to begin to relax the confinement: epidemiological criteria; sufficient health system capacity; and appropriate monitoring capacity[738].

Moreover, in acknowledging that the spread of the virus cannot be contained within national borders, the European Commission affirms the need for a common framework for action, based on three basic principles: action should be based on science and have public health at its centre; action should be coordinated between the Member States; and respect and solidarity between Member States remains essential[739].

Accompanying measures

The European Commission recognizes that a successful lifting of the confinement measures requires a set of accompanying measures relevant for all Member States, including: gathering data and developing a robust system of reporting; creating a framework for contact tracing and warning with the use of mobile apps; expanding testing capacity and harmonising testing methodologies; increasing the capacity and the resilience of health care systems as well as the medical and personal protective equipment capacity; and developing a safe and effective vaccine, together with safe and effective treatments and medicines[740].

[737] *Ibidem.*
[738] *Ivi,* Criteria.
[739] *Ivi,* Principles.
[740] *Ivi,* Accompanying measures.

Recommendations

The European Commission sets out some recommendations to Member States on how to gradually lift containment measures. It recommends action to be gradual, to progressively replace general measures with targeted ones, and to start lifting measures with a local impact and then gradually extend the lifting to measures with a broader geographic coverage. It advises to phase in the re-start of the economic activity, encouraging to not let all the population go back to the workplace at the same time, and recommends to progressively allow gatherings of people and gradually reintroducing transport services. It acknowledges the need for a phased approach for the opening of the internal and external borders, and recommends to first lift internal border controls in a coordinated manner and then reopen the external borders in a second stage. It invites to sustain efforts to prevent the spread of the virus, and to continuously monitor action and develop preparedness for returning to stricter containment measures if needed[741].

4.3.6 European Union's response in the field of public health

In the field of public health, the European Union's response has been mainly focused on providing medical guidance, ensuring the provision of medical equipment, and developing a vaccine strategy.

Medical guidance

On 17 March, the European Commission set up an advisory panel on COVID-19 composed of 7 expert epidemiologists and virologists from several Member States to formulate science-

[741] *Ivi,* Recommendations.

based guidelines for the European Union response to the pandemic[742]. The panel provides science-based guidelines and advise upon response measures, gaps in clinical management, prioritisation of health care, civil protection and other resources, and policy measures for long-term consequences of coronavirus[743].

Based on the scientific advice of the advisory panel on COVID-19 and the European Centre for Disease Prevention and Control[744], the European Commission has issued recommendations and guidelines on issues including community measures, the supply and availability of medicines, testing methodologies and tracing mobile apps[745].

Medical equipment: The Join Procurement Agreement and RescEU

In line with article 5 of Decision No 1082/2013/EU on serious cross-border threats to health, the institutions of the European Union and the Member States can engage in a joint procurement procedure with a view to the advance purchase of medical countermeasures for serious cross-border threats to health[746]. Through this instrument, the European Union Member States can join forces and negotiate better terms with the suppliers[747], thus securing a more equitable

[742] European Commission (EC), *A European Team of coronavirus experts*, in Coronavirus response > Public health, available at https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/public-health_en#a-european-team-of-coronavirus-experts.

[743] European Commission (EC), *Overview of the Commission's response: Public health*, in Coronavirus response, available at https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/overview-commissions-response_en#public-health.

[744] The European Centre for Disease Prevention and Control is the European Union agency charged with assessing health treats from a scientific perspective. It does so by producing rapid risk assessments and providing epidemiological updates and technical support through the issuing of guidance for how to best respond to the outbreak. Retrieved from European Commission (EC), *Public health: Risk Assessment*, in Coronavirus response, available at https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/public-health_en#risk-assessment.

[745] EC, *Overview of the Commission's response: Public health*, *op. cit.*

[746] EP and Council of the EU, *Decision No 1082/2013/EU,* art. 5.1.

[747] European Commission (EC), *EU medical and health support: Large-scale joint procurement of medical equipment*, in Coronavirus response, available at https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/eu-medical-and-health-support_en#large-scale-joint-procurement-of-medical-equipment.

access to certain medical countermeasures and more balanced prices[748]. Under the joint procurement mechanisms, each Member State uses its own national budget to purchase the medical equipment, and the European Commission has a primarily coordinating role, collecting the needs of Member States, drafting the technical specifications, organising the launch of the procedure, assessing the tenders and awarding the contract(s)[749]. All the European Union Member States are part of the Joint Procurement Agreement[750], and with regard to the COVID-19 pandemic, the European Union has already launched four joint procurement procedures allowing member states to make joint purchases of equipment and testing kits[751].

Moreover, to ensure the provision and swift distribution of medical equipment such as ventilators, personal protective equipment and therapeutics and laboratory supplies, on 19 March 2020[752] the European Commission has created a strategic RescEU medical stockpile and distribution mechanism[753], to which all the European Member States participate[754]. RescEU is part of the European Union Civil Protection Mechanism[755], which aims at reinforcing cooperation between Member States in the field of civil protection in order to improve prevention, preparedness and response to disasters, and which allows Member States to request

[748] European Commission (EC), *Crisis preparedness and response*, in Public health, available at https://ec.europa.eu/health/preparedness_response/joint_procurement_en.

[749] EC, *EU medical and health support: Large-scale joint procurement of medical equipment*, *op. cit*.

[750] *Ibidem*.

[751] European Council and Council of the European Union, *10 things the EU is doing to fight COVID-19*, in COVID-19 coronavirus pandemic, available at https://www.consilium.europa.eu/en/policies/coronavirus/10-things-against-covid-19/.

[752] European Commission (EC), *COVID-19: Commission creates first ever rescEU stockpile of medical equipment,* in Press release, 19 March 2020, available at https://ec.europa.eu/commission/presscorner/detail/en/IP_20_476.

[753] European Commission (EC), *EU medical and health support: rescEU strategic medical stockpile,* in Coronavirus response, available at https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/eu-medical-and-health-support_en#resceu-strategic-medical-stockpile.

[754] EC, *COVID-19: Commission creates first ever rescEU stockpile of medical equipment, op. cit*.

[755] "Since 2001, the EU Civil Protection Mechanism has been activated more than 330 times to respond to emergencies. The Mechanism pools response capacities from all EU Member States, 6 Participating States and the UK during the transition period. The Mechanism can be deployed inside the EU and around the world. Joint disaster prevention and preparedness actions." Retrieved from European Commission (EC), *EU Civil Protection Mechanism: FACTS & FIGURES*, available at https://ec.europa.eu/echo/what/civil-protection/mechanism_en.

assistance in case of an emergency which overwhelms their response capabilities[756]. The RescEU medical stockpile is hosted by one or more European Union Member States, which are then responsible for procuring the equipment[757], and is managed by the European Commission[758].

The vaccine strategy

A cornerstone of the European Union's response in the field of public health consists of the development and distribution of an effective and safe vaccine against the COVID-19, considered as the most probable lasting solution to the pandemic[759].

To this end, the European Union has decided to dedicate a significant part of the €2.7 billion available under the European Support Instrument[760] to secure the production of vaccines in the European Union and sufficient supplies for its Member States[761]. Moreover, the European Union's Horizon 2020 research programme[762] is funding 18 research projects and 151 teams across Europe to help find a vaccine quickly against COVID-19[763].

[756] EC, *COVID-19: Commission creates first ever rescEU stockpile of medical equipment, op. cit*.
[757] *Ibidem*.
[758] EC, *EU medical and health support: rescEU strategic medical stockpile, op. cit.*
[759] European Commission (EC), *Coronavirus vaccines strategy,* in Coronavirus response > Public health, available at https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/public-health/coronavirus-vaccines-strategy_en.
[760] EC, *Communication from the Commission to the European Parliament, the European Council, the Council and the European Investment Bank. EU Strategy for COVID-19 vaccines, op. cit.*
[761] European Commission (EC), *Emergency Support Instrument,* in Coronavirus response, available at https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/emergency-support-instrument_en.
[762] "Horizon 2020 is the biggest EU Research and Innovation programme ever with nearly €80 billion of funding available over 7 years (2014 to 2020) – in addition to the private investment that this money will attract. It promises more breakthroughs, discoveries and world-firsts by taking great ideas from the lab to the market. Horizon 2020 is the financial instrument implementing the Innovation Union, a Europe 2020 flagship initiative aimed at securing Europe's global competitiveness." Retrieved from European Commission (EC), *Horizon 2020,* in Funding programmes, available at https://ec.europa.eu/programmes/horizon2020/en.
[763] European Parliament (EP), *10 things the EU is doing to fight the coronavirus,* in News, 02 April 2020, updated on 07 May 2020, available at https://www.europarl.europa.eu/news/en/headlines/society/20200327STO76004/10-things-the-eu-is-doing-to-fight-the-coronavirus.

A European Union strategy to accelerate the development, manufacturing, and deployment of vaccines against COVID-19 has been proposed in a communication issued by the Commission on 17 June 2020[764]. The proposed strategy aims at ensuring the quality, safety and efficacy of vaccines, securing timely access to vaccines for Member States and their population, and ensuring equitable access for all in the European Union to an affordable vaccine as early as possible. The Commission acknowledges that no Member State on its own has the capacity to secure the investment in developing and producing a sufficient number of vaccines, and that therefore sufficient and swift supplies of a safe and effective vaccine can only be ensured through unified action by the European Union and its Member States. Consequently, in the Communication the European Commission proposes to run a central procurement process, according to which it will enter into agreements with individual vaccine producers on behalf of Member States, and, in return for the right to buy a specified number of vaccine doses in a given timeframe and at a given price, part of the upfront costs faced by vaccines producers will be financed from the Emergency Support Instrument[765] in the form of Advance Purchase Agreements. Once any of the vaccines supported proves successful, Member States will be able to acquire it directly from the producer on the basis of the conditions laid down in the Advance Purchase Agreements[766].

To speed up the development and deployment of a vaccine against COVID-19[767], on 14 July 2020, the Council adopted a regulation on the conduct of clinical trials with and supply of

[764] EC, *Communication from the Commission to the European Parliament, the European Council, the Council and the European Investment Bank. EU Strategy for COVID-19 vaccines, op. cit.*

[765] "The Emergency Support Instrument helps Member States in their efforts to address the coronavirus pandemic. It responds to needs that can be best addressed in a strategic, coordinated manner at European level … The instrument helps mitigate the immediate consequences of the pandemic and anticipate the needs related to the exit and recovery. The Emergency Support Instrument is based on the principle of solidarity and pools efforts and resources to quickly address shared strategic needs." Retrieved from European Commission, *Emergency Support Instrument, op. cit.*

[766] EC, *Communication from the Commission to the European Parliament, the European Council, the Council and the European Investment Bank. EU Strategy for COVID-19 vaccines, op. cit.*

[767] European Council and Council of the European Union (Council of the EU), *COVID-19: how the EU is promoting research on COVID-19,* in COVID-19 coronavirus pandemic, available at https://www.consilium.europa.eu/en/policies/coronavirus/covid-19-research/.

medicinal products for human use containing or consisting of genetically modified organisms intended to treat or prevent COVID-19[768]. Under this regulation, all the operations related to the conduct of clinical trials containing or consisting of genetically modified organisms intended to treat or prevent COVID-19 no longer require a prior environmental risk assessment or consent[769], and a temporary derogation from certain provisions of European Union legislation[770] on operations related to the supply and use of medicinal products containing or consisting of genetically modified organisms that are intended to treat or prevent COVID-19 is established[771].

The European Commission has concluded exploratory talks with Sanofi-GSK on a contractual framework for the purchase of 300 million doses; Johnson and Johnson for an initial purchase of 200 million doses and the possibility to purchase 200 million more; CureVac for the purchase of 225 million doses; and Moderna for an initial purchase of 80 million doses and the option to purchase 80 million more[772], and on 14 August it reached a first agreement with the pharmaceutical company AstraZeneca to purchase 300 million doses, with an option to purchase 100 million more, of a potential vaccine against COVID-19[773]. On 27 August 2020, the contract the European Commission negotiated on behalf of the European Union Member States with AstraZeneca entered into force[774].

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[768] European Parliament (EP) and Council of the European Union (Council of the EU), *Regulation (EU) 2020/1043 of the European Parliament and of the Council of 15 July 2020 on the conduct of clinical trials with and supply of medicinal products for human use containing or consisting of genetically modified organisms intended to treat or prevent coronavirus disease (COVID-19),* PE/28/2020/REV/1, OJ L 231, 17.7.2020, p. 12–16, 15 July 2020.

[769] *Ivi,* art. 2.1.

[770] European Council and Council of the EU, *COVID-19: how the EU is promoting research on COVID-19, op. cit*.

[771] EP and Council of the EU, *Regulation (EU) 2020/1043,* art. 3.1.

[772] European Commission (EC), *Emergency Support Instrument: Vaccines*, in Coronavirus response, available at https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/emergency-support-instrument_en#vaccines.

[773] *Ibidem*.

[774] EC, *Timeline of EU action*, *op. cit.*

4.3.7 European Union's response in the field of the economy

The European Union has adopted a comprehensive economic response to the COVID-19 pandemic. It has applied the full flexibility of the European Union fiscal rules, revised its State Aid rules and set up a Coronavirus Response Investment Initiative. It has also launched a new initiative called SURE - Support mitigating Unemployment Risks in Emergency, and provided support to the tourism, the agricultural, the wine, fruit and vegetables sectors[775].

Moreover, on 21 July the European Union leaders have agreed on a comprehensive recovery package aimed at mitigating the effects of the COVID-19 pandemic[776].

Full flexibility of the European Union fiscal rules

The European Commission has activated the general escape clause of the Stability and Growth Pact[777], enabling national governments to better support their national economies as the budgetary rules have been significantly relaxed. Member States can indeed undertake measures to deal adequately with the crisis, while departing from the budgetary requirements that would normally apply under the European fiscal framework[778].

State Aid rules

[775] European Commission (EC), *Jobs and economy during the coronavirus pandemic*, in Coronavirus response, available at https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/jobs-and-economy-during-coronavirus-pandemic_en.

[776] European Council and Council of the European Union (Council of the EU), *COVID-19: the EU's response to the economic fallout*, in COVID-19 coronavirus pandemic, available at https://www.consilium.europa.eu/en/policies/coronavirus/covid-19-economy/.

[777] "The Stability and Growth Pact (SGP) is a set of rules designed to ensure that countries in the European Union pursue sound public finances and coordinate their fiscal policies." Retrieved from European Commission (EC), *Stability and Growth Pact*, in Economic and fiscal policy coordination, available at https://ec.europa.eu/info/business-economy-euro/economic-and-fiscal-policy-coordination/eu-economic-governance-monitoring-prevention-correction/stability-and-growth-pact_en.

[778] European Commission (EC), *Jobs and economy during the coronavirus pandemic: Flexibility under the EU's Fiscal Rules*, in Coronavirus response, available at https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/jobs-and-economy-during-coronavirus-pandemic_en#flexibility-under-the-eus-fiscal-rules.

The European Union has established flexible State Aid rules, allowing Member States to provide direct support for hard hit companies and small firms[779].

On 19 March, the European Commission has adopted the Temporary Framework for State aid measures to support the economy in the current COVID-19 outbreak, which provides for various types of aid aimed at ensuring that businesses retain the means to keep operating, or to temporarily freezing activity without implicating long-term growth prospects[780].

The Temporary Framework has subsequently been extended three times: on 3 April to enable Member States to accelerate the research, testing and production of coronavirus relevant products, to protect jobs and to further support the economy in the context of the outbreak; on 8 May to enable Member States to undertake public interventions in the form of recapitalisation aid to companies in need; and on 29 June to enable Member States to provide public support to all micro and small companies[781].

The Temporary Framework will be in place until the end of December 2020 and for recapitalisation issues until the end of June 2021. On 2 July 2020, the European Commission has further prolonged the validity of certain State aid rules which would have otherwise expired at the end of 2020[782].

Coronavirus Response Investment Initiative

To help Member States fund their COVID-19 crisis response, the European Union has set up a €37 billion Coronavirus Response Investment Initiative to provide liquidity to small businesses and the healthcare sector[783].

[779] European Commission (EC), *Jobs and economy during the coronavirus pandemic: State aid actions*, in Coronavirus response, available at https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/jobs-and-economy-during-coronavirus-pandemic_en#state-aid-actions.
[780] *Ibidem*.
[781] *Ibidem.*
[782] *Ibidem.*
[783] EC, *Jobs and economy during the coronavirus pandemic*, *op. cit.*

Under this initiative, Member States can spend €8 billion of pre-allocated unspent European Union cohesion money, matched with €29 billion of co-financing from the European Union budget for a total of up to €37 billion, to buy medical equipment, pay doctors and health workers, support the unemployed, keep people in jobs, and keep small and medium-size enterprises in business[784].

Under the Coronavirus Response Investment Initiative, the hardest-hit Member States can also rely on up to €800 million from the European Union Solidarity Fund[785], whose scope has been extended in response to the COVID-19 outbreak and the urgent need to tackle the associated public health crisis to cover major public health emergencies[786].

SURE - Support mitigating Unemployment Risks in Emergency

To protect jobs and workers affected by the COVID-19 pandemic[787], on 2 April 2020 the European Commission has launched an initiative called SURE - Support mitigating Unemployment Risks in Emergency[788]. Under this initiative, Member States can receive financial assistance of up to €100 billion in the form of loans granted on favourable terms to help cover the costs of national short-time work schemes[789] and similar measures allowing companies to safeguard jobs[790].

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[784] European Commission (EC), *Jobs and economy during the coronavirus pandemic: Coronavirus Response Investment Initiative*, in Coronavirus response, available at https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/jobs-and-economy-during-coronavirus-pandemic_en#coronavirusresponseinvestmentinitiative.

[785] *Ibidem.*

[786] European Commission (EC), *COVID-19 - EU Solidarity Fund*, in Regional Policy > Funding > EU Solidarity Fund, available at https://ec.europa.eu/regional_policy/en/funding/solidarity-fund/covid-19.

[787] European Commission (EC), *Jobs and economy during the coronavirus pandemic: Securing businesses and supporting jobs,* in Coronavirus response, available at https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/jobs-and-economy-during-coronavirus-pandemic_en#flexibilityundertheeusfiscalrules.

[788] EC, *Jobs and economy during the coronavirus pandemic*, *op. cit.*

[789] European Parliament (EP), *Covid-19: 10 things the EU is doing to ensure economic recovery*, 22 July 2020, updated on 24 July 2020, available at https://www.europarl.europa.eu/news/en/headlines/priorities/eu-response-to-coronavirus/20200625STO82007/covid-19-10-things-the-eu-is-doing-to-ensure-economic-recovery.

[790] European Commission (EC), *Jobs and economy during the coronavirus pandemic: Supporting recovery of EU tourism,* in Coronavirus response, available at https://ec.europa.eu/info/live-work-travel-

Tourism

The European Union has adopted a series of measures to allow for a gradual and coordinated reopening of tourism services and facilities, and specific support for tourism businesses. These measures encompass liquidity for tourism businesses; saving jobs; and connecting citizens to local offer, promoting tourism and Europe as a safe tourist destination[791]. The European Union has also adopted some relief measures for the transport sector to minimise the effects of the pandemic on airlines, railways, road and shipping companies[792].

Agricultural, wine, fruit and vegetables sectors

The European Union has also adopted emergency measures to help farmers and fishermen affected by the COVID-19 pandemic, and exceptional market measures have been introduced to support wine, fruit and vegetable producers[793].

For the agricultural sector, the European Commission has adopted measures such as private storage aid, temporary authorisations for operators to self-organise market measures in hard-hit sectors, flexibility in the implementation of market support programmes, and temporary derogation from European Union competition rules in some sectors[794].

For the wine sector, the European Commission has adopted measures such as allowing self-organisation by market operators, advance payments covering up to 100% of distillation and storage costs, and a 10% increase of European Union's contribution for wine national support programmes, which will then reach 70%[795].

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eu/health/coronavirus-response/jobs-and-economy-during-coronavirus-pandemic_en#supporting-recovery-of-eu-tourism.

[791] *Ibidem*.

[792] EP, *Covid-19: 10 things the EU is doing to ensure economic recovery*, *op. cit*.

[793] *Ibidem*.

[794] European Commission (EC), *Jobs and economy during the coronavirus pandemic: Securing essential food supplies*, in Coronavirus response, available at https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/jobs-and-economy-during-coronavirus-pandemic_en#securing-essential-food-supplies.

[795] *Ibidem*.

Finally, the fruit and vegetables sector has benefited from a 20% increase of European Union's contribution for programmes managed by producer organisations, which has provided producer organisations with greater flexibility in the implementation of their programmes[796].

The Recovery Plan: Budget for 2021-2027 and Next Generation EU

On 23 April 2020, European Union leaders decided to work towards establishing a European recovery fund aimed at mitigating the effects of the crisis, and tasked the European Commission to come up with a proposal[797].

On 27 May 2020, the European Commission presented a recovery plan for Europe, and on 21 July European Union leaders agreed on a comprehensive package of €1 824.3 billion, which combines a €750 billion recovery effort, i.e. NextGenerationEU, and a €1 074.3 billion long-term European Union budget for 2021-2027[798].

Under the recovery plan, the European Commission will be authorised to borrow up to €750 billion of funds on behalf of the European Union on the capital markets. These funds will then be used by the European Union through the NextGenerationEU recovery effort to address the consequences of the COVID-19 crisis[799].

As part of the NextGenerationEU recovery plan, the European Union has also launched the EU4Health programme, which will strengthen Member States' health systems and promote innovation and investment in the sector.[800]

The European Stability Mechanism

[796] *Ibidem*.
[797] European Council and Council of the EU, *COVID-19: the EU's response to the economic fallout*, *op. cit.*
[798] *Ibidem*.
[799] European Council and Council of the European Union (Council of the EU), *A recovery plan for Europe*, in Policies, available at https://www.consilium.europa.eu/en/policies/eu-recovery-plan/.
[800] EP, *Covid-19: 10 things the EU is doing to ensure economic recovery*, *op. cit.*

The European Stability Mechanism was set up in 2012 as an international financial institution by the euro area Member States[801] to provide assistance in situations of severe financial distress[802]. It grants conditional financial assistance to euro area Member States undergoing financial difficulties[803], providing them with emergency loans in return of their undertaking reform programmes[804].

On 9 April the Eurogroup[805] included the European Stability Mechanism in the economic policy response to the COVID-19 crisis as a safety net for sovereigns[806]. The Eurogroup proposed to establish a Pandemic Crisis Support, based on the Enhanced Conditions Credit Line[807], as a safeguard available to all euro area Member States, with standardised terms agreed in advance by the European Stability Mechanism Governing Bodies on the basis of preliminary assessments by the European institutions[808].

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[801] "Although all the European Union Member States are part of the Economic and Monetary Union, only 19 of them have replaced their national currencies with the single currency – the euro. These countries form the euro area, also known as the eurozone. The Member States where the euro has still not been adopted are Bulgaria, Croatia, Czech Republic, Hungary, Poland, Romania and Sweden, plus Denmark which has negotiated an opt-out from the single currency." Retrieved from European Union (EU)*, Which countries use the euro*, in About the EU, available at https://europa.eu/european-union/about-eu/euro/which-countries-use-euro_en.

[802] European Stability Mechanism (ESM), *About us,* available at https://www.esm.europa.eu/about-us/intro.

[803] Banca d'Italia, *The European Stability Mechanism (ESM) and its reform: FAQs and answers*, available at https://www.bancaditalia.it/media/fact/2019/mes_riforma/index.html?com.dotmarketing.htmlpage.language=1.

[804] ESM, *About us, op. cit.*

[805] "The Eurogroup is an informal body where the ministers of the euro area member states discuss matters relating to their shared responsibilities related to the euro." Retrieved from European Council and Council of the (Council of the EU) European Union, *Eurogroup*, in The Council of the EU, available at https://www.consilium.europa.eu/en/council-eu/eurogroup/.

[806] European Stability Mechanism (ESM), *ESM Pandemic Crisis Support: ESM's role in the European response*, available at https://www.esm.europa.eu/content/europe-response-corona-crisis.

[807] "Precautionary financial assistance may be provided via a Precautionary Conditioned Credit Line (PCCL) or via an Enhanced Conditions Credit Line (ECCL). A PCCL and an ECCL credit line can be drawn via a loan or a primary market purchase … Access to a PCCL shall be based on pre-established conditions and limited to ESM Members where the economic and financial situation is still fundamentally sound … Access to an ECCL shall be open to ESM Members that do not comply with some of the eligibility criteria required for accessing a PCCL but whose general economic and financial situation remains sound." Retrieved from European Stability Mechanism (ESM), *Guideline on Precautionary Financial Assistance,* 2012, art. 2.

[808] Eurogroup, *Report on the comprehensive economic policy response to the COVID-19 pandemic*, in Press release, 9 April 2020, available at https://www.consilium.europa.eu/en/press/press-releases/2020/04/09/report-on-the-comprehensive-economic-policy-response-to-the-covid-19-pandemic/.

On 23 April, the European Council endorsed this agreement[809] and on 8 May the Eurogroup issued a Statement on the Pandemic Crisis Support, outlining its features and standardized terms[810]. The Eurogroup established that the Pandemic Crisis Support is available to all euro area Member States for amounts of 2% of the respective Member State's gross domestic product as of end-2019, as a benchmark, with the only requirement to access the credit line being the commitment to use such credit line to support domestic financing of healthcare, cure and prevention costs related to the COVID-19 crisis[811].

On 15 May 2020 the European Stability Board of Governors[812] agreed to make the Pandemic Crisis Support available, and the credit line thus became operational[813].

4.3.8 European Union's response in the field of borders and mobility

The European Union's response to the COVID-19 pandemic has also encompassed borders and mobility. The adopted measures include guidelines for border management and guidance on the repatriation of European Union citizens, and they concern both the internal and the external borders.

Repatriation of European Union citizens

Since the beginning of the COVID-19 crisis, the European Union has taken action to help Member States in providing consular support and repatriating their citizens from third

[809] European Council, *Conclusions of the President of the European Council following the video conference of the members of the European Council, 23 April 2020,* in Press releases, 23 April 2020, available at https://www.consilium.europa.eu/en/press/press-releases/2020/04/23/conclusions-by-president-charles-michel-following-the-video-conference-with-members-of-the-european-council-on-23-april-2020/.

[810] Eurogroup, *Eurogroup Statement on the Pandemic Crisis Support,* in Press releases, 8 May 2020, available at https://www.consilium.europa.eu/en/press/press-releases/2020/05/08/eurogroup-statement-on-the-pandemic-crisis-support/.

[811] *Ibidem*.

[812] "The ESM's highest decision-making body composed of the 19 euro area finance ministers." Retrieved from ESM, *ESM Pandemic Crisis Support: ESM's role in the European response*, *op. cit*.

[813] ESM, *ESM Pandemic Crisis Support: ESM's role in the European response*, *op. cit*.

countries[814]. This help has been provided under the European Union Civil Protection Mechanism, which has been activated in the context of the COVID-19 pandemic on 28 January in response to a request for assistance from France to provide consular support to its citizens in Wuhan[815]. As of 1 July, almost 600 000 European Union citizens have been brought home[816].

Guidelines for border management measures

On 16 March the European Commission presented guidelines to Member States for an integrated approach to an effective border management to protect health and ensure the availability of goods and essential services, and thus the integrity of the Single Market [817].

The European Commission affirms the necessity of ensuring unobstructed transport of goods and professional travel. It states that appropriate measures need to be taken for people identified as posing a risk to public health from COVID-19, and recommends the adoption of some measures at external borders, including screening measures; locator forms or declarations of health; and isolation of suspected cases. The European Commission also recognizes Member States with the possibility to refuse entry to non-resident third country nationals where they present relevant symptoms or have been particularly exposed to risk of infection. It concedes that Member States may reintroduce temporary border controls at the internal borders for reasons of public policy or internal security, such as a reaction to the risk posed by a contagious disease, but it specifies that such controls should be applied in a proportionate manner and with due regard to the health of the individuals concerned, and that persons who are clearly sick should not be refused entry but appropriate measures should be taken. It further underlines that

[814] European Council and Council of the EU, *10 things the EU is doing to fight COVID-19*, *op. cit*.
[815] EC, *Timeline of EU action*, *op. cit.*
[816] European Council and Council of the EU, *10 things the EU is doing to fight COVID-19*, *op. cit*.
[817] EC, *Guidelines for border management measures to protect health and ensure the availability of goods and essential services, op. cit*.

non-discrimination between Member States' own nationals and resident European Union-citizens must be ensured[818].

Internal borders

In order to contain the spread of COVID-19, some European Union Member States have reintroduced internal border controls, and some have even shut them[819].

Under the Schengen Borders Code, in the event of a serious threat to public policy or internal security, Member States can temporarily reintroduce border control at the internal borders, but it must be an exception, it must respect the principle of proportionality and it should only be used as a measure of last resort[820]. Moreover, in the guidelines for border management measures, the European Commission acknowledges that Member States can, in a proportionate non-discriminatory manner and with due regard to the health of the individuals concerned, reintroduce temporary border controls at the internal borders as a reaction to the risk posed by a contagious disease[821].

In the Joint European Roadmap towards lifting COVID-19 containment measures, it has been recognised that the reintroduction of internal border controls has been necessary to slow down the spread of the virus, but also that it has severely impacted the functioning of the Single Market and limited the free movement of people, therefore making a phased, gradual and coordinated approach for the reopening of the internal borders necessary[822].

On 13 May, the European Commission issued a communication on tourism and transport[823] presenting a set of guidelines and recommendations to help Member States gradually and safely

[818] *Ibidem.*
[819] Hasselbach, C., *Coronavirus and the EU: The nation versus the union?, op. cit*.
[820] EC, *Temporary Reintroduction of Border Control*, *op. cit.*
[821] EC, *Guidelines for border management measures to protect health and ensure the availability of goods and essential services, op. cit*.
[822] EC, *Joint European Roadmap towards lifting COVID-19 containment measures*, *op. cit*.
[823] EC, *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. Tourism and transport in 2020 and beyond, op. cit.*

lift travel restrictions[824]. The communication was accompanied by a package providing guidance and recommendations to inter alia safely restore transport and connectivity and safely resume tourism services[825]. The package also included a communication providing guidance and recommendations to safely restore unrestricted free movement and reopen internal borders, in which the European Commission set out a three-phases process[826] for lifting restrictions to free movement and internal border controls across the European Union[827]. The process towards the lifting of travel restrictions and internal border controls should be based on a defined set of criteria[828], shall be carried out in a non-discriminatory and coordinated way, and should be flexible, in that it should allow for the reintroduction of certain measures if needed[829].

In a video conference on 5 June 2020, Home Affairs Ministers acknowledged that all Member States were in the process of gradually lifting internal border controls and fully restoring the free movement of persons[830], and in the third assessment of the temporary restriction on non-essential travel to the European Union of 11 June, the European Commission observed that several Member States had already finalised the lifting of restrictions to free movement and

[824] EC, *Travel and transportation during the coronavirus pandemic: Safely resuming travel*, *op. cit.*

[825] EC, *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. Tourism and transport in 2020 and beyond, op. cit.*

[826] Phase 0, the current state of play, in which most Member States have introduced temporary internal border controls; Phase 1, moving towards the restoration of freedom of movement by partially lifting restrictions and controls at the internal borders; and Phase 2, general lifting of restrictions and controls at the internal borders.

[827] European Commission (EC), *Communication from the Commission. COVID-19. Towards a phased and coordinated approach for restoring freedom of movement and lifting internal border controls,* C(2020) 3250 final, Brussels, 13 May 2020.

[828] The criteria on which the lifting of travel restrictions and internal border controls must be based on include: the assessment of epidemiological situations in the Member States; the possibility to apply containment measures, such as physical distancing; and proportionality, meaning comparing the benefits of maintaining restrictions with the economic and social considerations.

[829] EC, *Communication from the Commission. COVID-19. Towards a phased and coordinated approach for restoring freedom of movement and lifting internal border controls, op. cit*.

[830] Council of the European Union (Council of the EU), *Video conference of home affairs ministers, 5 June 2020,* in Meetings, 5 June 2020, available at https://www.consilium.europa.eu/en/meetings/jha/2020/06/05/.

internal border controls, and it encouraged the remaining Member States to finalise the process by 15 June 2020[831].

On 15 June, the European Commission launched 'Re-open EU', a web platform containing essential information on borders, available means of transport, travel restrictions, public health, safety measures and other practical information for travellers, with a view to help a safe relaunch of free movement and tourism across the European Union[832].

External borders

Having acknowledged that uncoordinated travel restrictions by individual Member States for their parts of external borders risked being ineffective, and having recognized that a temporary restriction of non-essential travel from third countries could only be effective if decided and implemented by Member States for all external borders at the same time and in a uniform manner, on 16 March the European Commission adopted a Communication[833] inviting the Schengen States[834] to adopt a coordinated decision to apply a temporary restriction of non-essential travel from third countries into the EU+ area[835] [836].

[831] EC, *Communication from the Commission to the European Parliament, the European Council and the Council on the third assessment of the application of the temporary restriction on non-essential travel to the EU*, *op. cit.*

[832] EC, *Travel and transportation during the coronavirus pandemic: Safely resuming travel*, *op. cit.*

[833] EC, *Communication from the Commission to the European Parliament, the European Council and the Council. COVID-19: Temporary restriction on non-essential travel to the EU*, *op. cit.*

[834] "The Schengen Area encompasses most European Union States, except for Bulgaria, Croatia, Cyprus, Ireland and Romania. However, Bulgaria, Croatia and Romania are currently in the process of joining the Schengen Area. Of non-EU States, Iceland, Norway, Switzerland and Liechtenstein have joined the Schengen Area." Retrieved from European Commission (EC), *Schengen Area,* in Migration and Home Affairs, available at https://ec.europa.eu/home-affairs/what-we-do/policies/borders-and-visas/schengen_en.

[835] "The "EU+ area" includes 30 countries: 26 out of the 27 EU Member States as well as the four Schengen Associated States: Iceland, Liechtenstein, Norway and Switzerland. Ireland does not currently apply the travel restriction." Retrieved from European Commission (EC), *Travel and transportation during the coronavirus pandemic: Travel restrictions,* in Coronavirus response, available at https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/travel-and-transportation-during-coronavirus-pandemic_en#travel-restrictions.

[836] EC, *Communication from the Commission to the European Parliament, the European Council and the Council. COVID-19: Temporary restriction on non-essential travel to the EU*, *op. cit.*

On 17 March, the European Council endorsed the European Commission's Communication and agreed to reinforce the European Union's external borders by applying a coordinated temporary restriction of non-essential travel from third countries for a period of 30 days[837].

To assist Member States in the implementation of these restrictions, on 30 March the European Commission adopted guidance providing advice and practical instructions[838]. The European Commission recognized that under the Schengen Borders Code[839] it is possible to refuse entry to non-resident third-country nationals where they present relevant symptoms or have been particularly exposed to risk of infection and are considered to be a threat to public health, but it also underlined that any decision to refuse entry must be proportionate, non-discriminatory and respectful of the human dignity of the persons concerned[840].

The temporary restriction of non-essential travel from third countries was initially meant to last for a period of 30 days, but based on the developments of the epidemiological situation, the European Commission acknowledged that the measures applied to fight the spread of the pandemic required more than 30 days to be effective and produce the desired results, and on 8 April it therefore issued a first assessment of the application of the temporary restriction inviting Member States to prolong them until 15 May[841]. It subsequently issued two other assessments

[837] European Council, *Conclusions by the President of the European Council following the video conference with members of the European Council on COVID-19*, *op. cit.*

[838] European Commission (EC), *Communication from the Commission. COVID-19. Guidance on the implementation of the temporary restriction on non-essential travel to the EU, on the facilitation of transit arrangements for the repatriation of EU citizens, and on the effects on visa policy,* COM(2020) 2050 final, Brussels, 30 March 2020.

[839] European Parliament (EP) and Council of the European Union (Council of the EU), *Regulation (EU) 2016/399 of the European Parliament and of the Council of 9 March 2016 on a Union Code on the rules governing the movement of persons across borders (Schengen Borders Code),* OJ L 77, 23.3.2016, p. 1–52, 9 March 2016.

[840] EC, *Communication from the Commission. COVID-19. Guidance on the implementation of the temporary restriction on non-essential travel to the EU, on the facilitation of transit arrangements for the repatriation of EU citizens, and on the effects on visa policy, op. cit.*

[841] EC, *Communication from the Commission to the European Parliament, the European Council and the Council on the assessment of the application of the temporary restriction on non-essential travel to the EU, op. cit.*

of the application of the temporary restriction inviting Member States to further prolong the travel restriction until 15 June[842], and then until 30 June[843].

In the third assessment, the European Commission also put forward an approach for a gradual and coordinated phasing out of the travel restriction on non-essential travel from third countries[844]. Such approach is based on a set of common principles – non-discrimination, flexibility, common and coordinated approach[845] – and some criteria – the assessment of the epidemiological situation and response to COVID- 19 in the third country, the application of containment measures during travel, reciprocity and travel advice[846] – allowing to identify which third countries it is possible to lift the travel restriction with[847].

On 30 June 2020, the Council of the European Union issued a recommendation on the lifting of the temporary restriction on non-essential travel into the European Union affirming that Member States should gradually and coordinately lift them as from 1 July 2020 with regard to the residents of Algeria, Australia, Canada, China, Georgia, Japan, Montenegro, Morocco, New

[842] EC, *Communication from the Commission to the European Parliament, the European Council and the Council on the second assessment of the application of the temporary restriction on non-essential travel to the EU, op. cit*.

[843] EC, *Communication from the Commission to the European Parliament, the European Council and the Council on the third assessment of the application of the temporary restriction on non-essential travel to the EU*, *op. cit.*

[844] *Ibidem.*

[845] Non-discrimination means that residence should be the deciding factor to establish whether the restriction applies to a third-country national, and not nationality. Flexibility refers to the fact that travel restrictions can be reintroduced for a specific third country if the conditions in the checklist are no longer met. Common and coordinated approach means that decisions on lifting travel restrictions have to be taken in a coordinated way and should be implemented by all Member States for all external borders at the same time and in a uniform manner.

[846] Regarding the first criteria, i.e. the assessment of the epidemiological situation and response to COVID- 19 in the third country, the European Commission affirms that travel restrictions should be lifted only with third countries whose epidemiological situation is comparable or better than the average in the European Union. The second criteria, i.e. the application of containment measures during travel, entails that it is necessary to be able to ensure that containment measures, such as physical distancing, will be respected throughout the whole journey. The third and last criteria, i.e. reciprocity and travel advice, requires the third country to also lift travel restrictions towards the European Union.

[847] EC, *Communication from the Commission to the European Parliament, the European Council and the Council on the third assessment of the application of the temporary restriction on non-essential travel to the EU*, *op. cit.*

Zealand, Rwanda, Serbia, South Korea, Thailand, Tunisia and Uruguay[848]. On 6 August 2020, the Council of the European Union updated the list of countries for which travel restrictions should be lifted[849], establishing that as from 8 August 2020, Member States should gradually lift them with regard to the residents of Australia, Canada, China, Georgia, Japan, New Zealand, Rwanda, South Korea, Thailand, Tunisia and Uruguay[850].

Conclusion

Especially at the beginning, the COVID-19 has mainly been dealt with at the national level. Without clear guidance and coordination, despite their pledge to an ever-closer union, most European Union Member States have reacted selfishly and chaotically, taking gradual, sparse and inconsistent steps and adopting unilateral measures. As President von der Leyen has affirmed, "When Europe really needed to be there for each other, too many initially looked out for themselves. When Europe really needed an 'all for one' spirit, too many initially gave an 'only for me' response. And when Europe really needed to prove that this is not only a 'fair weather Union', too many initially refused to share their umbrella" [851].

The adoption of measures such as quarantines, school closures, suspension of economic activities and lockdowns has probably been best implemented at each national level, but at the

[848] Council of the EU, *Council Recommendation on the temporary restriction on non-essential travel into the EU and the possible lifting of such restriction*, *op. cit*.

[849] Council of the European Union (Council of the EU), *Lifting of travel restrictions: Council reviews the list of third countries*, in Press releases, 7 August 2020, available at https://www.consilium.europa.eu/en/press/press-releases/2020/08/07/lifting-of-travel-restrictions-council-reviews-the-list-of-third-countries/.

[850] Council of the European Union (Council of the EU), *Council Recommendation (EU) 2020/1186 amending Council Recommendation (EU) 2020/912 on the temporary restriction on non-essential travel into the EU and the possible lifting of such restriction*, ST/10095/2020/INIT, OJ L 261, 11.8.2020, p. 83–85, Brussels, 6 August 2020.

[851] European Commission (EC), *Speech by President von der Leyen at the European Parliament Plenary on the European coordinated response to the COVID-19 outbreak*, in Press corner, 26 March 2020, available at https://ec.europa.eu/commission/presscorner/detail/en/SPEECH_20_532.

same time other measures such as travel bans and border closures risked being ineffective or even dangerous if not enacted in a coordinated way, as measures adopted in a Member States generally have consequences in other Member States as well[852].

Moreover, it appeared clear that no Member State could handle the COVID-19 crisis on its own, and that there was thus a need for coordinated measures, to work together and for a joint European approach to deal with a cross-border health threat such as the COVID-19 pandemic. Although with some difficulties, the European Union has eventually undertaken actions in this regard, taking action in a variety of field, sustaining and helping Member States, coordinating their responses and providing practical advice and guidance.

[852] Renda, A., and Castro, R., *Towards stronger EU governance of health threats after the COVID-19 pandemic, op. cit.*

Final remarks

From the discussion on how the right to health and to healthcare has been acknowledged under international and European law, it emerges that the protection of health and the provision of medical assistance have been recognised as fundamentally important both at the international and at the European level.

What noticeably emerges is how the right to health is not intended as a right to be healthy, but rather as a right to the enjoyment of the highest possible standard of health attainable. Moreover, it appears that the right to health is inevitably linked to the right to healthcare, intended as the right to the enjoyment of the goods, facilities, services and conditions necessary for the realisation of the right to health. For this reason, even when the right to healthcare is not explicitly addressed, the right to health is to be intended as including it.

Although the right to health and to healthcare is acknowledged by the European Union, and consequently by its Member States, there are some differences in how individual Member States acknowledged it in their national constitutions, with some Member States not including it at all.

The differences in how the right to health and to healthcare is conceptualised influences, together with other factors, the way each national health system is structured. Indeed, although all health systems are made up of the same six fundamental building blocks, they are all deeply embedded in the specific social, cultural, political and economic context of their country, which influences and shapes their way of funding, providing and governing healthcare. Several typologies have been developed to try classify the various health system types, but no unique typology has been agreed on yet.

The European Union is composed of 27 different Member States, each with its own specific social, cultural, political and economic context. This variety is reflected in the existence of 27

separate national health systems, all based on a set of common values and principles, but still presenting considerable differences. Some health system typologies have been developed also for European Union health systems, which appear to be clustered in different typologies, thus not creating a European healthcare model.

The differences among European health systems are reflected in the differences in the state of health among the various Member States. Indeed, even though the European Union presents a generally good state of health, it is characterised by major health and healthcare gaps and inequalities across Member States. The state of health in the European Union clearly shows that a full realisation of the right to health and to healthcare in the European Union is still far from being a reality, especially for what concerns the right to the enjoyment of the goods, facilities, services and conditions necessary for the realisation of the right to health. A clear example is that, even though all Member States are committed to universal coverage of health services, they deal with health coverage in very different ways, providing different baskets of services on different basis to different population groups, and with some countries leaving out of coverage more than 10% of their population.

The existence of 27 different fairly independent and autonomous European national health systems, with the related differences in the state of health, can be explained by the fact that the definition of health policy and the organisation and delivery of health services and medical care are responsibilities of the individual Member States.

While this is understandable considering the different social, cultural, political and economic contexts of the various Member States, it risks hampering a full realisation of the right to health and to healthcare across the whole European Union as well as hindering the process of European integration. A single European health system is hardly conceivable due to the conspicuous differences between Member States, but greater harmonisation and convergence between European national health systems is advisable, with a view to reduce, and if possible eradicate, the gaps and differences in the state of health of the various Member States, such as those

concerning health coverage, thus moving towards a full realisation of the right to health and to healthcare across the whole European Union.

With the definition of health policy and the organisation and delivery of health services and medical care being responsibilities of the individual Member States, the European Union is mostly relegated to a role of coordination, support and completion of national health policies and actions.

However, even if only with a view to coordinate, support and complete Member States' national health policies and actions, the role of the European Union in the field of health and healthcare appears to be of fundamental relevance, especially with regard to those areas in which health and healthcare trespass national boundaries and involve more than one Member States, such as cross-border healthcare and serious cross-border threats to health.

Cross-border healthcare allows every person covered by the healthcare service of a Member State to receive medical treatment in all the other Member States, thus fostering the interaction, harmonisation and coordination of European health systems. Moreover, in allowing a patient to receive treatment in another Member States, it also helps addressing issues such as shortages of medical personnel or hospital beds and long waiting times. However, as it has emerged, cross-border healthcare is based on two legislative instruments appertaining to different and somewhat conflicting frameworks, which gives rise to the existence of a not perfectly coherent dual system of cross-border healthcare. Indeed, cross-border healthcare is based on the one hand on the framework of social security coordination and Regulation (EC) No 883/2004 on the coordination of social security systems, and on the other hand on the framework of the internal market with its economic freedoms and Directive 2011/24/EU on the application of patients' rights in cross-border health care. These two legislative instruments differ with regard to reimbursement of costs, prior authorisation, treatment that can be obtained abroad, and healthcare providers, and patients have the freedom to choose whichever system they want to

use, whether they want to access cross-border healthcare as socially insured persons or economic subjects.

The role of the European Union with regard to serious cross-border threats to health is also of fundamental importance in fostering the interaction and harmonisation of European health systems, and it shows the fundamental importance of coordination among Member States especially when health and healthcare trespass national boundaries and involve more than one Member States. An increasingly integrated European Union means population movements and supply chains, which make it easier for infectious diseases to trespass national borders. Since serious cross-border threats to health spread or entail a significant risk of spreading across the national borders of the Member States, they inevitably require coordination at European Union level and harmonisation of policies and measures. The responsibility to manage public health crises at national level still lies with each Member State, but it is necessary to ensure coordination and harmonisation among the various national measures to guarantee that such measures do not negatively affect other Member States and that a high level of human health is protected.

The European Union has been recently called to act with respect to its role in serious cross-border threats to health in the event of the COVID-19 pandemic, which has clearly shown the importance of a coordinated European action. Member States have initially reacted selfishly and chaotically, adopting different and sometimes conflicting responses and approaches, looking out for themselves and giving an ‘only for me' response, adopting measure that could even be potentially harmful for other Member States and hamper the proper functioning of the European Union. One of the clearest examples has been the imposition by some Member States of border controls at the internal borders, or even their total closure. However, it has appeared that no Member State can handle a cross-border health threat such as the COVID-19 pandemic on its own, and that a coordinating and harmonising European action is necessary. The European Union has indeed taken action with regard to the monitoring, early warning of and

combating COVID-19 in line with Decision No 1082/2013/EU on serious cross-border threats to health, and it has adopted measures in a variety of fields, including public health, the economy and borders and mobility, sustaining and helping Member States, coordinating their responses and providing practical advice and guidance to harmonise their actions.

Summing up the main conclusions that can be drawn from this work, it appears that, although a right to health and to healthcare is explicitly acknowledged in European law and thus by European Member States, its full realisation across the whole European Union is still far from being a reality. Indeed, as the health and healthcare gaps and inequalities demonstrate, the implementation of this right varies across Member States, depending on their conceptualization of it and their national health systems. The heterogeneity of European health systems is understandable considering the different national contexts, and a single European health system is currently hardly conceivable. However, in order to move towards a full realisation of the right to health and to healthcare across the whole European Union, the gaps and differences in the state of health of the various Member States need to be eradicated, or at least reduced, and this requires greater harmonisation and convergence of European national health systems and policies. Moreover, as in the case of cross-border healthcare and serious cross-border threats to health, in an always more integrated European Union health and healthcare can no longer be considered as merely national matters, and the fundamental role of the European Union in this regard has therefore to be strengthened and Member States national policies further coordinated and harmonised.

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Summary

Health can be considered as the most important component of everyone's life, as the most basic and essential asset of every human being. It has been defined by the World Health Organization as a state of complete physical, mental and social well-being, and it has been recognised as one of the fundamental rights of every human being.

The right to health is strictly connected to the right to healthcare, i.e. the enjoyment of the goods, facilities, services and conditions necessary for its realization, and when a right to healthcare is not explicitly mentioned, the right to health has to be intended as including it.

At the international level, the right to health is included in Article 25 of the Universal Declaration of Human Rights, which recognizes the right of everyone to a standard of living adequate for their health and well-being, and in the 1966 International Covenant on Economic, Social and Cultural Rights, which recognizes in Article 12 the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. This Article has been interpreted as also including the right to the enjoyment of the facilities, goods, services and conditions necessary for the realization of the highest attainable standard of health.

European Union Member States have an obligation to respect and implement the right to an adequate standard of living included in the Universal Declaration of Human Rights, and they have all ratified the International Covenant on Economic, Social and Cultural Rights, thus making the whole European Union bound to respect and promote the right to the enjoyment of the highest attainable standard of physical and mental health included in it.

The European Union has also recognized the right to health and to healthcare in its own legislation, and in particular in Article 35 of the Charter of Fundamental Rights of the European Union, which recognizes to everyone the right to access to preventive health care and to benefit from medical treatment, and in the European Social Charter, whose Article 11 recognizes to

everyone the right to benefit from any measures enabling him to enjoy the highest possible standard of health attainable. This Article has been interpreted as enshrining both the right to the highest possible standard of health and the right of access to healthcare. Moreover, in Article 13 the European Social Charter also grants anyone without adequate resources the right to social and medical assistance. Although the majority of the European Member States are bound by the European Social Charter, some countries have made declaration thereby not accepting all the provisions relating to health and healthcare, and some have either signed but not ratified it, or neither signed nor ratified it.

The right to health and to healthcare is often given remarkable protection also at the national level. Even if in different degrees, most European Member States have committed to the protection of the right to health and to healthcare, and, with few exceptions (Austria, Cyprus, Denmark, France, Germany, Ireland, Malta and Sweden), they all acknowledge and protect it in their national constitutions.

A full realisation of the right to health and to healthcare is inevitably linked to the existence of an adequate and effective health system, defined as consisting of all the activities whose primary purpose is to promote, restore or maintain health.

Every health system has the fundamental objectives of better health, fairness in financial contribution and responsiveness to people's expectations in regard to non-health matters, alongside the essential functions of stewardship, creating resources, delivering services and financing. These functions have been broken down into a set of six fundamental building blocks that make up every health system: service delivery; health workforce; information; medical products, vaccines and technologies; financing; and leadership and governance.

Even though every health system is made up of the same building blocks, there are no two exactly identical health systems. This is because health systems are deeply embedded in the social, demographic, cultural, political and economic context of their country, and therefore

each health system presents some peculiar characteristics that are the product of a multitude of country-specific factors.

The European Union is composed of 27 Member States, each with its own history and its own social, cultural, political and economic context, and this variety is reflected in the existence of 27 different national health systems. The European health systems are all built on a set of common values and principles, identified in a 2006 Council Conclusions as including universality, access to good quality care, equity and solidarity. Although they share common values and principles, European health systems differ considerably among each other, and they can be clustered in different health systems typologies, thus not forming a single European health model.

The heterogeneity of health systems within the European Union matches the differences in the state of health of the various Member States. Indeed, even though across the European Union the state of health is generally good, there are major health and healthcare gaps and inequalities across Member States, with some countries clearly still lagging behind in the process of ensuring a full realisation of the right to health and to healthcare.

These gaps and inequalities are particularly striking when considering health financing, healthcare accessibility and health coverage.

In 2016, across the whole European Union 41% of total health expenditure was financed through compulsory health insurance, 36% through government schemes, 18% through out-of-pocket payments and 4% through voluntary health insurance. The share of total health expenditure financed through government schemes ranged from 84% in Denmark and Sweden to 2% in Croatia; through compulsory health insurance from 78% in France and Germany to 5% or less in Cyprus, Denmark, Ireland, Italy, Latvia, Malta, Portugal, Spain and Sweden; and from out-of-pocket spending from 45% or more in Bulgaria, Cyprus and Latvia, to 16% or less in Belgium, Croatia, Czech Republic, Denmark, France, Germany, Ireland, Luxemburg, The Netherlands, Slovenia and Sweden.

Healthcare accessibility can be assessed on the basis of unmet needs and the availability of medical personnel and hospital beds. On average, in 2016 only 2.5% of European citizens reported unmet healthcare needs, but this share ranged from 0.2% in Austria and the Netherlands, to 15.3% in Estonia. One of the main reasons for unmet healthcare needs was financial barriers, with 4.2% of Europeans experiencing great difficulty in affording healthcare services, 8.4% experiencing moderate difficulties and 16.2% some difficulties. Particularly marked difficulties are experienced in Bulgaria, Cyprus, Greece, Hungary, Ireland, and Latvia. Financial barriers are often linked to excessive out-of-pocket payments, which may lead to catastrophic health spending, whose incidence ranged from 2% in France, Ireland, Slovenia and Sweden, to 8% in Greece, Hungary, Latvia, Lithuania, Poland and Portugal. With regard to healthcare availability, in 2016 across the European Union there were averagely 3.6 doctors per 1000 population, ranging from 6.6 in Greece to 2.4 in Poland; 8.4 nurses per 1000 population, ranging from 16.9 in Denmark to 3.3 in Greece; and 5.1 hospital beds per 1000 population, ranging from 8.1 in Germany to 2.3 in Sweden.

Overall in the European Union population coverage is very high, and in many cases universal or nearly universal. Nonetheless, some countries still have more than 5% of the population excluded from coverage, a share that goes up to 11% in Romania, 11.8% in Bulgaria and 17% in Cyprus. Moreover, even in countries with an almost universal population coverage, some population groups, such as irregular residents, homeless people and Roma people, might still be excluded from coverage. The differences in population coverage are explained by whether entitlement to coverage is be conditional on citizenship, on residence status - as in most countries with a tax-funded national health service system such as Italy and Sweden - or on employment status or payment of contributions - as in most countries with a social health insurance system, such as Romania. Despite these gaps in population coverage, most European countries guarantee coverage for some essential healthcare goods and services also to groups not covered by the statutory system. Moreover, benefit packages tend to be relatively

comprehensive across the European Union, even though basic health coverage generally leaves out of coverage some benefits and, in many cases, coverage involves a certain degree of cost-sharing. In order to receive additional coverage, in some countries it is possible to purchase a private insurance, which plays virtually no role in some countries, such as Sweden (0.1%), but is purchased by a considerable share of the population in Belgium (82.7%), France (95.5%), the Netherlands (87.3%) and Slovenia (84.3%).

As the state of health of the European Union clearly shows, there are still some countries lagging behind in the process of full realization of the right to health and to healthcare, and it appears that there is a discrepancy between a common recognition of and commitment to the right to health and to healthcare and the existence of different health systems.

The existence of 27 fairly independent and autonomous European national health systems is linked to the fact that health and healthcare are primarily a responsibility of the individual Member States. Indeed, Article 168 of the Treaty on the Functioning of the European Union establishes that each European Union Member State is responsible for the definition of its national health policy and for the organisation and delivery of health services and medical care, thus relegating the European Union to a role of coordination, support and completion of national health policies and actions.

To fulfil this role, the European Union has adopted health legislation in some areas and a European Commission's Directorate-General for Health and Food Safety has been established, alongside other Directorates-General playing an indirect role in the field of health and healthcare, such as the Directorate-General for Employment, Social Affairs and Inclusion, whose responsibilities include social security coordination in cross-border healthcare.

The role of the European Union in the field of health and healthcare appears to be of fundamental relevance especially with regard to those areas in which health and healthcare trespass national boundaries and involve more than one Member State, making the coordination and an at least partial harmonisation of European health systems and policies inevitable.

Examples of such areas are cross-border healthcare and serious cross-border threats to health. Cross-border healthcare allows every person covered by the healthcare service of a Member State to receive medical treatment in all the other Member States, thus fostering the interaction, harmonisation and coordination of European health systems. Moreover, in allowing a patient to receive treatment in another Member States, it also helps addressing issues such as shortages of medical personnel or hospital beds and long waiting times. Cross-border healthcare encompasses all those situations in which a patient is treated in a Member State different from the one in which he is insured, and it applies to unexpected and emergency situations as well as planned care. It is regulated by Regulation (EC) No 883/2004 on the coordination of social security systems and Directive 2011/24/EU on the application of patients' rights in cross-border health care.

Regulation (EC) No 883/2004 on the coordination of social security systems aims at simplifying and clarifying the rules on the coordination of social security systems, and it guarantees that insured persons do not lose their social protection when moving to another Member State. It applies to all the nationals of a European Member State, and it covers all areas of social security, including the provision of medically necessary and urgent healthcare treatments during a temporary stay outside the competent Member State and the possibility of receiving planned healthcare treatments in a Member State other than the competent one.

Directive 2011/24/EU on the application of patients' rights in cross-border health care allows European citizens to obtain health services in another European Member State and be reimbursed for the costs incurred as long as the treatment and the costs involved would be covered in their own national health system. It applies to the provision of healthcare regardless of how it is organised, delivered and financed, with the exception of long-term care, organ transplants and public vaccination programmes, and its main aim is to ensure patient mobility with a view to improve the functioning of the internal market and the free movement of goods, persons and services.

The coexistence of Regulation (EC) No 883/2004 and Directive 2011/24/EU has created a dual system of cross-border healthcare, which is based on one hand on the framework of social security coordination, and on the other hand on the framework of the internal market. This dual system leaves patients the freedom to choose which system they want to use, whether they want to access cross-border healthcare as socially insured persons or as economic subjects. The main differences between Regulation (EC) No 883/2004 and Directive 2011/24/EU concern reimbursement of costs and prior authorisation: while Regulation (EC) No 883/2004 is based on direct healthcare and considers prior authorisation as the rule, Directive 2011/24/EU is based on indirect healthcare and considers prior authorisation as the exception.

The other health area in which the coordinating role of the European Union is clearly fundamental is serious cross-border threats to health, as they spread or entail a significant risk of spreading across the national borders of the Member States.

Although the responsibility to manage public health crises at national level lies with each Member State, it is necessary to ensure coordination among the various national measures to guarantee that such measures do not negatively affect other Member States and that a high level of human health is protected. In line with this, Article 168 of the Treaty on the Functioning of the European Union explicitly requires the European Union to take action in the monitoring, early warning of and combating serious cross-border threats to health, although always with a view to complement national policies.

The European Union has been recently called to act with respect to its role in serious cross-border threats to health in the event of the COVID-19 pandemic.

First identified in China in December 2019, COVID-19 has rapidly spread to the world, and on 11th March 2020 it was declared a global pandemic by the World Health Organization. By mid-March 2020, Europe had become the epicentre of the COVID-19 pandemic, reporting over 40% of globally confirmed cases. As of 23 September 2020, the European Union reported 2 547 342

cases, out of the 31 658 573 reported worldwide, and 144 999 deaths, out of the 971 869 reported worldwide.

The crisis brought about by the diffusion of coronavirus has been dealt with in the European Union at a communitarian level as well as at the national levels.

Despite their pledge to an ever-closer European Union, Member States have initially reacted selfishly and chaotically, adopting different and sometimes conflicting responses and approaches, looking out for themselves and giving an ‘only for me' response, adopting measures that could even be potentially harmful for other Member States and hamper the proper functioning of the European Union. The most evident case has been the reintroduction of border controls at the internal borders and in some cases even their complete closure.

Although the severity and timing of the measures taken in response to the COVID-19 pandemic varied from country to country, most Member States have however adopted relatively similar measures. Some European Union Member States, such as Italy, Spain and France, have imposed national lockdowns, while others, such as Denmark, Germany, Luxemburg and Malta, have limited their response to the introduction of strict restrictions, banning or limiting events, imposing a limit on the number of people allowed to gather, and shutting down or limiting the functioning and opening hours of bars, restaurants and non-essential stores. A unique case within the European Union has been Sweden, which still implemented some social distancing measures, but deployed fewer restrictions than any other European Union Member States.

However, it soon became clear that no Member State could handle a cross-border health threat such as the COVID-19 pandemic on its own, and that a coordinating and harmonising European action was indispensable.

The European Union has taken action with regard to the monitoring, early warning of and combating COVID-19 in line with Decision No 1082/2013/EU on serious cross-border threats to health, and it has adopted measures in a variety of fields, sustaining and helping Member

States, coordinating their responses and providing practical advice and guidance to harmonise their actions.

Alongside fighting disinformation on COVID-19, putting forward a Joint European Roadmap towards lifting COVID-19 containment measures, and issuing guidelines to facilitate the transfer of patients from one Member State to another, help qualified medical personnel to offer their assistance in other Member States and ease the pressure on overburdened national health systems, the European Union has taken action in response to the COVID-19 pandemics with regard to public health, the economy and borders and mobility.

In the field of public health, the European Union's response has been mainly focused on providing medical guidance, ensuring the provision of medical equipment, and developing a vaccine strategy. An advisory panel on COVID-19 to formulate science-based guidelines for the European Union response has been set up, some joint procurement procedures allowing member states to make joint purchases of equipment and testing kits have been launched, and a strategic RescEU medical stockpile and distribution mechanism has been created. A cornerstone of the European Union's response in the field of public health has consisted of the development and distribution of an effective and safe vaccine against the COVID-19. In this regard, the European Union has developed a common strategy to accelerate the development, manufacturing, and deployment of vaccines against COVID-19, adopted a regulation relaxing the rules on the conduct of clinical trials with and supply of medicinal products containing or consisting of genetically modified organisms intended to treat or prevent COVID-19, and concluded exploratory talks with several pharmaceutical companies, reaching a first agreement with AstraZeneca on 14th August 2020.

The European Union has also adopted a comprehensive economic response to the COVID-19 pandemic. It has applied the full flexibility of the European Union fiscal rules; revised its State Aid rules allowing Member States to provide direct support for hard hit companies and small firms; set up a Coronavirus Response Investment Initiative to provide liquidity to small

businesses and the healthcare sector; launched a Support mitigating Unemployment Risks in Emergency initiative to protect jobs and workers; agreed on the establishment of a European Stability Mechanism's Pandemic Crisis Support; and provided support to the tourism, agricultural, wine, fruit and vegetables sectors. Moreover, on 21st July the European Union leaders agreed on a comprehensive recovery package of €1 824.3 billion aimed at mitigating the effects of the COVID-19 pandemic, combining a recovery effort and the European Union budget for 2021-2027.

The European Union's response to the COVID-19 pandemic has also encompassed borders and mobility. In this regard, the European Union has taken action to help Member States in providing consular support and repatriating their citizens from third countries under the European Union Civil Protection Mechanism, and adopted guidelines for an integrated approach to an effective border management to protect health and ensure the availability of goods and essential services, and thus the integrity of the Single Market. It has also issued a set of guidelines and recommendations to help Member States gradually and safely lift travel restrictions, inter alia providing guidance and recommendations to safely reopen internal borders and restore unrestricted free movement across the European Union. Moreover, it has adopted a temporary restriction of non-essential travel from third countries into the EU+ area, and subsequently put forward an approach for a gradual and coordinated phasing out of such restriction.

As cross-border healthcare and serious cross-border threats to health clearly highlight, in an always more integrated European Union, health and healthcare can no longer be considered as merely national matters, and especially in those areas in which health and healthcare trespass national boundaries and involve more than one Member State, the fundamental role of the European Union has to be recognised and strengthened. A single European health system is hardly conceivable due to the conspicuous differences between Member States, but greater harmonisation and convergence between European national health systems is advisable in order

to allow for greater European coordination, also with a view to eradicate, or at least reduce, the gaps and differences in the state of health of the various Member States, moving towards a full realisation of the right to health and to healthcare across the whole European Union.