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Bartłomiej
Oręziak

TELEMEDICINE

The Right to Health from the Perspective of Cross-Border Medical Services Provision in the European Union

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Telemedicine
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List of abbreviations

ACHPR	African Charter on Human and Peoples' Rights
CG	Constitution of Greece
CH	Constitution of Hungary
CJEU	Court of Justice of the European Union
CKB	Constitution of the Kingdom of Belgium
Commission Implementing Decision on COVID-19 Data Exchange and Alerting	Commission Implementing Decision (EU) 2020/1023 of 15 July 2020 amending Implementing Decision (EU) 2019/1765, which addresses the cross-border exchange of data between national contact tracing and warning mobile applications with regard to combatting COVID-19
Commission Implementing Decision on eHealth Network	Commission Implementing Decision 2019/1765 of 22 October 2019 which provides the rules for the establishment, management and functioning of the network of national authorities responsible for eHealth as well as repealing Implementing eHealth, the management and operation of that network, and repealing Implementing Decision 2011/890/EU
Convention Against Discrimination Against Women	Convention on the Elimination of All Forms of Discrimination against Women
Convention on Cybercrime or Budapest Convention	Convention on Cybercrime of 23 November 2001
Convention on Human Rights and Biomedicine	Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine
CoRoB	Constitution of the Republic of Bulgaria
CoRoC	Constitution of the Republic of Croatia
CoRoE	Constitution of the Republic of Estonia
CoRoF	Constitution of the Republic of Finland
CoRoI	Constitution of the Italian Republic
CoRoP	Constitution of the Republic of Poland
Council Directive 93/42/EEC	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

CRC	Convention on the Rights of the Child
CS	Constitution of Spain
CZ CFR	Charter of Fundamental Rights and Freedoms (Czech Republic)
Decision On Serious Cross-border Threats To Health	Decision No 1082/2013/EU of the European Parliament and the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC
Directive on Patient's Rights in Cross-border Healthcare/DPRCH	Directive 2011/24/EU of the European Parliament and the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare
Directive on the Recognition of Professional Qualifications	Directive 2005/36/EC of the European Parliament and the Council of 7 September 2005 on the recognition of professional qualifications
EC	European Community
ECSC	European Coal and Steel Community
EEC	European Economic Community
ESC	European Social Charter
EU CFR	Charter of Fundamental Rights of the European Union
EU	European Union
EURATOM	European Atomic Energy Community
GDPR	Regulation (EU) 2016/679 of the European Parliament and the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC
Guidelines on EU Emergency Assistance on Cross-Border Cooperation in Healthcare related to the COVID-19 crisis	Communication from the Commission Guidelines on emergency EU assistance for cross-border cooperation in healthcare related to the COVID-19 pandemic crisis
Healthcare	Healthcare, including medical care
Human Blood Directive	Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting quality and safety standards for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC

Human Tissues and Cells Directive	Directive 2004/23/EC of the European Parliament and the Council of 31 March 2004 on setting quality and safety standards for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells
ICESCR	International Covenant on Economic, Social and Cultural Rights
Introduction to the CoFR of 1946	Introduction to the Constitution of the French Republic of 27 October 1946
Maastricht Treaty/TEU	Treaty on European Union of 7 February 1993
Medical Device Regulation	Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
Member State of Affiliation	The EU Member State in which the patient is entitled to receive healthcare services in accordance with the state's legislation
Member State of Treatment	The EU Member State on whose territory healthcare is actually provided
Merger Treaty	Treaty establishing a Single Council and a Single Commission of the European Communities of 8 April 1965
PC	Act of 6 June 1997 Penal Code
Regulation 883/2004	Regulation (EC) No 883/2004 of the European Parliament and the Council (EC) of 29 April 2004 on the coordination of social security systems
Regulation 987/2009	Regulation (EC) No 987/2009 of the European Parliament and the Council of 16 September 2009 laying down the procedure for implementing Regulation (EC) No 883/2004 on the coordination of social security systems
Regulation on Medicinal Products	Regulation (EC) No 726/2004 of the European Parliament and the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency
San Salvador Protocol to the ACHRC	Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights
SEA	Single European Act of 17 February 1986

Services Directive	Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market
TEAEC	Treaty establishing the European Atomic Energy Community of 25 March 1957
TEC	Treaty establishing the European Community
TECSC	Treaty establishing the European Coal and Steel Community of 18 April 1951
TEEC	Treaty establishing the European Economic Community of 25 March 1957
TEU	Treaty on European Union
TFEU	Treaty on the Functioning of the European Union
Tobacco Products Directive	Directive 2014/40/EU of the European Parliament and the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC
Treaty of Amsterdam	Treaty of Amsterdam amending the Treaty on European Union, the Treaties establishing the European Communities and certain related acts of 2 October 1997
Treaty of Lisbon	Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community of 13 December 2007
Treaty of Nice	Treaty of Nice amending the Treaty on European Union, the Treaties establishing the European Communities and certain related acts of 26 February 2001
UDHR	Universal Declaration of Human Rights
UN Charter	Charter of the United Nations
USA	United States of America
WHO	World Health Organisation

Introductory remarks

Description of the research problem and methodology

The currently perceived technical, technological, and civilisational advances that are associated with the application of modern technologies for practical use are increasingly transforming traditional solutions into innovative alternatives. This state of affairs forces practitioners and legal theorists to react in order to adapt or create a legal framework that is effective in the changing reality. The law should normatively regulate technical or technological innovations in such a way that problems or risks associated with implementation are limited and the development of laws is not impeded. Legal sciences, therefore, has an important role in this process as both a knowledge source and a conceptual base for legislators. Legal research and analysis should be increasingly sensitive to changes in the external world to safeguard both the legitimate interests of those who participate in legal transactions and the system that protects human rights and freedoms, which has been developed over decades.

The purpose of this monograph is related to the right to health from the perspective of cross-border provision of telemedicine services in the European Union, which fits into the above research area. It is an uncommon issue that deserves an in-depth study presented in the form of a monograph. In addition, the conclusions resulting from an in-depth analysis may be more interesting as the subject or scope of the study has not yet been exhaustively explored by other legal science researchers. This lack of exploration is likely due to the specificity of the subject matter and the combination of topics in question; the right to health and the cross-border provision of telemedicine services are typically examined independently rather than in relation to each other.

This monograph aims to analyse the potential of telemedicine solutions and determine which more fully realize the right to health from the chosen research perspective. This study must therefore demonstrate the potential of telemedicine use to protect, support, and strengthen the realisation of the individual's right to health. The essential research question of this work will therefore examine the relevance, place, systematics, role, essence, goals, characteristics, specificity, and functions of telemedicine in the implementation of the right to health from the perspective of cross-border provision of telemedicine services in the European Union.

In addition, possible risks or problems associated with the realisation of the right to health by telemedicine remain relevant to the study will thus be defined. The issues analysed in this monograph may therefore have important theoretical and practical relevance. In addition, this monograph asks whether, at the current stage of civilizational, technical, technological, as well as legal development, telemedicine can be treated as a new and modern means of supporting the realization of the right to health in a more complete scope, or at least one which has not been examined thus far. This issue, which constitutes the key scientific dilemma of this monograph, is closely related to the realisation of the study's main objective.

Achieving the main objective of the monograph and answering the fundamental scientific dilemma posed in it would not be possible without defining subsidiary objectives. These include, first, a semantic approximation of the terminology used in the context of modern technologies that are used in medicine, including an indication of the possibility of certifying digital medicine solutions and a presentation of the benefits and risks of telemedicine. Second, it is important to indicate the scope and significance of the right to health in the European Union, which also includes the presentation of the concept of the right to health *in genere*. Third, the conditions, principles, and interpretation of the law in the context of cross-border provision of healthcare services in the European Union will be analysed, which will directly lead to demonstrating whether it is possible to qualify telemedicine services as services within the meaning of European Union law. Fourth, the problems involved in realizing the right to health and the functioning of cross-border healthcare in the European Union during the COVID-19 pandemic will be presented, together with a proposal for their solution. Fifth, solutions will be identified that will level out the phenomenon of telemedicine cybercrime, which poses a threat to the realisation of the right to health in telemedicine. Fulfilment of the subsidiary objectives should make it possible to gather the information necessary to effectively realise the research problem and answer the fundamental scientific dilemma of the study.

The totality of the above observations leads to the proposed thesis of the monograph: which is based on the idea that telemedicine should be conceived as a new and modern means of supporting the realisation of the right to health in a more complete or at least existing scope. To prove this thesis, this monograph will scientifically analyse the three fundamental issues contained in its title.

The first issue is how modern technologies are put to practical use in medicine. The 21st century has seen a dynamic development in civilization and technology. This affects the daily lives of the vast majority of the global population, which is shifting from traditional solutions to modern alternatives. Most areas of human life have already encountered or are encountering the potential benefits as well as the threats of modern technology. Neither law nor medicine are exempt from this phenomenon; both can benefit from new, effective, safe, and innovative solutions that increase the possibility of achieving their most important goals more widely, faster, more universally or equally, and sometimes at a lower expense; each of these

possibilities should be primarily focused on the value of life and care for human health. Telemedicine is both one of these solutions and the main analytical axis of this monograph. Appropriate legislation should, among other things, guarantee that the modern medical technologies put into practical use are in fact safe, serve the purposes assumed and declared by their creators, and remain in compliance with and implement the current legal standards. These standards include various norms in the protection of human rights, particularly those that are directly related to human health. Legal regulations in this area should both consider the specificity of modern technologies put into practical use in medicine and adequately safeguard the legitimate interests of the subjects of legal transactions. In this respect, legal science has an important role to play, which should indicate, through research and analysis, the desired direction for practice and legislation.

The second issue is the concept of the right to health. It is worth emphasising that all modern solutions derived from the issue of modern technologies put into practical use in medicine should be compatible with the subject of the right to health and support the realisation of this right. Therefore, it can be stated that the right to health, including the right to its protection, healthcare services, and its material and executive aspects, should determine the release of new and modern solutions in medicine. A proper understanding of the nature and definition of the relevant material scope of the right to health is of paramount importance for the effectiveness of the analysis in this monograph. In addition, it is no less important to pay attention to the image of the right to health in a non-traditional environment, i.e., in the eponymous digital environment, defined according to the scope, meaning, and essence of telemedicine and its role in medicine. The correlation of the analytical themes outlined here leads to the assertion that modern technologies put to practical use in medicine in the form of telemedicine must comply with the totality of human rights norms, and especially and primarily with those norms whose core directly shows a connection with the essence of telemedicine. Such rights appear to be those relating to human health. The realisation of the right to health thus justifies the use of telemedicine solutions and the use, creation, or adaptation of a legal framework for telemedicine solutions, such as the free movement of services within the European Union.

The third issue is the cross-border provision of healthcare within the European Union. In an era of advanced and barrier-free mobility of the population, including patients, one issue in realizing the right to health through the cross-border provision of health services within the European Union is of major importance. Determining the meaning, scope, and nature of these services and whether they fall within the scope of the EU freedom of movement of services in its internal market is important. At the same, there is significant importance in the scientific discourse related to patients' rights in cross-border healthcare and the ways that telemedicine as a form of healthcare service promoting efficiency, speed, equity of access, or universality of cross-border healthcare in the EU. These are important research areas requiring reference to a number of different sources and careful analysis

leading to conclusions on telemedicine, the concept of the right to health, and the substantive law of the European Union. Conclusions potentially arising from this correlation may relate to the interpretation of EU law regarding the possibility of telemedicine services qualifying as services under European Union law. This has legally relevant implications for realizing the right to health through modern technology in cross-border and EU healthcare. In the context of these considerations, it is necessary not only to examine the role or function that telemedicine and its services may play or perform, in line with their potential, on this analytical plane; the meaning of the concept of telemedicine services also needs to be determined. It should therefore be noted that the issue of cross-border provision of telemedicine services in the European Union contains a combination of important research suppositions for the main objective of the monograph.

The formal–legal (linguistic–logical) method has been adopted as the principal research method in this monograph, which allows for a *de lege lata* analysis of the applicable law on the basis of an exegesis of the content of the legal act. The analysis in question is supplemented by the application of linguistic hermeneutics and the views of representatives of the doctrine (theoretical–legal method). In addition, the specificity of the research problem constituting the main objective of the work justifies the possibility, but not the necessity, of the complementary application of other methods as well, such as the sociological method (law as a social fact), the psychological method (law as a kind of mental experience, based on Leon Petrażycki), the axiological method (law as a value), and the statistical method (exclusively for descriptive-research purposes). Irrespective of the above, the legal comparative method is a research method that was considered and could be usable in this monograph. Through comparative law, by means of *de lege lata* analysis of Polish and foreign law, court rulings and opinions of doctrine representatives may lead to the discovery of legislative differences and similarities between various legal systems, which may inspire valuable conclusions. In the monograph, particular attention will be paid to the views of the doctrine of the law, which will be expressed using a wide range of international literature. Considering that the scientific statements in question were written at different times and in the context of different normative systems, they may provide the basis for numerous insights or conclusions that can enrich the scientific discourse in this work. In addition, heuristic and other research methods will be used when appropriate. When conducting scientific research, it is important to determine the correct methodological approach through the selection of appropriate methods, but in terms of the quality of legal analysis, it is no less important to maintain openness to externalities of national laws and legal doctrines along with objectivity and scientific integrity. The course of logical reasoning in this work will be mainly based on the deductive method, but the inductive method will not be excluded when its use benefits the research problem. The cognitive and interpretative functions and, subsidiarily, the didactic function have been considered as the purpose of the application of the research instrumentation described above.

The issues presented so far directly determine the structure of the monograph, which comprises five main research segments. These include modern technologies in medicine, the concept of the right to health in the European Union, cross-border healthcare provision in the European Union, problems in realizing the right to health and the operation of cross-border healthcare in the European Union during the COVID-19 pandemic, and telemedicine cybercrimes as a threat to the realisation of the right to health in telemedicine. *Prima facie,* the first three research segments are clearly characterised by a theoretical approach with relevant elements of research analytics. The other two, meanwhile, are characterised by a predominantly problem-based approach, where research analytics come to the fore and theoretical elements are presented as necessary. Identifying these research segments makes it possible to propose a specific structure for the chapters of this monograph by organising its subject matter into predetermined analytical areas.

The first chapter defines the terminology that is used regarding the concept of how modern technology is used during the practice of medicine throughout the monograph. It considers the necessary reporting elements as well as the monograph's contribution to the overall discussion on this topic in terms of existing literature and selected international or non-governmental organisations. This is done through the author's proposal regarding how modern technology can be used during the practice of medicine. The goal is to demonstrate, as precisely as possible, the scope of each subject and its internal correlation with concepts such as digital medicine, eHealth, mHealth, telehealth, sensory health, and medical informatics. Within the framework of these considerations, the author proposes a method that can unify and systematise the terminology used by introducing legal definitions in terms of EU law. In addition, the issue of certification of digital medical solutions is presented; this issue is important for both the theory and practice of law, particularly in the context of different types of modern technologies being implemented during the practice of medicine. The discussion also includes an interpretation of how a medical device is defined under EU law and the possibility of classifying digital medicine solutions as medical devices. In this context, a postulate concerning EU law is presented. An analysis of the concept of telemedicine, which constitutes the main research axis of this work, is also presented. As part of these considerations, the different definitions of telemedicine found in the literature and documents of international or non-governmental organisations is examined. This leads to an attempt to interpret the essence of telemedicine and its most important structural elements. The current and foreseeable future benefits and risks of telemedicine is also discussed. The chapter concludes with a concise summary containing the author's observations regarding its content and emphasising the normatively significant purpose of telemedicine as a new guarantor of the right to health protection and a modern tool for the implementation of the right to healthcare services.

The second chapter presents the scope and importance of the right to health in the European Union, including the concept of the right to health *in genere* as central to the main analytical axis of this monograph. Considerations related to

the object of the right to health are presented. Within this analytical designator, insights on the right to health as a determinant of modern technologies in medicine and outlines of the right to health protection and healthcare services are presented. In addition to the necessary reporting elements, a voice in the discussion with the representatives of the doctrine is proposed for the author's examination of the right to health based on the division of this topic into the right to health protection and healthcare services, including medical care, along with the proper definition of healthcare services' normative character. The deviations that relate to the correlation of the essence of the right to health protection and healthcare services, which should lead to proposing the material and executive aspect of the right to health, are also important. In addition, a historical outline of the right to health in the primary law of the European Union is presented, where the points of reference are the legal situation both before and after the Maastricht Treaty, singling out observations on the significance of the Lisbon Treaty as the next stage in the evolution of European integration. The research question of the possibility of historically establishing direct and indirect references to the subject of the right to health in the primary law of the European Union becomes the object of analysis in this case. The manifestations of the right to health in the current law of the European Union are also approached. This is done by indicating the provisions of the Charter of Fundamental Rights of the European Union, the Treaty on the Functioning of the European Union, and the Treaty on European Union, reflecting the object of the right to health and identifying selected manifestations of its concretisation in the secondary law of the European Union. The purpose of this discourse is to show the level of significance of these provisions in the system of Union law in the context of the right to health. Next, considerations related to the right to health in telemedicine are presented. In this context, the author's definition of the specific functions of telemedicine in the right to health is proposed, taking into account the division between the right to health protection and healthcare services, including medical care. These functions provide the basis for postulation within the scope of Polish and international law. Considerations related to the relationship of telemedicine with the requirement of equal access to healthcare services are also presented. The chapter concludes with a concise summary containing the author's observations concerning the issues discussed in the chapter and emphasising, above all, an important condition for the provision of telemedicine services that guarantees and implements the right to health. This condition focuses on enhancing equality of access to healthcare services, including medical care, through cross-border provision.

The third chapter analyses the conditions, principles, and interpretation of the law in the context of cross-border provision of healthcare services in the European Union. It also directly demonstrates whether it is possible to define telemedicine services as services within the meaning of European Union law. Considerations of a general nature concerning the internal market in the light of the free movement of services are presented. Attention is turned towards the characteristics of the internal market *in genere*, the outline of the free movement of services, and the EU definition

of a service. As part of these observations, in addition to the necessary reporting elements, an element of the discussion is highlighting the importance of the issues presented in terms of the main research area of this work. In particular, observations regarding the normative character of the treaty norms related to the freedom of movement of services are mentioned, where the need to establish a more complete relationship between the right to health and the cross-border provision of telemedicine services in the European Union is emphasised. The issue of the free movement of healthcare services is then analysed; the concept of healthcare service is proposed in this section. Building on these findings and considering other research positions and case law, the eligibility of healthcare services as services within the European Union internal market is examined. An integral complement to this is a discussion of the possibility of introducing restrictions on the free movement of healthcare services, including in the light of the proportionality test of the Court of Justice of the European Union. These observations form the basis for further conclusions, in particular those concerning cross-borderism, which is understood as an alternative solution. After that, the issue of patients' rights in cross-border healthcare is discussed. Here, the focus is on both the cross-border rights of patients and the obligations of the Member States of the European Union. This allows for the consideration of telemedicine as a subject of cross-border healthcare. This section also includes an analysis of telemedicine services in cross-border healthcare; a definition of telemedicine services is proposed, and an attempt to establish the eligibility of telemedicine services as a service of the European Union internal market is made. The chapter ends with a concise summary containing the author's observations on the issues raised within the chapter and emphasises two selected and current scientific problems arising from the implementation of the right to health and related to cross-border provision of telemedicine services in the European Union.

The fourth chapter presents the problems related to implementing the right to health and the functioning of cross-border healthcare in the European Union during the COVID-19 pandemic in the context of how telemedicine services can be implemented across borders, along with a proposal for a solution to these problems. First, a general characterisation of the COVID-19 pandemic is made, consisting of the main events related to it, its statistics, and a history of the development of COVID-19 vaccines. This is followed by a discussion of the impact of COVID-19 on the legal system, including a discussion of the law as an instrument for combating the pandemic. In this respect, the legal measures against COVID-19 adopted in selected European Union Member States are be presented, and the actual possibility of exercising the powers of individuals in the reality of the pandemic is outlined. Importantly, the findings so far allow the problems that constitute the main point of reference for this chapter to be identified. The problem of exercising the right to health during a pandemic and the problem of the operation of cross-border healthcare under the same conditions is presented. It should be emphasised that this analysis should provide a basis for interpreting and naming the core of these problems. In this way, the desirable characteristics that should characterise the

object of solutions to the defined problems are established. This is also supported by the conclusions drawn from the analysis of the actions taken by the European Union to offset the negative impact of the COVID-19 pandemic on the functioning of cross-border healthcare. In addition, proposals are made to address the realisation of the right to health and how cross-border healthcare in the European Union functions under pandemic conditions. The chapter ends with a summary containing the author's observations on the matter under discussion and an outline of *de lege ferenda* postulates for the legislator.

The fifth chapter establishes solutions to mitigate the phenomenon of telemedicine cybercrime as a threat to the realisation of the right to health through telemedicine. To this end, it mainly identifies ways to respond before and after a telemedicine cybercrime is committed. These solutions aim to protect and strengthen the ability of telemedicine to help realise the right to health. Insights related to the theoretical characteristics of telemedicine cybercrime are presented, turning attention towards the impact of telemedicine cybercrime on the right to health and referring to the concept of cybercrime and the term telemedicine cybercrime. Furthermore, the types of telemedicine cybercrimes that can be interpreted from the relevant public international law norms are analysed. In this regard, a method for determining specific types of telemedicine cybercrimes and their types are presented. Subsequently, the issue of telemedical evidentiary acts that can be interpreted using relevant norms of public international law are analysed. Here, too, a method for determining the types of telemedical evidentiary acts is indicated, together with the specific types of such acts. This is followed by a proposal for the standardisation of telemedicine systems containing two main demands. The first is the standardisation of telemedicine service IT systems on the basis of the types of telemedicine cybercrimes, and the second is the standardisation of telemedicine service IT systems on the basis of the types of telemedicine evidentiary acts. In this context, a proposal for EU law is also presented. The chapter concludes with a summary containing the author's observations on the matter under discussion and an outline of *de lege ferenda* postulates for the legislator.

The monograph concludes with a comprehensive summary of the findings and conclusions for the future.

Reason for choice of topic

There are many reasons that the topics in this work, such as the concept of the right to health, the application of modern technology for practical use in medicine, and the cross-border provision of healthcare services in the European Union, should be examined. Therefore, it is necessary to present several of the most relevant motives behind the choice of topic for this work.

First, these issues are part of the current technical, technological and civilisational progress. Modern developments touch and, in part, determine human life in

many aspects. Law as a field is no exception, nor is medicine in its broadest sense. For this reason, it is essential to study, analyse, and constructively consider new solutions for these issues so that, even as their positive aspects are revealed, negative consequences can be identified and eliminated.

The second reason, which is closely related to the first one, is the need to establish the predisposition of modern technologies to realise human rights protection norms as much as possible. The topic of this work is the application of modern medical technologies from the perspective of realising the right to health. It is therefore reasonable to determine whether the use of telemedicine actually supports or sustains the functioning of the traditionally understood healthcare system and the realisation of the right to health.

Third, the current demographic projections of modern countries clearly indicate a progressive ageing of the population. This has an undeniable effect on the capacity of traditional healthcare systems. Telemedicine, as an innovative method of providing healthcare services, including cross-border services, aimed at increasing the efficiency of providing services as well as the accessibility and quality of services. Telemedicine attempts to support the work of medical personnel, and thus the entire healthcare system. Such a solution allows for the efficient and Europe-wide use of existing human, financial, and material resources. This justifies examining the main issue of the paper in terms of modern technologies whose aim is presumed to be strengthening and supporting the functioning of healthcare systems and realising the right to health to the highest scope possible.

Fourth, it is necessary to analyse the concept of the right to health and its key elements, namely the rights to health protection and healthcare services and to deepen the research on the subject matter. Such an analysis may lead to new conclusions or a different perspective on the insights already presented in the literature. In particular, the right to health as a determinant of modern technologies in medicine, where the standard of protection should be an essential element that legitimises the practical use of such solutions and the creation or proposal of new legal frameworks.

Fifth, it is important and legitimate to analyse the traditionally understood concept of the right to health in terms of the application of telemedicine as a specific type of modern technology put to practical use in medicine. The main issue of this work should help determine the role of telemedicine in the right to health and whether telemedicine can in fact be seen as a new guarantor of the right to health protection or as a modern tool for realising the right to healthcare services. In this respect, the relationship of telemedicine to equal access to healthcare services is also important. It is therefore important for legal science to determine the function of telemedicine in the right to health.

Sixth, the European Union is emerging as a geographical area where traditional national borders are beginning to lose their meaning due to existing EU freedoms, including the freedom of movement of services; this is crucial for the point of view of this monograph's research goal. The above observation sufficiently justifies the choice

of topic for the monograph, including the analysis of the implementation of the right to health through the use of modern medical technologies increasing the popularity of cross-border healthcare. This need arises not only from the current factual state of affairs, but also from the legal state existing in the European Union, including its primary and secondary law. The existing trends and directions of European integration therefore demonstrate the importance of the analysis presented in this monograph, as it addresses some of the priorities of the EU's current activities.

The seventh reason, which is related to sixth, is that a legal framework for cross-border healthcare is currently in place within the European Union. Combining that with the contemporary trends of European integration, the topic of this work is important for examining the conditions, principles and interpretation of EU law in the context of cross-border provision of healthcare services in the European Union to prejudge or further confirm the normative character of the treaty norms of the freedom of movement of services. This allows for the determination of whether healthcare services, in the proper sense of the word, benefit from the freedom of movement of services within the internal market of the European Union. This determination is critical as its findings may alter the perception of the legal situation. Also, there is a need to establish or demonstrate the sensitivity of the current legal framework in terms of cross-border healthcare in the EU to ensure that it appropriately addresses modern developments in the medical field. In this context, it becomes important to determine whether it is legally possible to qualify telemedicine services as services within the meaning of European Union law. Determining the principles of the interface between law and modern medical technology is also an important aim of this monograph.

Eighth, it is generally necessary to face current problems and threats in the field of legal sciences in terms of this paper's topic as these problems and threats often result from changes in the external world. There are also problems from traditional legal institutions, where the solution may be a specific type of modern technology put into practical use. However, some risks may directly result from the implementation and practical use of modern technology. This work aims to determine if telemedicine may both constitute a solution to the problems currently occurring in the right to health and be a source of specific threats.

Ninth, examining the topic of this paper is useful because representatives of legal sciences have not sufficiently explored it, most likely due to the topicality of the analysed matter and its innovation. As a rule, these fields have not been juxtaposed in the literature to date; instead they have been treated as independent from each other. This makes addressing the issue even more relevant.

Finally, it should be noted that exploring this issue can also be justified by the axiological background present in the world of science. This background is characterised by the intrinsic value of investigating, analysing, or determining what is known or unknown, but not exhaustively explored. This value can be described as cognitive, and it carries a certain evaluative load in terms of the work's topic because, clearly, not every innovative or modern method, measure, instrument, or

solution has exclusively positive consequences. The benefits of these types of solutions always outweigh the risks or problems associated with their implementation. At the same time, not every innovative or modern solution has only negative consequences and, in addition, the risks or problems associated with the implementation of such a solution always outweigh its benefits. In such cases, it is usually necessary to weigh the positive and negative aspects of an innovation and, from the perspective of the issue at hand, modern technologies put to practical use in medicine. Hence, the assessment of the usefulness of a specific solution should be obligatorily preceded by a reliable, consistent, objective, and correct analysis using appropriate research methods. This analysis should lead to specific conclusions diagnosing the degree of intensity of either positive or negative levels of innovative or modern solutions. This diagnosis, within the framework of the issue addressed in this monograph, should allow for a clear, essentially unconditional verdict on the validity of the implementation of telemedicine from the perspective of the realisation of the right to health. Without such an analysis, the assessment of innovative or modern solutions would be subjective and even arbitrary or unfair.

The reasons outline above fully justify the need to analyse this issue, which combines, in a pioneering manner, the coexistence of the right to health, the application of modern technologies for practical use, and the cross-border provision of healthcare services in the European Union.

The body of doctrine

An analysis of the subject presented and to the extent indicated would not have been possible without the extensive use of the body of doctrine, particularly the international literature. Examining the papers that correlated with the main research aim of this paper, it should be noted that they include a wealth of thought and knowledge and are also incredibly diverse. The specificity of the scientific problem addressed in this monograph, which requires a complex scientific analysis, is responsible for this state of affairs. To achieve the main objective of the study and answer the fundamental scientific dilemma presented herein, a complete analysis of the already described subsidiary objectives is first required. Understanding their perspective requires adopting an attitude that is open to the multidimensionality, multifacetedness, or multigenicity of the matter under study, which seems to directly determine the peculiarity, especially the mentioned diversity, of the doctrinal output used. Justification can be sought in the structure of this work. Each chapter corresponds to one of the paper's main objectives, leading to an understanding of the main objective and answering the fundamental dilemma of the study. Moreover, it constitutes a separate and, in principle, independent scientific issue having *in abstracto* its own already established and quite numerous bibliographical sources. Consequently, in presenting the body of literature related to the issue in this paper, it is important to remember that it consists of at least five essential thematic segments.

First, the literature examined is delineated by sources valuable to the analysis of modern technologies in medicine. It is possible to identify positions that make it possible to propose a systematisation of the application of modern technologies used in medicine. We examine the existing literature to determine the meaning and material scope of various concepts, such as digital medicine[1], eHealth[2], mHealth[3], telehealth[4], sensory health[5], and medical informatics[6], together with their mutual correlation. Sources regarding the certification of digital medicine solutions, including the qualification of medical devices as a certification system, the interpretation of the definition of a medical device, and the classification of digital medicine solutions as a medical device[7], were also important in this segment. Literature related

1 Görlitz, Kaltenbach and Herzig, 2013, p. 4.; Lupton, 2013, p. 257.; Elenko, Underwood and Zohar, 2015, pp. 456-461.; André, 2019, p. 4.; Austin and Kusumoto, 2016, pp. 51-52.; Greene and Lea, 2019, pp. 480-485.; Nash et al., 2017, pp. 2527-2531.; Ince et al. 2014, pp. 74-83.; Ramo et al., 2014, pp. 58-64.; Hamilton, 2019, p. 3.; Ramesh et al., 2004, p. 334.; Buch, 2018, p. 143.; Bache, Flear and Hervey, 2013, pp. 7-46.; Tallacchini, 2017, pp. 9-38.

2 Frączkowski, 2005, pp. 54-58.; Lipowicz, Świerczyński and Szpor (eds), 2019.; Batko, 2012, pp. 95-113.; Bujnowska-Fedak, 2013, pp. 302-317.; Czerwińska, 2013, pp. 539-551.; Janyszek and Frączkowski, 2006, pp. 60-63.; Furmankiewicz, Sołtysik-Piorunkiewicz and Ziuziański, 2016, pp. 46-61.; Terry, 2000, pp. 605-607.; Mars and Scott, 2010, pp. 237-243.; de Pietro and Francetic, 2018, pp. 69-74.; Oh et al., 2005, pp. 34-35.; Barbabella et al., 2017, p. 7.; Sood et al., 2007, pp. 257-268.

3 Santosh et al., 2013, pp. 228-231.; Luxton et al., 2011, pp. 506-508.; Mechael, 2009, pp. 103-106.; Gagnon et al., 2016, pp. 212-216.; Paglialonga et al., 2019, p. 6.; Istepanian, Laxminarayan and Pattichis, 2006, p. XXIII.; Sezgin, 2018, p. 1.; *mHealth*…, 2011, p. 6.; *From Innovation to Implementation*…, 2016, p. 41.; Al-Azzam and Alazzam, 2019, pp. 173-174.; Dwivedi et al., 2016, pp. 174-176.; Silva et al., 2015, pp. 265-267.

4 Dorsey and Topol, 2016, pp. 154-160.; Koch, 2006, pp. 565-576.; Weinstein et al., 2014, pp. 183-187.; Van Dyk, 2014, pp. 1279-1298.; Maimone et al., 2012, pp. 791-793.; Wang et al., 2014, pp. 314-324.; Faison et al., 2001, p. 338.; Roffer, 2017, p. 207.; Kim, 2010, p. 66.; Edirippulige, 2009, p. 271.; Raza et al., 2018, p. 523.; Brennan and Starren, 2006, p. 536.; Martin-Khan et al., 2017, p. 174.; LaFramboise et al., 2003, pp. 275-288.; Castolo and Camarinha-Matos, 2005, pp. 149-150.; Držanič et al., 2019, p. 252.; Chuang and Tsai, 2012, p. 237.; Afsarmanesh et al., 2004, pp. 211-212.

5 Gao et al., 2020, pp. 55-56.; Surya and Ravi, 2020, p. 207.; Babović et al., 2011, p. 262.; Nordin et al., 2011, p. 306.; Jo et al., 2010, pp. 552-553.; Han, 2011, p. 20.; Zhang, 2008, p. 583.; Fragoulis, Tsagaris, and Anastassopoulos, 2009, pp. 320.; Venkatasubramanian et al., 2005, p. 406.

6 Choctaw, 2008, p. 47.; Huang, 2009, p. 1423.; Closa et al., 2010, p. 155.; Venot et al., 2014, pp. 3-4.

7 Marković, 2006, pp. 364-365.; Seelman, Hartman and Yu, 2014, pp. 136-137.; Abdmeziem and Tandjaoui, 2015, p. 39.; Zúquete, Gomes and Cunha, 2008, p. 484.; Chávez, Krishnan and Finnie, 2009, pp. 740-741.; Wąsik and Wąsik, 2015, pp. 27-39.; Poździoch, 2012, pp. 59-85.; Zhelyazkova and Torenvlied, 2009, pp. 35-62.; Komárek, 2007, pp. 87-98.; Toshkov, 2008, pp. 379-402.; König and Luetgert, 2009, pp. 163-194.; Kaeding, 2006, pp. 229-253.; French-Mowat and Burnett, 2012, pp. 22-28.; Mantovani and Bocos, 2017, p. 256.; Alsaadi et al., 2019, p. 585.; Osiejewicz, 2017, pp. 362-370.; Kornobis-Romanowska, 2007, pp. 45-63.; Niedźwiedź, 2004, pp. 6-10.; Górski, 2008, pp. 30-32.; Barta and Markiewicz, 2016, pp. 528-531.; Helios and Jedlecka, 2018, p. 126.

to the concept of telemedicine and referring to the definition of telemedicine and its essence and basic building blocks[8] is also considered. The last pillar deals with the benefits and risks of telemedicine[9]. The literature reviewed in this part of the study should enable a semantic approximation of the terminology used in the context of this work along with an analysis of the accompanying issues.

The literature used also consists of sources on the right to health in the European Union. The important value of the materials that allow for the conceptualisation of this topic and refer to it as a determinant of modern technologies in medicine,[10] and to the rights to health protection[11] and healthcare servic-

8 Adelakun and Garcia, 2019, p. 85.; Otto, 2001, p. 106.; Cohendet, Valignon and Sylla, 1998, p. 191.; Klar and Pelikan, 2011, p. 1119.; Zimpfer, 1999, p. 77.; Linkous, 2001, p. 226.; de Lucena et al., 2013, p. 129.; Argy and Caputo, 2001, p. 227.; Shaw, 2009, pp. 13-18.; Bhattacharyya, 2017, p. 6.; Spradley, 2001, p. 291.; Reynolds, 2019, p. 4.; Dafoulas et al., 2017, p. 340.; Mohr et al., 2019, p. 255.; Lynn, 2019, p. 107.; Melton et al., 2019, p. 253.; Simmons, Hamilton and McDonald, 2008, p. 163.; European Commission, 2018, p. 25.; Raskas et al., 2017, p. 206.; Czarnucha et al., 2015, pp. 13-21.; Maziarz, 2010, pp. 33-35.; Ben-Assuli, 2015, pp. 287-297.; Kalra, 2006, pp. 136-144.; Hodge, Gostin and Jacobson, 1999, pp. 1466-1471.; Dumortier and Verhenneman, 2013, pp. 25-56.; Christiansen et al., 2017, pp. 1234-1239.; Peters and Khan, 2014, pp. 515-522.; Ries and Moysa, 2005, pp. 18-25.; Warren, 2007, pp. 374-388.; Helsper, 2012, pp. 403-426.; Bach, Shaffer and Wolfson, 2013, pp. 247-266.; Porter, 2010, p. 2478.

9 Hailey, Roine and Ohinmaa, 2002, pp. 1-7.; Reed, 2005, pp. 176-180.; Dimmick et al., 2000, pp. 124-135.; Berman and Fenaughty, 2005, pp. 559-573.; Miyahara et al., 2006, pp. 691-697.; Bilalović, Paties and Mason, 1998, pp. 91-93.; Hancock, 2000, pp. 306-307.; Wible, 2003, pp. 1577-1623.; Sinrod and Reilly, 2000, pp. 1-53.; Speer, 2000, pp. 259-273.; Gercke, 2009, pp. 409-420.; Brenner and Schwerha, 2004, pp. 111-114.; Hilley, 2005, pp. 171-174.; Moitra, 2005, pp. 435-464.; Wang, 2007, pp. 216-223.; Chung et al., 2006, pp. 669-682.; Boni, 2001, pp. 18-19.; Clough, 2014, pp. 698-736.; Gercke, 2004, p. 802.; Cyriax, Wilson, and Wilson, 2009, p. 46.; Clough, 2010, p. 50.; Kerr, 2003, p. 60.; Jakobsson and Ramzan, 2008, p. 3.

10 Jasudowicz, 2010, pp. 491-495. Also worth noting: Evans, 2002, pp 197-215.; Jamar, 1994, pp 17-35.; Leary, 1994, pp. 24-56.; Waldenström et al., 1972, pp. 117-182.; Jain, Leka, and Zwetsloot 2018, pp. 139-173.; Gunn, 2008, pp. 3-7.; Amzat and Razum, 2018, pp. 17-33.; Libal and Harding, 2015, pp. 19-37.; Montgomery, 1992, pp. 184-203.; Pestova, 2014, pp. 341-372.; Iguiñiz, Palomino, and Barboza, 2014, pp. 313-337.; McAuley, 2014, pp. 373-401.; Walker, 2014, pp. 165-192.; Evans, 2014, 233-257.; Heus and Sartawi, 2014, pp. 193-229.; Munesue, 2014, pp. 121-132.; Qiu, 2014, pp. 97-120.; Rawaf and Hassounah, 2014, pp. 135-163.; Wu, 2019, pp. 457-469.; Oke, 2016, pp. 91-122.; France, 2014, pp. 335-352.; Oke, 2017, pp. 311-326.; Claude, 1989, pp. 19-38.; Mann et al., 1994, pp. 6-23.; Braveman and Gruskin, 2003, pp. 539-545.; Mann, 1997, pp. 6-13.; Pogge, 2005, pp. 182-209.; Mann, 1995, pp. 229-233.

11 Urbaniak, 2008, p. 99.; Surówka, 2012, p. 91.; Zubik, 2008, pp. 112-121.; Staśkiewicz, 2011, pp. 21-83.; Karpińska and Karp 2012, pp. 51-118.; Mycielski, 1947, pp. 9-10.; Trócsányi and Króliczek, 2017, p. 133.; Piechota, 2010, pp. 137-142.; Zoll, 2000, p. 8.; Mikos and Urbaniak, 2016, pp. 160, p. 166.; Ryś, 2017, p. 119.; Surówka, 2009, p. 395.; Piechota, 2012, pp. 93-102.; Rex, 1980, pp. 391-403.; Sarnecki, 2002, p. 1.; Banaszak, 2002, p. 27.; Zawadzka, 1996, p. 9.; Karp, 2007, p. 150.

es[12] should be emphasised. The literature also includes items addressing the historical outline of the right to health in the primary law of the European Union, such as the legal situation both up to and following the Maastricht Treaty, with a separate section on the Lisbon Treaty[13]. The above has also provoked examination of the literature on the right to health in current European Union law. We refer to the reflection of the right to health in EU CFR, TFEU, and TEU, as well as the concretisation of this right in secondary law[14]. This part of the study highlighted the issue

12 Arras, 1984, pp. 23-45.; Childress, 1984, pp. 47-70.; Kluge, 2002, pp. 29-48.; Cummiskey, 2004, pp. 187-202.; Green, 2004, pp. 203-221.; Toebes and San Giorgi, 2014, pp. 403-436.; Sass, 1991, pp. 243-255.; Halper, 1991, pp. 135-168.; Marmor, 1991, pp. 23-49.; Agich, 1991, pp. 185-198.; Daniels, 1991, pp. 201-212.; Engelhardt, 1991, pp. 103-111.; Buchanan, 1991, pp. 169-184.; Beauchamp, 1991, pp. 53-81.; Merrill, 1994, pp. 99-128.; Mpedi, 2020, pp. 77-100.; Tu, 2019, 59-84.; Kirchner, 2018, pp. 141-151.; Holder, 1989, pp. 161-172.; Sulmasy, 2008, pp. 25-36.; Tomossy, 2008, pp. 341-352.; Serwach, 2011, p. 20.; Lach, 2011, p. 178.; Baka, 2010, pp. 124-125.; Dercz and Rek, 2012, p. 41.; Bujny, 2007, pp. 109-110.; Jarosz-Żukowska, 2014, p. 660.; Ostrzyżek, 2005, p. 65.; Jończyk, 2005, p. 110.

13 Van Panhuys et al., 1968a, pp. 655-705.; Glockner and Rittberger, 2012, pp. 16-47.; Paxton, 1976, pp. 161-192.; Walsh and Paxton, 1975, pp. 61-66.; Bouscaren, 1969, pp. 106-114.; Harvey, 1974, pp. 99-101.; Van Panhuys et al., 1968b, pp. 752-888.; Chilver, 1984, pp. 239-242.; Van Panhuys, (1968c), pp. 706-751.; Nelson, 1958, pp. 36-64.; Van Panhuys et al., 1968d, pp. 889-904.; Laursen, 2012a, pp. 77-97.; Weil, 1967, pp. 57-65.; Dinan, 2012, pp. 124-146.; Noël, 1991, pp. 57-63.; Moravcsik, 1994, pp. 211-233.; Wessels, 1991, pp. 143-160.; de Ghellinck, 1988, pp. 133-156.; Contogeorgis, 1993, pp. 33-38.; Mazzucelli, 2012, pp. 147-179.; Jordan, 2002, pp. 79-96.; Watson, 1997, pp. 49-65.; Dehousse, 1997, pp. 15-32.; Bierbach, 2017, pp. 301-345.; Stubb, 2002, pp. 58-105.; Zbinden, 1998, pp. 207-241.; Vanhoonacker, 2012, pp. 180-195.; Hug and König, 2006, pp. 133-150.; Maurer, 2006, pp. 115-133.; Dinan, 2012, pp. 124-146.; Beneyto, 2008, 1-19.; Laursen, 2012, pp. 196-216.; Phinnemore, 2013, pp. 1-15, pp. 211-228.; Murray, 2012, pp. 179-189.; Ziller, 2008, 309-335.; Ziller, 2012, pp. 244-268.; Stajano, 2009, pp. 269-307.; Jahn, 2015, pp. 141-156.; Wouter, Coppens, and De Meester, 2008, pp. 143-203.; Ponzano, 2008, pp. 135-141.; Hecker, 2015, pp. 1-6.; Quisthoudt-Rowohl, 2013, pp. 107-111.; Pernice, 2008, pp. 235-256.; Louis, 2008, pp. 285-298.; Häde, 2012, pp. 421-441.; de Witte, 2008, pp. 79-108.

14 Craig and De Búrca, 2015, pp. 105-124.; Weatherill, 2016, pp. 24-73.; Berry, Homewood, and Bogusz, 2019, pp. 87-122.; Bradley, 2014, pp. 103-104.; Arnull, 2017, pp. 3-18.; Storey and Turner, 2014, pp. 1-21.; Curtin, 2018, pp. 10-14.; Davies, 2013, pp. 54-56.; Gianfrancesco, 2012, pp. 295-310.; Blanke, 2012, pp. 159-232.; Pérez de las Heras, 2017, pp. 117-139.; Kerikmäe, 2014, pp. 5-19.; Eriksen and Stubberud, 2017, pp. 229-252.; Balsamo, 2018, pp. 99-170;. Bisset, 2012, p. 356.; Smith, 2015, p. 129.; Bussata, 2017, p. 200.; Kenner, 2014, p. 203.; Elgard, 2018, p. 22.; Di Federico, 2011, pp. 15-54.; Szpunar, 2019, pp. 123-134.; Kostoris, 2018, pp. 67-98.; Bernardeau, 2017, pp. 133-143.; Nußberger, 2006, pp. 592-593.; Vermeulen, 2012, p. 34.; Neegaard, 2011, p. 23.; Hellmann, 2019, p. 195.; Biernat, 2012, p. 31.; Biernat, 2011, p. 9.; Barnard, 2016, p. 559.; Maletić, 2013, p. 68.; Engel, 2018, pp. 20-27.; Hijmans, 2016, pp. 266, 317-326.; Lopp, 2013, p. 241.; Ciotti, 2013, p. 57.; Flear, 2015, p. 40.; Nistor, 2011, p. 300.; den Exter and Hervey, 2012, pp. 25-26.; Garben, 2019 pp. 1445-1456.; Guy and Sauter, 2017, p. 30.; Geber, 2015, p. 153.; Bosek, 2011, pp. 138-139.; Földes, 2019, pp. 216-221.; Jarman, 2013, pp. 110-125.; Blanke, 2013, pp. 45-109.; Baeten and Palm, 2013, p. 398.; Costigliola, 2012, p. 239.; Fløistad, 2018, p. 47.; Marušič, Rupel and Mihelj, 2017, pp. 154-155.; Cappelletti, 2015, pp. 254-255.; Evans-Brown and Sedefov, 2018, pp. 5-6.; Švedas, 2021, pp. 134-138.; Engelhart, 2021, p. 54.; Foltea, 2020, pp. 67-70.;

of the right to health in telemedicine. It has allowed for an analysis of telemedicine as a new guarantor of the right to health protection and a modern tool for realising the right to healthcare services. It has also allowed for analysis of the relationship that exists between telemedicine and equal access to healthcare services. Using this literature helps to establish the scope and meaning of the right to health in the EU, which includes the presentation of the concept of the right to health *in genere* as having a key significance for the main analytical axis of this work, as well as the place of telemedicine in the right to health.

An important part of the body of doctrine used in this monograph consists of bibliographical items relating to the cross-border provision of healthcare services in the European Union. Within the framework of these considerations, sources related to the internal market in the light of the free movement of services were used, which made it possible to characterise the internal market *in genere,* the outline of the freedom of movement of services, the EU definition of a service, and the normative character of the treaty norms for the freedom of movement of services[15]. These findings provided the apex for further discourse on the main topic. This section includes the body of literature related to the concept of healthcare services, the qualification of healthcare services as internal market services in the EU, and the restrictions on the free movement of healthcare services and cross-borderism as an alternative in the free movement of healthcare services[16]. The acquis used also includes items thematically linked to patients' rights in cross-border healthcare and the obligations of the Member States of the European Union and telemedicine as

de Oliveira and Pereira, 2015, pp. 231-244.; Rynning, 2009, pp. 277-313.; Migliaccio and Pintus, 2012, pp. 287-299.; Tiedemann and Sethe, 2013, pp. 1139-1171.; Dederer, 2016, pp. 139-168.; Müllner and Eichler, 2010, pp. 19-31.; Chowdhury, 2014, pp. 121-139.; Stornaiuolo, 2005, p. 50.

15 Rama Murthy, Evans and Sarkis, 2019, pp. 54-55.; Voogsgeerd, 2004, p. 278.; Curzon, 2011, p. 125.; Czermińska, 2016, p. 63.; Szewczyk, 2016, p. 76.; Tomaszewski, 2003, p. 109.; Oliver and Roth, 2004, p. 407.; Łacny, 2020, p. 157.; Koikkalainen, 2019, pp. 121-124.; De Somer, 2019, p. 195, p. 210, pp. 251-277.; Barnard, 2019, p. 44.; Barnard and Peers, 2020a, p. 1032.; Shuibhne, 2013, p. 302.; Öberg, 2020, p. 332.; Amtenbrink et al., 2019, p. 854.; Weiss and Kaupa, 2014, p. 360.; Syrpis, 2012, p. 386.; Zawidzka-Łojek and Łazowski, 2017, pp. 1-626.; Grzeszczak and Zawidzka-Łojek, 2015, pp. 1-434.; Barcz and Bacia, 2011, p. 1208.; Skibińska, 2014, pp. 1-746.; Barcik and Wentkowska, 2014, pp. 1-600.; Miąsik, Półtorak, and Wróbel (eds.), 2012, pp. 1-1342.; Kowalik-Bańczyk, Szwarc-Kuczer, and Wróbel, 2012, p. 1-1684.; Kornobis-Romanowska, Łacny, and Wróbel, 2012, pp. 1-1230.; Mavroidis, 2020, p. 87.; Barnard, 2020, p. 443.; Moens and Trone, 2010, p. 100.; Wiberg, 2014, p. 20.; van de Gronden, 2013, p. 125.; Foster, 2020, p. 312;. Foster, 2019, p. 377.

16 Gekiere, Baeten and Palm, 2010, pp. 506-508.; Maliszewska-Nienartowicz, 2006, pp. 59-82.; Emiliou, 1966, pp. 320.; de Búrca, 2000, p. 95., quoted by Maliszewska-Nienartowicz, 2006, p. 60.; Długosz, 2017, pp. 283-300.; Jacobs, 1999, pp. 1-23.; Tridimas, 2018, pp. 243-265.; Planzer, 2014, pp. 233-244.; Ostrowska, 2021, pp. 33-35.; Young et al., 2019, pp. 117-119; Krunke and Baumbach, 2019, p. 296.; Golec, 2018, pp. 162-163.

a subject of cross-border healthcare[17]. The literature cited so far has provided the impetus to explore the issue of telemedicine services in cross-border healthcare and made it possible to carry out an analysis related to the definition of the meaning of telemedicine services and their qualification as internal market services EU. The body of doctrinal work presented constitutes such a solid base of material that it should be possible to analyse the conditions, principles, and interpretation of the law in the context of the cross-border provision of healthcare services in EU. This also leads to directly demonstrating whether it is possible to qualify telemedicine services as services within the meaning of the EU's laws.

The relevant sources include literature relating to the problems of implementing the right to health and the function of cross-border healthcare in the EU during the COVID-19 pandemic. References to items based on their general characteristics, including thematic links to the most important related events, statistical data on the COVID-19 pandemic, and the issue of vaccination against COVID-19[18] are discussed. Next, sources relating to the issue of the law vis-à-vis the COVID-19 pandemic can be identified which analysed the law as an instrument to combat this threat, as well as legal measures taken to mitigate COVID-19 spread in selected Member States EU and the exercise of the individual's rights during the pandemic[19]. This part of the study also draws on the opportunities offered by the body of literature correlating the right to health and cross-border healthcare in the realities of the COVID-19 pandemic, which should result in valuable findings related to both the right to health and cross-border healthcare in these difficult circumstances, and in the EU countering the negative impact of COVID-19 on the functioning of cross-border healthcare[20]. The quantity and quality of the sources used should, within the framework of the issue under review, lead to an examination of two

17 Hervey and Mchale, 2015, pp. 184-211.; Goscinska, 2014, pp. 1-40.; McLean, 2013, pp. 35-40.; Meyer, 2013, pp. 83-103.; Forni, 2011, pp. 142-143.; Hervey and McHale, 2014, pp. 951-969.; McHale, 2011, p. 259.; Uścińska, 2013, pp. 307-346.; Nowak, 2018, pp. 36-44.

18 Akkoc, 2020, p. 169.; Li and Ito, 2021, pp. 490-491.; Bonotti and Zech, 2021, pp. 1-250.; Fong, Dey and Chaki, 2021, p. 10.; Yuan, 2021, pp. 70-76.; Cowan, Mar and Reich, 2021, pp. 1-3.; Gaia, 2021, pp. 11-37.; Rafajlowicz, 2021, pp. 195-215.; Tran, 2021, pp. 280-292.; Dash and Chakraborty, 2021, pp. 8-23.; Al-Hashemi, Zageer and Risan, 2021, pp. 3225-3234.; Pawar, Patil and Raut, 2021, pp. 253-266.; Sawant et al. 2021, pp. 133-155.; Do et al., 2021, pp. 737-752.; Liu et al., 2021, pp. 962-983.; Wang et al.; 2021, pp. 22-26.; Young et al., 2021, pp. 15-26.; Radlińska, 2020, pp. 113-126.; Niemczyk et al., 2020, pp. 19-27.; Stojczew, 2021, pp. 64-84.; Partyk, 2020, pp. 42-52.; Kruczalak-Jankowska, 2020, pp. 13-17.

19 Wielec, 2017, pp. 93-94.; Radzinska, 2014, pp. 58-68.; Bunikowski, 2013, pp. 757-765.; Hilpold, 2015, pp. 257-285.; Küçük, 2018, pp. 38-60.; Attané et al., 2021, pp. 137-159.; Fabiani et al., 2021, pp. 1757-1771.; Díez-Gutiérrez and Espinoza, 2021, pp. 1-24.; Pfeiffer-Ruiz and Schroder, 2021, pp. 46-49.; Landmesser, 2021, pp. 539-556.; Theoret and Ming, 2020, pp. 591-592.; Tarkar, 2020, pp. 3812-3814.; Rashid and Yadav, 2020, pp. 340-343.; Gori and Pahladsingh, 2021, pp. 561-577.; Lipiński, 2020, pp. 37-47.; Traczyk, 2020, pp. 132-141.; Manikowski, 2021, pp. 105-122.

20 Byszek, 2021, pp. 747-757.; Neergaard, 2021, pp. 213-217.; Golda-Sobczak, 2020, pp. 127-142.; Sobczak, 2020, pp. 7-22.

issues: the problems regarding realising the right to health and the functioning of cross-border healthcare in the EU during the COVID-19 pandemic in the context of the possibility of cross-border provision of telemedicine services in EU; and to concrete proposals for their solution.

Furthermore, those sources that deal with how telemedicine cybercrime threatens the realisation of the right to health in telemedicine are important in the present work. We refer here to items that have enabled a theoretical characterisation of telemedicine cybercrime, thus providing a basis for analysis related to how telemedicine cybercrime affects the right to health, the concept of cybercrime, and the term telemedicine cybercrime itself[21]. This provided an opportunity to present specific types of telemedicine cybercrimes and telemedicine evidentiary actions. Taken as a whole, the research in this area leads to the identification of solutions to offset the phenomenon of telemedicine cybercrime as a threat to the realisation of the right to health in telemedicine. The main reference here is to identify ways of responding before and after a telemedicine cybercrime is committed, aiming to protect and strengthen telemedicine's implementation of the right to health.

Taken together, the literature review used in this monograph should enable the main study objective to be achieved and its fundamental research question to be answered.

21 Filar, 2002, p. 25. cited by Tarapata, 2009, p. 133.; Frumento and Freschi, 2016, pp. 237-258.; Pollard, Karimi and Ficcaflia, 2017, pp. 308.; Luna et al., 2016, pp. 1-9.; Basile and Amate, 2011, pp. 486-490.; Wróbel, 2014, p. 75.; Siwicki, 2012, pp. 246-250.; Wasilewski, 2016, p. 149.; Chałubińska-Jentkiewicz, 2021, pp. 15-16.; Gordon and Ford, 2006, pp. 13-20.; Jaroszewska, 2017, pp. 10-13.; Zbrojewska et al., 2016, pp. 64-65.; Golonka, 2016, pp. 63-64.; Gruodytė and Bilius, 2014, pp. 217-249.; Ghosh, 2011, pp. 341-362.; Saini, Rao and Panda, 2012, pp. 202-209.; Jaishankar, 2007, pp. 7-9.; Wall, 2004, pp. 20-21.; Kshetri, 2006, pp. 33-39.; Abdullah, 2019, pp. 1540-1546.; Padmaavathy, 2019, pp. 1-9.; Boukemidja, 2018, pp. 34-44.; Lewandowski and Malinowski, 2003, p. 61.; Szymanek, 2004, p. 83.; Nieznański, 2011, pp. 108-114.; Wall, 2017, p. 537.; Holyst and Pomykała, 2011, p. 17.; Jibril et al., 2020, p. 149.; Warren et al, 2017, p. 541.; Suchorzewska, 2010, p. 152.; Clough, 2012, pp. 363-391.; Cangemi, 2004, pp. 165-171.; Weber, 2003, pp. 425-446.; Young, 2004, pp. 346-421.; Csonka, 2000, pp. 329-330.; Carr and Williams, 2002, pp. 83-90.; Moise, 2017, pp. 28-38.; Jonkisz, 2017, pp. 95-109.; Walden, 2004, pp. 321-336.; Katyal, 2001, pp. 1003-1114.; Simon, 1998, pp. 1015-1048.; Nuth, 2008, pp. 437-446.; Waltoś and Hofmański, 2015, p. 357.; Staszków, 2004, pp. 129-138.; Wójtowicz, 2004, pp. 43-70.

1

Emerging technologies in medicine

1.1 Introduction

This chapter aims to provide definitions of the terms used in this paper in the context of using modern technologies in medicine in practical ways. First, in addition to the necessary reporting elements, a voice in the discussion with doctrine and selected international or non-governmental organisations is presented by proposing an authorial systematisation of the practical use of modern technologies in medicine. The primary analytical objective is to identify the subject scopes as precisely as possible and then to determine their internal correlation, creating a foundation for further, more advanced inquiries. The issue of certification of digital medicine solutions, which is of relevance to both the theory and practice of law, is described, particularly in the context of systematising the practical application of modern technologies in the health sector. A certification system that determines what qualifies as a medical device is proposed, followed by an interpretation of the current definition of a medical device under the EU law and how digital medicine solutions can qualify. The present and foreseeable future benefits and risks of telemedicine are presented. These reflections allow for a creative analysis of the concept of telemedicine, which constitutes the main research axis of this work.

This chapter concludes with a succinct summary containing the author's observations on the issues raised therein and emphasising the normatively momentous purpose of telemedicine as a new guarantor of the right to health protection and a modern tool for implementing the right to healthcare services.

1.2 Systematics of the application of modern technology for practical use in medicine

1.2.1 Digital medicine

To use an appropriate methodological and logical approach, characteristic of analytical activity, it is appropriate to present a general concept related to how modern

technology is used during the practice of medicine[22]. This involves decoding a term that constitutes the foundation for further, more advanced theoretical considerations which will serve as a matrix for other, narrower subject-related concepts concerning specific uses of innovative technologies in medicine. Digital medicine can be considered as a concept that meets the above criteria because the literature emphasises that it is a general synonym for the digitalisation of the traditionally understood healthcare system[23]. All manifestations of the application of modern technologies during the practice of medicine therefore fit into this term, implying that digital medicine also includes the concept of e-health and the entire technical infrastructure, including subsidiarily supporting areas like large data sets[24] and the technologies that manage them[25], or artificial intelligence algorithms[26]. Digital medicine therefore encompasses a wide variety of services, and presenting a complete catalogue of these services is impossible; even providing an open catalogue is extremely difficult as the technical, technological, and civilisation progress of medicine is constantly increasing. This implies the avant-garde possibilities of medicine[27], where any catalogue of forms of application of modern technologies in practical use must be constantly updated. These changes mean there is no validity in trying to define the term 'digital medicine'. However, it can be noted that digital medicine includes, for example, the use of advanced and digitised health information systems, portable digital devices or biosensors[28], health applications for patients, medical consultations using tools in cyberspace[29], or creating electronic

22 The author's systematisation of the application of modern technologies for practical use in medicine was inspired by Görlitz, 2013, p. 4.
23 Lupton, 2013, p. 257.; Elenko, Underwood and Zohar, 2015, pp. 456-461.; André, 2019, p. 4.
24 Austin and Kusumoto, 2016, pp. 51-52.; Greene and Lea, 2019, pp. 480-485.
25 Nash et al., 2017, pp. 2527-2531.; Ince et al. 2014, pp. 74-83.; Ramo et al., 2014, pp. 58-64.
26 Hamilton, 2019, p. 3.; Ramesh et al., 2004, p. 334.; Buch, 2018, p. 143. In the context of the topic of artificial intelligence, it is worth mentioning the initiative taken by the European Union to issue a regulation on artificial intelligence. See Proposal for a Regulation of the European Parliament and of the Council, laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts (COM/2021/206 final).
27 Which also has an impact on the shape of the legal framework for the application of modern health technologies for practical use: Bache et al., 2013, pp. 7-46.; Tallacchini, 2017, pp. 9-38.
28 Their purpose, for example, is to continuously monitor a patient's wellbeing or physical functions. This issue raises the question of analysing the admissibility of the classification of sensors, applications and software related to digital medicine as medical devices: See the judgment of the Court of Justice of the European Union of 22 November 2012 in Case C-219/11 in Brain Products GmbH v BioSemi VOF, Antonius Pieter Kuiper, Robert Jan Gerard Honsbeek, Alexander Coenraad Metting van Rijn (ECLI:EU:C:2012:742).
29 It should be noted that Poland is one of the few countries where a legal definition of cyberspace has been adopted. It can be found in the Act of 29 August 2002 on martial law and the competences of the Commander-in-Chief of the Armed Forces and the principles of his subordination to the constitutional bodies of the Republic of Poland (consolidated text; Journal of Laws of 2017, item 1932): 'The cyberspace referred to in paragraph 1 shall be

medical databases[30]. Digital medicine thus represents the process of adapting the art of medicine and medical science to the realities of information and communication technologies (ICT); the intention to provide and scale the healthcare system for all stakeholders is the main aim of implementing and using advanced technologies. These technologies include providing medical services not only to patients, but also to consumers, which helps them manage their medical data.

In conclusion, given the issues raised above, it should be postulated *de lege ferenda* that the concept of digital medicine should be equated with all manifestations of applying modern technologies during the practice of medicine with the fields that support their function. It seems legitimate to conclude that, from this perspective, digital medicine will be a mirror image of the traditionally understood concept of medicine that includes a digital element.

1.2.2 eHealth

A concept with a slightly narrower scope than digital medicine is eHealth[31], which refers to medical services that are supported by ICT. The aim of such solutions is to increase the quality, safety, and accessibility of the medical services provided using modern technologies[32].

Many semantic proposals for the term are presented in the literature about eHealth[33]. Most readings agree that this term is general and encompasses healthcare services provided through ICT, such as electronic medical records, health information systems, remote monitoring and consultation services, or self-management and health data analysis tools[34]. Some proposals emphasise that eHealth refers several different topics, including: the electronicisation of healthcare; the use of modern technology by the public; health professionals and others to access health and lifestyle information; services and support; the use of ICT networks to improve a patient's health; or the convergence between cyberspace and the healthcare industry, which provides consumers with a wide range of healthcare-related information[35]. The World Health Organisation defines eHealth as the use of ICT

understood as the space for processing and exchange of information created by information and communication systems, as defined in Article 3(3) of the Act of 17 February 2005 on Informatisation of the Activity of Entities Performing Public Tasks (Journal of Laws of 2017, item 570), together with the links between them and the relations with users.'

30 Lupton, 2013, p. 257.
31 Lipowicz, 2019.; Frączkowski, 2005, pp. 54-58.; Batko, 2012, pp. 95-113.; Bujnowska-Fedak, 2013, pp. 302-317.; Czerwińska, 2013, pp. 539-551.; Janyszek et al., 2006, pp. 60-63.; Furmankiewicz et al., 2016, pp. 46-61.
32 Terry, 2000, pp. 605-607.; Mars and Scott, 2010, pp. 237-243.; de Pietro and Francetic, 2018, pp. 69-74.
33 Oh et al., 2005, pp. 34-35.
34 Barbabella et al., 2017, p. 7.
35 Oh et al., 2005, pp. 34-35.

for health, which provides an opportunity to advance public health by improving equity, solidarity, and quality of life and care[36]. The European Union, on the other hand, notes that eHealth is the combination of modern technologies with the objectives of traditional medicine, with possible benefits for stakeholders, including patients, health professionals, health institutions, and public authorities[37].

These different definitions imply that, due to the lack of a legal definition of eHealth, there are many semantic proposals[38] that do not support a clear understanding of the analysed issue, especially since the concept of digital medicine has already been defined. e-Health should not only be equated with the fields supporting and enabling the digital transformation of traditionally understood medicine, but the semantic boundary between the two concepts is difficult to clearly identify. It is only possible to recommend that eHealth services should not be equated with technical infrastructure that is invisible to the ordinary user. This has the merit of precisely defining the subject scopes of these semantically similar terms. From this view, eHealth would be the *de lege ferenda* external layer of digital medicine, i.e. it would represent its services to both medical staff and patients. Therefore, within the concept of eHealth, there is the possibility of defining more specific terms, such as mHealth, telehealth, and sensory health. The concept of eHealth can be considered the starting point for presenting terms related to how modern technologies are used in the practice of medicine. The multiplicity of implications in this case should not lead to pejorative assessments, as the solutions discussed here are intended to comprehensively map the possibilities of traditionally understood medicine, and which is more complex than it appears based on the terminology.

1.2.3 mHealth

mHealth is part of the overall concept of eHealth. mHealth refers to medical personnel performing tasks related to improving a patient's health using mobile tools, such as mobile phones, tablets, or other types of specialised portable medical devices[39]; these services are most commonly delivered via mobile applications. The literature notes that mHealth should be understood as the use of medical applications via mobile devices to remotely deliver, access or process medical data, provide medical services or support healthcare delivery[40]. The importance of mHealth

36 Fifty-Eighth World Health Assembly, A58/21, Provisional Agenda Item 13.17, eHealth. Report by the secretariat.
37 European Parliament resolution of 14 January 2014 on the e-health Action Plan 2012-2020: innovative healthcare for the 21st century (2013/2061[INI]) (OJ of the EU C 482, 23 December 2016, pp. 14-21).
38 Sood et al., 2007, pp. 257-268.; Oh et al., 2005, pp. 34-35.
39 Santosh et al., 2013, pp. 228-231.; Luxton et al., 2011, pp. 506-508.; Mechael, 2009, pp. 103-106.; Gagnon et al., 2016, pp. 212-216.
40 Paglialonga et al., 2019, p. 6.

as an emerging and developing mobile communication technology for healthcare systems is also stressed, in part because the evolution of eHealth systems have been improved by the possibilities of modern technologies in biomedicine[41]. mHealth may help communities overcome traditional healthcare problems, such as access to medical care, quality and safety of services provided, or proper planning for the use of available resources[42].

Another semantic proposal suggests that mHealth should be considered an umbrella term for the use of mobile information technology to access healthcare systems and services, which includes mobile and peripheral devices used by healthcare professionals, patients, and clients to collect, store, and analyse data for decision-making[43]. The World Health Organisation states that mHealth is part of eHealth and that mHealth refers to the practice of medicine supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices. Wireless devices includes the use of voice and SMS-type messaging services as well as more complex functions, including the general radio service GPRS, third and fourth generation mobile telephony (3G and 4G), and the global positioning system (GPS)[44]. This facilitates the transformation of healthcare services and data delivery by reaching vast geographical areas[45]. In contrast, the EU states that mHealth encompasses activities in the medical and public health sector that are carried out using mobile devices such as mobile phones, patient monitoring devices, PDAs, and other wireless devices[46].

In conclusion, it should be emphasised that the solutions proposed by mHealth should be assessed as a valuable contribution of technical, technological, and civilisational progress to the development of innovative medicine. These solutions can help people manage their own health, promote a healthy lifestyle, and access useful information wherever there is a need. Given these considerations, it is necessary to postulate *de lege ferenda* that mHealth should be understood as a segment of eHealth, in which modern mobile technologies enable medical personnel to improve the patient's health using mobile tools, such as: mobile phones, tablets, and medical applications, among others. Defining the subject scope of mHealth in this way allows a precise distinction from other terms used in the context of using modern technologies in medicine and the understanding that mHealth is part of the overall concept of eHealth[47].

41 Istepanian et al., 2006, p. XXIII.
42 Paglialonga et al., 2019, p. 6.
43 Sezgin, 2018, p. 1.
44 *mHealth*, 2011, p. 6.
45 *From innovation* …, 2016, p. 41.
46 Green Paper on mobile Health ('mHealth') /* COM/2014/0219 final */.
47 Al-Azzam and Alazzam, 2019, pp. 173-174.; Dwivedi et al., 2016, pp. 174-176.; Silva et al., 2015, pp. 265-267.

1.2.4 Telehealth

The concept of telehealth is another pillar of the overall eHealth concept. It implies the use of virtual communication technologies that remotely transmit data to provide medical care or to train patients and medical staff remotely[48]. Essentially, telehealth is used in modern medicine as video conferencing, robotics, or other forms of telepresence that gives the impression that a person is in one location when they are actually in another[49]. The literature emphasises that telehealth involves the use of remote communication tools and technologies to provide healthcare regardless of time or distance[50] or the delivery of medical services directly to the home[51]. Telehealth is also defined as the use of electronic information and telecommunication technologies to support clinical healthcare at a distance[52], as well as the technology to provide universal support for healthcare services that connect rural residents to appropriate healthcare[53], or a remote system that provides direct patient care[54]. The World Health Organisation states that telehealth is the provision of healthcare or the exchange of health information through telecommunications technology when participants are separated by a significant distance[55]. Such solutions are a way to improve healthcare management by offering self-care practices and more convenient and frequent health monitoring compared to traditional healthcare delivery[56]. *Prima facie,* it can be seen that there are many different definitions.

To systematise the nomenclature used concerning the use of modern technologies in the practice of medicine, it should be postulated *de lege ferenda* that telehealth can be defined as the provision of medical services at a distance using telepresence techniques. The subject matter of the concept examined in this way includes those eHealth services that take place remotely with the direct participation of medical personnel in both real time and asynchronously. The indicated definition of telehealth makes it possible to distinguish two important subcategories: telemedicine and telecare. Due to the specific methodological order of this scientific monograph, the concept of telemedicine will be presented in detail later in the work; here, it is useful to highlight that telemedicine *de lege ferenda* should be understood as the part of telehealth responsible for the doctors providing medical services at a distance using telepresence techniques[57]. Telemedicine, meanwhile, uses programmes focused on nursing or on supporting the public in caring for the

48 Dorsey and Topol, 2016, pp. 154-160.; Koch, 2006, pp. 565-576.; Weinstein et al., 2014, pp. 183-187.; Van Dyk, 2014, pp. 1279-1298.
49 Maimone et al., 2012, pp. 791-793.; Wang et al., 2014, pp. 314-324.
50 Faison et al., 2001, p. 338.
51 Roffer, 2017, p. 207.
52 Kim, 2010, p. 66.; Edirippulige, 2009, p. 271.
53 Raza, 2018, p. 523.
54 Brennan and Starren, 2006, p. 536.
55 Martin-Khan et al., 2017, p. 174.
56 LaFramboise et al., 2003, pp. 275-288.
57 See Chapter 1.4: The concept of telemedicine.

right level of health[58]. The main aim of this type of technology is to enable patients to maintain their safety and medical independence in their own homes, particularly where older people are concerned[59]. Telecare services can range from basic alarm or medication reminder services, providing the ability to respond to specific situations, to integrated early warning and detection systems, including sensing falls or fire and gas concentrations that trigger alerts at specialised response centres[60].

In summary, the concept of telecare *de lege ferenda* refers to the provision of medical services by non-physicians using telepresence techniques. The difference between this term and telemedicine therefore lies in the level of sophistication that exists in the healthcare provided as determined by the involvement of a specific type of medical personnel.

1.2.5 Sensory health

The last segment of the eHealth concept highlighted in this work is sensory health. The literature often points out that part of mHealth is mobile technologies that monitor patients' health through specialised medical personnel using mobile tools such as mobile phones, tablets, medical apps or other types of mobile tools[61]. This observation is only somewhat true because sensory solutions do not always have to be mobile, and mobile techniques are not exclusively sensory. Therefore, the use of ICT for remote diagnosis, monitoring of vital functions, or treatment using mobile or non-mobile tools that enable the transfer of medical data to specialised databases can be defined as sensory health. In this sense, a medical sensor is any device with pre-programmed system functions for wireless diagnosis, vital function monitoring or treatment, and transferring medical data between consumers and patients and medical facilities, whether mobile or non-mobile in nature. Such a sensor usually uses a built-in or embedded sensor system that mimics the nervous system, which can both detect and predict internal concerns with medical significance[62]. This type of solution leads to lower costs and easier maintenance compared to traditional healthcare, which should in principle take place in a clinical or ambulatory setting[63].

There are three main components in sensory health. The first is medical sensors that are responsible for collecting selected health data; the second is the communication system between these sensors and the medical facility databases programmed for this purpose; and the third is the object of observation, which will

58 Martin-Khan et al., 2017, p. 174.
59 Castolo et al., 2005, pp. 149-150.; Držanič et al., 2019, p. 252.
60 Chuang and Tsai, 2012, p. 237.; Afsarmanesh et al., 2004, pp. 211-212.
61 Santosh et al., 2013, pp. 228-231.; Luxton et al., 2011, pp. 506-508.; Mechael, 2009, pp. 103-106.; Gagnon et al., 2016, pp. 212-216.
62 Gao et al., 2020, pp. 55-56.
63 Surya et al., 2020, p. 207.

most often be the patient[64]. The medical sensory therefore brings together two basic elements, namely the medical sensors and the communication system. The proper correlation of the elements presented is in fact the essence of sensory health; this has universal applications but is most commonly used with older adults, infants, and individuals with chronic illnesses[65]. It should also be noted that this application of modern technology in medicine is characterised by a higher level of security compared to traditional forms of medical care due to a broader independence from external infrastructure, which creates a lower possibility of interruption[66]. It is therefore postulated that the solution in question should be seen as a medical monitoring system that is reliable, energy efficient, and secure, and collects health data in real time[67]. The above remarks lead to a clear statement that *de lege ferenda* sensor health should be treated as a separate segment of the general concept of eHealth which is responsible for wireless care through the use of medical sensors that enable the collection and transmission of medical data regardless of the patient's mobility. It should also be suggested that the criterion presented precisely differentiates mHealth and sensory health, indicating their essential differences.

1.2.6 Medical informatics

It was noted above that eHealth can be distinguished as a category within digital medicine, but these terms are not the same in the subject matter. Therefore, this work suggests that eHealth should be understood as the external layer of digital medicine, i.e., the service layer, which is visible from the point of view of the ordinary user, i.e. the medical staff or the patient. e-Health should therefore not be equated with the technical infrastructure aspect of digital medicine, including fields that fall within the semantic scope indicated and subsidiarily support the development of modern technologies that can be applied to the practice of medicine, such as big data sets[68] and the technologies that manage them[69] or artificial intelligence algorithms[70]. The subject of digital medicine is addressed using medical informatics, which are defined either as the use of computer technology combined with information management to provide patient care[71] or as a scientific field dealing with the collection, processing, and transmission of information related to

64 Gao et al., 2020, pp. 55-56.; Babović et al., 2011, p. 262.; Nordin et al., 2011, p. 306.; Jo et al., 2010, pp. 552-553.
65 Han, 2011, p. 20.; Zhang, 2008, p. 583.
66 Fragoulis, 2009, pp. 320.
67 Venkatasubramanian, 2005, p. 406.
68 Austin and Kusumoto, 2016, pp. 51-52.; Greene and Lea, 2019, pp. 480-485.
69 Nash et al., 2017, pp. 2527-2531.; Ince et al. 2014, pp. 74-83.; Ramo et al., 2014, pp. 58-64.
70 Hamilton, 2019, p. 3.; Ramesh et al., 2004, p. 334.; Buch, 2018, p. 143.
71 Choctaw, 2008, p. 47.

healthcare services[72]. Health informatics is therefore at the intersection of informatics and healthcare, involving resources, devices, and methods used to optimise the acquisition, storage, retrieval, and use of health information[73]. In addition, the literature notes that the term health informatics comprises three further categories. First, bioinformatics dealing with the molecular and cellular level of medicine, i.e. methods for gene sequence analysis and high-throughput sequencing. Second, clinical informatics aiming to provide methodological and technical solutions for the representation of data and knowledge as well as the organisation, capture, and storage of consultation and medical interpretation used in practice. Third, public health informatics combining tools, techniques and applications that enable logical inference to be performed at the level of the general population, so that tools can be obtained for cohort tracking, disease registries, or vigilance systems[74]. A basic example of medical informatics as described here is computerised methods for recording patient data, managing this data, and using it to help medical personnel complete diagnostics or medical treatments and support patients in their daily work or life[75].

In summary, in this work, medical informatics *de lege ferenda* will be understood as the use of advanced ICT and programming methods to create the technical infrastructure to apply modern technology to the practice of medicine. The above considerations suggest that each category of eHealth, i.e. mHealth, telehealth and sensory health, has a service layer made available to the interested user as well as a technical infrastructure layer. The latter is the responsibility of medical informatics, i.e. the technical infrastructure of digital medicine.

1.2.7 Subject correlation in digital medicine

The systemisation described thus far may give the impression that each term defined above has its own precise meaning and scope. It should be noted that this work indicates semantic proposals for the term digital medicine and its derived terms. The digital medicine should be understood as all manifestations of the application of modern technologies in the practice of medicine combined with the fields supporting its function[76]. Beginning with this assumption, this chapter has suggested that eHealth should not be identified with a technical infrastructure that is invisible to the ordinary user. From this point of view, the external layer of digital medicine

72 Huang, 2009, p. 1423.
73 Closa et al., 2010, p. 155.
74 Venot et al., 2014, pp. 3-4.
75 Closa et al., 2010, p. 155.
76 Author's proposal is based on: Lupton, 2013, p. 257.; Elenko et al., 2015, pp. 456-461.; André, 2019, p. 4.; Austin and Kusumoto, 2016, pp. 51-52.; Greene and Lea, 2019, pp. 480-485.; Nash et al., 2017, pp. 2527-2531.; Ince et al. 2014, pp. 74-83.; Ramo et al., 2014, pp. 58-64.; Hamilton, 2019, p. 3.; Ramesh et al., 2004, p. 334.; V. Buch, 2018, p. 143.

is the service layer for stakeholders, both medical staff and patients[77]. This section then highlighted that mHealth refers to the segment of eHealth in which modern mobile technologies enable medical staff to improve patient health using mobile tools, including mobile phones, tablets, medical apps, and other mobile tools[78]. Subsequently, it was suggested that telehealth should be equated with the delivery of medical services at a distance using telepresence techniques[79]. Therefore, the subject outlined thus far includes remote eHealth services that have the direct participation of medical personnel, both in real time and asynchronously. This section also highlighted that sensory health should be considered as a separate component of the overall e-Health concept which is responsible for the care of patients by using medical sensors that enable the collection and transmission of medical data independently of the patient's mobility[80]. At the very end, this section proposed that medical informatics be defined as the use of advanced ICT and programming methods to create a technical infrastructure for the application of modern technologies in the practice of medicine[81]. The definitions proposed may provide useful material for the legislator, whose aim should be systematising and standardising the nomenclature around modern technologies used in medical practice. It would seem appropriate to introduce legal definitions of various terms, such as digital medicine, e-health, telehealth, telemedicine, telecare, sensory health, and medical informatics, into EU law. For example, legal definitions would be useful in Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC

77 Author's proposal is based on: Terry, 2000, pp. 605-607.; Mars and Scott, 2010, pp. 237-243.; de Pietro and Francetic, 2018, pp. 69-74.; Oh et al., 2005, pp. 34-35.; Frączkowski, 2005, pp. 54-58.; Batko, 2012, pp. 95-113.; Bujnowska-Fedak, 2013, pp. 302-317.; Czerwińska, 2013, pp. 539-551.; Janyszek et al., 2006, pp. 60-63.; Furmankiewicz et al., 2016, pp. 46-61.; Barbabella et al., 2017, p. 7.; Sood et al., 2007, pp. 257-268.

78 Author's proposal is based on: Santosh et al., 2013, pp. 228-231.; Luxton et al., 2011, pp. 506-508.; Mechael, 2009, pp. 103-106.; Gagnon et al., 2016, pp. 212-216.; Paglialonga et al., 2019, p. 6.; Istepanian et al., 2006, p. XXIII.; Sezgin, 2018, p. 1.; *mHealth,* 2011, p. 6.; *From innovation …*, 2016, p. 41.; Al-Azzam and Alazzam, 2019, pp. 173-174.; Dwivedi et al., 2016, pp. 174-176.; Silva et al., 2015, pp. 265-267.

79 Author's suggestion is based on: Dorsey and Topol, 2016, pp. 154-160.; Koch, 2006, pp. 565-576.; Weinstein et al., 2014, pp. 183-187.; Van Dyk, 2014, pp. 1279-1298.; Maimone et al., 2012, pp. 791-793.; Wang et al., 2014, pp. 314-324.; Faison et al., 2001, p. 338.; Roffer, 2017, p. 207.; Kim, 2010, p. 66.; Edirippulige, 2009, p. 271.; Raza, 2018, p. 523.; Martin-Khan et al., 2017, p. 174.; LaFramboise et al., 2003, pp. 275-288.; Castolo et al., 2005, pp. 149-150.; Držanič et al., 2019, p. 252.; Chuang and Tsai, 2012, p. 237.; Afsarmanesh et al., 2004, pp. 211-212.

80 Author's proposal is based on: Gao et al., 2020, pp. 55-56.; Surya et al., 2020, p. 207.; Babović et al., 2011, p. 262.; Nordin et al., 2011, p. 306.; Jo et al., 2010, pp. 552-553.; Han, 2011, p. 20.; Zhang, 2008, p. 583.; Fragoulis, 2009, pp. 320.; Venkatasubramanian, 2005, p. 406.

81 Author's suggestion is based on: Choctaw, 2008, p. 47.; Huang, 2009, p. 1423.; Closa et al., 2010, p. 155.; Venot et al., 2014, pp. 3-4.

and 93/42/EEC (hereinafter: Medical Device Regulation)[82], and more specifically, its Article 2. This item was chosen because of the request described later in this work to require digital medicine solutions to be certified as medical devices. For this to be done, terminology must be standardised and systematised, and specific legal definitions must be introduced. The systematisation of terminology proposed above serves this purpose and can serve as a foundation for legislative efforts to introduce appropriate legal definitions in Article 2 of the Medical Device Regulation. Nevertheless, it should remembered that, in terms of how modern technology is applied in real life situations, the subject ranges of the mentioned terms are fluid. It may still be that the semantic criteria of a certain type of application may not also meet the definition of another application. The concept of digital medicine may therefore fit into more than one subject area based on the terms presented in this work. For example, a particular digital medicine solution that clearly delivers medical services remotely using telepresence techniques may also use mobile technologies supported by a mobile tool. That solution would therefore fall under the definitions of both telehealth and mHealth. It should still be emphasised, however, that all terms discussed in this work are different from one another.

1.3 Certification of digital medicine solutions

1.3.1 Qualification of medical devices as a certification system

The certification of digital medicine solutions, determined by the specific application of the technology that is being used during medical practice, is of significant importance in both the theory and practice of law. It is important to emphasise that, when seeking the necessary legal solutions to the title issue, the question of what legal construction will be used remains relevant. First, it should be considered whether it is necessary to create new, previously unknown regulations, or whether regulations that have an already tested legal basis can be used, either directly or with appropriate modifications. It would seem that priority should be given to legal norms already in force, assuming that they are suitable. Therefore, in the first instance, priority should be given to a system which is currently provided, irrespective of the existence or otherwise of other certification systems[83]. The qualification of digital medical solutions as medical devices according to the definition contained in the Medical Device Regulation, which has its origin in the Council Directive

82 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002, and Regulation (EC) No 1223/2009, and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ of the EU L 117 of 5 May 2017, pp. 1-175).

83 Marković, 2006, pp. 364-365.; Seelman, 2014, pp. 136-137.; Abdmeziem et al., 2015, p. 39.; Zúquete et al., 2008, p. 484.; Chávez et al., 2009, pp. 740-741.

93/42/EEC of 14 June 1993 concerning medical devices (hereinafter: Council Directive 93/42/EEC)[84], can be regarded as such a certification system[85]. This definition should also be included in the normative orders of the Member States of the EU[86] as they were obliged to implement Council Directive 93/42/EEC[87]. This seems to be crucial from the point of view of safety for patients, consumers and medical personnel, which is determined by applying a number of legal standards related to medical devices that provide digital medicine solutions[88]. According to Article 2(1) of the Medical Device Regulation,

> 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: – diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease, – diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability, – investigation, replacement or modification of the anatomy or of a physiological or pathological process or state, – providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal

84 Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ of the EU L 169 of 12 July 1993, pp. 1-43).

85 What is also important, according to Article 120 (2) of the Medical Devices Regulation: 'Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC prior to 25 May 2017 shall remain valid until the end of the period indicated on the certificate, except for certificates issued in accordance with Annex 4 to Directive 90/385/EEC or Annex IV to Directive 93/42/EEC which shall become void at the latest on 27 May 2022. Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC from 25 May 2017 shall remain valid until the end of the period indicated on the certificate, which shall not exceed five years from its issuance. They shall however become void at the latest on 27 May 2024.'

86 For example, the Polish legislator decided to implement the definition in question in the Act of 20 May 2010 on medical devices (consolidated text; Journal of Law. of 2020, item 186), where, according to Article 2 paragraph 1(38), a medical device is a 'tool, instrument, device, software, material or other article, used alone or in combination, including software intended by its manufacturer to be used specifically for diagnostic or therapeutic purposes and necessary for its proper use, intended by the manufacturer to be used in humans for: (a) diagnosing, preventing, monitoring, treating or alleviating the course of a disease, (b) diagnosing, monitoring, treating, alleviating or compensating for the effects of an injury or handicap, (c) studying, replacing or modifying an anatomical structure or physiological process, (d) regulating conception – which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but whose action may be assisted by such means' (see Wąsik and Wąsik, 2015, pp. 27-39.; Poździoch, 2012, pp. 59-85).

87 Zhelyazkova and Torenvlied, 2009, pp. 35-62.; Komárek, 2007, pp. 87-98.; Toshkov, 2008, pp. 379-402.; König and Luetgert, 2009, pp. 163-194.; Kaeding, 2006, pp. 229-253.

88 Recital 5 of Council Directive 93/42/EEC confirms that: 'Whereas medical devices should provide patients, users and third parties with a high level of protection and attain the performance levels attributed to them by the manufacturer; whereas, therefore, the maintenance or improvement of the level of protection attained in the Member States is one of the essential objectives of this Directive.'

> intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means. The following products shall also be deemed to be medical devices: – devices for the control or support of conception, – products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.'

Meanwhile, according to the now repealed Article 1(2). (a) of Council Directive 93/42/EEC

> 'medical device' means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of: – diagnosis, prevention, monitoring, treatment or alleviation of disease, – diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, – investigation, replacement or modification of the anatomy or of a physiological process, – control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.[89]

As the Medical Device Regulation is a relatively new piece of the legislation in the EU, its interpretation will be based mainly on conclusions concerning Council Directive 93/42/EEC, which was developed regarding the definition of a medical device, where the similarity of different definitions is significant. This plays an important role in the context of the decision of the Court of Justice of the European Union (CJEU)[90] analysed in section 1.3.2 as it is a prerequisite for maintaining the relevance of the concept's interpretation.

1.3.2 Interpretation of the definition of a medical device

It is important to determine what criteria are used EU law to designate whether digital medical solutions are eligible to be medical devices. This is even more important considering the obligation of the Member States of the EU to interpret national law in accordance with the EU laws designated by CJEU[91]. The concept of medical device in the Medical Device Regulation and Council Directive 93/42/EEC has the

90 In this research monograph, the term CJEU denotes a Community or the EU judicial institution, irrespective of the nomenclature used in the past.

91 Osiejewicz, 2017, pp. 362-370.; Kornobis-Romanowska, 2007, pp. 45-63.; Niedźwiedź, 2004, pp. 6-10.; Górski, 2008, pp. 30-32.; Barta and Markiewicz, 2016, pp. 528-531.; Judgment of the Court of Justice of the European Union of 17 May 1972 in Case C-93/71 in proceedings Orsolina Leonesio v Ministero dell'Agricoltura e Foreste della Repubblica Italiana (ECLI:EU:C:1972:39); Judgment of the Court of Justice of the European Union of 17 December 1970 in Case C-30/70 in proceedings Otto Scheer v Einfuhr und Vorratsstelle für Getreide und Futtermittel (ECLI:EU:C:1970:117).

value of being an autonomous characteristic of the EU normative order, which has developed its own principles and concepts and uses autonomous terminology[92]. This is because EU law has created terms and concepts that do not appear in national legal orders and has given a different meaning to the terms and concepts in Member States' national laws[93]. For this reason, CJEU is responsible for independently and uniformly interpreting the concepts used in EU law that do not contain a direct reference to the Member State's law to determine a law's meaning and scope[94]. As the concept of medical device does not contain a direct reference to the national law of the Member States of the EU, an interpretation must be sought that considers the context of the provision and the purpose of the regulation in case law CJEU. The judgment CJEU of 22 November 2012 in Case C-219/11 in Brain Products GmbH v BioSemi VOF, Antonius Pieter Kuiper, Robert Jan Gerard Honsbeek, Alexander Coenraad Metting van Rijn[95] is of relevance to the present subject of analysis. However, it only answers whether an article intended by the manufacturer for use in humans with the aim of studying a physiological process constitutes a medical device within the meaning of the third indent of Article 1(2)(a) of Council Directive 93/42/EEC; the answer is that it constitutes a medical device only if it is intended for medical purposes[96], which therefore provides an interpretation of the concept of medical device within EU law. It should be emphasised unequivocally that the ruling in question is also of relevance for the proper interpretation of the definition in the Medical Device Regulation, where partial identity with the definition in Council Directive 93/42/EEC is relevant. In light of the above ruling, it should also be noted that only the first, second, and third indents of Article 1(2)(a) of Council Directive 93/42/EEC are inextricably linked to the premise of medical use; the same cannot be said of the fourth indent of this provision[97]. This is also indirectly apparent from Recital 18 of Council Directive 93/42/EEC; it is noted here that, in view of the specific aims of the fight against AIDS, the EU legislator decided to bring contraceptives within the scope of the legislation to ensure effective quality

92 Helios and Jedlecka, 2018, p. 126.
93 Helios and Jedlecka, 2018, p. 126.
94 Judgment of the Court of Justice of the European Union of 18 January 1984 in Case C-327/82 in proceedings Ekro Vee en Vleeshandel v. Produktschap voor Vee en Vlees (ECLI:EU:C:1984:11).
95 Judgment of the Court of Justice of the European Union of 22 November 2012 in Case -219/11 in Brain Products GmbH v BioSemi VOF, Antonius Pieter Kuiper, Robert Jan Gerard Honsbeek, Alexander Coenraad Metting van Rijn (ECLI:EU:C:2012:742).
96 Recital 11 of the judgment of the Court of Justice of the European Union of 22 November 2012 in Case C-219/11….
97 Recital 20 of the judgment of the Court of Justice of the European Union of 22 November 2012 in Case C-219/11….

control regardless of whether they were used for a medical purpose[98]. Through this recital, the EU legislator indicated that Council Directive 93/42/EEC was applied to devices for human use to regulate conception; however, it did not provide the same reasoning for other devices referred to in Article 1(2)(a) of Council Directive 93/42/EEC. This could imply that the intended use of a device for medical purposes is inextricably linked to the definition of a medical device[99]. Accordingly, the complete definition of a medical device is determined by the premise that it is used for a medical purpose, apart from devices intended for human beings for the purpose of regulating conception[100].

1.3.3 Digital medicine solutions as medical devices

These considerations also apply to digital medicine solutions since the concept of a medical device covers objects created by the manufacturer for use in humans for the purposes referred to in the Medical Device Regulation and Council Directive 93/42/EEC only if they are intended for medical purposes. This implies that, if a digital medicine device has not been developed by the manufacturer for medical use, its certification as a medical device is not legally required[101]. In addition, in the context of digital medicine solutions potentially qualifying as medical devices under EU legislation, it is particularly important to note that a medical device can include instruments, apparati, devices, materials, or other articles, as well as software itself[102]. Digital medicine solutions may therefore qualify as medical devices in both tangible and intangible dimensions. Tangible digital medicine will include any instrument, apparatus, device, material, or other article used in the practice of medicine using modern technology while intangible digital medicine will include either independently functioning software or software that allows a tangible item to function. Stand-alone software may qualify as a medical device if it is specifically

98 Recital 18 of Council Directive 93/42/EEC: 'Whereas, in the fight against AIDS and in the light of the conclusions of the Council adopted on 16 May 1989 regarding future activities on AIDS prevention and control at Community level (15), medical devices used for protection against the HIV virus must afford a high level of protection; whereas the design and manufacture of such products should be verified by a notified body.'

99 Recital 23 of the judgment of the Court of Justice of the European Union of 22 November 2012 in Case C-219/11….

100 In the field of medical devices, not only health protection but also the requirements of the free movement of goods must be considered. The Council Directive 93/42/EEC should therefore reconcile the protection of patients' health with the EU freedom of movement of goods (Judgment of the Court of Justice of the European Union of 14 June 2007 in Case C 6/05 in Medipac-Kazantzidis AE v Venizeleio-Pananeio [PE.S.Y. KRITIS] [ECLI:EU:C:2007:337]).

101 Recital 30 of the judgment of the Court of Justice of the European Union of 22 November 2012 in Case C-219/11….

102 Recital 16 of the judgment of the Court of Justice of the European Union of 22 November 2012 in Case C-219/11….

intended by the manufacturer to be used for one or more medical purposes[103]. Regarding software, the EU legislator has emphasised the fact that, for an item to fall within the scope of the Medical Device Regulation, formerly the Council Directive 93/42/EEC, it is not sufficient for the item to be used in a medical context[104]. The manufacturer must have intended for it to fulfil at least one medical purpose[105]. This means, for example, that general-purpose software used in healthcare facilities, which unquestionably belongs to the category of digital medicine, cannot be considered a medical device[106].

In conclusion, it is clear from the above analysis that, if digital medicine solutions in both the tangible and intangible dimensions are intended to be used for at least one medical purpose, their qualification as medical devices as defined under EU law is both legally permissible and required. However, in this context, it is important to consider whether this qualification formula remains valid for digital medical solutions, which have their own particular characteristics determined by the application of modern technology in the practice of medicine. It seems necessary here to distinguish between two different legal situations. The first is when certification of digital medicine solutions as medical devices is optional, and the second is when certification of digital medicine solutions as medical devices is mandatory. In this context, the *de lege ferenda* certification system for digital medicine solutions in terms of whether they qualify as medical devices should be two-pronged. First, any digital medicine solution, regardless of whether it is directly used for one or more medical purposes, should have the option of being admitted to the certification system as a medical device. Second, those digital medicine solutions that are used for one or more medical purposes should be mandatorily referred to this certification scheme. This solution offers a balanced option as it would in fact be most effective *de lege ferenda* to have a mandatory system of certification as a medical device for any digital medicine solution, whether tangible or intangible, and irrespective of the premise of direct medical use. This is because the safety of patients or medical staff and the application of a number of standards provided by law for medical devices to digital medicine solutions are at stake. However, the postulate in such a variant, due to the need to ensure the efficiency of the healthcare system, must remain in the realm of abstraction; therefore, it does not apply to the presented question in this work.

103 Recital 16 of the judgment of the Court of Justice of the European Union of 22 November 2012 in Case C-219/11….

104 Recital 17 of the judgment of the Court of Justice of the European Union of 22 November 2012 in Case C-219/11….

105 Recital 17 of the judgment of the Court of Justice of the European Union of 22 November 2012 in Case C-219/11….

106 Recital 16 of the judgment of the Court of Justice of the European Union of 22 November 2012 in Case C-219/11….

1.4 The concept of telemedicine

1.4.1 Definition of telemedicine

As the concept of telemedicine is the main analytical axis of this monograph, it is necessary to define its meaning in detail. It appears that many different definitions of the term under analysis can be found both in the literature and in documents from international organisations or NGOs[107]. The doctrine notes that telemedicine is the study, monitoring, management, and education of patients and medical staff by means of systems that allow remote access to doctors' advice and medical information regardless of location of the patient, staff, or the data sought[108]. Such a system uses a combination of telecommunications and technology as a substitute for the traditional face-to-face contact between patient and doctor[109]. It also emphasises that telemedicine refers to the use of telecommunications and informatics in medical applications[110] or transmission and exchange of medical data via telecommunications networks in real time or asynchronously[111]. Further semantic proposals assume that telemedicine involves the exchange of medical information between stakeholders via electronic communication in order to protect the health of the patient and the consumer and improve the quality of healthcare provided to them[112] or the transformation of traditional medicine through the use of interactive audio-visual methodologies for the transmission of data to assist, educate and research in the field of health[113]. Other authors postulate that telemedicine is:

- the exchange of medical information at a distance, where the data transmitted may include images, calls, laboratory data and any other medically relevant information[114],
- the use of telecommunications technology for medical diagnosis, monitoring and therapeutic purposes when stakeholders are separated by distance[115],
- technology that makes it possible to deliver care anywhere, anytime, to anyone, regardless of the physical location of the parties involved[116],
- interactive audio-visual communication between healthcare providers and their patients[117],

107 Adelakun and Garcia, 2019, p. 85.
108 Otto, 2001, p. 106.
109 Cohendet et al., 1998, p. 191.
110 Klar and Pelikan, 2011, p. 1119.
111 Zimpfer, 1999, p. 77.
112 Linkous, 2001, p. 226.
113 de Lucena et al., 2013, p. 129.
114 Argy and Caputo, 2001, p. 227.
115 Shaw, 2009, pp. 13-18.
116 Bhattacharyya, 2017, p. 6.
117 Spradley, 2001, p. 291.

- an initiative to enable remote patient-centred monitoring[118],
- a model of healthcare delivery, the implementation of which depends on the will of clinical, administrative and policy makers in hospitals, communities, or regions[119],
- a tool to solve real problems in medicine concerning people, patients, service quality, and processes[120],
- a new approach to caring for patients in remote locations where specialist doctors may not be available[121] that has been gaining popularity in recent years,
- geographical separation between medical expertise and medical expert, including interaction via technology[122].

Already *prima facie,* it can be seen that, when analysing the concept of telemedicine, as was the case with the rest of the terminology concerning the application of modern technologies in the practice of medicine, there is a negative phenomenon of definitional chaos. This occurs because most of the authors dealing with this specific research field create their own semantic proposals, considering them appropriate. A remedy to this state of affairs would be to create a legal definition of telemedicine at the level of international cooperation. The definitions already created by recognised organisations could be helpful in this context. For example, the World Health Organisation considers telemedicine to be healthcare services provided in situations where distance is a key factor and which are provided by health professionals using ICT to exchange information for diagnosis, treatment, prevention of illness and injury, research and evaluation, and education of healthcare providers in the interest of improving the health of patients[123]. Meanwhile, the EU assumes that telemedicine is the provision of healthcare services where traditional patient–doctor or doctor–doctor contact is replaced by remote interaction through ICT[124]. According to the American Telemedicine Society, telemedicine encompasses an increasing number of applications and services that use two-way video, email, smartphones, wireless tools, and other forms of telecommunications technology[125]. *De lege ferenda,* it would seem that these three semantic proposals could provide the substantive foundations for an international initiative to adopt a legal definition of telemedicine. Without such a definition, the literature will continue to produce varying ones, which will further reduce the clarity of the language used in relation to the use of modern technologies in the practice of medicine.

118 Reynolds, 2019, p. 4.
119 Dafoulas et al., 2017, p. 340.
120 Mohr et al., 2019, p. 255.
121 Lynn, 2019, p. 107.
122 Melton et al., 2019, p. 253.
123 Bhattacharyya, 2017, p. 6.
124 European Commission, 2018, p. 25.
125 Raskas et al., 2017, p. 206.

1.4.2 Essence of telemedicine

Telemedicine belongs to the broader notion of telehealth, which should be understood as the use of modern technologies in the practice of medicine, where medical services are provided at a distance using telepresence technology[126]. This definition allows two subcategories to be distinguished: telecare and telemedicine. As already noted, telecare refers to the provision of medical services by non-doctors using telepresence techniques[127] while telemedicine is the provision of medical services by doctors at a distance using telepresence techniques[128]. The proposed semantic boundary between these terms has the advantage of precisely defining their actual material scope and is justified by the level of sophistication of the healthcare services provided depending on what type of medical professional is involved. Discussing the potential solution was important for this paper[129] as they demonstrate that, without a legal term to analyse, various definitions appear that may not be fully compatible with each other. However, the intention of explaining the different definitions was to present a universal priority representing their common denominator, the transmission of medical data using ICT to improve patient health. Further, ICT-enabled transmission implies the need to also address the issue of the routineness of the provision of telemedicine services, and that improving the patient's health should be directly linked to realising the right to health protection and healthcare services, including medical care. This priority, combined with the correct terminological meaning, seems to be the essence of telemedicine. It combines a sensitivity to providing clinical support, overcoming geographical barriers, utilising different types of modern technology, improving health outcomes and, above all, realising the right to health protection and healthcare services, including medical care[130]. This remark is central to this work as telemedicine is the main axis of reference under analysis. It is critically important to identify the basic building blocks of telemedicine. It is also important to note that the essence of telemedicine thus

126 Dorsey and Topol, 2016, pp. 154-160.; Koch, 2006, pp. 565-576.; Weinstein et al., 2014, pp. 183-187.; L. Van Dyk, 2014, pp. 1279-1298.; Maimone et al., 2012, pp. 791-793.; Wang et al., 2014, pp. 314-324.; Faison et al., 2001, p. 338.; Roffer, 2017, p. 207.; Kim, 2010, p. 66.; Edirippulige, 2009, p. 271.; Raza, 2018, p. 523.; Brennan and Starren, 2006, p. 536.; Martin-Khan et al., 2017, p. 174.; LaFramboise et al., 2003, pp. 275-288.

127 Castolo et al., 2005, pp. 149-150.; Držanič et al., 2019, p. 252.; Chuang and Tsai, 2012, p. 237.; Afsarmanesh et al., 2004, pp. 211-212.

128 Author's proposal based on: Adelakun and Garcia, 2019, p. 85.; Otto, 2001, p. 106.; Cohendet et al., 1998, p. 191.; Klar and Pelikan, 2011, p. 1119.; Zimpfer, 1999, p. 77.; Linkous, 2001, p. 226.; de Lucena et al., 2013, p. 129.; Argy and Caputo, 2001, p. 227.; Shaw, 2009, pp. 13-18.; Bhattacharyya, 2017, p. 6.; Spradley, 2001, p. 291.; Reynolds, 2019, p. 4.; Dafoulas et al., 2017, p. 340.; Mohr et al., 2019, p. 255.; Lynn, 2019, p. 107.; Melton et al., 2019, p. 253.; Simmons et al., 2008, p. 163.; European Commission, 2018, p. 25.; Raskas et al., 2017, p. 206.

129 See Chapter 1.4.1: Definition of telemedicine.

130 Bhattacharyya, 2017, p. 6.

defined directly prevents the dehumanisation of healthcare that could be caused by the use of modern technology; instead, telemedicine becomes a tool that can help improve accessibility, speed, equity, safety, and quality and reduce the cost of medical services[131]. It can also support physicians' work by improving efficiency. However, and this should be strongly emphasised, the widespread implementation of telemedicine solutions is not an end unto itself. It is an adaptation of the achievements of technical, technological, and civilisation progress to the needs and problems of traditionally understood medicine.

1.4.3 Basic building blocks of telemedicine and their implications

The above proposed essence of telemedicine provides both a starting point and a target point for defining the most important building blocks of this type of application of modern technology to medical practice; at least three basic building blocks of the telemedicine concept are apparent. First, there is medical data in a form that enables its transmission via ICT. This refers to an electronic medical record, which is a digital reproduction of traditional medical records with functionalities adapted to the current technical, technological, and civilisation progress[132]. The second building block is the use of an ICT network by doctors for medical purposes. It is necessary not only to use a properly designed ICT network[133], but also to ensure that final access to it is provided[134]. The cross-border nature of telemedicine service provision must therefore also be discussed. The third, and most importantly from an axiological point of view, basic building block of telemedicine is the improvement of the patient's health[135], which should be equated with the realisation of the right to health protection and healthcare services, including medical care. This leads, therefore, to the conclusion that the correlation of the basic structural elements of telemedicine stems, both from the universal priority that is part of its essence, understood as the transmission of medical data using ICT to improve the health of the patient, and on the foundation for the proper semantic meaning which is the rest

131 Communication from the Commission to The European Parliament, The Council, The European Economic and Social Committee and the Committee of the Regions on telemedicine for the benefit of patients, healthcare systems and society. COM/2008/0689, p. 3.; Czarnucha et al., 2015, pp. 13-21.; Maziarz, 2010, pp. 33-35.

132 Ben-Assuli, 2015, pp. 287-297.; Kalra, 2006, pp. 136-144.; Hodge et al., 1999, pp. 1466-1471.; Dumortier and Verhenneman, 2013, pp. 25-56.; Christiansen et al., 2017, pp. 1234-1239.; Peters et al., 2014, pp. 515-522.; Ries and Moysa, 2005, pp. 18-25.

133 The aspect in question is addressed by medical informatics: Choctaw, 2008, p. 47.; Huang, 2009, p. 1423.; Closa et al., 2010, p. 155.; Venot et al., 2014, pp. 3-4.

134 This is relevant from the point of view of the so-called digital exclusion, which defines the difference between those individuals or societies that have access to information technology (the Internet) and those that do not: Warren, 2007, pp. 374-388.; Helsper, 2012, pp. 403-426.; Bach et al., 2013, pp. 247-266.

135 Porter, 2010, p. 2478.

of the essence of telemedicine. In this case, telemedicine is understood as the provision of medical services by doctors at a distance using telepresence techniques[136]. For this reason, the basic structural elements of telemedicine are, from the scientific point of view, extremely interesting. They imply that important criteria of telemedicine include adaptation elements that are of momentous importance during implementation: universality, accessibility and permanent substitutability[137]. Universality refers to who uses telemedicine, which may include, for example, the entire population or a specific group of individuals. Accessibility evaluates the actual ability and capacity of the final beneficiaries to use the implemented solutions. Permanent substitutability assesses whether a traditional solution will be permanently and irrevocably replaced by a modern alternative. The combination these criteria *de lege ferenda* identifies the actual directives for the adaptation of telemedicine. From a theoretical point of view, these can lead to situations in which it becomes impossible or significantly more difficult to fully implement telemedicine in practical use. For example, they imply that telemedicine can be implemented with several different types of coverage:

- global (e.g. entire population) with full availability, together with permanent substitution,
- global (e.g. entire population) with limited availability and no permanent replacement,
- regional (e.g. community groups) with full accessibility, together with permanent substitution,
- regional (e.g. community groups) with limited availability but no permanent replacement,
- non-universal (e.g. selected and informed individuals) with limited availability combined with a permanent substitution.

The main objective of these criteria is to prevent the deployment of telemedicine that is not adapted to the realities of a specific society.

136 Adelakun and Garcia, 2019, p. 85.; Otto, 2001, p. 106.; Cohendet et al., 1998, p. 191.; Klar and Pelikan, 2011, p. 1119.; Zimpfer, 1999, p. 77.; Linkous, 2001, p. 226.; de Lucena et al., 2013, p. 129.; Argy and Caputo, 2001, p. 227.; Shaw, 2009, pp. 13-18.; Bhattacharyya, 2017, p. 6.; Spradley, 2001, p. 291.; Reynolds, 2019, p. 4.; Dafoulas et al., 2017, p. 340.; Mohr et al., 2019, p. 255.; Lynn, 2019, p. 107.; Melton et al., 2019, p. 253.; Simmons et al., 2008, p. 163.; European Commission, 2018, p. 25.; Raskas et al., 2017, p. 206.

137 The terminology presented are proposed by the author and are of a dogmatic nature.

1.5 Benefits and risks of telemedicine

1.5.1 Benefits of telemedicine

The implementation of telemedicine solutions can have a number of benefits improving how the healthcare system functions as well as the status of patients and medical staff. The situation in question does not seem peculiar, as the justification for the application of any modern technology for practical use is usually a catalogue of possible positive effects. Attention is drawn to this fact by researchers[138] and to the EU in their normative activity, particularly within the framework of the so-called soft law[139]. In these sources, the already mentioned potential positive effects of the implementation of telemedicine for general use can be pointed out. Nevertheless, for methodological reasons, these effects should be divided into general and specific benefits. The general benefits of telemedicine can be considered as improving the efficiency of the healthcare system *sensu largo* and supporting the work of doctors by increasing their efficiency. These indicators also lead to an increase in

138 For example: Hailey et al., 2002, pp. 1-7.; Reed, 2005, pp. 176-180.; Dimmick et al., 2000, pp. 124-135.; Berman and Fenaughty, 2005, pp. 559-573.; Miyahara et al., 2006, pp. 691-697.; Bilalović et al., 1998, pp. 91-93.

139 In particular: Commission Staff Working Document of 21 December 2007 Action Plan on eHealth Lead Market Initiative (COM[2007]0860 final, SEC[2007]1730); Communication From The Commission To The European Parliament, The Council, The European Economic And Social Committee and The Committee Of The Regions on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society (COM[2018]0233); Communication From The Commission To The Council, The European Parliament, The European Economic And Social Committee And The Committee Of The Regions – e-Health -making healthcare better s: An Action Plan for a European eHealth Area (COM[2004]0356); Communication from the Commission to The European Parliament, The Council, The European Economic and Social Committee and the Committee of the Regions on telemedicine for the benefit of patients, healthcare systems and society (COM[2008]0689); Communication from the Commission to The European Parliament, The Council, The European Economic and Social Committee and the Committee of the Regions: eHealth Action Plan 2012-2020 – Innovative healthcare for the 21st century (COM[2012]0736); Council conclusions on Health in the Digital Society – making progress in data-driven innovation in the field of health society (OJ.OJ of the EU C 440, 21.12.2017, p. 3); Question to the Commission on enabling the digital transformation of health and social care in the digital single market, empowering citizens and building a healthier society (O-00042/2019 – B9-0062/2019); European Parliament resolution of 18 December 2019 on enabling the digital transformation of health and care in the Digital Single Market, empowering citizens and building a healthier society (2019/2804[RSP]); Commission Recommendation (EU) 2019/243 of 6 February 2019 on a European Electronic Health Record exchange format (OJ.OJ of the EU L 39, 11.02.2019, p. 18); Commission Recommendation of 2 July 2008 on cross-border interoperability of electronic health record systems (OJ of the EU L 190, 18.07.2008, p. 37).

the confidence and satisfaction of the final beneficiaries. In this light, telemedicine can be understood as a guarantor of the right to health protection as well as a modern tool for the implementation of the right to healthcare services. This observation is crucial for further considerations related to the title issue, particularly the right to health in telemedicine. Meanwhile, the specific benefits of telemedicine can be considered to be improving the accessibility, speed, equity, safety, and quality of medical services and reducing their costs. These benefits are visible as overcoming challenges such as the barriers caused by the distance between the patient and the provider, the lack of access to transport, and the fragmentation of healthcare due to a lack of available appointments and appropriate medical staff. Telemedicine can be particularly beneficial for patients in communities in rural geographic areas where there are staff shortages, in particular because telemedicine avoids concerns regarding distance and travel time. Telemedicine can also increase the efficiency of the healthcare provided while reducing costs by reducing traditional hospitalisation as much as possible. Ultimately, this kind of application of modern technology in practical medicine facilitates greater patient involvement in their healthcare through convenient and flexible medical services delivered in real time or asynchronously. Increased satisfaction of healthcare providers, including medical staff, is also significant.

In summary, the possible positive effects of implementing telemedicine at the current stage of technical, technological and civilisation progress mean that it should be evaluated as necessary for the proper functioning of modern healthcare systems, which are aimed at full realisation of the right to health protection and healthcare services, including medical services.

1.5.2 Risks of telemedicine

A noticeable trend in the literature and the documents from international or non-governmental organisations is that discourses on telemedicine-related topics are conducted exclusively or predominantly from the perspective of the possible positive effects of the use of these technologies in medical practice[140]. This is clearly

140 Hailey et al., 2002, pp. 1-7.; Reed, 2005, pp. 176-180.; Dimmick et al., 2000, pp. 124-135.; Berman and Fenaughty, 2005, pp. 559-573.; Miyahara et al., 2006, pp. 691-697.; Bilalović et al., 1998, pp. 91-93.. The state of affairs in question is primarily related to the positive nature of the interpreted definition of telemedicine, which defines it as the provision of medical services by doctors at a distance using telepresence techniques (see Adelakun and Garcia, 2019, p. 85.; Otto, 2001, p. 106.; Cohendet et al., 1998, p. 191.; Klar and Pelikan, 2011, p. 1119.; Zimpfer, 1999, p. 77.; Linkous, 2001, p. 226.; de Lucena et al., 2013, p. 129.; Argy and Caputo, 2001, p. 227.; Shaw, 2009, pp. 13-18.; Bhattacharyya, 2017, p. 6.; Spradley, 2001, p. 291.; Reynolds, 2019, p. 4.; Dafoulas et al., 2017, p. 340.; Mohr et al., 2019, p. 255.; Lynn, 2019, p. 107.; Melton et al., 2019, p. 253.; European Commission, 2018, p. 25.; Raskas et al., 2017, p. 206.) and, secondly, from the universal priority, which can be considered to be the transmission of medical data using ICT to improve patient health.

an important aspect of the topic of this work that justifies the initiation of implementation activities. However, it is also considered necessary in this work to present the possible negative effects of implementing telemedicine. It should first be noted that the emergence of legal problems associated with the introduction of telemedicine into general use is not of a pejorative nature. These aspects may be described as difficulties for telemedicine at most, but they are not by any means associated risks. The difficulties in question have positive overtones for the legal sciences as they give rise to ways of regulating new, previously unknown matters. For example, their designations within the framework of this monograph are problems related to realising the right to health in telemedicine or the cross-border provision of medical services.

Still, every innovation has positive and negative factors. It is not possible to make an unambiguously positive or negative assessment of the impact of implementing telemedicine as it is necessary objectively and constructively judge the ratio of possible positive and negative effects. The negative effects of telemedicine can be considered to be its risks. Given that the digital transformation of medicine opens it up to a new field of application, namely cyberspace, cybercrimes become major threats[141], particularly those standardised in the Council of Europe Convention on Cybercrime[142], on the basis of which it is possible to interpret telemedicine cybercrimes[143]. This raises the possibility of new types of criminal acts in relation to the telemedical provision of medical services in cyberspace, including several illegal and intentional activities: gaining access to part or all of an information system; using technology to intercept non-public transmissions of data to, from, or within an information system, including electromagnetic emissions from the transmitting information system; destroying, deleting, damaging, or altering data; interfering with the functioning of an information system through introducing, transmitting, destroying, deleting, damaging or altering data; inputting, altering, deleting, or concealing data in such a way that the end product creates inauthentic data; an action designed to deprive another person of their property rights by inputting, altering or deleting data, or through any interference with the functioning of an IT system[144]. Nevertheless, the risk of cybercrime is part of the nature of the application of modern technology for practical use and cannot be completely

141 The issue of cybercrimes already has a rich body of doctrine, for example: Hancock, 2000, pp. 306-307.; Wible, 2003, pp. 1577-1623.; Sinrod and Reilly, 2000, pp. 1-53.; Speer, 2000, pp. 259-273.; Gercke, 2009, pp. 409-420.; Brenner and Schwerha, 2004, pp. 111-114.; Hilley, 2005, pp. 171-174.; Moitra, 2005, pp. 435-464.; Wang, 2007, pp. 216-223.; Chung et al., 2006, pp. 669-682.; Boni, 2001, pp. 18-19.; Clough, 2014, pp. 698-736.; Gercke, 2004, p. 802.

142 Council of Europe Convention on Cybercrime, drawn up in Budapest on 23 November 2001 (OJ 2015, item 728).

143 See Chapter 5. Telemedicine cybercrimes as a threat to the realisation of the right to health in telemedicine.

144 McQuade, 2009, p. 46.; Clough, 2010, p. 50.; Kerr, 2003, p. 60.; Jakobsson and Ramzan, 2008, p. 3.

eliminated. It should be remembered that these risks can be reduced by introducing legal requirements to use standardised telemedicine systems[145] and ensuring that telemedicine programmes have high security standards[146]. If these conclusions are taken into account, then the ratio of risks to possible positive effects in this case sufficiently justifies the implementation of telemedicine solutions for general use.

1.6 Summary

This chapter presents the author's reflections on the application of modern technologies for practical use in medicine. The author proposed a systematisation of the application of modern technologies in the practice of medicine along with an indication of precise potential scopes of terms such as digital medicine, eHealth, mHealth, telehealth, sensory health, and medical informatics. The author recommended that the term digital medicine should be understood as all manifestations of applications of modern technology in the practical use in medicine, as well as the fields that support its functions. The chapter highlighted that eHealth is the outer layer of digital medicine, i.e. its service layer for stakeholders, both medical staff and patients. It was then suggested that mHealth should considered as the segment of eHealth in which modern mobile technologies enable medical staff to improve a patient's health using mobile tools, such as mobile phones, tablets, or medical apps, among others. It was further noted that telehealth should be equated with the delivery of medical services at a distance using telepresence techniques. It was emphasised that the subject thus outlined includes eHealth services that take place remotely with the direct participation of medical personnel in both real time and asynchronously. Attention was also drawn to the appropriateness of treating sensory health as a separate component of the overall e-Health concept, which is responsible for the wireless care of patients by means of medical sensors that enable the collection and transmission of medical data regardless of the patient's mobility. Finally, the author proposed that medical informatics means the use of advanced communication and information technologies and programming methods to create a technical infrastructure for implementing modern technologies in medical practice. The internal correlation of the subject scopes of the above terminology was further defined. It was noted that the scope of the presented definitions are fluid in nature, and that the essence of each of the terms presented is different.

Accordingly, a semantic basis for further, more advanced scientific considerations was built. The issue of certification of digital medicine solutions was then presented. As part of these considerations, the qualification of digital medicine

145 See Chapter 5. Telemedicine cybercrimes as a threat to the realisation of the right to health in telemedicine.

146 This issue is addressed by medical informatics: Choctaw, 2008, p. 47.; Huang, 2009, p. 1423.; Closa et al., 2010, p. 155.; Venot et al., 2014, pp. 3-4.

solutions as medical devices, as defined in the Medical Device Regulation and, earlier, in Council Directive 93/42/EEC, was proposed. It was noted that this is crucial from the point of view of patient and healthcare personnel safety, which is determined by the application of a number of standards provided by law for medical devices used for digital medicine solutions. This was followed by an interpretation of the definition of a medical device under EU law by referencing the relevant CJEU case law. This clarified the EU definition of a medical device as being used for a medical purpose beyond devices intended for human use to regulate reproduction. Importantly, the possibility of qualifying digital medical solutions as medical devices has also been submitted for consideration. In this context, an extensive *de lege ferenda* postulate is presented.

These reflections have enabled the author to creatively analyse the concept of telemedicine, providing a basis for interpreting its most important structural elements and the essence of its proper terminological meaning. The author proposed that the universal priority of telemedicine should be the transmission of medical data using ICT to improve patient health, and that telemedicine itself should be understood as the provision of medical services by doctors at a distance using telepresence techniques. In this context, it was logical to present both the current and foreseeable future benefits and risks of using modern technology in medical practice.

The chapter contains a number of proposals or postulates, and considering them using the theory or practice of law will produce positive results. However, all considerations presented in this chapter should be considered in terms of the overall benefit of telemedicine, i.e., improving the efficiency of the healthcare system *sensu largo* and supporting doctors' work by increasing their effectiveness. Telemedicine can thus be seen as a new guarantor of the right to health protection as well as a modern tool for implementing the right to healthcare services. This is crucial for further considerations related to the paper's aims, particularly the right to health in telemedicine.

2

The right to health in the European Union

2.1 Introduction

This chapter aims to present the scope and relevance of the right to health in the EU, which will lead to proposing the concept of the right to health *in genere*, which is critical to the main analytical axis of this work. The right to health as a determinant of modern technologies in medicine will be discussed, and an outline of the right to health protection and healthcare services will be presented. In this case, in addition to the necessary reporting element, the main purpose of the discussion with be the author's proposal regarding the right to health based on its division into the rights to health protection and healthcare services, including medical care, and the appropriate definition of each term. The conclusions will derive from the correlation of the essence of the right to health protection and the right to healthcare services, which should lead to a proposal of the substantive and executive aspect of the right to health.

This discussion is followed by a historical outline of the right to health in EU primary laws, with the legal situation both before and after the Maastricht Treaty as the points of reference, and singling out insights into the significance of the Lisbon Treaty as the next stage in the evolution of European integration. The indicated part of Chapter 2.3, "Historical outline of the right to health in primary law European Union", aims to highlight the historical possibility of decoding both direct and indirect references to the subject matter of the right to health in primary law of the EU.

After the above considerations, as a logical continuation of the scientific discourse conducted, the manifestations of the right to health in the current EU law are approximated. This is done by indicating the provisions of the EU CFR, TFEU, and TEU, reflecting the subject matter of the right to health and identifying selected manifestations of its concretisation in secondary EU law. The above considerations allow for the realisation of the significance of the provisions discussed in the EU law system in the context of the law analysed in this chapter.

Next, the author's definition of the specific functions of telemedicine in the right to health is proposed, taking into account the distinction between the right to health protection and the right to healthcare services, including medical care. In addition, considerations related to the relationship between telemedicine and equal access to healthcare services are presented.

This chapter concludes with a concise summary containing the author's observations on the issues raised. Particular emphasis will be placed on the important prerequisite of telemedicine services guaranteeing and realising the right to health to a fuller extent, i.e. increasing equality of access to health services, including medical services, by means of cross-border provision.

2.2 The subject of the right to health

2.2.1 The right to health as a determinant of modern technology in medicine

The issue addressed here requires a methodologically appropriate introduction. The right to health protection and healthcare services, including medical care, are integral and key elements of the right to health as understood through the lens of the research plane analysed within the framework of this monograph[147]. Importantly, the above assumption is further confirmed in the literature, where one encounters manifestations of how the conceptualisation of the right to health is justified[148]. The entitlements in question can justifiably be regarded as a critical part of a normatively defined system of human rights protection[149]. It is necessary to emphasise that, from a theoretical point of view, any modern technology put into practical use should be created and implemented for and applied to human beings. The main goal of innovation should improve everyday life, possibly followed by an increase in the efficiency of the results of the processes carried out. Different types of assumptions seem pointless. This implies, in turn, that modern technologies in the form of telemedicine services that are used in the practice of medicine are obliged to comply with norms of the protection of human rights and, in particular, with those whose core is directly related to the essence of telemedicine, understood as the correlation

147 Inspiration for the definition and presentation of the subject of the right to health came from: Jasudowicz, 2010, pp. 491-495. The following studies provide additional information: Evans, 2002, pp 197-215.; Jamar, 1994, pp 17-35.; Leary, 1994, pp. 24-56.

148 The basis for the substantive elaboration of the subject of the right to health presented in this chapter were bibliographic items containing manifestations of conceptualisation in this field, for example: Waldenström et al., 1972, pp. 117-182.; Jain, 2018, pp. 139-173.; Gunn, 2008, pp. 3-7.; Amzat and Razum, 2018, pp. 17-33.; Libal and Harding, 2015, pp. 19-37.; Montgomery, 1992, pp. 184-203.; Pestova, 2014, pp. 341-372.; Iguiñiz, 2014, pp. 313-337.; McAuley, 2014, pp. 373-401.; Walker, 2014, pp. 165-192.; Evans, 2014, 233-257.; Heus and Sartawi, 2014, pp. 193-229.; Munesue, 2014, pp. 121-132.; Qiu, 2014, pp. 97-120.; Rawaf and Hassounah, 2014, pp. 135-163.; Wu, 2019, pp. 457-469.; Oke, 2016, pp. 91-122.; France, 2014, pp. 335-352.; Oke, 2017, pp. 311-326.; Claude, 1989, pp. 19-38.

149 For example: Mann et al., 1994, pp. 6-23.; Braveman and Gruskin, 2003, pp. 539-545.; Mann, 1997, pp. 6-13.; Pogge, 2005, pp. 182-209.; Mann, 1995, pp. 229-233.

of the universal priority of telemedicine with its proper terminological meaning[150]. It seems indisputable that such rights are those relating to human health, which should be an essential part of determining the legitimacy of authorising a particular type of modern technology in medicine.

2.2.2 Outline of the right to health protection

The right to health protection is the normatively defined right of every human being to be able to take care of his or her health in material or substantive terms[151]. What is important here is the abstractly understood concept of the opportunity for individuals to take care of their health, which is both a fundamental human good and extremely subjective in nature, as it is based on the individual's idea of what health is and on the concrete expectations connected with it[152]. According to the definition recognised by the World Health Organisation: ' Health is a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity'[153]; the ability to enjoy the highest attainable level of health is also a fundamental right of every human being, regardless of race, religion, political beliefs, and economic or social conditions[154]. The right to health protection is

150 As already noted, telemedicine should be equated with the provision of medical services by doctors at a distance using telepresence techniques (author's proposal based on: Adelakun and Garcia, 2019, p. 85.; Otto, 2001, p. 106.; Cohendet et al., 1998, p. 191.; Klar and Pelikan, 2011, p. 1119.; Zimpfer, 1999, p. 77.; Linkous, 2001, p. 226.; de Lucena et al., 2013, p. 129.; Argy and Caputo, 2001, p. 227.; Shaw, 2009, pp. 13-18.; Bhattacharyya, 2017, p. 6.; Spradley, 2001, p. 291.; Reynolds, 2019, p. 4.; Dafoulas et al., 2017, p. 340.; Mohr et al., 2019, p. 255.; Lynn, 2019, p. 107.; Melton et al., 2019, p. 253.; Simmons et al., 2008, p. 163.; European Commission, 2018, p. 25.; Raskas et al., 2017, p. 206.).

151 Health protection is also identified as one of the most important human rights in Urbaniak, 2008, p. 99.

152 Surówka, 2012, p. 91.

153 Constitution of the World Health Organisation, the Agreement concluded by the Governments represented at the International Health Conference and the Protocol concerning the International Office of Public Hygiene, signed in New York on 22 July 1946 (OJ 1948, No. 61, item 477).

154 The preamble to the Constitution of the World Health Organization confirms the above: 'The States Parties to the present Constitution declare in conformity with the Charter of the United Nations, that the following principles are basic to the happiness, harmonious relations and security of all peoples:
'Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition. The health of all peoples is fundamental to the attainment of peace and security and is dependent upon the fullest co-operation of individuals and States. The achievement of any State in the promotion and protection of health is of value to all. Unequal development in different countries in the promotion of health and control of disease, especially communicable disease, is a common danger. Healthy

referred to in a number of instruments of international law. First Article 55 of the Charter of the United Nations (hereinafter: UN Charter) states that the international community shall promote solutions for international economic, social, health and related issues as well as international cultural and educational cooperation[155]. Several other documents should also be noted, including: Article 25 of the Universal Declaration of Human Rights (hereinafter: UDHR)[156], Article 12 of the International Covenant on Economic, Social and Cultural Rights (hereinafter: ICESCR)[157], Article 12 of the Convention on the Elimination of All Forms of Discrimination against Women (hereafter: Convention Against Discrimination Against Women)[158], Articles 24 and 25 of the Convention on the Rights of the Child (hereafter: CRC)[159], Articles 11 and 13 of the European Social Charter (hereafter: ESC)[160], Article 10 of the San Salvador Protocol to the American Convention on Human Rights (hereafter: San Salvador Protocol to the ACHRC)[161], Article 16 of the African Charter on Human and Peoples' Rights (hereafter: ACHPR)[162], Article 35 of the Charter of Fundamental Rights of the European Union (hereafter: EU CFR)[163], Article 6 and 168 of the Treaty on the Functioning of the European Union (hereafter: TFEU)[164] and Article 3 of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (hereafter:

development of the child is of basic importance; the ability to live harmoniously in a changing total environment is essential to such development. The extension to all peoples of the benefits of medical, psychological and related knowledge is essential to the fullest attainment of health. Informed opinion and active co-operation on the part of the public are of the utmost importance in the improvement of the health of the people. Governments have a responsibility for the health of their peoples which can be fulfilled only by the provision of adequate health and social measures. Accepting these principles, and for the purpose of co-operation among themselves and with others to promote and protect the health of all peoples, the Contracting Parties agree to the present Constitution and hereby establish the World Health Organization as a specialized agency within the terms of Article 57 of the Charter of the United Nations.'

155 Charter of the United Nations, Statute of the International Court of Justice and the Agreement Establishing the United Nations Preparatory Commission (OJ 1947, No. 23, item 90).

156 Universal Declaration of Human Rights (United Nations General Assembly Resolution 217A).

157 International Covenant on Economic, Social and Cultural Rights opened for signature in New York on 19 December 1966 (OJ 1977, No. 38, item 169).

158 Convention on the Elimination of All Forms of Discrimination against Women adopted by the United Nations General Assembly on 18 December 1979 (OJ 1982, No. 10, item 71).

159 Convention on the Rights of the Child, adopted by the United Nations General Assembly on 20 November 1989 (OJ 1991, No. 120, item 526).

160 European Social Charter drawn up in Turin on 18 October 1961 (Journal of Laws 1999, No. 8, item 67).

161 Zubik, 2008, pp. 112-121.

162 Zubik, 2008, pp. 121-130.

163 Charter of Fundamental Rights of the European Union (OJ of the EU C 326, 26.10.2012, pp. 391-407).

164 Consolidated version of the Treaty on the Functioning of the European Union (OJ of the EU C 326, 26.10.2012, pp. 47-390).

Convention on Human Rights and Biomedicine)[165]. References to the right to health protection can be found in all of the above-cited legal provisions, demonstrating its relevance in an international arena that is sensitive to ensuring rights related to human health. The constitutional regulations of modern states are also significant where, as in the international system, the right to health protection is provided for directly or indirectly. This remark applies, for example, to Article 23 of the Constitution of the Kingdom of Belgium (hereafter: CKB[166], Article 52 of the Constitution of the Republic of Bulgaria (hereafter: CoRoB)[167], Article 59 of the Constitution of the Republic of Croatia (hereafter: CoRoC)[168], § 28 of the Constitution of the Republic of Estonia (hereafter: CoRoE)[169], § 19 of the Constitution of the Republic of Finland (hereafter: CoRoF)[170], § 11 of the Introduction to the Constitution of the French Republic of 27 October 1946 (hereafter: Introduction to the 1946 CoFR.)[171], Article 5 of the Constitution of Greece (hereafter: CG)[172], Article XX of the Constitution of Hungary (hereafter: CH)[173], Article 32 of the Constitution of the Italian Republic (hereafter: CoRoI)[174], Article 31 of the Charter of Fundamental Rights and Freedoms (Czech Republic) (hereafter: CZ CFR)[175], Article 43 of the Constitution of Spain (hereafter: CS)[176] or Article 68 of the Constitution of the Republic of Poland (hereafter: CoRoP)[177].

From this paper's point of view, the issue that needs the most scientific clarification is the normative character of the right to health protection. The literature notes that this is generally classified as a second-generation right, but it remains directly linked to first-generation rights, such as the rights to life, privacy, and information, as well as the freedom from inhuman or degrading treatment or punishment, or the freedom of conscience and religion[178]. Because of this special connection, the right to health protection is sometimes classified not only as a

165 *A selection of documents…*, pp. 679-682.
166 Staśkiewicz, 2011, pp. 21-83.
167 Karp 2012, pp. 51-118.
168 Constitution of the Republic of Croatia (Croatian Official Gazette 56/90, 135/97, 8/98 – vol., 113/2000, 124/2000 – t. j., 28/2001, 41/2001 – t. j., 55/2001 – correction, 76/2010).
169 *Constitutions of the States of the European Union…*, pp. 227-247.
170 *Constitutions of the States of the European Union…*, pp. 249-270.
171 Mycielski, 1947, pp. 9-10.
172 *Constitutions of the States of the European Union…*, pp. 297-340.
173 Trócsányi, 2017, p. 133.
174 *Constitutions of the States of the European Union…*, pp. 845-870.
175 *Constitutions of the States of the European Union…*, pp. 191-212.
176 *Constitutions of the States of the European Union…*, pp. 341-374.
177 Constitution of the Republic of Poland of 2 April 1997 passed by the National Assembly on 2 April 1997, adopted by the Nation in a constitutional referendum on 25 May 1997, signed by the President of the Republic of Poland on 16 July 1997 (Journal of Laws of 1997, No. 78, item 483.; of 2001, No. 28, item 319.; of 2006. No. 200, item 1471.; of 2009. No. 114, item 946.).
178 Jasudowicz, 2010, pp. 491-495.

typical social right, but also as a personal right[179]. This distinction is crucial because the concepts protected as personal rights are all goods of the human being that commonly regarded as the most valuable from the point of view of physical, psychological and legal existence, which serving to create appropriate conditions for development and protect against any unjustified interference[180]. In addition, every human being has the right to these protections, regardless of his or her qualities[181]. For this reason, personal rights tend to be more general concepts. The normative character of a personal right seems abstract from additional conditions as the essence of such legal norms excludes their relevance. Social rights, on the other hand, generally are programmatic norms addressed to the public authority. They require specific, concrete actions be taken by public authority to guarantee their realization and the material basis of their existence[182]. Importantly, the subject of a social right is, as a rule, made concrete by indicating its specific feature that links a specific individual with a specific public authority in a legal relationship. Given how this type of relationship functions, it will often be based on the legal status of citizenship. The scope of realisation of the social right is also made dependent on additional conditions, such as the economic conditions of the state that is obliged to take positive action. In the light of this, it is noticeable that there is a dispute about the proper conceptualisation, including the actual normative character of the right to health protection. This dispute is based on the distinction presented above regarding the necessity of deciding whether the right to health protection should be classified as a social or a personal right. However, an important caveat is needed. The right to health protection under analysis here should not be understood through the lens of a specific legal provision, but instead should be understood in the abstract, i.e., as a general human right. This caveat is of momentous theoretical value as it detaches scientific considerations from the specific legal system and the question of how legal provisions are formulated, focusing exclusively on the normative nature of the essence of the right to health protection. A subordinate question of a legal nature, secondarily related to the above, is whether the right to health protection gives rise to a claim on the part of its beneficiary against the State, and thus whether the right to health protection is a subjective right.

It is important to lean into the scientific issues outlined above in a logical, chronological order because determining the primary issue will affect the understanding of the secondary issue. In this view, the primary legal issue will be to decide whether the right to health protection should be classified as a social right or as a personal right. It is also worth noting that the existence of the already

179 Piechota, 2010, pp. 137-142.; Zoll, 2000, p. 8.; Mikos and Urbaniak, 2016, pp. 160-166.; Surówka, 2012, p. 98.; K. Ryś, 2017, p. 119.; Surówka, 2009, p. 395.; Piechota, 2012, pp. 93-102.

180 Rex, 1980, pp. 391-403.; Surówka, 2012, p. 93.

181 Sarnecki, 2002, p. 1.

182 Piechota, 2012, p. 93.; Banaszak, 2002, p. 27.; Zawadzka, 1996, p. 9.; Karp, 2007, p. 150.

presented dogmatic dispute relating to the subject of the conducted analysis[183] does not affect the essence of the dilemma put forward for consideration. Therefore, it is necessary that the essence of the question directly refer to the establishment of a desirable and strictly defined course of reasoning. This must be determined from the point of view of assumptions regarding humanity and the system that protects human rights. The question is related not only to issues that concern legal science, but also, and perhaps, more so foundations of the axiology of human functioning. A critical element is identifying the fundamental matter reflecting the autonomous, internal thinking of the individual. From a methodological point of view, this point of view seems appropriate to clarify whether the right to health protection should be classified as a personal right because a negative result demonstrates that the right to health protection should be classified as a social right.

To this end, it is first necessary to determine what good constitutes the object of protection of the right to health. Undoubtedly, such a good is not health considered independently; it also includes the abstract understanding of taking care of health and the indirect protection of the right to life[184]. This is good unquestionably one of the most basic human goods from the point of view of physical, psychological, or legal existence. Significantly, the claim that it serves both to create the right conditions for development and to protect against unjustified external interference seems legitimate. The above theses do not seem controversial; their negation would constitute an unjustified instrumentalisation of the analysed right. Therefore, the presented line of reasoning fulfils the premises of the classification of a personal right in its material aspect[185].

Second, determining the subjective scope of the right to health protection, i.e., concretising the beneficiaries of the mentioned goods is necessary. It should be established whether the right to health protection as understood in the concept of

183 The issue in question is widely discussed in the foreign literature, where the following are particularly noteworthy: Waldenström et al., 1972, pp. 117-182.; Jain, 2018, pp. 139-173.; Gunn, 2008, pp. 3-7.; Amzat and Razum, 2018, pp. 17-33.; Libal and Harding, 2015, pp. 19-37.; Montgomery, 1992, pp. 184-203.; Pestova, 2014, pp. 341-372.; Iguiñiz, 2014, pp. 313-337.; McAuley, 2014, pp. 373-401.; Walker, 2014, pp. 165-192.; Evans, 2014, 233-257.; Heus and Sartawi, 2014, pp. 193-229.; Munesue, 2014, pp. 121-132.; Qiu, 2014, pp. 97-120.; Rawaf and Hassounah, 2014, pp. 135-163.; Wu, 2019, pp. 457-469.; Oke, 2016, pp. 91-122.; France, 2014, pp. 335-352.; Oke, 2017, pp. 311-326.; Claude, 1989, pp. 19-38. Additionally, it should be noted that the research problem in question is also evident in the Polish literature, specifically: Piechota, 2010, pp. 137-142.; Zoll, 2000, p. 8.; Mikos and Urbaniak, 2016, pp. 160-166.; Surówka, 2012, p. 98.; Ryś, 2017, p. 119.; Surówka, 2009, p. 395.; Piechota, 2012, pp. 93-102.

184 It is for this reason that a foreigner may not be denied medical care, with the proviso that it need not be free of charge. This means that, from a theoretical point of view, a foreigner arriving under the jurisdiction of a foreign public authority has the right to health protection, however, he/she is not necessarily entitled to healthcare services, including medical care, as the latter entitlement is usually reserved for citizens of a specific state. For example, the solution in question is provided for by the Polish legal order.

185 Rex, 1980, pp. 391-403.; Surówka, 2012, p. 93.

the above-mentioned observations belongs to every human being solely because he or she is a human being. This follows directly from the assumptions of equality and human dignity, and the classification premise of a personal right in the aspect of subjectivity is also fulfilled[186]. In view of the above remarks, it should be proposed *de lege ferenda* that the right to health protection as understood within the presented semantic limits should be classified as a personal right, constituting a material guarantee of health protection. The latter should at the same time be regarded as a specific, core feature of the right to health. In addition, the findings presented thus far imply, both primarily and secondarily, that the right to health protection should oblige the public authorities to take positive action that will ensure the essence of the good that will be protected by law, and thus should be seen as a subjective right. A caveat must be made, however, that the claims made fall only within the substantive limits of the right to health as presented.

2.2.3 Outline of the right to healthcare services

As was the case when analysing the right to health protection, the right to healthcare services, including medical care, is envisaged in many acts of international law and in the constitutional orders of modern states. Interestingly, as a general rule, the legal bases relevant to the former right are simultaneously relevant to the latter. This is because legal provisions from which the right to health protection can be directly or indirectly interpreted usually also refer directly or indirectly to the right to healthcare services, including medical care, or vice versa, and thus contain at least a general reference to the right to health. Therefore, the right to healthcare services, including medical care, can be identified in Article 55 of the UN Charter, Article 25 of the UDHR, Article 12 of the ICESCR, Article 12 of the Convention Against Discrimination Against Women, Articles 24 and 25 of the CRC, Articles 11 and 13 of the ESC, Article 10 of the Protocol of San Salvador to the ACHRC[187], Article 16 of the ACHRC[188], Article 35 of the EU CFR, Arts. 6 and 168 of the TFEU, Article 3 of the Convention on Human Rights and Biomedicine[189], and in the relevant national regulations, more specifically in Article 23 of the CKB[190], Article 52 of the CoRoB[191], Article 59 of the CoRoC, Article 28 of the CoRoE[192], Article 19 of the CoRoF[193], Article 11 of the CFR

186 Sarnecki, 2002, p. 1.
187 Zubik, 2008, pp. 112-121.
188 Ibid, pp. 121-130.
189 Ibid, pp. 679-682.
190 Staśkiewicz, 2011, pp. 21-83.
191 Karpińska, 2012, pp. 51-118.
192 Staśkiewicz, 2011, pp. 227-247.
193 Staśkiewicz, 2011, pp. 249-270.

1946[194], Article 5 of the CG[195], Article XX of the CH[196], Article 32 of the CoRoI[197], Article 31 of the CZ CFR[198], Article 43 of the CS[199] or Article 68 of the CoRoP.

The right to healthcare services, including medical care, is a normatively stipulated entitlement of a person to benefit from universally available healthcare services offered by a specific public authority exercising jurisdiction over a well-defined geographical area or individuals over whom it has *de facto* authority and who exhibit an actual state of unhealth[200]. From a methodological approach, it should be noted that the material scope of the concept of healthcare is much broader than that of medical care. This is because, in principle, the latter should be determined by the actual medical need, particularly as understood through the lens of clinical, hospital, or pharmacological services. Healthcare, meanwhile, also encompasses all non-clinical, non-hospital, or non-pharmacological health services that have a positive impact on general health. The relationship between these concepts is governed by the unidirectional principle of inclusion of medical care in healthcare. According to this principle, every medical care benefit is also a healthcare benefit, but not every healthcare benefit is a medical care benefit[201]. As a rule, beneficiaries of the right to healthcare services, including medical care (hereinafter: healthcare), are guaranteed access to the entire health system *in genere*, and not selectively to a single or selected benefit[202]. Although the right in question is multifaceted[203], it seems that, from a theoretical point of view, its most important element is the concretisation of the medical protection of life and the abstract possibility of taking care of one's health. This takes place in the form of a precise indication of the types of healthcare services to which specific groups of beneficiaries will be entitled. To this end, public authorities issue legal regulations reflecting the rights under consideration. The main premise of these regulations is to adapt the care offered to the development of medicine by providing increasingly modern healthcare[204]. Howev-

194 Mycielski, 1947, pp. 9-10.
195 Staśkiewicz, 2011, pp. 297-340.
196 Trócsányi, 2017, p. 133.
197 Staśkiewicz, 2011, pp. 845-870.
198 Ibid, pp. 191-212.
199 Ibid, pp. 341-374.
200 Author's suggestion is based on: Arras, 1984, pp. 23-45.; Childress, 1984, pp. 47-70.; Kluge, 2002, pp. 29-48.; Cummiskey, 2004, pp. 187-202.; Green, 2004, pp. 203-221.; Toebes and San Giorgi, 2014, pp. 403-436.; Sass, 1991, pp. 243-255.; Halper, 1991, pp. 135-168.; Marmor, 1991, pp. 23-49.; Agich, 1991, pp. 185-198.; Daniels, 1991, pp. 201-212.; Engelhardt, 1991, pp. 103-111.; Buchanan, 1991, pp. 169-184.; Beauchamp, 1991, pp. 53-81.; Merrill, 1994, pp. 99-128.; Mpedi, 2020, pp. 77-100.; Tu, 2019, 59-84.; Kirchner, 2018, pp. 141-151.; Holder, 1989, pp. 161-172.; Sulmasy, 2008, pp. 25-36.; Tomossy, 2008, pp. 341-352.; Serwach, 2011, p. 20.
201 For example, a heart transplantation is both a health and medical benefit, whereas a visit to a dietician to work out a healthy meal schedule is purely a healthcare benefit.
202 Lach, 2011, p. 178.; Baka, 2010, pp. 124-125.; Dercz and Rek, 2012, p. 41.
203 Bujny, 2007, pp. 109-110.
204 Jarosz-Żukowska, 2014, p. 660.

er, the latter unfortunately results in a negative tendency to limit the scope of the healthcare in question rather than expand it due to limited material, personnel or financial resources[205]. It is also important to note that, for the right to healthcare services, there is a social perception regarding to what level the entitlement in question is realised, which usually takes the form of the ideal of a long life in good health and equal and fair access to healthcare services[206].

From the perspective of the present work's research aim, the key issue requiring clarification is the normative nature of the right to healthcare services. It is necessary to confirm whether the right in question is a social right rather than one giving rise to claims against public authority on the part of the beneficiary[207]. This is of major theoretical importance as it will determine whether the right to healthcare services in the light of the right to health is characterised by the nature of a purely material guarantee or whether it has a more procedural or executive value. The test already presented is therefore conducted based on two qualifying premises—subjective and material—to verify whether the right to healthcare services is a personal right. A positive result shows that the analysed right has a personal normative character while a negative result certifies that it is a social right. It is therefore essential to immediately establish what type of good is the object of protection of the right to healthcare services. Based on the views represented in the literature, it seems reasonable to suggest that equal access to healthcare, which effectively protects health and guarantees participation in treatment regardless of the material situation of the beneficiary[208], should be regarded as such a good. It should be emphasised that such a good is not the healthcare system as such, but is instead fair

205 Ostrzyżek, 2005, p. 65.

206 Jończyk 2005, p. 110.

207 Although it is sometimes indirect evidence, the literature shows that advocacy for qualifying the right to healthcare services is a social right, for example: Arras, 1984, pp. 23-45.; Childress, 1984, pp. 47-70.; Kluge, 2002, pp. 29-48.; Cummiskey, 2004, pp. 187-202.; Green, 2004, pp. 203-221.; Toebes and San Giorgi, 2014, pp. 403-436.; Sass, 1991, pp. 243-255.; Halper, 1991, pp. 135-168.; Marmor, 1991, pp. 23-49.; Agich, 1991, pp. 185-198.; Daniels, 1991, pp. 201-212.; Engelhardt, 1991, pp. 103-111.; Buchanan, 1991, pp. 169-184.; Beauchamp, 1991, pp. 53-81.; Merrill, 1994, pp. 99-128.; Mpedi, 2020, pp. 77-100.; Tu, 2019, 59-84.; Kirchner, 2018, pp. 141-151.; Holder, 1989, pp. 161-172.; Sulmasy, 2008, pp. 25-36.; Tomossy, 2008, pp. 341-352.; Serwach, 2011, p. 20.

208 The basis for interpreting the legal good protected by the right to healthcare services was the correlation between selected literature regarding the right to health, health protection, or healthcare services: Pestova, 2014, pp. 341-372.; Iguiñiz, 2014, 313-337.; McAuley, 2014, pp. 373-401.; Walker, 2014, pp. 165-192.; Evans, 2014, 233-257.; Heus and Sartawi, 2014, pp. 193-229.; Munesue, 2014, pp. 121-132.; Qiu, 2014, pp. 97-120.; Surówka, 2012, p. 98.; Ryś, 2017, p. 119.; Green, 2004, pp. 203-221.; Marmor, 1991, pp. 23-49.; Buchanan, 1991, pp. 169-184.; Tu, 2019, 59-84. An additional, subsidiary basis was the legal provisions referring to the right to healthcare services (in various semantic scopes: Article 55 UN Charter, Article 25 UDHR, Article 12 ICESCR, Article 12 Convention Against Discrimination Against Women, Article 24 and 25 CRC, Article 11 and 13 ESC, Article 10 San Salvador Protocol to the ACPHRC, Article 16 of the ACCC, Article 35 EU CFR, arts. 6 and 168 TFEU, Article 3 of the Convention on Human Rights and Biomedicine, Article 23 CKB, Article 52 CoRoB,

access to the healthcare system, with the system itself based on the principles of speed, cost reduction, accessibility, equality, safety, and the highest possible quality of services provided. It is worth noting that, in this view, the healthcare system is drawn as an infrastructural component of the right to healthcare services, and the possibility of participating in it appears as the material basis of the entitlement in question. It seems that, due to the particularly close connection between the described legal good and healthcare *in genere*, it is reasonable to claim that this kind of good may meet the criteria of the personal right in question. However, determination of this would require additional justification beyond the scope of this work. Regardless, healthcare is, as a rule, offered to an individual in a concrete state of facts, where the medical risk can be identified[209]. The individualisation indicated will most often be linked to the legal status of the nationality of the state obliged to take positive action. This means that the right to healthcare services *ex definitione* does not belong to every person just because he or she is a human being, but to the person who fulfils additional conditions. The analysis so far therefore leads to the conclusion that the right to healthcare services does not meet the subjective premise of a personal right. For this reason, it has a social normative character that directly affects the determination of its essence. This, in turn, is founded on guaranteeing the realisation of the right to health in the institutional aspect, constituting a means to realise the main objective, i.e. health protection.

2.2.4 Correlation of the essence of the right to health protection and healthcare services

In view of the observations made so far, it seems justifiable to postulate that the subject of the right to health, as understood within the semantic boundaries set, should be identified primarily in correlation with the essence of the rights to health protection and healthcare services. The above is a fundamental component of the right to health, which is the main research axis of this paper monograph. In addition, it is worth pointing out that the subject matter also complements other generic elements[210]. It seems rational, therefore, to theorise that the right to health protection is a substantive guarantee of the right to health, while the right to healthcare services is more executive in nature. First, this means that the right to health has a material aspect, where there is both a legally protected good in the form of self-treated health, the abstractly understood possibility for individuals to care for their health on their own, and the indirect protection of the right to life, and an unconditional subjective scope, according to which every human being, regardless

Article 59 CoRoC, § 28 CoRoE, § 19 CoRoF, § 11 of the 1946 CFR, Article 5 CG, Article XX CH, Article 32 CoRoI, Article 31 CZ CFR, Article 43 CSor Article 68 CoRoP).

209 Lach, 2011, p. 178.

210 For example, in this context, it refers to individuals managing their own physical condition.

of his or her qualities, should have such a right simply because he or she is a human being. The subjective aspect is of a personal normative nature and materialises in the form of the material core of the right to health.

Second, the right to health has an executive aspect, in which both the legally protected good (equal access to healthcare that effectively protects health and guarantees access to treatment regardless of the material situation of the beneficiary) and the contingent subjective scope are evident. In this respect, the right *ex definitione* does not belong to every person just because he or she is a human being, but to the person who fulfils additional conditions[211]. Consequently, this aspect has a social normative character, concretising itself in the form of the right to healthcare services, which constitutes an institutional guarantee for the realisation of the material aspect of the right to health, which is the most essential means for the realisation of the main objective, i.e. health protection.

In summary, the above observations on the subject of the right to health postulate that the right to health protection defines the endpoint while the right to healthcare services is the main means to its realisation. Consequently, it is not possible to speak fully of the right to health without any of its aspects, either material or executive.

2.3 Historical outline of the right to health in primary law of the European Union

2.3.1 Evolution of the right to health up to the Maastricht Treaty

When analysing the evolution of the right to health in EU law, it is important to remember the Treaty history, including the idea of European integration and that it was originally purely economic in nature. It was only later that social and political integration mechanisms began to be implemented, with the gradual emergence of guarantees for personal and social human rights as fundamental rights, including the right to health as a reference point. To present the analysed process, it is necessary to examine the treaties that are the most important foundations of the currently functioning EU in chronological order and determine whether there are legal norms directly or indirectly referring to the subject of the right to health. This will be done based on the author's division of European integration into two stages: economic, leading up to the Treaty on European Union of 7 February 1993 (hereinafter: Maastricht Treaty/TEU)[212], and socio-political, after the Maastricht Treaty[213].

211 For example, the condition of citizenship from the state obliged to take positive action.
212 Treaty on European Union of 7 February 1993 (OJ of the EU C 191, 29.07.1992, pp. 1-112).
213 The semantic definition of the stages of European integration is only intended to give an indicative indication of the main reference point for this academic monograph.

There are five treaties within the economic phase. The first treaty was the Treaty establishing the European Coal and Steel Community of 18 April 1951 (hereinafter: TECSC)[214]. Its main objective, according to Article 2 TECSC, was to define interdependence and contribute to economic development, increase employment, and raise living standards by creating a common market for coal and steel[215]. This was intended to build confidence and minimise tensions in post-World War II Europe. TECSC therefore lacks indirect or direct references to the right to health.

Second was the Treaty establishing the European Economic Community of 25 March 1957 (hereinafter: TEEC)[216], and third was the Treaty establishing the European Atomic Energy Community of 25 March 1957 (hereinafter: TEAEC)[217]. Both treaties represented a further stage of integration, the aim of which became general European economic cooperation[218]. In addition to the purely economic elements, TEEC also included provisions on raising living standards and closer ties between Member States. In the original version of TEEC, as in TECSC, there are no indirect or direct references to the right to health. Notwithstanding this, TEAEC included provisions alluding to a high level of health protection; however, these were only concerned with the use of nuclear energy.

Fourth was the Treaty establishing a Single Council and a Single Commission of the European Communities of 8 April 1965 (hereinafter: Fusion Treaty)[219]. The aim of this legislation was to streamline the activities of the Community institutions by establishing a single structure for the European Economic Community (hereafter: EEC), European Atomic Energy Community (hereafter: EURATOM) and European Coal and Steel Community (hereafter: ECSC)[220]. While the Merger Treaty had a technical value as it maintained the economic nature of European cooperation, it did not contain provisions directly or indirectly referring to the right to health.

214 Treaty establishing the European Coal and Steel Community of 18 April 1951 (Document 11951K/TXT) available on the official database of European Union legislation (https://eur-lex.europa.eu/legal-content/PL/TXT/?uri=CELEX: 11951K/TXT – accessed 30.06.2020.).

215 This issue is addressed in, for example: Van Panhuys et al., 1968.; Glockner and Rittberger, 2012, pp. 16-47.; Paxton, 1976, pp. 161-192.; Walsh and Paxton, 1975, pp. 61-66.; Bouscaren, 1969, pp. 106-114.

216 Treaty establishing the European Economic Community of 25 March 1957 (Document 11957E) available on the official database of European Union legislation (https://eur-lex.europa.eu/legal-content/PL/TXT/?uri=CELEX:11957E – accessed 30.06.2020.).

217 Consolidated version of the Treaty establishing the European Atomic Energy Community (OJ of the EU C 203, 7.06.2016, pp. 1-112).

218 The problem is addressed, for example: Harvey, 1974, pp. 99-101.; Van Panhuys et al., 1968, pp. 752-888.; Chilver, 1984, pp. 239-242.; Idem, 1984, pp. 706-751.; Nelson, 1958, pp. 36-64.

219 Treaty establishing a Single Council and a Single Commission of the European Communities of 8 April 1965 (OJ 152, 13.07.1967, pp. 2-17); Van Panhuys et al., 1968, pp. 889-904.

220 This issue is addressed in, for example: Laursen, 2012, pp. 77-97.; Weil, 1967, pp. 57-65.

Fifth was the Single European Act of 17 February 1986[221] (hereinafter: SEA)[222]. This treaty made further reforms to the Community institutions, accelerating the decision-making process in preparation for the Single Market primarily by modifying voting procedures in terms of the required majority, strengthening the influence of the parliament, and introducing cooperation and consent procedures[223]. The SEA implemented the legal basis for the extension of Community policies to new areas related to cooperation at the political and social level into the Treaty provisions, taking a significant step towards fuller European integration that was focused only focused on economic matters, but also on scientific research, environmental protection, or technological development. In turn, from the point of view of the provisions concerning the subject matter of the right to health, the SEA provided for the addition of a new Article 100a to TEEC, according to which, in the legislative procedure, the Commission of the European Communities was obliged to use a high level of base protection in the fields of health, safety, environmental protection, and consumer protection. In addition, the SEA also introduced Article 118a, previously unknown in TEEC, which obliged Member States to attach particular importance to the promotion of improvements, especially in the fields of working environment and protection of workers' health and safety, and to consider harmonizing conditions in this area to be their objective. The above provisions of the SEA directly refer to the subject matter of the right to health protection, while its provisions for matters such as environmental protections do so indirectly.

These considerations lead to the conclusion that the idea of European integration was initially of an economic nature, based on the direct and indirect matters of measures related to the right of health, has evolved over time to have a more social and political integration. TECSC, TEEC, TEAEC, and the Merger Treaty did not contain legal norms correlating to the right to health. The SEA did, and by doing so, it represented a significant re-profiling of the idea of European integration towards opening up to social and political cooperation among Member States. The SEA is of momentous importance for the right to health in the EU as it laid the foundation for a new, previously undefined area of EU action, which was fleshed out in the Maastricht Treaty.

2.3.2 Evolution of the right to health since the Maastricht Treaty

Four key episodes in the evolution of European integration can be discerned within the socio-political phase. The final episode will be discussed in detail in the next section due to its importance.

221 All member states (other than Italy, Greece, and Denmark) signed the Single European Act at that time; Italy, Greece, and Denmark signed the act on 28 February 1986 in The Hague.
222 Single European Act of 17 February 1986 (OJ of the EU L 169 of 29.06.1987, pp. 1-28.).
223 This issue is addressed by, for example: Dinan, 2012, pp. 124-146.; Noël, 1991, pp. 57-63.; Moravcsik, 1994, pp. 211-233.; Wessels, 1991, pp. 143-160.; de Ghellinck, 1988, pp. 133-156.

The first episode was the Maastricht Treaty, which introduced the foundations of a monetary union and a political union, particularly through its provisions for a common foreign and home affairs policy and citizenship[224]. From a historical point of view, this act is important for the development of the EU ideas, as it created the EU[225] and renamed the EEC the European Community (hereafter: EC), gave the parliament more powers in the decision-making process, and introduced new levels of cooperation, such as defence or justice[226]. For these reasons, this piece of legislation should be seen as opening up a new stage of European integration. The Treaty of Maastricht made direct reference to the subject of the right to health, in particular by introducing the new wording of Article 3 of the Treaty establishing the European Community (hereinafter: TEC)[227], according to which Community activities were required to contribute to the attaining a high level of health protection. An extension of the above was added to Title X 'Public Health' in TEC, where it was confirmed that the EC contributes to ensuring a high level of human health protection in the form of supporting and encouraging cooperation between Member States in the field of public health. Unfortunately, the role of the EC in this respect and for the time being has been limited to incentive measures and recommendations. The provisions of the Maastricht Treaty on consumer protection and the environment did indirectly refer to the subject of the right to health.

The second episode included the Treaty of Amsterdam, which amended the Treaty on European Union, the Treaties establishing the European Communities, and certain related acts of 2 October 1997 (hereinafter: the Treaty of Amsterdam)[228], which clarified TEU and TEC and made further structural changes to prepare EU

224 This issue is addressed in, for example: Contogeorgis, 1993, pp. 33-38.; Mazzucelli, 2012, pp. 147-179.; Jordan, 2002, pp. 79-96.; Watson, 1997, pp. 49-65.; Dehousse, 1997, pp. 15-32.; Bierbach, 2017, pp. 301-345.

225 According to Article A of the Maastricht Treaty: 'By this Treaty, the High Contracting Parties establish among themselves a European Union, hereinafter called 'the Union.' This Treaty marks a new stage in the process of creating an ever closer union among the peoples of Europe, in which decisions are taken as closely as possible to the citizen. The Union shall be founded on the European Communities, supplemented by the policies and forms of cooperation established by this Treaty. Its task shall be to organize, in a manner demonstrating consistency and solidarity, relations between the Member States and between their peoples.' Translation based on the official database of the Sejm of the Republic of Poland (http://oide.sejm.gov.pl/oide/images/files/dokumenty/traktaty/Traktat_z_Maastricht_PL_1.pdf – accessed 3.07.2020).

226 This issue is addressed in, for example: Contogeorgis, 1993, pp. 33-38.; Mazzucelli, 2012, pp. 147-179.; Jordan, 2002, pp. 79-96.; Watson, 1997, pp. 49-65.; Dehousse, 1997, pp. 15-32.; Bierbach, 2017, pp. 301-345.

227 Under Article G of the Maastricht Treaty: 'The Treaty establishing the European Economic Community shall be amended in accordance with the provisions of this Article, in order to establish a European Community. A – Throughout the Treaty: 1) The term 'European Economic Community' shall be replaced by the term 'European Community.''

228 Treaty of Amsterdam amending the Treaty on European Union, the Treaties establishing the European Communities and certain related acts of 2 October 1997 (OJ of the EU C 340, 10.11.1997, pp. 1-144.).

for the accession of new Member States. This was primarily done by increasing the importance of the ordinary legislative procedure to minimise the complexity of EU decision-making in the EU[229]. Although the Treaty of Amsterdam was more technical, it also included provisions that directly addressed the subject of the right to health. Under it, Article 129 TEC was amended to indicate that a high level of human health protection should be ensured in the definition and implementation of all Union policies and activities. This emphasis was directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health, including health information and education and combating pandemics. The Treaty of Amsterdam provided the EU with a mandate not only to take incentive measures and recommendations, as the Maastricht Treaty did, but also to adopt legal instruments that set high standards of quality and safety for organs and substances of human origin, blood and blood derivatives, and to adopt measures in the veterinary and phytosanitary fields that were directly aimed at protecting public health. It was emphasised that any Community action in the field of public health must respect the responsibility of the Member States for the organisation and delivery of healthcare and medical care services. The Amsterdam Treaty also included provisions indirectly relating to the subject of the right to health, particularly the legislative procedure, the working environment and occupational safety, and consumer protection.

The third episode involved the Treaty of Nice, which amended the Treaty on European Union, the Treaties establishing the European Communities, and certain related acts of 26 February 2001 (hereinafter: the Treaty of Nice)[230]. These amendments were made mainly through changes in the method of composition of the Union's institutions, enabling the EU to function effectively and efficiently with 25 Member States[231]. Due to the extremely technical nature of the treaty in question, it did not provide for provisions directly addressing the subject of the right to health protection. It contains only indirect references on this level in the form of provisions concerning the protection of the health and safety of workers and the conclusion of international agreements on trade in human health services.

In conclusion, the considerations so far justify the claim that, from the Maastricht Treaty, via the Treaty of Amsterdam, to the Treaty of Nice, it is possible to observe an increasingly fuller, more complete, and more effective handling of the issues of both health protection and access to healthcare services, i.e., *in genere* the

229 Such moves are shown in, for example: Stubb, 2002, pp. 58-105.; Zbinden, 1998, pp. 207-241.; Jordan, 2002, pp. 97-112.; Vanhoonacker, 2012, pp. 180-195.; Hug and König, 2006, pp. 133-150.; Maurer, 2006, pp. 115-133.; Dinan, 1999, pp. 290-310.

230 Treaty of Nice amending the Treaty on European Union, the Treaties establishing the European Communities and certain related acts of 26 February 2001 (OJ of the EU C 80, 10.03.2001, pp. 1-87).

231 This issue is addressed in, for example: Beneyto, 2008, pp. 1-19.; Stubb, 2002, pp. 106-122.; Laursen, 2012, pp. 196-216.

right to health in the EU. This clearly shows that this issue is a priority for the EU and requires an in-depth and comprehensive academic approach.

2.3.3 The Lisbon Treaty as the next chapter in evolution

The separation of the Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community of 13 December 2007 (hereinafter: the Treaty of Lisbon)[232] for a separate analysis is justified by the two-pronged nature of its significance. The Treaty of Lisbon can be examined from a historical point of view, but it is also a source of current primary law in the EU. The Treaty should therefore be seen through the lens of the boundary between what can be defined in terms of the past and what remains current today. Under it, TEC was renamed TFEU, and the main objective of the changes carried out at the time was to enable the EU to represent a unified position on global issues[233]. This was also designed to strengthen the efficiency and democratic principles throughout EU[234]. To this end, the Lisbon Treaty provided for a citizens' initiative, a new EU diplomatic service, a new High Representative for Foreign Affairs, a permanent President of the European Council, a change in voting procedures in the EU Council, an increase in the powers of the European Parliament, and a clarification of which powers belong to the EU, to the Member States, and which ones are shared between them[235]. In addition, compatible modifications were made to the objectives and values of the EU. Importantly, the Lisbon Treaty also amended Article 6 of TEU where, according to its new wording, EU recognised the rights, freedoms and principles set out in the Charter of Fundamental Rights of the European Union of 7 December 2000, as adapted on 12 December 2007 in Strasbourg[236]. By virtue of the same provision, EU CFR was given a legal force equal to that of the Treaties, making it an integral part of primary law. Since the legal status of primary law of the EU, as shaped in accordance with the provisions of the Lisbon Treaty, is current and universally applicable, a discussion of its direct and indirect references on the subject matter of the right to health will be discussed in the next subsection. However, for the moment, it can be pointed out that this Treaty represents a furthering of European integration but does not seem to be its final manifestation.

232 Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community of 13 December 2007 (OJ of the EU C 306, 17.12.2007, pp. 1-271).

233 This issue is addressed in, for example: Phinnemore, 2013, pp. 1-15, pp. 211-228.; Murray, 2012, pp. 179-189.; Ziller, 2008, pp. 309-335.

234 This issue is addressed in, for example: Ziller, 2012, pp. 244-268.; Stajano, 2009, pp. 269-307.; Jahn, 2015, pp. 141-156.

235 The issue is presented in, for example: Wouters et al., 2008, pp. 143-203.; Ponzano, 2008, pp. 135-141.; Hecker, 2015, pp. 1-6.; Quisthoudt-Rowohl, 2013, pp. 107-111.; Pernice, 2008, pp. 235-256.; Louis, 2008, pp. 285-298.; Häde, 2012, pp. 421-441.; de Witte, 2008, pp. 79-108.

236 The Charter of Fundamental Rights of the Union…

2.4 The right to health in current European Union law

2.4.1 Reflecting the right to health in the EU CFR

A number of references to the subject of the right to health can be seen in the current primary law of the EU as shaped by the Lisbon Treaty. It should be emphasised, however, that primary EU law consists essentially of the founding treaties, the accession treaties of the Member States of the EU, and their protocols and annexes[237]. In addition, as noted above, under the Lisbon Treaty, EU CFR has been given a legal force equal to that of the Treaties. This means that the EU CFR should also be counted as a primary law of the EU[238]. Due to the different nature of the indicated sources of the EU law, it becomes necessary to select the group of primary law acts that are most important for determining references to the subject of the right to health protection. This group appears to be EU CFR and the founding Treaties, and TEU and TFEU in particular, as they constitute the foundation of the current EU and how it functions. In this regard, EU CFR includes Article 35, according to which:

> Everyone has the right of access to preventive healthcare and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities.[239]

It therefore follows that one of the EU is to guarantee a high level of protection for human health, as the quoted provision constitutes a fundamental right in the EU[240]. Interestingly, the quoted legal norm not only confirms that the EU respects the right to healthcare services and to benefit from medical treatment, but it directly ensures the right of access to such services[241]. This means that Article 35 of the EU CFR directly references the executive aspect of the right to health. In addition, its declaration that the EU is concerned with a high level of health protection constitutes an abstractly understood reference to the object of the right to health in the material aspect. Unfortunately, despite the positive qualities of the norm presented, it has an illusory character because the content of Article 35 EU CFR introduces a

237 Craig and De Búrca, 2015, pp. 105-124.; Weatherill, 2016, pp. 24-73.; Berry et al., 2019, pp. 87-122.; Bradley, 2014, pp. 103-104.; Arnull, 2017, pp. 3-18.; Storey and Turner, 2014, pp. 1-21.; Curtin, 2018, pp. 10-14.; Davies, 2013, pp. 54-56.

238 Gianfrancesco, 2012, pp. 295-310.; Blanke, 2012, pp. 159-232.; Pérez de las Heras, 2017, pp. 117-139.; Kerikmäe, 2014, pp. 5-19.; Eriksen and Stubberud, 2017, pp. 229-252.; Balsamo, 2018, pp. 99-170.

239 Bisset, 2012, p. 356.; Smith, 2015, p. 129.; Bussata, 2017, p. 200.; Kenner, 2014, p. 203.; Elgard, 2018, p. 22.

240 Di Federico, 2011, pp. 15-54.; Szpunar, 2019, pp. 123-134.; Kostoris, 2018, pp. 67-98.; Bernardeau, 2017, pp. 133-143.

241 Nußberger, 2006, pp. 592-593.

significant limitation by referring to conditions established in national legislation and practices[242]. This leads to the conclusion that, although the EU is formally the addressee of the norm in question, it has only been obliged to implement claims that have arisen under the national law of the Member States and not to determine the types or scope of said claims[243]. Accordingly, it may indeed be justified to claim that this right in the EU forum is illusory in nature, and that its concretisation can occur by referencing legislation from the Member States of the EU. In addition, the EU CFR includes provisions that indirectly refer to the subject matter of the right to health, specifically concerning due and fair working conditions[244], the prohibition of child labour, and the protection of young people at work[245].

2.4.2 Reflecting the right to health in TFEU and TEU

To keep the analysis systematic, it is necessary to make similar observations about TFEU and TEU as were considered for the EU CFR. In the context of the first treaty, it should be emphasised that TFEU contains numerous references to the subject of the right to health, which is already evident directly in its Article 6. According to this provision, the EU is competent to carry out actions to support, coordinate, or supplement the action of the Member States in the field of protection and improvement of human health[246]. Therefore, irrespective of other provisions of the EU law, the EU has an independent treaty basis to take action on both the right to health and the right to healthcare services, and thus on the subject of the right to health in general. This carries the proviso that the action in question should be subsidiary to the above. However, according to Article 9 TFEU, in defining and implementing its policies and activities, the EU should consider the requirements linked not only to the provision of adequate social protection or the fight against social exclusion, but also to the provision of a high level of employment, education, training and protection of human health[247]. The legal norms outlined above make it clear that the EU focuses its activities to the fullest possible on fulfilling the demands from the Member States for effective quality, safety, and accessibility of national health systems.

242 Nußberger, 2006, pp. 592-593.
243 Nußberger, 2006, pp. 592-593.
244 Article 31(1) EU CFR: '1. Every worker has the right to working conditions which respect his or her health, safety and dignity.'
245 Article 32 EU CFR: 'The employment of children is prohibited. The minimum age of admission to employment may not be lower than the minimum school-leaving age, without prejudice to such rules as may be more favourable to young people and except for limited derogations. Young people admitted to work must have working conditions appropriate to their age and be protected against economic exploitation and any work likely to harm their safety, health or physical, mental, moral or social development or to interfere with their education.'
246 Vermeulen, 2012, p. 34.; Neegaard, 2011, p. 23.
247 Hellmann, 2019, p. 195.; Biernat, 2012, p. 31.; Idem, 2011, p. 9.

Turning to more specific treaty provisions, it should be noted that, based on Article 114 TFEU, the European Commission has an obligation[248] to use a high base level of protection in the field of healthcare, particularly considering any changes based on scientific facts[249].

Nevertheless, the most momentous TFEU provisions directly related to the right to health are those contained in Title XIV *Public Health*. Firstly, according to Article 168 TFEU(1), a high level of human health protection must be ensured in the definition and implementation of all policies and activities of the EU with a view to improving public health, preventing human diseases and ailments, and removing sources of danger to physical and mental health[250]. This includes combating pandemics by promoting research into their causes, how they spread, and how they can be prevented, as well as by collecting information, enhancing health education, and monitoring serious cross-border health threats, providing early warning when they occur and combating them. The cited legal standard also emphasises that EU complements Member States' actions to reduce the harmful effects of drug abuse on health, including information and prevention.

Second, according to Article 168(2) TFEU, the EU encourages cooperation between Member States in the field of health and, where necessary, supports their actions by encouraging cooperation between them to increase the complementarity of their healthcare services in border regions[251]. In addition, Member States of the EU should, in cooperation with the European Commission, coordinate their own policies and programmes relating to the areas in paragraph 1 of Article 168 TFEU among themselves.

Third, in accordance with Article 168(3) TFEU, the EU and Member States remain open to cooperation with developing countries and international organisations competent in the field of public health[252]. Fourth, in accordance with Article 168(4) TFEU, the European Parliament and the Council of the European Union promote the described objectives by adopting not only measures that set high standards of quality and safety for organs and substances of human origin, blood and blood derivatives. This article also references to the veterinary and phytosanitary

248 For measures concerning the approximation of the laws, regulations and administrative provisions of the Member States of the EU which have as their object the establishment and functioning of the internal market.

249 See: Barnard, 2016, p. 559.; Maletić, 2013, p. 68.; Engel, 2018, pp. 20-27.; Hijmans, 2016, p. 266, pp. 317-326.; Lopp, 2013, p. 241.

250 See: Ciotti, 2013, p. 57.; Flear, 2015, p. 40.; Nistor, 2011, p. 300.; Exter and Hervey, 2012, pp. 25-26.; Garben, 2019, pp. 1445-1456.; Guy and Sauter, 2017, p. 30.; Geber, 2015, p. 153.; Bosek, 2011, pp. 138-139.

251 See: Földes, 2019, pp. 216-221.; Jarman, 2013, pp. 110-125.; Flear, 2015, p. 40.; Nistor, 2011, pp. 300.; Exter and Hervey, 2012, pp. 25-26.; Garben, 2019 pp. 1445-1456.; Guy and Sauter, 2017, p. 30.; Geber, 2015, p. 153.

252 See: Flear, 2015, p. 40.; Exter and Hervey, 2012, pp. 25-26.; Garben, 2019 pp. 1445-1456.; Guy and Sauter, 2017, p. 30.

fields that directly relate to the protection of public health or measure that set high standards of quality and safety for medicinal products and medical devices[253].

Fifth, under Article 168(5) TFEU, the European Parliament and the Council of the European Union are empowered to adopt many different measures, including: incentive measures designed to protect and improve human health; measures concerning monitoring, early warning of, and combating serious cross-border threats to health; and measures that are directly intended to protect public health in relation to tobacco and alcohol abuse[254]. Sixth, according to Article 168(6) TFEU, the Council of the European Union may, on a proposal from the European Commission, adopt recommendations for the attainment of the objectives set out in Article 168 TFEU[255].

Seventh, Article 168(7) TFEU includes a declaration that the EU shall conduct its activities with due regard to the responsibilities of the Member EU States regarding definitions of their health policy and the organisation and delivery of health services and medical care. These items are designed to include the management of health services and medical care as well as the allocation of resources assigned to them[256]. In the context of Article 168 TFEU as a whole, it should be emphasised that this Article provides a concrete treaty basis for EU public health action that manifests particularly through secondary EU acts and soft law acts[257]. This suggests

253 See: Nistor, 2011, p. 300.; Exter and Hervey, 2012, pp. 25-26.; Garben, 2019 pp. 1445-1456.; Guy and Sauter, 2017, p. 30.; Geber, 2015, p. 153.; Bosek, 2011, pp. 138-139. In addition, it is necessary to underline that, according to the Declaration relating to Article 168(4)(c) TFEU, which is attached to the Final Act of the Intergovernmental Conference and was adopted the Treaty of Lisbon: 'The Conference declares that the measures to be adopted pursuant to Article 168(4)(c) must meet common safety concerns and aim to set high standards of quality and safety where national standards affecting the internal market would otherwise prevent a high level of human health protection being achieved.'

254 See: Flear, 2015, p. 40.; Nistor, 2011, p. 300.; Exter and Hervey, 2012, pp. 25-26.; Garben, 2019 pp. 1445-1456.; Guy and Sauter, 2017, p. 30.; Bosek, 2011, pp. 138-139.

255 See: Exter and Hervey, 2012, pp. 25-26.; Garben, 2019 pp. 1445-1456., Guy and Sauter, 2017, p. 30.; Geber, 2015, p. 153.

256 See: Jarman, 2013, pp. 110-125.; Flear, 2015, p. 40.; Nistor, 2011, p. 300.; Exter and Hervey, 2012, pp. 25-26.; Garben, 2019 pp. 1445-1456.; Guy and Sauter, 2017, p. 30.; Bosek, 2011, pp. 138-139.

257 For example, already cited in the context of telemedicine: Communication from the Commission to The European Parliament, The Council, The European Economic and Social Committee and the Committee of the Regions on the benefits of telemedicine…; Commission Staff Working Document of 21 December 2007 *Action Plan on…; Communication From The Commission To The European Parliament, The Council, The European Economic and Social Committee And The Committee Of The Regions on enabling the digital transformation of health and care in the Digital Single Market…*; Communication From The Commission To The Council, The European Parliament, The European Economic And Social Committee And The Committee Of The Regions – e-Health -making healthcare better….; Communication from the Commission to The European Parliament, The Council, The European Economic and Social Committee and the Committee of the Regions : eHealth *Action Plan on…*; Council conclusions on Health in the Digital Society – making progress in data-driven innovation

that the correlation of Articles 6, 9, 114, and 168 TFEU confirms the increasing prominence of public health in the EU, including the rights to health protection and healthcare services[258]. This means, therefore, that one of the priorities of the EU is to ensure that the dispositions of the legal norms cited above are fulfilled, respecting the obligations of the Member States in defining their health policy as well as the organisation and delivery of health services and medical care. This is further confirmed by the indirect references to the right to health in TFEU, which mentions shared competences between the EU and the Member States EU[259] that improve the working environment[260], promote consumer protection[261], and protect the environment[262]. TEU, however, lacks direct references to the right to health because it is a more programmatic treaty that functions as the basis of the EU's ability to achieve the common objectives of the Member States[263]. TEU sets the general orientations, values, and objectives of the EU[264], and represents a new stage in the process of creating an ever closer union in Europe, where decisions are taken with the utmost respect for the principle of openness and as close to the citizens as possible[265]. This does not mean, however, that indirect references to the right to health cannot be

in the field of health…; Question to the Commission on enabling the transformation of…; European Parliament Resolution of 18 December 2019 on enabling the transformation of…; Commission Recommendation (EU) 2019/243 of 6 February 2019 on a European Electronic Health Record…; Commission Recommendation of 2 July 2008 on cross-border…

258 Flear, 2015, p. 40.

259 Article 4(1) and (2) TFEU: '1. The Union shall share competence with the Member States where the Treaties confer on it a competence which does not relate to the areas referred to in Articles 3 and 6. 2. Shared competences between the Union and the Member States applies in the following principal areas: a) internal market; b) social policy, for the aspects defined in this Treaty; c) economic, social and territorial cohesion; d) agriculture and fisheries, excluding the conservation of marine biological resources; e) environment; f) consumer protection; g) transport; h) trans-European networks; i) energy; j) area of freedom, security and justice; k) common safety concerns in public health matters, for the aspects defined in this Treaty.'

260 Article 153(1)(a) TFEU: '(1) With a view to achieving the objectives of Article 151, the Union shall support and complement the activities of the Member States in the following fields:(a) improvement in particular of the working environment to protect workers' health and safety.'

261 Article 169(1) TFEU: '1. In order to promote the interests of consumers and to ensure a high level of consumer protection, the Union shall contribute to protecting the health, safety and economic interests of consumers, as well as to promoting their right to information, education and to organise themselves in order to safeguard their interests.'

262 Article 191(1) TFEU: '(1) Union policy on the environment shall contribute to pursuit of the following objectives: – preserving, protecting and improving the quality of the environment, – protecting human health, – prudent and rational utilisation of natural resources, – promoting measures at international level to deal with regional or worldwide environmental problems, and in particular combating climate change.'

263 Blanke, 2013, pp. 45-109.

264 TFEU is the treaty that sets out the more detailed principles and rules for EU operation.

265 Blanke, 2013, pp. 45-46.

identified in TEU. They are visible primarily in the provisions on values[266] and objectives of the EU[267], as well as declaring the recognition of the rights, freedoms and principles contained in the EU CFR[268].

In conclusion, the above analysis of primary law in the EU clearly shows that there are indirect and direct references to the right to health, which increases the level of significance of the subject matter by determining its general directions and objectives. This seems to be the way to read the role of the legal norms relevant to the title issue at this research level. Obviously, these general directions, objectives or principles await concretisation within the framework of the EU law, which generally takes place in the form of secondary EU law.

2.4.3 Concretisation of the right to health in secondary legislation

As noted above, the conclusions of the analysis of primary law of the EU from the point of view of the existence of direct and indirect references to the right to health emphasised the need to examine how the indicated general directions, objectives, or principles were concretised within the framework of secondary law in the EU. Obviously, due to the volume of the presented issue and in view of the primary research aim of this work, it is necessary to limit the discussion to specific, relevant references to the right to health in secondary EU law.

These examples include acts from areas that relate to patients' rights in cross-border healthcare, cross-border health risks, tobacco products, organs, blood, tissues, cells, pharmaceuticals, and medical devices. Therefore, the first example is 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[269] (hereinafter: *Directive on Patient's Rights in Cross-border Healthcare/DPRCH*), which was adopted on the basis of Articles 114 and 168 TFEU. It constitutes a normative development of the primary EU legislation regarding these matters, i.e., facilitating access to safe and high-quality cross-border healthcare and promoting cooperation in the context of healthcare between Member States of the EU while fully respecting

266 Article 2 TEU: 'The Union is founded on the values of respect for human dignity, freedom, democracy, equality, the rule of law and respect for human rights, including the rights of persons belonging to minorities. These values are common to the Member States in a society in which pluralism, non-discrimination, tolerance, justice, solidarity and equality between women and men prevail.'

267 Article 3(1) TEU: 'The Union's aim is to promote peace, its values and the well-being of its peoples.'

268 Article 6(1) TEU: 'The Union recognises the rights, freedoms and principles set out in the Charter of Fundamental Rights of the European Union of 7 December 2000, as adapted at Strasbourg, on 12 December 2007, which shall have the same legal value as the Treaties.'

269 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 of the EU L 88 of 4.04.2011, pp. 45-65).

national competencies in the organisation and delivery of healthcare[270]. This directive is central to this work and will therefore be discussed in detail in the following sections[271].

Another example of these secondary laws is Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (hereinafter: the *Decision On Serious Cross-border Threats To Health*)[272]. This Decision was adopted mainly on the basis of Article 168(5) TFEU, concretising it. It specifies rules related to epidemiological surveillance and monitoring of serious cross-border health threats to allow for early warning and control, including preparedness and response planning to coordinate and complement national policies[273].

A third example is Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States on the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (hereinafter: the *Tobacco Products Directive*)[274], which was issued specifically on the basis of Article 53(1), 62 and 114 TFEU[275]. The purpose of this Directive is to approximate the laws, regulations, and administrative provisions of the Member States of the EU, inter alia, on ingredients, emitted substances, and distance selling, labelling, and packaging of tobacco products over borders[276].

A fourth example is Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003, which set standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components. This Directive amended Directive 2001/83/EC (hereinafter: Human Blood Directive)[277] and Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 which had set standards of quality and safety for the donation, procurement, testing, processing, preservation, storage, and distribution

270 Baeten and Palm, 2013, p. 398.; Costigliola, 2012, p. 239.; Fløistad, 2018, p. 47.; Marušič et al., 2017, pp. 154-155.; Cappelletti, 2015, pp. 254-255.

271 See in particular: Chapter 3.4: Patients' rights in cross-border healthcare.

272 Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ of the EU L 293, 5.11.2013, pp. 1-15).

273 Evans-Brown and Sedefov, 2018, pp. 5-6.

274 Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ of the EU L 127, 29.4.2014, pp. 1-38).

275 The legal basis referred to in the Tobacco Products Directive is paragraph 3 of Article 114 TFEU (See recital 8 of the Tobacco Products Directive).

276 Švedas, 2021, pp. 134-138.; Engelhart, 2021, p. 54.; Foltea, 2020, pp. 67-70.

277 Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ of the EU L 33, 8.02.2003, pp. 30-40).

of human tissues and cells (hereinafter: *Human Tissues and Cells Directive*)[278]. These standards were adopted following the use of Article 152(4)(a) TEC, which is the equivalent of Article 168(4)(a) TFEU. The object of both Directives is to define standards of quality and safety for human blood and blood components as well as human tissues and cells intended for human applications to ensure a high level of human health protection[279].

A fifth example is Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004, which laid down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and established a European Medicines Agency (hereinafter: the Medicinal Products Regulation)[280]. It was adopted on the basis of Article 152(4)(b) TEC, which has identical wording to Article 168(4)(b) TFEU. However, Article 168(4)(c) appears to be the relevant legal basis for the regulation. The main task of the Medicinal Products Regulation is to implement the EU standards for medicinal products for human use and veterinary medicinal products[281].

A final example is the already cited Medical Device Regulation, which was issued specifically based on Articles 114 and 168(4)(c) TFEU. All of these examples show how treaty provisions defined as relating to the right to health are concretised under secondary law. The Directive on Patients' Rights in Cross-Border Healthcare, the Decision on Serious Cross-Border Health Risks, the Tobacco Products Directive, the Human Blood Directive, the Human Tissues and Cells Directive, the Medicinal Products Regulation, and the Medical Device Regulation all present different sectoral approaches to the right to health in the EU; they all address particular details of treaty provisions that include general orientations, objectives, or principles related to the right to health.

278 Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ L 102, 7.4.2004, pp. 48-58).

279 de Oliveira and Pereira, 2015, pp. 231-244.; Rynning, 2009, pp. 277-313.; Migliaccio and Pintus, 2012, pp. 287-299.; Tiedemann and Sethe, 2013, pp. 1139-1171.

280 Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ of the EU L 136, 30.04.2004, pp. 1-33).

281 Dederer, 2016, pp. 139-168.; Müllner and Eichler, 2010, pp. 19-31.; Chowdhury, 2014, pp. 121-139.

2.5 The right to health in telemedicine

2.5.1 Telemedicine as a new guarantor of protection of the right to health

Considering the observations to this point, it is appropriate to discuss the function of telemedicine in the context of the personal right to health protection. The key elements of this analysis will be the essence of telemedicine, the definition of the right to health, and the material aspect of the right to health protection, as already presented.

In this regard, following the order above, it should be recalled that the essence of telemedicine consists of a combination of its universal priority and its proper terminological meaning[282]; it constitutes the provision of medical services by doctors at a distance using telepresence techniques that transmit medical data using ICT with the goal of improving patient health. Next, it is important that the right to health protection should be understood as a normatively defined personal right of every individual, providing the possibility to take care of one's health in a material or substantive aspect. The importance lies on the abstractly understood opportunity to take care of one's health, which is both a fundamental good and of an extremely subjective nature[283]. Ultimately, no less important is the suggestion that protection of the right to health is a material guarantee of the right itself[284]. This work has suggested that there is a material aspect to the right to health, which is both a legally protected good in the form of health taken on its own, the abstractly understood possibility to take care of one's health, and the indirect protection of the right to life. There is also an unconditional subjective scope, according to which every person, regardless of his or her qualities, should have the right to health simply because he or she is a human being.

Relying on the above-mentioned elements of this work, additional authorial insights on the topic are justified. To decode the function of telemedicine in the context of the personal right to health protection, a cross-interpretation of the components thus defined appears to be sufficient. Therefore, *de lege ferenda*, after presenting the main motives of logical reasoning, the function of telemedicine in protecting the right to health should be seen as a substantive guarantee of a normatively defined personal right for every human being, ensuring that his or her health can be cared for substantively. There should also be a properly defined, legally protected scope for both goods and subjective aspects that provide medical services by doctors across distances using telepresence techniques and ICT methods

282 See Chapter 1.4.2. Essence of telemedicine.
283 Chapter 2.2.2 Outline of the right to health protection.
284 Chapter 2.2.4. Correlation of the essence of the right to health protection and healthcare services.

to transmit medical data with the goal of improving the patient's health[285]. This means, simplistically, that the claim that telemedicine is fully predisposed to act as a new guarantor of the substantive nucleus of the right to health, i.e., to act as a guarantor of the right to health protection, seems justified[286]. While this may be the case in areas other than the EU, as already noted, the EU faces elaborate legal references to the right to health.

2.5.2 Telemedicine as a modern tool for realising the right to healthcare services

Along with its function in protecting the right to health, telemedicine must be examined in the context of the right to healthcare services. This is done with a similar procedure that is based on the same methodology. However, the logical premises differ because the essence of telemedicine should be considered the first premise, the determination of the right to healthcare services as the second, and the enforcement of the right to health as the third.

Given that the essence of telemedicine has been presented previously in this paper, it is appropriate both to refer to the previous sections of this paper and to provide an overview of the other two premises. It should be reiterated that the right to healthcare services must be understood that universally available healthcare services should be a normatively stipulated social entitlement of a human being. These services should be offered by a specific public authority exercising jurisdiction over a well-defined geographical area or individuals over whom it has *de facto* authority and who exhibit an actual state of unhealth[287]. The right to health has both a material and an executive aspect; the material aspect refers to the legally protected good in the form of equal access to healthcare that effectively protects health and guarantees access to treatment regardless of the individual's material situation while

285 Author's proposal is based on: Waldenström et al., 1972, pp. 117-182.; Jain, 2018, pp. 139-173.; Gunn, 2008, pp. 3-7.; Amzat and Razum, 2018, pp. 17-33.; Zoll, 2000, p. 8.; Mikos and Urbaniak, 2016, pp. 160-166.; Surówka, 2012, p. 98.; Libal and Harding, 2015, pp. 19-37.; Montgomery, 1992, pp. 184-203.; Pestova, 2014, pp. 341-372.; Iguiñiz, 2014, pp. 313-337.; Ryś, 2017, p. 119.; Surowka, 2009, p. 395.; Piechota, 2012, pp. 93-102.; Rawaf and Hassounah, 2014, pp. 135-163.; Wu, 2019, pp. 457-469.; Oke, 2016, pp. 91-122.; France, 2014, pp. 335-352.; Zimpfer, 1999, p. 77.; Linkous, 2001, p. 226.; Simmons et al., 2008, p. 163.; European Commission, 2018, p. 25.; Raskas et al., 2017, p. 206.; Piechota, 2012, pp. 137-142.; Zoll, 2000, p. 8.; Mikos and Urbaniak, 2016, pp. 160-166.; Surówka, 2012, p. 98.; Adelakun and Garcia, 2019, p. 85.; Otto, 2001, p. 106.; Cohendet et al., 1998, p. 191.; McAuley, 2014, pp. 373-401.; Walker, 2014, pp. 165-192.; Evans, 2014, 233-257.; Heus and Sartawi, 2014, pp. 193-229.; Munesue, 2014, pp. 121-132.; Qiu, 2014, pp. 97-120.; Oke, 2017, pp. 311-326.; Claude, 1989, pp. 19-38.; Spradley, 2001, p. 291.; Reynolds, 2019, p. 4.; Dafoulas et al., 2017, p. 340.; Mohr et al., 2019, p. 255.; Lynn, 2019, p. 107.

286 The premise of the traditional healthcare system's inefficiency is also significant.

287 See Chapter 2.2.3 Outline of the right to healthcare services.

the executive aspect is the conditional subjective scope[288]. Essentially, the right to health consists of offering healthcare services to an individualised subject in a concretised factual situation where medical risks can be identified. As with the function of telemedicine regarding protecting the right to health, a cross interpretation of the analytical segments presented suggests that, *de lege ferenda,* the function of telemedicine in the right to healthcare services should be viewed through the lens of executive realisation of a normatively envisaged human social entitlement. This ensures that the provision of telemedicine offers an individual equal enjoyment of universally available healthcare services that have a well-defined legally protected good and subjective scope[289]. Telemedicine appears to have the necessary qualities to act as a new institutional guarantor for realising the material aspect of the right to health and constituting the most relevant means for achieving its main objective, i.e., health protection. Telemedicine should therefore be considered as a modern tool for realising the right to healthcare services.

The functions of telemedicine in the right to health that have been defined thus far suggest that access to telemedicine, like access to healthcare services, should be treated as a human right, specifically, a patient right. This acknowledgement should be made internationally; one example of how this could be done would be amending Article 3 of the Convention on Human Rights and Biomedicine. In terms of Polish law, the Act of 6 November 2008 on Patients' Rights and the Ombudsman for Patients' Rights[290] could be amended. This would involve either amending the current Articles 6, 7, and 8 of the Act by adding the right of access to telemedicine

288 See Chapter 2.2.4 Correlation of the essence of the right to health protection and healthcare services.

289 Author's suggestion is based on: Buchanan, 1991, pp. 169-184.; Beauchamp, 1991, pp. 53-81.; Merrill, 1994, pp. 99-128.; Mpedi, 2020, pp. 77-100.; Tu, 2019, 59-84.; Kirchner, 2018, pp. 141-151.; Holder, 1989, pp. 161-172.; Sulmasy, 2008, pp. 25-36.; Tomossy, 2008, pp. 341-352.; Serwach, 2011, p. 20.; Rawaf and Hassounah, 2014, pp. 135-163.; Wu, 2019, pp. 457-469.; Oke, 2016, pp. 91-122.; France, 2014, pp. 335-352.; Oke, 2017, pp. 311-326.; Claude, 1989, pp. 19-38.; Bhattacharyya, 2017, p. 6.; Spradley, 2001, p. 291.; Reynolds, 2019, p. 4.; Dafoulas et al., 2017, p. 340.; Mohr et al., 2019, p. 255.; Lynn, 2019, p. 107.; Melton et al., 2019, p. 253.; Simmons et al., 2008, p. 163.; European Commission, 2018, p. 25.; Raskas et al., 2017, p. 206.; Arras, 1984, pp. 23-45.; Childress, 1984, pp. 47-70.; Kluge, 2002, pp. 29-48.; Cummiskey, 2004, pp. 187-202.; Green, 2004, pp. 203-221.; Toebes and San Giorgi, 2014, pp. 403-436.; Sass, 1991, pp. 243-255.; Halper, 1991, pp. 135-168.; Marmor, 1991, pp. 23-49.; Agich, 1991, pp. 185-198.; Daniels, 1991, pp. 201-212.; Engelhardt, 1991, pp. 103-111.; Waldenström et al., 1972, pp. 117-182.; Jain, 2018, pp. 139-173.; Gunn, 2008, pp. 3-7.; Amzat and Razum, 2018, pp. 17-33.; Libal and Harding, 2015, pp. 19-37.; Montgomery, 1992, pp. 184-203.; Pestova, 2014, pp. 341-372.; Adelakun and Garcia, 2019, p. 85.; Otto, 2001, p. 106.; Cohendet et al., 1998, p. 191.; Klar and Pelikan, 2011, p. 1119.; Zimpfer, 1999, p. 77.; Linkous, 2001, p. 226.; de Lucena et al., 2013, p. 129.; Argy and Caputo, 2001, p. 227.; Shaw, 2009, pp. 13-18.; Iguiñiz, 2014, pp. 313-337.; McAuley, 2014, pp. 373-401.; Walker, 2014, pp. 165-192.; Evans, 2014, 233-257.; Heus and Sartawi, 2014, pp. 193-229.; Munesue, 2014, pp. 121-132.; Qiu, 2014, pp. 97-120.

290 Act of 6 November 2008 on Patients' Rights and Patients' Ombudsman (consolidated text; Journal of Laws 2022, item 1876, as amended).

services to their material scope, or adding a new Article 6 *prim,* which would directly provide for the patient's right of access to telemedicine.

2.5.3 Telemedicine and equal access to healthcare services

In light of the above considerations, one more point must be highlighted. The premise of equal access to health services has been presented as a key structural element of the legally protected good in the right to healthcare services. It is significant that the same legally protected good has been indicated as part of the telemedicine function in the same law. This implies agreement with the concept that equality requires that the beneficiaries of the indicated right should receive care determined by their health needs and not by non-health factors, for example, such as their ability to pay for the services provided[291]. The principle of equality in the right to health is therefore fundamental; however, unfortunately, the actual achievement of precisely equal access to healthcare services can only be assessed in abstract terms. Action to reduce manifestations of inequality should therefore be seen as a priority.

The indicated enhancement of *prima facie* equality should be directly linked to the realisation of the right to healthcare services, which also constitutes the implementation aspect of the right to health. It guarantees the realisation of the substantive aspect of the right to health, which is the most relevant means for realising the main objective, i.e. health protection. This also implies that the objective of increasing equality in access to healthcare services should be indirectly linked to the right to health protection, thus constituting an essential component of the entire concept of the right to health. In turn, applying modern technology in the form of telemedicine to the practice of medicine can lead not only to increased speed, safety, quality, and reduced costs, it can also improve equality in access to healthcare services. However, for this to be possible, barriers caused by the distance between patient and provider must be overcome. One factor supporting the realisation of the outlined objective is the guarantee of a well-defined cross-border nature of healthcare services, including telemedicine services, which is the focus of Chapter 3 in this monograph.

In light of this discussion, it seems reasonable to claim that telemedicine, when able to function across borders, is an even more complete instrument for increasing equality of access to healthcare services *in genere*, allowing distance and travel time to become irrelevant.

291 Stornaiuolo, 2005, p. 50.

2.6 Summary

This chapter presented the author's reflections on the right to health in the EU. The fundamental premise was to propose a concept of the right to health *in genere*, which has momentous significance for the main analytical axis of this work. The discussion found that the rights to health protection and healthcare services are integral elements of the right to health as understood through the lens of the research analysed within this work.

Considering this, the right to health as a determinant of modern technologies in medicine is presented. Modern technologies, such as telemedicine services, are used in medical practice to comply with norms in the field of human rights protection, specifically those whose core is directly related to the priority and terminology of telemedicine, i.e., with rights that concern human health.

The outlines of the rights to health protection and healthcare services were then presented. It was emphasised that the right to health protection is the normatively determined right of every human being to be able to take care of his or her health in material or substantive terms, while the right to healthcare services is the normatively determined entitlement of a human being to benefit from generally available healthcare services that are offered by a specific public authority exercising jurisdiction over a well-defined geographical area or individuals over whom it has actual authority and who exhibit an actual state of health. An analysis of their normative nature was also conducted. Based on this, the right to health protection should be classified as a personal right constituting a material guarantee of health protection, and that the right to healthcare services should be viewed through its social normative character. This character directly influences the determination of its essence based on guaranteeing the implementation of the right to health in the institutional aspect, constituting a means to achieve the main objective, i.e. health protection.

The conclusions drawn from the correlation of the essence of the rights to health protection and healthcare services led to proposing the substantive and enforcement aspects of the right to health. On this basis, a historical outline of the right to health in EU primary law was presented, noting the reference points in the legal situations both before and after the Maastricht Treaty and singling out insights on the significance of the Lisbon Treaty as the next stage in the evolution of European integration. A historical perspective can decode both direct and indirect references to the right to health in the EU's primary law.

As a logical continuation of this discourse, the manifestations of the right to health in the current EU law were approximated by identifying provisions under EU CFR, TFEU, and TEU that reflected the right to health and identifying specific manifestations of its concretisation in secondary EU law. The importance of the provisions referring to the right to health in the EU was highlighted, and attention was also drawn to how the primary law of the EU, by setting general directions,

objectives, or principles concerning its human health policy, is concretised in the secondary law of the EU.

The final subsection addressed how to define the specific functions of telemedicine in the right to health protection, considering the distinction between the rights to health protection and healthcare services. Telemedicine was proposed as a new guarantor of the right to health protection and as a modern institutional implementer of the material aspect of the right to health, constituting the most relevant means of achieving health protection. It was stressed that it is currently impossible to achieve equal access to healthcare services, and that telemedicine can reduce inequalities as it works across borders and makes distance and travel time irrelevant.

Based on this, it can be argued that telemedicine is useful as a subsidiary instrument to the traditional healthcare system, with the two systems operating in parallel. Currently, however, it seems unreasonable to see telemedicine as a permanent successor to current solutions, although this may be possible in the future. To exploit the full potential of telemedicine solutions, it is necessary to emphasise its cross-border nature, which enhances equality of access to healthcare services. This observation is crucial for further considerations related to the major aim of this work, particularly the cross-border provision of healthcare services in the EU.

3

Cross-border healthcare provision in the European Union

3.1 Introduction

This chapter aims to analyse the conditions, principles and interpretation of the law in the context of the cross-border provision of healthcare services in the EU. This leads directly to demonstrating whether it is possible to qualify telemedicine services as services within the meaning of the EU law. To this end, general considerations regarding the internal market in the light of the free movement of services are presented. Within this framework, attention is turned towards the characteristics of the internal market *in genere*, the outline of the free movement of services, and the EU definition of a service. In addition to the necessary reporting elements, the discussion also draws attention to the relevance of the presented issue not only for the main research area of this work, but also more broadly, i.e., for the discipline of legal sciences in general. The chapter is concluded with a discussion of treaty norms regarding the freedom of movement of services, where the need to establish a more complete relationship between the right to health and the cross-border provision of telemedicine services in the EU will be highlighted.

The issue of the free movement of healthcare services is then analysed; the concept of healthcare services is first proposed within this section. Building on these findings and considering literature and case law, the possibility of healthcare services qualifying as services of the EU internal market is examined. In addition, an integral complement to this will be discussing the possibility of introducing restrictions to the free movement of healthcare services in light of the CJEU proportionality test. These insights will form the basis for more far-reaching conclusions, including those on cross-borderism, as alternative solutions.

Following the above discourse, the issue of patients' rights in cross-border healthcare is discussed as a logical consequence. Within this framework, attention is directed towards both the aim of defining cross-border patients' rights and the obligations of Member States of the EU. This will make it possible to undertake a reflection on telemedicine as a subject of cross-border healthcare. The final chapter analyses telemedicine services in cross-border healthcare in the final part of the chapter; a definition for telemedicine services is presented, and an attempt is

made to establish qualifying telemedicine services as internal market services of the EU.

The chapter will conclude with a succinct summary of the author's observations on the issues raised in the chapter, emphasising specific, topical issues related to the cross-border provision of telemedicine services in the EU that arise from realising the right to health.

3.2 The internal market in the light of the free movement of services

3.2.1 Characteristics of the internal market in genere

The basic principles of the EU's internal market are set out in the relevant provisions of primary law. According to Article 26 TFEU, the internal market comprises an area without internal frontiers in which the free movement of goods, persons, services, and capital is ensured[292]. The broad nature of this topic exceeds the scope of this monograph, so the discussion is limited to presenting the general assumptions underlying the concept of the EU's internal market, which is one of the most important achievements of the EU's legal, political, and economic[293] value.

In the light of the above observations, it should first be noted that the free movement of goods is intended to remove any direct or indirect impediment to EU trade, either potential or actual[294]. It consists of three key prohibitions: under Article 30 TFEU, customs duties and charges having equivalent effect are prohibited; under Articles 34 and 35 TFEU, quantitative restrictions on imports and exports and all measures having equivalent effect are prohibited; and under Article 110 TFEU, discriminatory or protectionist taxation of goods originating in other Member States is prohibited[295].

Second, it should be mentioned that the free movement of persons generally consists of three essential components. This combines the free movement of workers in Article 45 TFEU, the freedom of establishment in Article 49 TFEU, and the

292 Rama Murthy, Evans and Sarkis, 2019, pp. 54-55.; Voogsgeerd, 2004, p. 278.; Curzon, 2011, p. 125.; Czermińska, 2016, p. 63.; Szewczyk, 2016, p. 76.; Tomaszewski, 2003, p. 109.

293 Oliver and Roth, 2004, p. 407.

294 Judgment of the Court of Justice of the European Union of 11 July 1974 in Case C-8/74 in proceedings Procureur du Roi v Benoît and Gustave Dassonville (ECLI:EU:C:1974:82); Judgment of the Court of Justice of the European Union of 12 June 2003 in Case C-112/00 in proceedings Eugen Schmidberger, Internationale Transporte und Planzüge v Austria (ECLI:EU:C:2003:333); Judgment of the Court of Justice of the European Union of 9 December 1997 in Case C-265/95 in proceedings Commission of the European Communities v French Republic (ECLI:EU:C:1997:595).

295 Łacny, 2020, p. 157.

freedoms that derive from simply possessing EU citizenship[296]. Article 21 TFEU, according to which every EU37 citizen has the right to move and reside freely within the territory of the EU Member States, subject to the limitations and conditions indicated in primary and secondary law, is of momentous importance[297]. Taken as a whole, the beneficiaries of the EU law institution in question include not only natural citizens but also legal entities. The CJEU interpretation of the legal norms defining the free movement of persons is also significant as it directly indicates that these provisions aim to facilitation EU citizens' ability to conduct professional activities in the EU area and oppose actions that could disadvantage them in other Member States[298], even if the measures adopted are not of a discriminatory nature[299].

Third, the free movement of capital comprises the prohibition of restrictions on capital movements and payments between Member States of the EU as well as between Member States and developing countries. National measures that consist of discouraging non-residents from investing in a particular Member State of the EU or residents of one Member State from investing in another country[300] are therefore impermissible. Finally, the free movement of services, which is one of the essential points of reference in this work, will be discussed in more detail in the next subsection.

The issues raised so far have been aimed at presenting a general characterisation of the idea of the internal market of the EU, which is the foundation for cross-border provision of healthcare services in the European Union. The intentional generality of the presented issues has been forced by the size of the overall topic and the desire to thoroughly address the main research aim of this work. However,

296 Koikkalainen, 2019, pp. 121-124.

297 De Somer, 2019, p. 195, p. 210, pp. 251-277.

298 Judgment of the Court of Justice of the European Union of 26 January 1999 in Case C-18/95 in proceedings F.C. Terhoeve v Inspecteur van de Belastingdienst Particulieren/Ondernemingen buitenland (ECLI:EU:C:1999:22); Judgment of the Court of Justice of the European Union of 15 June 2000 in Case C-302/98 in proceedings Manfred Sehrer v Bundesknappschaft (ECLI:EU:C:2000:322); Judgment of the Court of Justice of the European Union of 17 March 2005 in Case C-109/04 in proceedings Karl Robert Kranemann v Land Nordrhein-Westfalen (ECLI:EU:C:2005:187).

299 Judgment of the Court of Justice of the European Union of 26 January 1999 in case C-18/95…; Judgment of the Court of Justice of the European Union of 15 June 2000 in Case C-302/98…; Judgment of the Court of Justice of the European Union of 17 March 2005 in Case C-109/04….

300 Judgment of the Court of Justice of the European Union of 23 February 2006 in Case C-513/03 Heirs of M.E. A. van Hilten-van der Heijden v Inspecteur van de Belastingdienst/Particulieren/Ondernemingen buitenland te Heerlen (ECLI:EU:C:2006:131); Judgment of the Court of Justice of the European Union of 14 November 1995 in Case C-484/93 in proceedings Peter Svensson and Lena Gustavsson v Ministre du Logement et de l'Urbanisme (ECLI:EU:C:1995:379).

the importance of these issues cannot be denied. It is therefore necessary to refer to the body of doctrine[301] and case law CJEU[302].

301 For example, in the form of signaling: Barnard, 2019, pp. 744.; Barnard and Peers, 2020, p. 1032.; Shuibhne, 2013, p. 302.; Öberg, 2020, p. 332.; Amtenbrink et al., 2019, p. 854.; Weiss and Kaupa, 2014, p. 360.; Syrpis, 2012, pp. 386.; Zawidzka-Łojek and Łazowski, 2017, p. 626.; Grzeszczak and Zawidzka-Łojek, 2015, p. 434.; Barcz, 2011, p. 1208.; Skibińska, 2014, p. 746.; Barcik and Wentkowska, 2014, p. 600.; Miąsik et al., 2012, pp. 1352.; Kowalik-Bańczyk et al., 2012, p. 1692.; Kornobis-Romanowska et al., 2012, p. 1240.

302 For example, in the form of signaling: Judgments of the Court of Justice of the European Union: of 10 December 1968 in Case C-7/68 in proceedings Commission of the European Communities v. Italian Republic (ECLI:EU:C:1968:51); of 1 July 1969 in Case C-24/68 in proceedings Commission of the European Communities v. Italian Republic (ECLI:EU:C:1969:29); of 11 July 1974 in Case C-8/74…; of 31 October 1974 in Case C-15/74 in proceedings Centrafarm BV and Adriaan de Peijper v Sterling Drug Inc (ECLI:EU:C:1974:114); of 4 December 1974 in Case C-41/74 in proceedings Yvonne van Duyn v Home Office (ECLI:EU:C:1974:133); of 14 February 1978 in Case C-27/76 in proceedings between United Brands Company and United Brands Continentaal BV v Commission of the European Communities (ECLI:EU:C:1978:22); of 13 February 1979 in Case C-85/76 in proceedings between Hoffmann-La Roche & Co. AG v. Commission of the European Communities (ECLI:EU:C:1979:36); of 20 February 1979 in Case C-120/78 in proceedings Rewe-Zentral AG v. Bundesmonopolverwaltung für Branntwein (ECLI:EU:C:1979:42); of 27 February 1980 in Case C-168/78 in proceedings Commission of the European Communities v. French Republic (ECLI:EU:C:1980:51); of 23 March 1982 in Case C-53/81 in proceedings D.M. Levin v Staatssecretaris van Justitie (ECLI:EU:C:1982:105); of 13 July 1983 in Case C-152/82 in proceedings Sandro Forcheri and his wife Marisa Forcheri, née Marino v Belgium and asbl Institut Supérieur de Sciences Humaines Appliquées – Ecole Ouvrière Supérieur (ECLI:EU:C:1983:205); of 31 January 1984 in Joined Cases C-286/82 and C-26/83 in Graziana Luisi and Giuseppe Carbone v Ministero del Tesoro (ECLI:EU:C:1984:35); of 3 July 1986 in Case C-66/85 in Deborah Lawrie-Blum v Land Baden-Württemberg (ECLI:EU:C:1986:284); of 15 October 1987 in Case C-222/86 in proceedings Union nationale des entraîneurs et cadres techniques professionnels du football (Unectef) v Georges Heylens and others (ECLI:EU:C:1987:442); of 27 September 1988 in Case C-18/87 Commission of the European Communities v Federal Republic of Germany (ECLI:EU:C:1988:453); of 19 March 1991 in Case C-205/89 Commission of the European Communities v Hellenic Republic (ECLI:EU:C:1991:123); of 7 May 1991 in Case C-340/89 Irène Vlassopoulou v Ministerium für Justiz, Bundes- und Europaangelegenheiten Baden-Württemberg (ECLI:EU:C:1991:193); of 25 July 1991 in Case C-76/90 Manfred Säger v Dennemeyer & Co. Ltd (ECLI:EU:C:1991:331); of 4 October 1991 in Case C-159/90 in proceedings The Society for the Protection of Unborn Children Ireland Ltd v Stephen Grogan and Others (ECLI:EU:C:1991:378); of 30 November 1995 in Case C-55/94 in proceedings Reinhard Gebhard v Consiglio dell'Ordine degli Avvocati e Procuratori di Milano (ECLI:EU:C:1995:411); of 15 December 1995 in Case C-415/93 in proceedings Union royale belge des sociétés de football association ASBL v Jean-Marc Bosman, Royal club liégeois SA v Jean-Marc Bosman and others and Union des associations européennes de football (UEFA) v Jean-Marc Bosman (ECLI:EU:C:1995:463); of 26 June 1997 in Case C-368/95 in proceedings Vereinigte Familiapress Zeitungsverlags- und vertriebs GmbH v Heinrich Bauer Verlag (ECLI:EU:C:1997:325); of 9 December 1997 in Case C-265/95…; of 9 March 1999 in Case C-212/97 Centros Ltd v Erhvervs- og Selskabsstyrelsen (ECLI:EU:C:1999:126); of 3 February 2000 in Case C-228/98 in Charalampos Dounias v Ypourgio Oikonomikon (ECLI:EU:C:2000:65); of 6 June 2000 in Case C-281/98 in Roman Angonese v Cassa di Risparmio di Bolzano SpA (ECLI:EU:C:2000:296); of 22 January 2002 in Case C-390/99

3.2.2 Outline of the free movement of services

Notably, pursuant to Article 56 TFEU, restrictions on the free provision of services within the EU are prohibited for nationals of EU Member States who are established in a Member State other than the one where they will receive a service. The freedom to provide services therefore prohibits any form of discrimination against a service provider established in another Member State of the EU on the basis of nationality and abolishes any restriction which stops or further restricts the activities of a service provider from another Member State where he or she lawfully provides his services[303], regardless of whether the restrictions in question apply equally to national service providers and those from other Member States of the EU. This institution also prohibits the existence or introduction of national rules that make it more difficult to provide cross-border services than to provide services exclusively on the market of one Member State of the EU[304]. Further, Article 56 TFEU directly authorises the European Parliament and the Council of the EU to extend the benefits of the free movement of services to nationals from developing countries who are established within the EU. In turn, according to Article 61 TFEU, as long as the

in proceedings Canal Satélite Digital SL v Adminstración General del Estado, with the participation of Distribuidora de Televisión Digital SA (DTS) (ECLI:EU:C:2002:34); of 4 June 2002 in Case C-503/99 in proceedings Commission of the European Communities v Kingdom of Belgium (ECLI:EU:C:2002:328); of 5 November 2002 in Case C-208/00 in proceedings Überseering BV v Nordic Construction Company Baumanagement GmbH (NCC) (ECLI:EU:C:2002:632); of 12 June 2003 in Case C-112/00…; of 11 December 2007 in Case C-438/05 in proceedings between International Transport Workers' Federation and Finnish Seamen's Union and Viking Line ABP and OÜ Viking Line Eesti (ECLI:EU:C:2007:772); of 23 April 2009 in Case C-544/07 in proceedings between Uwe Rüffler and Dyrektor Izby Skarbowej we Wrocławiu Ośrodek Zamiejscowy w Wałbrzychu (ECLI:EU:C:2009:258); of 4 June 2009 in Case C-142/05 in Åklagaren v Percy Mickelsson and Joakim Roos (ECLI:EU:C:2009:336); of 11 November 2014 in Case C-333/13 in Elisabeta Dano and Florin Dano v Jobcenter Leipzig (ECLI:EU:C:2014:2358).

303 Judgment of the Court of Justice of the European Union of 8 September 2005 in Joined Cases C-544/03 and C-545/03 in proceedings Mobistar SA v Commune de Fléron and Belgacom Mobile SA v Commune de Schaerbeek (ECLI:EU:C:2005:518); Judgment of the Court of Justice of the European Union of 5 December 2006 in Joined Cases C-94/04 and C-202/04 in the proceedings Federico Cipolla v Rosaria Portolese, née Fazari, and Stefano Macrino and Claudia Capoparte v Roberto Meloni (ECLI:EU:C:2006:758); Judgment of the Court of Justice of the European Union of 11 January 2007 in Case C-208/05 in proceedings ITC Innovative Technology Center GmbH v Bundesagentur für Arbeit (ECLI:EU:C:2007:16); Judgment of the Court of Justice of the European Union of 29 November 2001 in Case C-17/00 in proceedings François De Coster v Collège des bourgmestre et échevins de Watermael-Boitsfort (ECLI:EU:C:2001:651); Judgment of the Court of Justice of the European Union of 13 December 2007 in Case C-250/06 in United Pan-Europe Communications Belgium SA and Others v Belgian State (ECLI:EU:C:2007:783).

304 Judgment of the Court of Justice of the European Union of 13 December 2007 in Case C-250/06…; Judgment of the Court of Justice of the European Union of 11 September 2007 in Case C-76/05 in Herbert Schwarz and Marga Gootjes-Schwarz v Finanzamt Bergisch Gladbach (ECLI:EU:C:2007:492).

restrictions on the free provision of services have not been abolished, each Member State of the EU shall apply these restrictions to all service providers who are nationals from Member States and are established in a Member State of the EU37 which differs from the national origin of the person receiving the service, regardless of nationality or residence.

It is important to underline that the freedom to provide services is a treaty-based source for the analysis concerning the cross-border provision of healthcare services in the EU. In other words, it is a matter of general application which allows for more specific rules on the freedom of movement to be established regarding concretised types of services. Concretisation may take the form of either secondary legislation, which establishes specific rules on the freedom of movement of services, or case law CJEU, which may establish an autonomous understanding of the EU legal norms already in force.

3.2.3 EU definition of service

In the context of the freedom of movement of services within the internal market of the EU, the EU definition of a service is important as it constitutes the decisive criterion for qualifying a certain activity as a service within EU law[305]. A legal definition of a service was introduced in the EU under Article 57 TFEU. According to this provision, services are defined as services normally performed for remuneration to the extent that they are not covered by the provisions on free movement of goods, capital, and persons[306]. This provision clearly indicates that the free movement of services is complementary to the objects of the other EU freedoms, meaning that it fills potential gaps which may arise when applying the legal norms in the internal market of the EU. However, this characteristic does not prejudge either the lesser importance of the freedom of movement of services vis-à-vis the other EU freedoms or the possibility of parallel application of the legal norms defining the various freedoms of the internal market of the EU. The same provision of Article 57 TFEU further indicates that services within the meaning of the law of the EU include, in particular, activities of an industrial, commercial, craft, and professional nature. It should be emphasised that the legislative drafting of this provision clearly prejudges the open nature of the catalogue presented. This leads to the conclusion that the substantive enumeration of the notion of service contained in TFEU is merely exemplary and serves to adopt a proper line of interpretation. The considerations regarding the classification of other activities as services under law of the EU are therefore open to analysis.

This is a key observation in the context of this paper's goal of conducting scientific discourse as it justifies the research question regarding the possibility

305 Mavroidis, 2020, p. 87.; C. Barnard, 2016, p. 286.; Idem, 2020, p. 443.
306 Moens and Trone, 2010, p. 100.; Wiberg, 2014, p. 20.; van de Gronden, 2013, p. 125.

of treating healthcare services as services that benefit from the EU freedom of movement of services. In addition, the decision of the EU legislator to introduce a legal definition of a service into the legal circuit should be welcomed as it provides a starting point for determining the actual material scope of the freedom of movement of services. For example, it is crucial in determining whether a particular service under national law is also a service under EU law. This means that the usefulness and justification of this definition is characterised by its high legal significance both in theory and in practice.

3.2.4 Normative nature of the Treaty rules the free movement of services

The normative nature of the provisions that set out the prohibition of restrictions on the freedom to provide services (Article 56 TFEU) and the definition of a service (Article 57 TFEU) is also relevant to the institution of law of the EU being considered in this work. The crucial question is whether these norms have direct effects in the national law of the Member States of the EU.

According to case law CJEU, both Articles 56 TFEU and 57 TFEU fulfil the formal criteria for the attribution of direct effect[307], giving parties a legal basis for proceedings before the courts of Member States of the EU[308]. This further strengthens the need to analyse whether classifying activities other than those listed in Article 57 TFEU as EU services can benefit from the free movement of services in the EU. Nevertheless, it should be stressed that the direct effect of the provisions in question does not prejudge the impossibility of enacting relevant secondary EU law, which is a concretisation of the general principles found in primary law. We are referring specifically to two secondary pieces of legislation, namely Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications[309] (hereinafter: the Professional Qualifications Directive) and Directive 2006/123/EC of the European Parliament and of

307 In general, such a condition may be said to be characteristic of precision, clarity, unconditionality of a legal rule not referring to additional national or Union measures (Judgment of the Court of Justice of the European Union of 5 February 1963 in Case C-26/62 in proceedings NV Algemene Transport-en Expeditie Onderneming van Gend & Loos v Nederlandse administratie der belastingen (ECLI:EU:C:1963:1); Judgment of the Court of Justice of the European Union of 3 December 1974 in Case C-33/74 in proceedings Johannes Henricus Maria van Binsbergen v Bestuur van de Bedrijfsvereniging voor de Metaalnijverheid (ECLI:EU:C:1974:131).

308 Judgment of the Court of Justice of the European Union of 4 December 1986 in Case C-220/83 Commission of the European Communities v French Republic (ECLI:EU:C:1986:461).

309 Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications (OJ of the EU L 255 of 30.09.2005, pp. 22-142).

the Council of 12 December 2006 on services in the internal market[310] (hereinafter: the Services Directive). The cited sources of law are important as they detail the Treaty's comments on freedom of movement of services with issues that require more detailed regulation.

In this context, it is noteworthy that the Professional Qualifications Directive establishes rules that every Member State of the EU must abide by if they allow a regulated profession in its territory contingent upon possession of specific professional qualifications. The Member State must recognise, for the purpose of access to and pursuit of that profession, professional qualifications obtained in another Member State or States of the EU, allowing the qualification holder to pursue the same profession in that country[311]. The Services Directive also identifies general provisions that facilitate the exercise of the freedom of establishment for service providers and the free movement of services while ensuring a high level of quality of services[312]. The overall analysis, based on the premises presented above, suggests that it is fully justified to examine the subject matter identified by the research aim. This is even more important as establishing the validity of this thesis is directly linked to enabling an analysis of the possibility of allowing telemedicine services to benefit from the EU freedom of movement of services.

The latter issue is central to the main research objective of this work, i.e., to establish a more complete relationship between the right to health and the cross-border provision of telemedicine services in the EU. This focus is important because the relationship between telemedicine itself, including its services, and the right to health has already been identified[313], as have the functions of telemedicine in the context of these rights.

It is important to consider the conditions and principles of the legal nature of the cross-border provision of telemedicine services in the EU. To do so, however, it is necessary to introduce the more general issue of the free movement of healthcare services.

310 Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market (OJ L 376, 27.12.2006, pp. 36-68).
311 Foster, 2020, p. 312.
312 Idem, 2019, p. 377.
313 See Chapter 2.5.1 Telemedicine as a new guarantor of the right to health protection and Chapter 2.5.2 Telemedicine as a modern tool for the realisation of the right to healthcare services.

3.3 Free movement of healthcare services

3.3.1 The concept of healthcare services

First, it is important to determine whether healthcare services benefit, in the full sense of the word, from the freedom of movement of services within the internal market of the EU as outlined above. This is of momentous importance, as the determination of this thesis directly affects the picture of the cross-border provision of healthcare services in the EU, including the cross-border provision of telemedicine services. Nevertheless, a methodologically appropriate approach is crucial for the scientific question thus presented. Accordingly, the concept of healthcare service must first be addressed.

As already noted, the relevant provisions of CJEU means that there is a legal definition of a service in the EU; services are defined as normally provided for remuneration to the extent that they are not covered by the provisions on free movement of goods, capital and persons[314]. It also worth noting again healthcare and medical care are different terms with different material scopes, where the material scope of the term healthcare is much broader than that of medical care. The latter term refers to actual medical need, understood as clinical, hospital or pharmacological services. Healthcare, on the other hand, refers to medical care but also includes any non-clinical, non-hospital, or non-pharmacological health services that have a positive impact on the general state of health.

However, the premises for a proper understanding of a healthcare services presented thus far do not contain a direct reference to the right to health. It is therefore necessary to supplement these premises with the reason for the type of service being discussed. This seems to be the aim of realising the right to health, where the right to health protection and healthcare services are treated as integral and key elements of it. See Chapter 2.2.4 . This would mean that, from a dogmatic *de lege ferenda* point of view, healthcare services should be conceived as benefits related to an actual medical need, understood as clinical, hospital, or pharmacological services, complemented by any non-clinical, non-hospital, or non-pharmacological healthcare services that have a positive impact on the general state of health. These services realise the material and executive aspect of the right to health and are usually performed for remuneration to the extent that they are not covered by the provisions on free movement of goods, capital, and persons[315].

314 Moens and Trone, 2010, p. 100.; Wiberg, 2014, p. 20.; van de Gronden, 2013, p. 125.

315 Author's proposal is based, inter alia, on Jasudowicz, 2010, pp. 137-142.; Zoll, 2000, p. 8.; Mikos and Urbaniak, 2016, pp. 160-166.; Surówka, 2012, p. 98.; Ryś, 2007, p. 119.; Surówka, 2009, p. 395.; Piechota, 2012, pp. 93-102.; Rex, 1980, pp. 391-403.; Sass, 1991, pp. 243-255.; Halper, 1991, pp. 135-168.; Marmor, 1991, pp. 23-49.; Agich, 1991, pp. 185-198.; Daniels, 1991, pp. 201-212.; Engelhardt, 1991, pp. 103-111.; Buchanan, 1991, pp. 169-184.;

The proposed semantic meaning of the notion of healthcare service has the advantage of indicating as precisely as possible its object boundaries, but because of its open character, it does not omit any important profile of such a service while also referring to the right to health. From a theoretical point of view, the proposal put forward deserves approval is reasonable and fits with the argument of the overall analysis.

3.3.2 Healthcare Services. Internal market services of the EU

When a dogmatically decoded meaning of the concept of healthcare services has been proposed, the decisiveness of the key research problem is fully updated. The question then arises as to whether healthcare services in this sense are within the scope of the rules applying to the free movement of services within the internal market of the EU. Initially, the regulation of public health, the healthcare system, or the provision of healthcare services, i.e., the general regulations related to the right to health, was considered to be outside the scope of EU regulations; it was therefore considered to be an exclusive competence of the EU Member States[316]. It is important to remember the basic principle that EU public health carries out its activities with respect to the obligations the Member States have to determine their health policies while organizing and delivering their health and medical care services. This process includes both the management of health and medical care services and the allocation of resources[317]. This does not mean that the EU has no basis for defining and adopting regulations related to the right to health[318], or specifically that CJEU cannot interpret the principles expressed in primary law in accordance with the spirit and wording of the treaty norms.

The latter also applies where such an interpretation refers directly or indirectly to the right to health, especially if the internal market provisions of the EU

Beauchamp, 1991, pp. 53-81.; Merrill, 1994, pp. 99-128.; Mpedi, 2020, pp. 77-100.; Tu, 2019, 59-84.; Kirchner, 2018, pp. 141-151.; Holder, 1989, pp. 161-172.; Evans, 2002, pp 197-215.; Jamar, 1994, pp 17-35.; Leary, 1994, pp. 24-56.; Moens and Trone, 2010, p. 100.; Wiberg, 2014, p. 20.; van de Gronden, 2013, p. 125.; Montgomery, 1992, pp. 184-203.; Pestova, 2014, pp. 341-372.; Iguiñiz, 2014, 313-337.; McAuley, 2014, pp. 373-401.; Walker, 2014, pp. 165-192.; Evans, 2014, 233-257.; Heus and Sartawi, 2014, pp. 193-229.; Munesue, 2014, pp. 121-132.; Qiu, 2014, pp. 97-120.; Rawaf and Hassounah, 2014, pp. 135-163.; Wu, 2019, pp. 457-469.; Oke, 2016, pp. 91-122.; France, 2014, pp. 335-352.; Oke, 2017, pp. 311-326.

316 Opinion of Advocate General Tesauro in Case C-120/95 in Nicolas Decker v Caisse de maladie des employés privés (ECLI:EU:C:1997:399); Judgment of the Court of Justice of the European Union of 28 April 1998 in Case C-158/96 in Raymond Kohll v Union des caisses de maladie (ECLI:EU:C:1998:171).

317 See: Jarman, 2013, pp. 110-125.; Flear, 2015, p. 40.; Nistor, 2011, pp. 300.; Exter and Hervey, 2012, pp. 25-26.; Garben, 2019 pp. 1445-1456.; Guy and Sauter, 2017, p. 30.; Bosek, 2011, pp. 138-139.

318 See Chapter 2.4 The right to health in current European Union law.

are involved. In this context, literature and case law CJEU stress that any service which is normally provided for economic reasons is to be treated as a service under Article 57 TFEU provided that it is not subject to the provisions on free movement of persons, goods or capital[319]. The key determination is whether the provision of healthcare is related to the exercise of an economic activity for remuneration as the other specific characteristics of healthcare services do not affect whether they remain within the scope of the Treaty freedom of movement of services[320]. Since this has been confirmed, any national measure which would have the temporary or permanent purpose of limiting or preventing the use of cross-border services in another Member State of the EU is prohibited under Article 56 TFEU as it would formally constitute an obstacle to the free movement of services[321]. This observation applies irrespective of whether the assessment is made from the perspective of the position of service providers or service recipients[322]. This approach to the subject of the free movement of healthcare services is determined based on how the judgemental arguments of the CJEU are based directly on the Treaty provisions on the free movement of services, and thus, applied a mechanism beyond the decision-making reach of the ordinary EU legislator[323].

Based on the above observations, CJEU concluded that, according to the very literal wording of Article 57 TFEU, the legal definition of a service includes the exercise of liberal professions, including medical ones[324]. Medical professionals[325], when acting in a different Member State of the EU, are entitled to enjoy the same rights and guarantees as those enjoyed by doctors or dentists who are natively practising in that Member State in order to ensure the freedom to provide services[326].

319 van de Gronden, 2013, p. 125; On this basis, CJEU concluded that the termination of pregnancy, which is lawfully practised in several Member States of the EU, is a therapeutic activity that is normally carried out for remuneration and can be performed as a professional activity. In light of this, CJEU decided that the termination of a pregnancy by a doctor, carried out in accordance with the law of the EU Member State in which it is carried out, constitutes a service within the meaning of TFEU (Judgment of the Court of Justice of the European Union of 4 October 1991 in Case C-159/90…).

320 Nistor, 2011, pp. 33-35, 300.

321 Gekiere et al., 2010, pp. 506-508.

322 Gekiere et al., 2010, pp. 506-508.

323 Fløistad, 2018, p. 47.

324 Judgment of the Court of Justice of the European Union of 4 October 1991 in Case C-159/90…; Judgment of the Court of Justice of the European Union of 31 January 1984 in Joined Cases C-286/82 and C-26/83….

325 In the context of establishing a definition of medical professionals, it is worth noting Ruling CJEU, which defines how activities limited to the medical profession are, in principle, a matter for the Member States of the EU: Judgment of the Court of Justice of the European Union of 3 October 1990 in Case C-61/89 in Criminal proceedings against Marc Gaston Bouchoucha (ECLI:EU:C:1990:343). However, it should not be forgotten that technical medical professions (e.g., radiology technicians) also fall within the scope of Article 56 TFEU: Judgment of the Court of Justice of the European Union of 9 September 2004 in Case C-81/03 Commission v Austria (ECLI:EU:C:2004:508).

326 Judgment of the Court of Justice of the European Union of 28 April 1998 in case C-158/96…

Meanwhile, nationals of one EU Member State who practise their profession in another Member State are obliged to comply with the rules governing the practice of the particular profession in that other Member State. The rationale behind this is the need to ensure that the health of service recipients are protected as fully and effectively as possible[327]. This situation is acceptable in two ways as long as it does not lead to a double regulatory burden on the service provider[328]. This is the case if, first, the enforced national rules do not have the effect of restricting the free movement of services within the internal market of the EU. Second, if the enforced national rules have the effect of restricting the free movement of services within the internal market of the EU, these restrictions must be both applied on a non-discriminatory national basis[329] and justified by the specificities of the profession. These restrictions must not go beyond what is necessary to achieve the intended purpose[330]. However, it is always unacceptable for legislation to prohibit a provider from another Member State of the EU from providing healthcare services if that provider is not established in the Member State of the EU where the service is provided[331].

It should be remembered that the scope of the Professional Qualifications Directive includes the principle of automatic recognition of qualifications of medical specialities between different Member States of the EU[332]. However, this principle is limited nature and is conditioned by both legal considerations and the will of individual Member States[333]. Notwithstanding the above, *de lege ferenda* Member

327 Judgment of the Court of Justice of the European Union of 12 May 1998 in case C-85/96 in the proceedings between María Martínez Sala and Freistaat Bayern (ECLI:EU:C:1998:217).

328 Gekiere et al., 2010, pp. 506-508.

329 Judgment of the Court of Justice of the European Union of 15 December 1983 in case C-5/83 in proceedings against H.G. Rienks (ECLI:EU:C:1983:382).

330 The presented construction refers to the proportionality test used in interpretation CJEU, see: Maliszewska-Nienartowicz, 2006, pp. 59-82.; Judgment of the Court of Justice of the European Union of 12 May 1998 in Case C-85/96….

331 Judgment of the Court of Justice of the European Union of 12 May 1998 in Case C-85/96…; Judgment of the Court of Justice of the European Union of 15 December 1983 in Case C-5/83….

332 In this context, it is worthwhile to read Ruling CJEU regarding the interpretation of Council Directive 93/16/EEC of 5 April 1993, which facilitates the free movement of doctors and the mutual recognition of their diplomas, certificates and other evidence of formal qualifications (OJ of the EU L 165, 7.07.1993, pp. 1-24): Judgment of the Court of Justice of the European Union of 16 July 1998 in Case C-93/97 in proceedings between Fédération belge des chambres syndicales de médecins ASBL v Gouvernement flamand, Gouvernement de la Communauté française and Conseil des ministres (ECLI:EU:C:1998:375).

333 Indeed, according to recitals 20 and 21 of the Directive on the Recognition of Professional Qualifications: ‘20. To allow for the characteristics of the qualification system for doctors and dentists and the related acquis communautaire in the area of mutual recognition, the principle of automatic recognition of medical and dental specialities common to at least two Member States should continue to apply to all specialities recognised on the date of adoption of this Directive. To simplify the system, however, automatic recognition should apply after the date of entry into force of this Directive only to those new medical specialities common to at least two fifths of Member States. Moreover, this Directive does not prevent

States of the EU should be encouraged to mutually recognise their rules governing the entry of providers into the healthcare market, particularly since, within the context of the EU internal market rules, virtually any regulatory or institutional aspect requiring healthcare providers to adapt in order to be admitted to the market on the territory of another Member State of the EU can be challenged, even if it is not directly related to cross-border situations[334].

In turn, regarding the nature and importance of the funding source for healthcare services, it has been interpreted that the prohibition in Article 56 TFEU applies irrespective of whether the source of funding is public or private[335]. For example, services provided in one Member State of the EU and paid for by the patient do not cease to benefit from the Treaty freedom of movement of services within the internal market of the EU merely because they are subsequently reimbursed on the basis of a request made in accordance with the legislation of another Member State of the EU[336]. This may therefore lead to the conclusion that it is impermissible under Article 56 TFEU for prior authorisation from the Member State of the EU to be required before the Member State is obliged to cover the costs associated with the provision of healthcare services or reimburse expenses incurred by the patient; this constitutes an obstacle to the free provision of services by preventing the patient from choosing a healthcare provider from another Member State of the EU on the basis of objective considerations[337]. From the point of view of the EU regarding the freedom to provide services, the differentiation of whether the patient pays the costs himself and then seeks reimbursement from the Member State of the EU in which he has insurance or whether the national budget pays directly does not change the legal status of the situation under consideration[338]. In other words, if a recipient or a patient travels to another Member State of the EU to receive healthcare services, there is a service within the meaning of TFEU irrespective of the type of payment method adopted[339].

Member States from agreeing amongst themselves on automatic recognition for certain medical and dental specialities common to them but not automatically recognised within the meaning of this Directive, according to their own rules. (21) Automatic recognition of formal qualifications of doctor with basic training should be without prejudice to the competence of Member States to associate this qualification with professional activities or not.'

334 Gekiere et al., 2010, pp. 506-508.; Nistor, 2011, pp. 33-35.

335 Gekiere et al., 2010, pp. 506-508.

336 Judgment of the Court of Justice of the European Union of 13 May 2003 in Case C-385/99 in proceedings V.G. Müller-Fauré v Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA and E.E.M. van Riet v Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen (ECLI:EU:C:2003:270); Judgment of the Court of 12 July 2001 in Case C-157/99 in proceedings B.S.M. Smits, spouse of Geraets, v Stichting Ziekenfonds VGZ and H.T.M. Peerbooms v Stichting CZ Groep Zorgverzekeringen (ECLI:EU:C:2001:404).

337 Judgment of the Court of Justice of the European Union of 13 May 2003 in Case C-385/99….

338 Such circumstances are to be regarded as technical and not altering the substance of the enforceable right; Judgment of the Court of Justice of the European Union of 13 May 2003 in Case C-385/99…

339 Nistor, 2011, pp. 33-35.

This suggests that it is not permissible for the legislation in an EU Member State to entirely exclude the possibility of reimbursement or direct payment of costs for healthcare services provided in another Member State of the EU without prior authorisation[340]. However, this also does not mean that all requirements for prior authorization from the Member State of the EU are incompatible with Article 56 TFEU. This is still possible because the provisions of TFEU relating to the freedom of movement of services do not prevent the adoption, enforcement, or creation of legislation in individual Member States of the EU that make it possible for direct or indirect funding of healthcare services costs provided in another Member State of the EU to be subject to prior authorisation by the relevant national entity, provided that the prior authorisation mechanism is based on reasonable grounds.

The first premise justifying the application of a prior authorisation mechanism is based on the requirement that the healthcare services provided are considered typical. The second premise is based on the requirement that the recipient's health condition necessitates the requested healthcare services[341]. However, the prerequisites for applying a mechanism in this way would cause far-reaching interpretative difficulties[342], meaning they must be clarified.

The first premise must be interpreted to mean that the healthcare service provided is typical only if it has been sufficiently tried and tested and recognised by international medical science[343]. In such a case, prior authorisation cannot be refused on the basis of the atypicality of the healthcare service[344]. The second condition must be interpreted as meaning that consent may only be refused on the grounds of a lack of medical necessity if the same or equally effective healthcare services can be obtained without undue delay in a facility located in the home Member State of the EU[345]. It is also highlighted that subjecting the costs of hospital healthcare ser-

340 Judgment of the Court of Justice of the European Union of 5 October 2010 in case C-173/09 in Georgi Ivanov Elchinov v Natsionalna zdravnoosiguritelna kasa (ECLI:EU:C:2010:581).

341 Judgment of the Court of Justice of the European Union of 12 July 2001 in case C-157/99…

342 Specifically, how the adjective 'typical' should be interpreted or how to interpret the health requirement.

343 It should also be noted that, in the history of jurisprudence, one can find such references to recognition in the scientific community. For example, regarding the possibility of using scientific evidence in litigation, two standards developed in United States jurisprudence should be highlighted: Daubert v. Merrell Dow Pharmaceuticals, Inc, 509 U.S. 579; Frye v. United States of America 293 F. 1013 (D.C. Cir. 1923). Synthetically, it follows from these judgments that specific scientific evidence may be admitted in litigation if: it is itself verifiable and has already been subjected to such scrutiny; it has been the subject of publication in the professional literature; its magnitude of error (fallibility) is known, or at least is predictable; or it has received general acceptance by specialists.

344 Judgment of the Court of Justice of the European Union of 12 July 2001 in case C-157/99…

345 The jurisprudential interpretation proposed by CJEU directly relates to the subject matter of the right to health because of the reference to medical necessity, which is to be understood as a synonym for medical need; Judgment of the Court of Justice of the European Union of 12 July 2001 in Case C-157/99… In terms of exceeding the medically acceptable waiting time for healthcare services: Judgment of the Court of Justice of the European

vices in another Member State of the EU to prior authorisation it is not an obstacle to the internal market rules of the EU on the freedom of movement of services if the provider has not completed an agreement with the relevant body of the Member State that will pay the costs. Granting or refusing authorisation is based on the patient's actual medical need, understood as the condition that the specific health measure is necessary for the protection of that recipient's health[346]. However, even in such a case, consent may only be refused if the same or equally effective types of healthcare services can be obtained without undue delay from a national healthcare facility[347]. Interestingly, the interpretation of the principles behind financing the costs of non-hospital healthcare services is different[348]. In that case, an obstacle to the free movement of services within the internal market of the EU consists of making the financing of the costs of non-hospital healthcare services in another Member State of the EU subject to prior authorisation by the person concerned, where the service provider has not concluded a contract with the relevant body of the Member State which is to be responsible for covering those costs regardless of whether national legislation provides for a system of benefits in kind in the form of access to free healthcare[349].

The above considerations concerning the nature of the source of financing for healthcare services and its impact on the qualification of those services as services within the meaning of Articles 56 and 57 TFEU may lead to the conclusion that the premise of actual medical need, which is part of the proposed definition of a healthcare service, is of a primary nature and the premise of whether the healthcare services are typical is of a secondary nature. These two conditions, which are decisive for the legality of the restrictions on the free movement of healthcare services introduced by Member States of the EU, therefore must be considered separately.

The arguments put forward make it clear that, in principle, there are no restrictions under Article 56 TFEU, and that exceptions must be justified and are subject to careful examination[350]. Interestingly, one of the more recent CJEU rulings on this matter even indicated that healthcare services provided for remuneration fall

Union of 16 May 2006 in Case C-372/04 in Yvonne Watts v Bedford Primary Care Trust and Secretary of State for Health (ECLI:EU:C:2006:325).

346 Judgment of the Court of Justice of the European Union of 13 May 2003 in case C-385/99…

347 Particularly noteworthy is the condition of sameness of healthcare services or their effectiveness; Judgment of the Court of Justice of the European Union of 13 May 2003 in Case C-385/99….

348 It is important to remember that, with digital medicine solutions, particularly in the field of telehealth (telemedicine/telecare), the vast majority of healthcare services will be out-of-hospital.

349 Judgment of the Court of Justice of the European Union of 13 May 2003 in case C-385/99…

350 In this context, it is worth reading the interesting ruling CJEU, which held that the prior authorization mechanism analysed in the case constitutes a restriction on the freedom to provide services for both insured persons and healthcare providers: Judgment of the Court of Justice of the European Union of 5 October 2010 in Case C-512/08 European Commission v French Republic (ECLI:EU:C:2010:579).

within the scope of the provisions on freedom to provide services without the need to examine whether the care was provided in the context of hospital or non-hospital care[351]. Meanwhile, a line of jurisprudence incorporating most of the interpretative system presented above was indicated to be relevant and valid[352]. This seems to be to be interpreted as signalling a softening of the interpretation of the relevant Treaty provisions towards a global and, in principle, unconditional free movement of payable healthcare services while also respecting already developed interpretative standards.

3.3.3 Restrictions on the free movement of healthcare services

It should also be remembered that, when restrictions on the free movement of healthcare services are introduced and operate in the EU, the restrictions must meet the requirements of the proportionality test[353]. A restrictive measure meets this test when it enables the achievement of a legitimate aim. Of all measures, it is the least burdensome one that meets that objective and strikes a proportionate balance between the costs and legal disadvantages for the individual and the importance of the objective pursued[354]. A restrictive measure therefore meets the requirements of the proportionality test only if it is appropriate, necessary, and proportionate *stricto sensu*[355]. The burden of proof lies with Member States of the EU who wish to demonstrate that their measures satisfy the proportionality test, which entails the presentation of a series of difficult evidence that is also related to determining public interest[356]. It is worth remembering that, given that there are people in different communities who cannot pay for healthcare services they require due to financial reasons, it is incumbent on the particular Member State of the EU to organise its

351 Judgment of the Court of Justice of the European Union of 27 October 2011 in case C-255/09 in proceedings between the European Commission and the Portuguese Republic (ECLI:EU:C:2011:695).

352 Cited therein: Judgment of the Court of Justice of the European Union of 28 April 1998 in Case C-158/96; Judgment of the Court of Justice of the European Union of 13 May 2003 in Case C-385/99…; Judgment of the Court of Justice of the European Union of 16 May 2006 in Case C-372/04…; Judgment of the Court of Justice of the European Union of 5 October 2010 in case C-173/09…

353 This principle currently derives from Article 5(4) TEU as well as from Article 52(1) EU CFR. In view of the volume of the issue signaled at this point and in an effort to analyse the title issue efficiently, with regard to the principle of proportionality EU, see for example with the case law cited therein: Emiliou, 1966, pp. 320.; Maliszewska-Nienartowicz, 2006, pp. 59-82.; de Búrca, 2000, p. 95., quoted by Maliszewska-Nienartowicz, 2006, p. 60.; Długosz, 2017, pp. 283-300.; Jacobs, 1999, pp. 1-23.; Tridimas, 2018, pp. 243-265.; Planzer, 2014, pp. 233-244.; Ostrowska, 2021, pp. 33-35.; Young et al., 2019, pp. 117-119.; Krunke and Baumbach, 2019, p. 296.

354 Gekiere et al., 2010, pp. 506-508.

355 Golec, 2018, pp. 162-163.

356 Gekiere et al., 2010, pp. 506-508.

public healthcare system in such a way that it ensures universal, equal, and effective access for all people within its jurisdiction[357]. Conversely, in the context of private healthcare, where the provision of services is entrusted to third parties, it may be equally necessary to introduce quality standards to ensure the safety of the service recipients, which in certain cases may be justified on public interest grounds[358].

For this reason, any provision of Member State of the EU which constitutes a potential restriction within the meaning of Article 56 TFEU requires two basic considerations to be established. First, it must be considered whether the legislation under consideration actually constitutes a restriction under Article 56 TFEU. If this is confirmed, then it must be considered whether the restriction passes the proportionality test[359]. This type of mechanism, particularly due to the vague nature of the premises, may seem to effectively counteract the functions within the EU legal system of regulations that unjustifiably limit the Treaty freedoms. After all, it should be emphasised that the objective has generally been, and still is, justifying the definition and use of the proportionality test standard in the EU law.

To conclude the presented thought, in connection with all the observations made so far, *de lege ferenda,* in view of the comments raised, it should be postulated that any healthcare service, irrespective of additional conditions than its usual provision for remuneration, should be treated as a service within the meaning of Articles 56 and 57 TFEU while maintaining the fullest possible recognition of professional qualifications and respect for patients' rights in cross-border healthcare[360]. This demand seems reasonable based on the literal wording of the relevant provisions of primary law of the EU, its interpretation, and the normative content of the relevant secondary law of the EU.

3.3.4 Cross-border as an alternative in the free movement of healthcare services

It is noteworthy that healthcare services do not fall within the scope of one of the main secondary pieces of legislation in the EU relating to the free movement of services. Article 2(2)(f) of The Services Directive states that it does not apply to healthcare

357 Nistor, 2011, pp. 33-35.
358 Nistor, 2011, pp. 33-35.
359 Judgment of the Court of Justice of the European Union of 12 September 2013 in Case C-475/11 in proceedings against Kostas Konstantinides (ECLI:EU:C:2013:542).
360 Author's suggestion is based on: Opinion of Advocate General Tesauro in Case C-120/95…; Judgment of the Court of Justice of the European Union of 28 April 1998 in Case C-158/96… ; Jarman, 2013, pp. 110-125.; Flear, 2015, p. 40.; Nistor, 2011, pp. 33-35., p. 300.; Exter and Hervey, 2012, pp. 25-26.; Garben, 2019 pp. 1445-1456.; Guy and Sauter, 2017, p. 30.; Bosek, 2011, pp. 138-139.; van de Gronden, 2013, p. 125.; Gekiere et al., 2010, pp. 506-508.; Fløistad, 2018, p. 47.; Judgment of the Court of Justice of the European Union of 4 October 1991 in Case C-159/90…; Judgment of the Court of Justice of the European Union of 31 January 1984 in Joined Cases C-286/82 and C-26/83….

services regardless of whether they are provided in healthcare facilities, without reference to the way they are organised and financed at national level, and whether they are public or private. This is justified by the peer review procedure envisaged in the Services Directive, which would periodically check national regulations on healthcare services for unjustified barriers to the free movement of such services. In turn, this could lead to deregulation, forcing EU Member States to not only adapt their healthcare system's organization, but even to withdraw from its governance[361].

This state of affairs seems to have been influenced by other factors, particularly the unwillingness of Member States of the EU to confirm the classification of healthcare services as services benefiting from the EU freedom of movement of services. Such a confirmation in the light of the above-cited case law CJEU is unnecessary, although it is desirable for the purposes of transparency and legal consistency. This is even more true since the market dimension of a healthcare service does not depend on how its provision is defined in national healthcare legislation[362]. The decision to exclude healthcare services from the scope of application of the Services Directive must therefore be judged negatively as an unjustified negation of a fact established by CJEU because the mere exclusion provided for by the Services Directive does not change either the content of EU primary law or its interpretation by CJEU.

For these reasons, the EU legislator, being aware of the need to ensure that healthcare services can benefit from the freedom of movement of services within the internal market of EU, decided to establish a legal framework for patients receiving cross-border healthcare[363]. Such a manoeuvre is to be welcomed, in particular because it bypasses the sensitive issue of the direct impact of the EU on national healthcare systems. Attributing greater importance to patients' rights in cross-border healthcare and shifting the focus from healthcare systems themselves to the legal status of patients in cross-border situations is also to be welcomed, especially since the essence of the problem requiring a legislative solution has been retained. This implies, first, an indirect effect on the Member States' regulation of the healthcare system and, second, directly fulfils the interpretative demands of CJEU for the recognition of healthcare services as services under the freedom of movement of the EU services.

From the totality of the analysis conducted thus far on the legal classification of healthcare services as services within the meaning of the freedom of movement of services in the EU, considering the scientific problems outlined above, it should be noted that a service is considered a service within the meaning of Articles 56 and 57 TFEU when it is primarily for profit, regardless of whether the funding is public or private. Nevertheless, underestimating the importance of national rules governing the functioning of the health system is a mistake. In accordance with Article 168 TFEU, EU, the public health sector shall conduct its activities with due

361 Gekiere et al., 2010, pp. 506-508.
362 van de Gronden, 2013, p. 125.
363 Gekiere et al., 2010, pp. 506-508.

regard to the responsibilities of the Member States of the EU for the definition of their health policy and for the organisation and delivery of health services and medical care, which includes managing health services and medical care as well as allocating resources for them[364]. Given that Member States are responsible for defining their health policy, recognising professional qualifications[365], organising their healthcare system, providing healthcare services, managing these services, and financing them, it is, but *de facto* and *de jure,* the national law of the Member States that plays the primary role in making the right to health in the EU a reality. This fact is confirmed, inter alia, by the exclusion of healthcare services from the scope of application of the Services Directive, which suggests that creating an appropriate legal framework guarantees real enforcement of the legal norms for the freedom of movement of healthcare services was prioritized at that time.

Therefore, to ensure that the entitlements derived from the internal market rules in this area are not illusory, the EU legislator decided to adopt the Directive on Patient's Rights in Cross-border Healthcare. This must be seen as a positive sign of sensitivity to the political will of Member States of the EU when they adopted the Services Directive and as an expression of the realisation of the right to health in cross-border situations that is occurring in the EU. This can be seen as an alternative to making the free movement of healthcare services more of a reality. In addition, at this stage of the analysis in this work, this fact justifies considering patients' rights in cross-border healthcare as the key to a proper understanding and presentation of the principles and conditions for the movement of cross-border healthcare services in the EU. Apart from primary law of the EU, the provisions of the DPRCH are the most relevant source of EU law in this respect.

3.4 Patients' rights in cross-border healthcare

3.4.1 Purpose of defining cross-border patients' rights

It has already been noted that the reason for defining patients' rights regarding cross-border healthcare was both the normatively defined exclusion of healthcare services from the scope of application of the Services Directive and the jurisprudence

364 See: Jarman, 2013, pp. 110-125.; Flear, 2015, p. 40.; Nistor, 2011, p. 300.; Exter and Hervey, 2012, pp. 25-26.; Garben, 2019, pp. 1445-1456.; Guy and Sauter, 2017, p. 30.; Bosek, 2011, pp. 138-139.

365 It should be remembered that the Professional Qualifications Directive requires implementation into national normative orders. The direct source of rights and obligations in this respect will therefore, in principle, be national law. The possibility of direct effect from the EU directive must also be remembered (see Judgment of the Court of Justice of the European Union of 4 December 1974 in Case C-41/74 in Yvonne van Duyn v Home Office [ECLI:EU:C:1974:133]).

CJEU issued in the context of Articles 56 and 57 TFEU which developed single principles for cross-border healthcare[366]. The principles in question, however, required both internal codification and clarification of the substantive and regulatory aspects[367] of the right to health. This rationale, in view of the need for the EU to ensure the full realisation of the principles of free movement of services within the EU internal market and to effectively guarantee the right to health, and therefore the right to health protection and healthcare services throughout the EU, led to the issuance of the Directive on Patient's Rights in Cross-border Healthcare[368]. However, identifying the reason or reasons for a certain legislative action by the EU legislator is not the same as identifying the purpose and motives of the law being made. According to Article 1 and Recitals 10 and 33[369] of the Directive on Patients' Rights

366 See Chapter 3.2.2 Healthcare Services. Internal Market Services of the EU and the case law cited therein. Judgment of the Court of Justice of the European Union of 28 April 1998 in Case C-158/96…; Judgment of the Court of Justice of the European Union of 15 December 1983 in Case C-5/83…; Judgment of the Court of Justice of the European Union of 16 July 1998 in Case C-93/97…; Judgment of the Court of Justice of the European Union of 13 May 2003 in Case C-385/99…; Judgment of the Court of 12 July 2001 in Case C-157/99…; Opinion of Advocate General Tesauro in Case C-120/95…; Judgment of the Court of Justice of the European Union of 5 October 2010 in Case C-173/09….; Judgment of the Court of Justice of the European Union of 16 May 2006 in Case C-372/04…; Judgment of the Court of Justice of the European Union of 5 October 2010 in Case C-512/08…; Judgment of the Court of Justice of the European Union of 27 October 2011 in Case C-255/09….; Judgment of the Court of Justice of the European Union of 12 September 2013 in Case C-475/11…; Judgment of the Court of Justice of the European Union of 4 October 1991 in Case C-159/90…; Judgment of the Court of Justice of the European Union of 31 January 1984 in Joined Cases C-286/82 and C-26/83….; Judgment of the Court of Justice of the European Union of 3 October 1990 in Case C-61/89…; Judgment of the Court of Justice of the European Union of 9 September 2004 in Case C-81/03…; Judgment of the Court of Justice of the European Union of 12 May 1998 in Case C-85/96….

367 See Chapter 2.2.4. Correlation of the essence of the right to health protection and healthcare services.

368 Healthcare in other countries EU – patient rights (https://eur-lex.europa.eu/legal-content/PL/TXT/?uri=LEGISSUM%3Asp0002 – accessed 14.04.2021.); see also Hervey and Mchale, 2015, pp. 98-127.

369 As stated in Recital 10 of the DPRCH: 'This Directive aims to establish rules for facilitating access to safe and high-quality cross-border healthcare in the Union and to ensure patient mobility in accordance with the principles established by the Court of Justice and to promote cooperation on healthcare between Member States, whilst fully respecting the 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, in particular for sickness.' In turn, according to Recital 33 of the DPRCH: 'This Directive does not aim to create an entitlement to reimbursement of the costs of healthcare provided in another Member State, if such healthcare is not among the benefits provided for by the legislation of the Member State of affiliation of the insured person. Equally, this Directive should not prevent the Member States from extending their benefits-in-kind scheme to healthcare provided in another Member State. This Directive should recognise that Member States are free to organise their healthcare and social security systems in such a way as to determine entitlement for treatment at a regional or local level.'

in Cross-border Healthcare, the directive's aim is to establish rules that facilitate access to safe and high quality cross-border healthcare, ensure patient mobility in accordance with the principles established by CJEU, and promote cooperation on healthcare between Member States of the EU, fully respecting their competence both for the definition of social security benefits, the organisation and delivery of healthcare and medical care, and the organisation and delivery of social security benefits, particularly sickness benefits[370].

However, the legal norm of the Directive on Patients' Rights in Cross-Border Healthcare, so defined, requires additional analysis in terms of identifying the premises of the purpose of the DPRCH, which together seek to realise it. The first is to facilitate access to safe, high-quality cross-border healthcare. It should be emphasised that linking the availability of cross-border healthcare with the requirement for safe, high-quality healthcare provision should be welcomed. This has the caveat that, when considering the principles of law in the EU, particularly the directives of purposive interpretation, it is reasonable to conclude that the above premise of the purpose of the DPRCH also contains other designations defining standards for cross-border healthcare, particularly the standard of solidarity, speed, cost reduction, and equality of healthcare services provided, as confirmed by Article 4 of the DPRCH. This premise refers to the actual possibility for patients to receive healthcare services without normatively unjustified restrictions throughout the EU territory. In other words, the intended outcome of the DPRCH standards is to influence Member States by harmonizing national normative systems so that every EU citizen is legally and factually able to become a beneficiary of their healthcare systems. Do so may require patients to be equipped with claims for access to healthcare that are effective in practice, which should be provided for in the national laws of Member States.

It is worth emphasising that facilitating access is not conceptually the same as guaranteeing it. It appears reasonable to argue that the use of such nomenclature containing its semantically defined meaning is not accidental. Such a state of affairs follows directly from at least two norms of primary law of the EU. First, Article 35 of the CFREU implies that the primary responsibility for the realisation of the right to health in the EU is shifted to the legislation and practice of the Member States of the EU[371]. Second, the legal norm of Article 168 TFEU is not without significance here. Moreover, the rationale of facilitating accessibility to cross-border healthcare, which is analysed at this point, should be directly linked to the principles of the freedom of movement of services within the internal market of the EU. This

370 Hervey and Mchale, 2015, pp. 184-211.; Goscinska, 2014, pp. 1-40.; McLean, 2013, pp. 35-40.; Meyer, 2013, pp. 83-103.

371 According to Article 35 of the CFREU, 'Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities.' In this context, see: Forni, 2011, pp. 142-143.; Hervey and McHale, 2014, pp. 951-969.

is because the normative construction of the freedom of movement of services provides the foundation for guaranteeing that patients can actually benefit from healthcare services offered by other EU Member States. The latter would therefore seem to be possible only by considering the provisions of Articles 56 and 57 TFEU. This is confirmed both by Recital 11 of the DPRCH[372], which correlates the accessibility of the healthcare system of another Member State of the EU with the normative classification of healthcare services as benefiting from the freedom of movement of services, and by the fact that, currently, ensuring this accessibility does not appear to be conceptually identical with enabling the physical mobility of patients crossing traditional borders. By using ICT networks, patients can decide to receive healthcare in another Member State of the EU in real time without physically changing their geographical location.

For the above-mentioned reason, the second premise of the objective of the DPRCH is to ensure patient mobility in accordance with the principles set out by CJEU. This premise is related to general mobility, which involves not only about traditional concepts of mobility, implying legislative action to guarantee the realisation of the freedom of movement of persons[373], but also about the digital mobility provided by access to ICT networks, where time and place cease to matter.

The two premises presented so far and analysed for the purpose of the DPRCH require increased cooperation between Member States of the EU. The third premise exists to promote such cooperation, for example, through the issuance of soft law[374]. The DPRCH was mainly issued on the basis of Article 114 TFEU as most of its provisions aim to improve the functioning of the internal market and the free movement of goods, persons, and services, while fully respecting the standard of Article 168 TFEU, which sets a limit for EU public health activities.

372 Recital 11 of the DPRCH reads: 'This Directive should apply to individual patients who decide to seek healthcare in a Member State other than the Member State of affiliation. As confirmed by the Court of Justice, neither its special nature nor the way in which it is organised or financed removes healthcare from the ambit of the fundamental principle of the freedom to provide services. However, the Member State of affiliation may choose to limit the reimbursement of cross-border healthcare for reasons relating to the quality and safety of the healthcare provided, where this can be justified by overriding reasons of general interest relating to public health. The Member State of affiliation may also take further measures on other grounds where this can be justified by such overriding reasons of general interest. Indeed, the Court of Justice has laid down that public health protection is among the overriding reasons of general interest that can justify restrictions to the freedom of movement envisaged in the Treaties.'

373 See Chapter 3.2.1. Characteristics of the internal market in genere.

374 In principle, this must not be confused with the reports of the European Commission, which are issued on the basis of Article 20(1) of the DPRCH. Reference is made, for example, to the Report from the Commission to the European Parliament and the Council on the operating of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare (COM/2015/0421 final) or the Report from the Commission to the European Parliament and the Council on the operating of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare (COM/2018/651 final).

Considering the above points, the EU legislator also decided to establish a fourth premise that was limiting in nature. This premise is a guarantee of full respect for national competence in the organisation and delivery of healthcare.

In conclusion, it should be noted that the fulfilment of the objective of the DPRCH should ensure the wide recognition of the right to health and its material and executive aspects, especially as, in principle, the beneficiaries of the right to healthcare services should be able to access the entire health system, and not a single or selected service[375]. However, it should be noted that healthcare under the DPRCH has its own legal definition: 'health services provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices'. This definition appears to be contained in the semantic proposal presented in this work to understand the concept of healthcare[376].

3.4.2 Obligations of the Member States of the European Union

The DPRCH provides for a number of obligations for Member States of the EU, with the most relevant provisions being Articles 4, 5, and 6. However the importance of distinguishing between the two different functions that EU Member States can perform in cross-border healthcare should be emphasized. The first function refers to the Member State where the patient is entitled to receive healthcare services according to its legislation (hereinafter: Member State of affiliation)[377], and the second to the Member State on whose territory healthcare is actually provided (hereinafter: Member State of treatment)[378].

Article 4 of the DPRCH normatively defines the obligations of the Member State of treatment. The first obligation is to an information duty towards the patient, who is, inter alia, to be provided with data such as information on standards

375 Lach, 2011, p. 178.; Baka, 2010, pp. 124-125.; Dercz and Rek, 2012, p. 41.

376 See Chapter 2.2.3. Outline of the right to health protection.

377 According to Article 3(c) of the DPRCH, the Member State of affiliation is: for persons referred to in point (b)(i), the Member State that is competent to grant to the insured person a prior authorisation to receive appropriate treatment outside the Member State of residence according to Regulations (EC) No 883/2004 and (EC) No 987/2009; (ii) for persons referred to in point (b)(ii), the Member State that is competent to grant to the insured person a prior authorisation to receive appropriate treatment in another Member State according to Regulation (EC) No 859/2003 or Regulation (EU) No 1231/2010. If no Member State is competent according to those Regulations, the Member State of affiliation shall be the Member State where the person is insured or has the rights to sickness benefits according to the legislation of that Member State.

378 According to Article 3(d) of the DPRCH, 'Member State of treatment' means the Member State where the healthcare is actually provided to the patient. In the case of telemedicine, healthcare is considered to be provided in the Member State where the healthcare provider is established.

and guidelines, arrangements for supervision and evaluation of providers, accessibility of hospitals for people with disabilities, prices of healthcare services provided, or information to help patients make informed choices, including information on treatment options, accessibility, quality, and safety of healthcare in the Member State of treatment. Secondly, the Member State is obligated to provide, in the event of harm or injury to a patient, clear rules identifying procedures and mechanisms for seeking remedies in accordance with the law of the Member State of treatment. The third obligation involves having existing legal provisions that provide guarantee, insurance, or similar professional liability schemes commensurate with the nature and extent of the risk. The fourth obligation is to respect the right to privacy with regard to the personal data administered and processed, particularly in compliance with Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data, and on the free movement of such data and repealing Directive 95/46/EC[379] (hereinafter: GDPR). The fifth obligation highlights the implementation of procedures under which the patient will be entitled to receive either traditional or electronic access to the medical records of his/her treatment and to obtain at least one copy of such records. The sixth obligation is to apply the principle of non-discrimination on the basis of nationality, including with regard to the scale of charges for the healthcare services provided[380].

Article 5 of the DPRCH, meanwhile, provides for obligations of the Member State of affiliation which have a different material scope since they do not relate to the treatment process and activities directly related to it; this essentially refers to the time during which healthcare is provided in the Member State of treatment. These include obligations such as: reimbursement of treatment in accordance with the provisions of the DPRCH; ensuring the same quality of medical follow-up, justified on medical grounds, as for domestic patients not receiving cross-border healthcare; ensuring that patients receiving or seeking to receive cross-border healthcare have remote access to their medical records or at least one copy of them; allowing patients on request to obtain information on, inter alia, their rights and entitlements with regard to receiving cross-border healthcare, particularly the terms of reimbursement. In turn, according to Article 6 of the DPRCH, each Member State of the EU is obliged to establish at least one national contact point for cross-border healthcare, which provides information to patients on healthcare providers[381], patients' rights, complaint procedures, mechanisms for seeking remedies, or legal bases for dispute resolution.

379 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ of the EU L 119 of 4.05.2016, pp. 1-88).

380 McHale, 2011, p. 259.; Meyer, 2013, pp. 83-103.

381 According to Article 3(g) of the DPRCH, 'healthcare provider' means any natural or legal person or any other entity legally providing healthcare in the territory of a Member State.

In view of these observations, it should be noted that the standards of Articles 4, 5, and 6 of the DPRCH unambiguously emphasise the indispensable role of the Member States of the EU in the effective provision of cross-border healthcare, which is one of the prerequisites for the normatively stated objective of the DPRCH. Therefore, without their proactive action and cooperation, achieving the DPRCH objective could be either impossible or significantly hampered. This seems to be clearly confirmed not only by Article 1, but also by Article 4(1) of the DPRCH; according to these articles and considering the principles of universality, access to quality care, and the principles of equity and solidarity, cross-border healthcare shall be provided in accordance with the regulations of the Member State of treatment, the quality and safety standards and guidelines laid down by the Member State of treatment, and the EU provisions on safety standards.

In view of these considerations, the national law of the Member States clearly plays a key role in cross-border healthcare, assuming the position of the first and primary method of implementing the provisions of the DPRCH. This leads to the conclusion that the legislation of the Member States of the EU is the determinant premise for the actual possibility for patients to exercise their rights in cross-border healthcare in the EU. It must be further emphasised that the DPRCH is an EU Directive, which unequivocally implies an obligation for Member States to implement the DPRCH in their normative systems. This is underlined by the standard of Article 21 of the DPRCH, according to which Member States enacted the laws, regulations and administrative provisions necessary to implement the DPRCH by 25 October 2013. According to official EU data, all 27 Member States of the EU have enacted the appropriate legal measures, which were adopted, making cross-border healthcare a reality in the EU[382].

382 According to official data EU, among others: Belgium has adopted 44 national measures, including, for example, a law containing various health provisions (org. Wet van 17 juli 2015 houdende diverse bepalingen inzake gezondheid) (Official publication: Belgisch Staatsblad, OJ number: C-2015/24189, publication date: 17.08.2015, pp. 52851-52867.). Bulgaria has also adopted seven national measures, including, for example, Regulation No. 5 on conditions and procedures for the exercise of patients' rights in cross-border healthcare (org. НАРЕДБА № 5 от 21.03.2014 г. за условията и реда за упражняване правата на пациентите при трансгранично здравно обслужване) (Official publication: Държавен вестник, OJ number: 110, publication date: 28.12.2020, pp. 00044-00048.). The Czech Republic has adopted 18 national measures, including, for example, Act No. 372/2011 on health services and their conditions (Health Services Act) (org. Zákon č. 372/2011 Sb, o zdravotních službách a podmínkách jejich poskytování [Zákon o zdravotních službách]) (Official publication: Sbirka Zakonu CR, publication date: 8.12.2011). Denmark has adopted 10 national measures, including, for example, the provision on entitlement to benefits provided for in the Health Act for certain residents EU/EOG (org. Bekendtgørelse om ret til ydelser i sundhedsloven til visse personer med bopæl i et EU-/EØS-land) (Official publication: Lovtidende A, publication date: 27.12.2013). Germany has adopted 120 national measures, including, for example, the Act on the Application of Patients' Rights in Cross-Border Healthcare (org. Gesetz über die Ausübung der Patientenrechte in der grenzüberschreitenden Gesundheitsversorgung) (Official publication: Gesetz und Verordnungsblatt

It should also be noted that Member States of the EU have two further important obligations. When a patient is exercising his or her rights in cross-border healthcare, they should ensure that the provisions of the DPRCH are fully coherent with Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems (hereinafter: Regulation 883/2004)[383] and Regulation (EC) No 987/2009 of the European Parliament and of the Council of 16 September 2009 laying down the procedure for

[Länder], OJ number: 5, publication date: 28.05.2014, p. 00074-00075); Estonia has adopted 17 national measures, including, for example, the Health Service Organisation Act1 (org. Tervishoiuteenuste korraldamise seadus1) (Official publication: Elektrooniline Riigi Teataja, OJ no.OJ: RT I, 29.11.2013, 6). Ireland has adopted six national measures, including, for example, the Medical Practitioners [Amendment] Act 2017 (org. Medical Practitioners [Amendment] Act 2017) (Official publication: Iris Oifigiúl, publication date: 10.11.2017). Greece has adopted four national measures, including, for example, general rules for the calculation of costs to be reimbursed to the insured person in cross-border healthcare (Article 7 of Law 4213/2013) (org. Γενικές αρχές για τον υπολογισμό των εξόδων που πρόκειται να επιστραφούν σε ασφαλισμένο στα πλαίσια της διασυνοριακής υγειονομικής περίθαλψης [άρθρο 7 του Ν. 4213/2013]) (Official publication: Εφημερίς της Κυβερνήσεως [ΦΕΚ] [Τεύχος Β], OJ number: 2774, publication date: 16.10.2014, pp. 34013-34015). Spain has adopted two national measures, including, for example, Royal Decree 81/2014, of 7 February, establishing rules for the provision of cross-border healthcare and amending Royal Decree 1718/2010 on medical prescriptions and dispensing orders. (org. Real Decreto 81/2014, de 7 de febrero, por el que se establecen normas para garantizar la asistencia sanitaria transfronteriza, y por el que se modifica el Real Decreto 1718/2010, de 17 de diciembre, sobre receta médica y órdenes de dispensación) (Official publication: Boletín Oficial del Estado [B.O.E], OJ number: 34/2014, publication date: 8.02.2014, pp. 10915-10948). France has adopted three national measures, including, for example, Regulation No. 2014-1525 on the recognition of prescriptions for medical devices issued in another Member State of the European Union (org. Décret n o 2014-1525 du 17 décembre 2014 relatif à la reconnaissance des prescriptions de dispositifs médicaux établies dans un autre Etat membre de l'Union européenne) (Official publication: Journal Officiel de la République Française (JORF), publication date: 18.12.2014). Croatia has adopted 27 national measures, including, for example, the Healthcare Act (org. Zakon o zdravstvenoj zaštiti) (Official publication: Narodne Novine, OJ number: 100/2018, publication date: 1.01.2018); Italy has adopted 2 national measures, including, for example, a regulation on cross-border healthcare requiring prior authorisation (org. Regolamento in materia di assistenza sanitaria transfrontaliera soggetta ad autorizzazione preventive) (Official publication: Gazzetta Ufficiale della Repubblica Italiana, OJ number: 117, publication date: 22.05.2018). Cyprus has adopted 17 national measures, including, for example, the 2020 Regulation on the application of patients' rights in cross-border healthcare (org. Το περί Εφαρμογής των Δικαιωμάτων των Ασθενών στο πλαίσιο της Διασυνοριακής Υγειονομικής Περίθαλψης Διάταγμα του 2020) (Official publication: Cyprus Gazette, OJ number: 5202, publication date: 17.01.2020, pp. 00049-00053.). Poland has adopted 17 national measures, including, by translation, the Regulation of the Minister of Health of 3 September 2020 on the list of healthcare services requiring prior authorisation by the President of the National Health Fund (Journal of Law of 2020, item 1556.).

383 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 of the EU L 166 of 30.04.2004, pp. 1-123.).

implementing Regulation (EC) No 883/2004 on the coordination of social security systems (hereinafter: Regulation 987/2009)[384]. This obligation is clearly highlighted, for example, in Recitals 28-31, Articles 1, 2(m), or 5(b) of the DPRCH. Specifically, the common denominator of these provisions is need to ensure full coherence of the parallel application of the DPRCH and Regulation 883/2004 and Regulation 987/2009, which constitute two independent sources in different segments of the EU law[385]. This is because Regulation 883/2004 and Regulation 987/2009 belong to legal regulations of a different internal market freedom of the EU, namely the freedom of movement of workers and, possibly, of persons[386]. In contrast, the DPRCH is the legal framework for the free movement of healthcare services in the EU, which has been highlighted repeatedly and is why the DPRCH is an important part the scope of this work.

Based on the provisions of the DPRCH, Member States also have a general obligation to respond to the emerging conditions of the modern world. Undeniably, one of their designations is not only telemedicine, but also the emergence of the COVID-19 pandemic; this is supported by the European Commission's decision to issue a communication entitled 'Communication from the Commission Guidelines on EU Emergency Assistance on Cross-Border Cooperation in Healthcare related to the COVID-19 crisis [387], which was mainly addressed to Member States. The impact of a pandemic on the right to health is of upmost importance and should be clearly emphasized in both legal theory and in practice. This topic is therefore considered in a separate chapter[388].

3.4.3 Telemedicine as a subject of cross-border healthcare

Telemedicine is indisputably one of the designated legal norms that define the principles of cross-border healthcare provision in the EU. This therefore suggests that this type of modern technology used in the practice of medicine is as a normatively defined component of the legal framework of cross-border healthcare, and thus is part of its subject matter. This is confirmed by selected provisions of the DPRCH, which refer either directly to telemedicine or indirectly through the concept of eHealth.

384 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, pp. 1-42.).
385 Uścińska, 2013, pp. 307-346.
386 Ibid, pp. 307-346.
387 Communication from the Commission Guidelines on EU Emergency Assistance on Cross-Border Cooperation in Healthcare related to the COVID-19 crisis (OJ of the EU C 111I, 3.04.2020, pp. 1-5.).
388 See Chapter 4 Problems in the implementation of the right to health and the functioning of cross-border healthcare in the EU during the COVID-19 pandemic.

Based on the methodology adopted in legal sciences and that conducted in this analysis, it seems reasonable to first present the provisions of the DPRCH that explicitly refer to telemedicine[389]. Article 3(d) of the DPRCH provides the legal definition of the Member State of treatment, i.e., the Member State of the EU on whose territory healthcare is actually provided. However, this provision explicitly clarifies that, in the case of telemedicine, healthcare is deemed to be provided in the Member State of the EU in which the healthcare provider is established[390]. The fact that the EU legislator took notice and indicated that telemedicine can be a cross-border healthcare is evidence of its sensitivity towards modern medical technologies.

Article 7(7) of the DPRCH refers to telemedicine, stating that the Member State of affiliation may impose on an insured person seeking reimbursement for cross-border healthcare, including healthcare received by telemedicine, the same conditions, criteria of eligibility, and legal and administrative requirements at local, regional, or national levels as would be imposed if the same healthcare was provided on the EU territory. This example confirms the above observation on the telemedicine form of cross-border healthcare provision, but it is significant that the reference in question is placed in a legal norm that sets out the general principles of reimbursement in accordance with the DPRCH. The EU legislator seems to have considers the telemedicine mode of healthcare provision to be equivalent to the traditional prototype.

Turning to the legal norms that refer to the concept of telemedicine indirectly through the concept of eHealth, it should be noted that there are more normatively defined references to eHealth than there are direct references to telemedicine. Provisions relating to eHealth can be found in the preamble of the DPRCH itself (Recitals 26, 56 and 57 of the DPRCH)[391]. The first of these refers to the reimbursement of healthcare provided in another Member State of the EU and contains a provision on the equivalence in this respect of eHealth services. This standard is not identical in scope to Article 7(7) of the DPRCH, which refers to telemedicine. Recitals 56 and 57 of the DPRCH deal with ensuring the interoperability[392] of ICT

389 For the concept of telemedicine, see Chapter 1.4 The concept of telemedicine.

390 Cross-border healthcare, particularly healthcare provided through modern technologies, necessitates the application of appropriate laws. An extremely interesting study in this regard is: Nowak, 2018, pp. 36-44.

391 These recitals explicitly state the following. In recital 26 'The Court of Justice has held that the Treaty provisions on the freedom to provide services include the freedom for the recipients of healthcare, including persons in need of medical treatment, to go to another Member State in order to receive it there. The same should apply to recipients of healthcare seeking to receive healthcare provided in another Member State through other means, for example through eHealth services'. In recital 56, 'and to support patient access to eHealth applications, whenever Member States decide to introduce them'. In recital 57 'The interoperability of eHealth solutions should be achieved whilst respecting national regulations on the provision of healthcare services'.

392 Note Directive (EU) 2018/1972 of the European Parliament and of the Council of 11 December 2018 which established the European Electronic Communications Code (OJ of the EU L 321 of 17.12.2018, pp. 36-214.).

healthcare systems, including healthcare services delivered via electronic means, i.e. eHealth services. These provisions clearly emphasise that introducing modern technologies into the practice of medicine is occurring at the national level, and the full national legislation both created that protects patients and regulates the provision of healthcare services.

A recent example of indirect reference to telemedicine by EU legal norms on cross-border healthcare is the entire Article 14 of the DPRCH, which created the EU eHealth Network[393]. In this provision, the EU supports and facilitates cooperation and exchange of information between Member States of the EU operating within a voluntary network, bringing together the national authorities who are designated as responsible for eHealth in Member States. The eHealth Network does not have a single purpose, but serves at least three main priorities in this field. The first priority includes both taking action that focuses on the achievement of sustainable social or economic benefits of eHealth and implementing interoperable solutions to increase the efficiency and reach of this type of health innovation. The aim is to increase the parameter indicators for cross-border healthcare provided using modern methods. We are referring here to evaluation criteria such as trust and safety, continuity of care, and access to quality healthcare services.

The second priority of the eHealth Network is to produce guidelines. These may concern either effective methodologies or techniques for sharing medical data for public health and research purposes; they may also include an open catalogue of data to ensure continuity of care and patient safety across borders that would be included in patient records and be freely exchanged between health professionals.

The third priority is to support Member States of the EU in their efforts to develop common means of identification and authentication to facilitate the portability of data in cross-border healthcare. In addition, in light of Article 14 of the DPRCH as a whole, paragraph 3 gives the European Commission the ability to adopt measures necessary for the establishment, management, and transparent functioning of the eHealth network, which is significant. It should be noted that the European Commission has actively exercised this power by issuing numerous documents[394]. The most relevant of these is the Commission Implementing Decision

393 European Commission, n.d.

394 For example, the following documents have been issued: eHealth Network, 2020; Interoperability guidelines for approved contact tracing mobile applications in the EU (https://ec.europa.eu/health/sites/default/files/ehealth/docs/contacttracing_mobileapps_guidelines_en.pdf – accessed 25.06.2021.); eHealth Network Guidelines to the EU Member States and the European Commission on Interoperability specifications for cross-border transmission chains between approved apps Detailed interoperability elements between COVID+ Keys driven solutions V1.0 (https://ec.europa.eu/health/sites/default/files/ehealth/docs/mobileapps_interoperabilitydetailedelements_en.pdf – accessed 25.06.2021.); eHealth Network Towards a common approach for the use of anonymised and aggregated mobility data for modelling the diffusion of COVID-19, and optimising the effectiveness of response measures: Version 4.3 (https://ec.europa.eu/health/sites/default/files/ehealth/docs/modelling_mobilitydata_en.pdf – accessed 25.06.2021.); European Proximity Tracing

(EU) 2019/1765 of 22 October 2019, which provides rules for the establishment, management and operation of the network of national authorities responsible for eHealth and repeals Implementing Decision 2011/890/EU[395] (hereinafter: Commission Implementing Decision on the eHealth Network eHealth), which was further amended by Commission Implementing Decision (EU) 2020/1023 of 15 July 2020 amending Implementing Decision (EU) 2019/1765 regarding the cross-border exchange of data between national contact tracing and warning mobile applications with regard to combatting COVID-19[396] (hereinafter: Commission Implementing Decision on COVID-19 data exchange and alerting).

The Commission's Implementing Decision on the eHealth Network is momentous in that it establishes the principles necessary for the establishment, management, and operation of the eHealth Network. Recital 3 of the Decision stated that its purpose was to determine appropriate rules for the transparent functioning of the eHealth Network, including indicating the role of the Network and the European Commission regarding the overall infrastructure for cross-border digital eHealth services and the data protection requirements arising from the GDPR and

An Interoperability Architecture for contact tracing and warning apps (https://ec.europa.eu/health/sites/default/files/ehealth/docs/mobileapps_interop_architecture_en.pdf – accessed 25.06.2021); European Interoperability Certificate Governance A Security Architecture for contact tracing and warning apps (https://ec.europa.eu/health/sites/default/files/ehealth/docs/mobileapps_interop_certificate_governance_en.pdf – accessed 25.06.2021.); OUTLINE Interoperability of health certificates Trust framework V.1.0 (https://ec.europa.eu/health/sites/default/files/ehealth/docs/trust-framework_interoperability_certificates_en.pdf – accessed 25.06.2021.); Guidelines on verifiable vaccination certificates – basic interoperability elements Release 2 (https://ec. europa.eu/health/sites/default/files/ehealth/docs/vaccination-proof_interoperability-guidelines_en.pdf – accessed 25.06.2021.); Guidelines on COVID-19 citizen recovery interoperable certificates – minimum dataset Release 1 (https://ec.europa.eu/health/sites/default/files/ehealth/docs/citizen_recovery-interoperable-certificates_en.pdf – accessed 25.06.2021.); Guidelines on Value Sets for Digital Green Certificates Version 1.0 (https://ec.europa.eu/health/sites/default/files/ehealth/docs/digital-green-certificates_dt-specifications_en.pdf – accessed 25.06.2021.); Guidelines on Technical Specifications for Digital Green Certificates Volume 1 (https://ec.europa.eu/health/sites/default/files/ehealth/docs/digital-green-certificates_v1_en.pdf – accessed 25.06.2021.); Guidelines on Paper version of the EU Digital COVID Certificate V1.0.2 (https://ec.europa.eu/health/sites/default/files/ehealth/docs/covid-certificate_paper_guidelines_en.pdf – accessed 25.06.2021); Guidelines on Technical Specifications for EU Digital COVID Certificates JSON Schema Specification Schema version: 1.3.0 (https://ec.europa.eu/health/sites/default/files/ehealth/docs/covid-certificate_json_specification_en.pdf – accessed 25.06.2021.).

395 Commission Implementing Decision 2019/1765 of 22 October 2019 providing the rules for the establishment, the management and the functioning of the network of national authorities responsible for eHealth, and repealing Implementing Decision 2011/890/EU (OJ of the EU L 270, 24.10.2019, pp. 83-93.).

396 Commission Implementing Decision (EU) 2020/1023 of 15 July 2020 amending Implementing Decision (EU) 2019/1765 as regards the cross-border exchange of data between national contact tracing and warning mobile applications with regard to combatting the COVID-19 (OJ of the EU L 227I, 16.07.2020, pp. 1-9.).

Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the institutions, bodies, offices and agencies of the Union and on the free movement of such data, and repealing Regulation (EC) No. 45/2001 and Decision No. 1247/2002/EC[397]. In turn, the purpose of the Commission's COVID-19 Data Exchange and Alerting Executive Decision was to introduce regulations into the Commission's eHealth Network Executive Decision to facilitate the exchange of cross-border health data between designated national authorities or official bodies in the EU via a federation gateway[398].

The intention of issuing this type of regulation is to create in the EU a seamless and fully interoperable flow of information between the aforementioned entities identifying contact between a person using eHealth services and a person infected with the SARS-CoV-2 virus. The rationale for adopting this new standard is to enable the exposed person to be effectively informed of the potential risk and promote effective cross-border cooperation among the EU Member States in the field of. While it should not be noted that the adoption of these provisions was provoked by the COVID-19 pandemic, they will also be applicable for other communicable diseases. Both the Commission's Implementing Decision on the eHealth Network, the Commission's Implementing Decision on data exchange and alerting COVID-19, the series of acts issued under the eHealth Network, and the very establishment of such a network in accordance with the mandate provided by the DPRCH clearly show that eHealth services, including telemedicine services, are gaining recognition as an action priority by policy makers in the EU.

One may wonder whether the EU legislator uses the highlighted terms in the context of applying modern technologies to medical use with caution and awareness of their actual scope of meaning[399]. To assess this, it should be noted that he is far more likely to use the general term eHealth. Other terms are incidental and occur alongside or in connection with eHealth. Nevertheless, the concept of telemedicine is incorporated in the legal language of the EU, such as the wording of Articles 3(d) and 7(7) of the DPRCH and Recital 9 and Article 4(1)(c) of the Commission's Implementing Decision on an eHealth network. From the point of view of this paper's main research topic, the semantic relationship between the terms

397 Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data and repealing Regulation (EC) No. 45/2001 and Decision No. 1247/2002/EC (OJ of the EU L 295 of 21.11.2018, pp. 39-98.).

398 According to Article 1 of the Commission's Implementing Decision on Data Exchange and Alerting COVID-19, a federation gateway refers to a network gateway operated by the European Commission using a secure IT tool to receive, store, and share a minimum set of personal data between Member States' internal servers in the EU to ensure interoperability of national mobile contact tracing and alerting applications.

399 See Chapter 1.2 Systematics of the application of modern technology for practical use in medicine.

eHealth and telemedicine as used by the EU legislator is therefore puzzling. Does the term telemedicine in Acts of the EU represent the actual meaning of the term telemedicine, or is it used as a synonym for the term eHealth? The content of Recital 26 and Article 7(7) of the DPRCH can be used to assess this. Comparing these provisions shows that they deal with identical normative matter; both refer to the principles of reimbursement for cross-border healthcare provided in another Member State of the EU. The difference between them, however, concerns the indication of an equivalent form of healthcare provision using modern medical technology. In Recital 26, of the DPRCH these are eHealth services, and in Article 7(7) of the DPRCH, they are telemedicine.

It should also be remembered that the language in Article 7(7) of the DPRCH should be read as a legal norm that constitutes a kind of counterpart to and subject of the justification of Recital 26 of the DPRCH. There is a strong and direct relationship between these provisions, including a relationship of normative scope. It would appear, therefore, that the EU legislator did not deliberately deplete the subject matter of the regulation it was justifying, as this would be the result of using the concept of telemedicine in the sense proposed in this monograph instead of the concept of eHealth services. eHealth as a concept includes other forms of healthcare provision that use modern technology in medical practice, such as mHealth or sensory health.

The analysis in this paper therefore suggests that the EU legislator does not always use the concepts of eHealth and telemedicine in their actual framework of meaning; these concepts are used synonymously in the DPRCH example examined. However, the evidence does not imply that the EU legislator does not consciously use the concept of telemedicine or eHealth throughout the normative system of the EU. After all, it must be remembered that this evidence was based on a single premise of logical reasoning. Nevertheless, it confirms that there are instances of the use of these terms synonymously in the EU law. Regardless of the final verdict, however, the fact remains that telemedicine is a normatively defined designator of Law in the EU, including cross-border healthcare, without exhausting that subject matter. Even when telemedicine is used as a synonym for eHealth, its actual scope of meaning is contained within eHealth as it has a broader subject-matter framework[400]. However, it is desirable for the term telemedicine to be used to define actual telemedicine services from the point of view of legislation; when this is done, the real meaning of telemedicine is present in the law.

400 See Chapter 1.2.4 The concept of telemedicine.

3.5 Telemedicine services in cross-border healthcare

3.5.1 Services in telemedicine

To propose a definition of a telemedicine service, referring to the proposal for the definition of healthcare service presented above is necessary. According to this proposal, healthcare services are services relating to an actual medical need, particularly understood in terms of clinical, hospital, or pharmacological services, complemented by any non-clinical, non-hospital, or non-pharmacological health services that have a positive impact on the general state of health; healthcare services implement the material and executive aspects of the right to health and are normally provided for remuneration insofar as they are not covered by the provisions on free movement of goods, capital, and persons[401]. It is also important to refer to the suggested definition of telemedicine already put forward. According to that definition, telemedicine should be equated with the provision of medical services by doctors at a distance using telepresence techniques[402]. These two premises are sufficient analytical material for a definition of a telemedicine service because the notion of telemedicine service should both coincide with and be compatible with the notion of healthcare service as well as reflecting the specificity of telemedicine as a situation where modern technology is used in the practice of medicine. The essential core of the proposed definition for a telemedicine service will be that of a healthcare service, which should in this case constitute the semantic

401 Author's suggestions are based, inter alia, on Jasudowicz, 2010, pp. 491-495.; Piechota, 2010, pp. 137-142.; Zoll, 2000, p. 8.; Mikos and Urbaniak, 2016, pp. 160-166.; Surówka, 2012, p. 98.; Ryś, 2017, p. 119.; Surówka, 2009, p. 395.; Piechota, 2012, pp. 93-102.; Rex, 1980, pp. 391-403.; Sass, 1991, pp. 243-255.; Halper, 1991, pp. 135-168.; Marmor, 1991, pp. 23-49.; Agich, 1991, pp. 185-198.; Daniels, 1991, pp. 201-212.; Engelhardt, 1991, pp. 103-111.; Buchanan, 1991, pp. 169-184.; Beauchamp, 1991, pp. 53-81.; Merrill, 1994, pp. 99-128.; Mpedi, 2020, pp. 77-100.; Tu, 2019, 59-84.; Kirchner, 2018, pp. 141-151.; Holder, 1989, pp. 161-172.; Evans, 2002, pp 197-215.; Jamar, 1994, pp. 17-35.; Leary, 1994, pp. 24-56.; Moens and Trone, 2010, p. 100.; Wiberg, 2014, p. 20.; van de Gronden, 2013, p. 125.; Montgomery, 1992, pp. 184-203.; Pestova, 2014, pp. 341-372.; Iguiñiz, 2014, 313-337.; McAuley, 2014, pp. 373-401.; Walker, 2014, pp. 165-192.; Evans, 2014, pp. 233-257.; Heus and Sartawi, 2014, pp. 193-229.; Munesue, 2014, pp. 121-132.; Qiu, 2014, pp. 97-120.; Rawaf and Hassounah, 2014, pp. 135-163.; Wu, 2019, pp. 457-469.; Oke, 2016, pp. 91-122.; France, 2014, pp. 335-352.; Oke, 2017, pp. 311-326.

402 Author's proposal is based on: Adelakun and Garcia, 2019, p. 85.; Otto, 2001, p. 106.; Cohendet et al., 1998, p. 191.; Klar and Pelikan, 2011, p. 1119.; Zimpfer, 1999, p. 77.; Linkous, 2001, p. 226.; de Lucena et al., 2013, p. 129.; Argy and Caputo, 2001, p. 227.; Shaw, 2009, pp. 13-18.; Bhattacharyya, 2017, p. 6.; Spradley, 2001, p. 291.; Reynolds, 2019, p. 4.; Dafoulas et al., 2017, p. 340.; Mohr et al., 2019, p. 255.; Lynn, 2019, p. 107.; Melton et al., 2019, p. 253.; Simmons et al., 2008, p. 163.; European Commission, 2018, p. 25.; Raskas et al., 2017, p. 206.

prototype. However, it is inappropriate to simply or mechanically link this definition to the proposed meaning of telemedicine. The concept of telemedicine has a narrower scope as it does not include all healthcare services, particularly those of a non-hospital, non-clinical, or non-pharmacological nature. This is a corollary of the distinction of telehealth into telemedicine and telecare, where the level of sophistication of the healthcare service provided (i.e., whether a doctor is involved) is a key criterion[403].

Based on this, it seems justified to propose that, *de lege ferenda*, the notion of telemedicine service should be identified several characteristics: a service performed by a physician, related to an actual medical need, that has a positive impact on the general state of health, realizes the material and executive aspect of the right to health, and is performed at a distance using telepresence techniques, usually for remuneration to the extent that it is not covered by the provisions on free movement of goods, capital, and persons[404]. The proposal presented in this paper is logically consistent as it follows from the analysis developed and accounts for the possibility of a cross-border form of healthcare provision. This further reinforces the legitimacy of its content, which, by fitting into the actual scope of healthcare services provided using telemedicine solutions, takes into account its essence, objectives, and current level of advancement, where criteria such as time and place lose their importance. In other words, the demand put forward quite precisely defines the boundaries of the material scope of telemedicine services, which are of both dogmatic and pragmatic value. It is also significant that the noted proposal considers both the specificity of healthcare services and solutions using modern technologies for practical use in medicine. In view of the above, *de lege ferenda* the contemporary legislator should consider introducing a legal definition of telemedical services into its normative system with content that is identical or nearly identical to the presented proposal as soon as possible[405].

403 See Chapter 1.4.2 Essence of telemedicine.

404 Author's proposal is based on: Jasudowicz, 2010, pp. 491-495.; Holder, 1989, pp. 161-172.; Jamar, 1994, pp 17-35.; Tu, 2019, 59-84.; Kirchner, 2018, pp. 141-151.; de Lucena et al., 2013, p. 129.; Buchanan, 1991, pp. 169-184.; Beauchamp, 1991, pp. 53-81.; Merrill, 1994, pp. 99-128.; Evans, 2014, 233-257.; Heus and Sartawi, 2014, pp. 193-229.; Qiu, 2014, pp. 97-120.; Argy and Caputo, 2001, p. 227.; Shaw, 2009, pp. 13-18.; Spradley, 2001, p. 291.; Piechota, 2012, pp. 93-102.; Rex, 1980, pp. 391-403.; Reynolds, 2019, p. 4.; Dafoulas et al., 2017, p. 340.; Mohr et al., 2019, p. 255.; Lynn, 2019, p. 107.; Ryś, 2017, p. 395.; Montgomery, 1992, pp. 184-203.; Pestova, 2014, pp. 341-372.; Cohendet et al., 1998, p. 191.; Klar and Pelikan, 2011, p. 1119.; Leary, 1994, pp. 24-56.; Wiberg, 2014, p. 20.; van de Gronden, 2013, p. 125.; McAuley, 2014, pp. 373-401.; Walker, 2014, pp. 165-192.; Daniels, 1991, pp. 201-212.; Engelhardt, 1991, pp. 103-111.; Melton et al., 2019, p. 253.; Raskas et al., 2017, p. 206.; Rawaf and Hassounah, 2014, pp. 135-163.; Wu, 2019, pp. 457-469.; Mohr et al., 2019, p. 255.; Lynn, 2019, p. 107.; Ryś, 2017, p. 119.; Surówka, 2009, p. 395.; Sass, 1991, pp. 243-255.; Halper, 1991, pp. 135-168.; Marmor, 1991, pp. 23-49.

405 See European Commission 2018.

3.5.2 Telemedicine services as services in the European Union internal market

One more issue must be discussed before concluding the discussion on the cross-border provision of healthcare services in the EU: whether telemedicine services, as defined above, benefit from the freedom of movement of services within the internal market of the EU. As was the case for the appropriate definition of telemedicine services, the answer to this question follows from the logical reasoning established in this paper. We are referring here to the considerations already presented concerning the possibility of qualifying healthcare services as internal market services in the EU[406].

This analysis proposed a *de lege ferenda* suggestion, according to which any healthcare service, irrespective of additional conditions beyond its usual provision for remuneration, should be treated as a service within the meaning of Articles 56 and 57 TFEU with the fullest possible recognition of professional qualifications and respect for patients' rights in cross-border healthcare[407]. It would therefore seem that a simple statement based on the two conclusions established so far is sufficient. The first emphasises that the meaning of telemedicine services directly relates to the concept of healthcare services, which constitute a semantic prototype for them. The second, in turn, emphasises that healthcare services, which are usually performed for remuneration, benefit from the freedom of movement of services within

406 See Chapter 3.2 Healthcare services. Internal Market services of the EU along with the case law cited therein: Judgment of the Court of Justice of the European Union of 15 December 1983 in Case C-5/83…; Judgment of the Court of Justice of the European Union of 31 January 1984 in Joined Cases C-286/82 and C-26/83…; Judgment of the Court of Justice of the European Union of 3 October 1990 in Case C-61/89…; Judgment of the Court of Justice of the European Union of 4 October 1991 in Case C-159/90….; Judgment of the Court of Justice of the European Union of 28 April 1998 in Case C-158/96…; Judgment of the Court of Justice of the European Union of 12 May 1998 in Case C-85/96…; Judgment of the Court of Justice of the European Union of 16 July 1998 in Case C-93/97…; Judgment of the Court of 12 July 2001 in Case C-157/99….; Judgment of the Court of Justice of the European Union of 13 May 2003 in Case C-385/99…; Judgment of the Court of Justice of the European Union of 16 May 2006 in Case C-372/04…; Judgment of the Court of Justice of the European Union of 5 October 2010 in Case C-173/09…; Judgment of the Court of Justice of the European Union of 5 October 2010 in Case C-512/08….; Judgment of the Court of Justice of the European Union of 27 October 2011 in Case C-255/09…; Judgment of the Court of Justice of the European Union of 12 September 2013 in Case C-475/11…; Judgment of the Court of Justice of the European Union of 9 September 2004 in Case C-81/03…; Opinion of Advocate General Tesauro in Case C-120/95….

407 Opinion of Advocate General Tesauro in Case C-120/95…; Judgment of the Court of Justice of the European Union of 28 April 1998 in Case C-158/96…; Jarman, 2013, pp. 110-125; Flear, 2015, p. 40; Nistor, 2011, pp. 33-35, 300; Exter and Hervey, 2012, pp. 25-26; Garben, 2019 pp. 1445-1456; Guy and Sauter, 2017, p. 30; Bosek, 2011, p. 127; Gekiere et al., 2010, pp. 506-508; Fløistad, 2018, p. 47; Judgment of the Court of Justice of the European Union of 4 October 1991 in Case C-159/90…; Judgment of the Court of Justice of the European Union of 31 January 1984 in Joined Cases C-286/82 and C-26/83….

the internal market of the EU. The correlation of these two conclusions leads to the following idea: since the concept of healthcare services, which in principle benefit from the freedom of movement of services in the EU, is a source for telemedicine services, telemedicine services can also benefit from this freedom. This conclusion is logical, but to confirm it unequivocally, an additional comparison of the relationship between the material scope of healthcare services and telemedicine services is necessary. It should be emphasised that the material scope of telemedicine services is included in the material scope of healthcare services because they are services provided in modern medicine through the use of modern medical technology. This discourse leads to the assumption that every telemedicine service is also a healthcare service, but not that every healthcare service is a telemedicine service. It is therefore confirmed that telemedicine services benefit from the EU freedom of movement of services on the same basis as healthcare services. An additional argument in favour of this is Article 7(7) of the DPRCH; as previously noted, its normative content indicates the equivalence of traditional and telemedicine healthcare provision.

The totality of the above discussion would appear to conclusively establish the legitimacy of classifying telemedicine services normally provided for remuneration as services benefiting from the freedom of movement of services within the internal market of the EU, particularly in cross-border situations.

3.6 Summary

This chapter presents an original consideration of the cross-border provision of healthcare services in the EU. The aim was to point out the conditions, principles, and interpretations of the EU law that apply to this issue. The immediate aim was also to determine whether it is legally possible to qualify telemedicine services as services under EU law.

Towards this end, the first subchapter deals with the analysis of the internal market in the light of the free movement of services. On this subject, attention was first turned towards the characteristics of the internal market *in genere*, where the legal framework for the free movement of goods, persons, and capital was presented. The issues in question were addressed with the goal of presenting a general characterisation of the idea of an internal market of the EU, i.e., a kind of foundation for the cross-border provision of healthcare services in the EU. This was followed by an overview of the free movement of services which emphasized the treaty sources to analyse the relevant topic. Another element of this analysis was providing an overview of EU definition of a service and a brief attempt to assess it. As part of these considerations, it was emphasised that the drafting of the provision containing the legal definition of a service in EU law unambiguously determines whether the substantive enumeration of the notion of service contained in TFEU is only exemplary and serves to adopt the correct line of interpretation. It was noted

that this justifies the research question of whether healthcare services can benefit from EU freedom of movement of services, even though they are not provided for in TFEU itself. Quandaries concerning the normative nature of the treaty norms of the freedom of movement of services constitute the last element of the subsection. Importantly, it has been established that both Articles 56 TFEU and 57 TFEU meet the formal criteria for the attribution of direct effect, although this does not preclude the enactment of relevant secondary legislation.

The above analysis suggests that addressing whether healthcare services can be considered to benefit from the EU freedom of movement of services is justified. Consequently, the second subchapter presented the issue of the free movement of healthcare services, which began by considering the notion of healthcare services. It was highlighted that the proper understanding of this concept should be interpreted based on the correlation of the EU definition of service and the term healthcare with the purpose of healthcare services. In these circumstances, it was proposed that, *de lege ferenda*, healthcare services should be considered to be services relating to an actual medical need related to clinical, hospital or pharmacological services, complemented by any non-clinical, non-hospital, or non-pharmacological health service that has a positive impact on the general state of health, fulfils the material and executive aspect of the right to health, and is normally provided for remuneration to the extent that it is not covered by the provisions on free movement of goods, capital, and persons. Building on these findings and considering the contributions of both literature and case law, the possibility of qualifying healthcare services as internal market services in the EU was examined. An integral complement to this was a discussion of the possibility of imposing restrictions on the free movement of healthcare services, particularly in light of the proportionality test CJEU. This reasoning led to the conclusion that, in principle, there are no restrictions on the free movement of healthcare services in the EU under Article 56 TFEU, and that exceptions must be justified and carefully analysed.

This conclusion also gave rise to the proposal that, *de lege ferenda,* any healthcare service, irrespective of conditions additional to its usual provision for remuneration, should be treated as a service within the meaning of Articles 56 and 57 TFEU and have the fullest possible recognition of professional qualifications and respect for patients' rights in cross-border healthcare. This gave rise to more far-reaching observations, particularly regarding cross-borderism understood as an alternative solution. It was noted that, to preserve the entitlements under internal market rules of the EU for the free movement of healthcare services, the EU legislator decided to adopt the DPRCH. This assessment emphasised that this was a manifestation of sensitivity to the political will of the Member States of the EU, decoded when adopting the Services Directive, and an expression of the realisation of the right to health in cross-border situations occurring in the EU. It was also determined that this fact could be alternatively be read as allowing the freedom of movement of healthcare services to become more of a reality.

This observation warranted special attention to patients' rights in cross-border healthcare as a key to a properly understanding and presenting the principles and conditions for the movement of cross-border healthcare services in the EU. An in-depth analysis of the purpose of the DPRCH was conducted; this analysis referenced the rationale of facilitating access to safe, high-quality cross-border healthcare, ensuring patient mobility in accordance with the principles established by CJEU, promoting cooperation between Member States of the EU, and the rationale of guaranteeing full respect for national competences in the organisation and delivery of healthcare.

The obligations of Member States of the EU in the context of patients' rights in cross-border healthcare were discussed. One of the most important observations made in this subsection was that the standards of Articles 4, 5, and 6 of the DPRCH emphasise the indispensable role of the Member States in effectively guaranteeing cross-border healthcare in the EU, meaning that, without their proactive action and cooperation, it may be either impossible or much more difficult to achieve the objective of the DPRCH. In doing so, it was emphasised that the national law of the Member States clearly plays a key role in cross-border healthcare, functioning as the first and primary means of implementing the provisions of the DPRCH.

This was followed by a discussion of whether telemedicine is a cross-border healthcare topic in the EU. To this end, the provisions of the DPRCH that relate directly or indirectly to telemedicine were presented, including the legal standard underpinning the establishment and operation of the EU Network of eHealth. This made it possible to conclude that the EU legislator has chosen to explicitly indicate that one form of cross-border healthcare provision can be telemedicine. This may mean that, under EU law, telemedicine as a mode of healthcare provision is considered equivalent to the traditional prototype, including in terms of financing rules. At the end of the discourse conducted on this topic, it was assessed whether the EU legislator uses terms that are used in the context of applying modern technology to the practice of medicine with prudence and awareness for their actual scope of meaning.

The deliberations so far have prompted an analysis of the final academic issue addressed in this chapter, namely the possibility of qualifying telemedicine services in cross-border healthcare as services within the meaning of the EU freedom of movement of services. These reflections leaned towards an attempt to create a definition of telemedicine services, then dealt directly with the conundrum of telemedicine services as internal market services of the EU. The main means of this analysis was to compare the relationship between the material scope of healthcare services and telemedicine services. This led to the final conclusion that telemedicine services benefit from the EU freedom of movement of services on the same basis as healthcare services.

In accordance with the assumptions underlying the conception and structure of this woark, the discourse contained in the first three chapters has been characterised by a theoretical approach with elements of analytics in the field of legal

sciences. This has made it possible to arrive at creative conclusions, but it has also given rise to the suggestion of a number of solutions in the form of *de lege ferenda* postulates. These considerations form the basis for further work; at this stage of analysis, this would become problematic. We are referring here to the identification of specific dilemmas related to the cross-border provision of telemedicine services in the EU that arise from the realisation of the right to health. Already *prima facie,* it is apparent that there are two premises determining the definition of the problems that will be analysed further. The first is the cross-border provision of telemedicine services in the EU. This premise is dynamic in nature, meaning that its role may change and, depending on the context, represent the source of the problem, its solution, or the means to a solution.

The second premise is the realisation of the right to health protection. It is static in nature, since, in principle, it will always represent a target standard, the non-observance or under-observance of which causes a problem. Its solution will be aimed at restoring or striving towards the original standard. Considering this, the scope of the potential difficulties related to the cross-border provision of telemedicine services in the EU and arising from the realisation of the right to health is extremely broad. It is therefore necessary to highlight selected and real dilemmas on which reasonable and concrete proposals for solutions can be made in the context of this monograph. It is reasonable to select two different issues within this framework. The first is realising the right to health and the functioning of cross-border healthcare during the COVID-19 pandemic in the context of cross-border provision of telemedicine services in the EU. The second issue covers the impact of telemedicine cybercrime on the realisation of the right to health from the perspective of cross-border provision of telemedicine services in the EU. The proposed issues concern specific, topical, and momentous problems that are simultaneously related to cross-border provision of telemedicine services in the EU and stem from the realisation of the right to health. This justifies their selection as the subject of further analysis.

4

Implementing the right to health and the functioning of cross-border healthcare during the COVID-19 pandemic

4.1 Introduction

The chapter aims to present the problems involved in realising the right to health and the functioning of cross-border healthcare during the COVID-19 pandemic in the context of the possibility of cross-border provision of telemedicine services in the EU and proposes a solution. First, a general characterisation of the pandemic is made, consisting of the main events of the pandemic, statical data around it, and an analysis of the COVID-19 vaccination process. This discussion is followed by an examination of the pandemic's impact on the legal system, including the issue of law as an instrument for combating the spread of COVID-19. These considerations are followed by a presentation of the legal measures taken during the pandemic in selected Member States of the EU and the actual possibility that individuals could exercise their rights during the pandemic. This allows for the definition of the main issues in this chapter. Problems related to exercising the right to health and functions of the cross-border healthcare during the COVID-19 are presented. This analysis will provide a basis for identifying and interpreting the core of the dilemmas in question. Characteristics that are desired for the solutions to these problems are established. Additional support for these characteristics is provided by the conclusions regarding the analysis of measures that offset the negative impact of the COVID-19 pandemic on the functioning of cross-border healthcare in the EU.

These considerations lead to the proposal for a solution to the problem of the right to health during a pandemic state and the problem of cross-border healthcare in the EU during this period. The chapter concludes with a summary containing the author's observations on the discussed matter and *de lege ferenda* postulates for the legislator.

4.2 General characteristics of the COVID-19 outbreak

4.2.1 COVID-19 outbreak highlights[408]

The first case of infection with a new type of coronavirus occurred at the end of 2019 in China, specifically in the city of Wuhan, which is located in Hubei province[409]. The rate of spread of the SARS-CoV-2 virus was so rapid and widespread that the World Health Organisation (hereinafter: WHO) declared it a public health emergency of international concern on 30 January 2020[410]. On 1 March 2020, the WHO Director-General officially declared a global pandemic[411]. The first case of infection in Europe occurred on 24 January 2020 in France[412]; the first death in France due to COVID-19 was reported on 15 February[413]. According to official WHO data, as of 6 July 2021, there were 183,608,682 confirmed cases of COVID-19 infection globally[414]. On the same date, there were 3,978,675 globally confirmed deaths from COVID-19[415]. This series of events focused international attention on the fight against the SARS-CoV-2 virus that causes COVID-19 disease. One can point to the intensive activity of the WHO, including specific activities that were intended to combat the pandemic state. Focusing on the most recent data available at that time, on 30 March 2021, the WHO published a report regarding the visit of an international team studying the genesis of SARS-CoV-2 to Wuhan[416]; in turn, on 17 March 2021, it issued interim recommendations on the use of the COVID-19 vaccine from

408 Due to the dynamic nature of the COVID-19 pandemic, it was necessary to define a cut-off date to determine the validity of the data contained in this subsection. This was taken as 6 July 2021.
409 Akkoc, 2020, p. 169.; Li and Ito, 2021, pp. 490-491.
410 Statement on the second meeting of the International Health Regulations (2005), World Health Organization, 2020a.
411 Bonotti and Zech, 2021, p. 1.
412 Trois cas d'infection par le coronavirus (2019-nCoV) en France (https://solidarites-sante.gouv.fr/actualites/presse/communiques-de-presse/article/trois-cas-d-infection-par-le-coronavirus-2019-ncov-en-france-429100 – accessed 7.07.2021.), where it can be read that 'La ministre des Solidarités et de la Santé a annoncé ce vendredi 24 janvier deux premiers cas d'infection par le nouveau coronavirus 2019-nCoV' (own translation: 'The Minister of Social Affairs and Health announced on Friday 24 January the first two cases of infection with the new coronavirus 2019-nCoV').
413 Fong et al., 2021, p. 10.
414 WHO Coronavirus (COVID-19) Dashboard: Situation by Region, Country, Territory & Area (https://covid19.who.int/table – accessed 7.07.2021).
415 Ibid.
416 World Health Organization, n.d.

Johnson & Johnson/Janssen Pharmaceuticals[417]. On 24 February 2021, it published a document entitled *The COVID-19 Strategic Preparedness and Response Plan (SPRP) for 2021*[418].

From the perspective of the European continent, the actions taken by the EU are no less important. Initiatives related to EU digital certificates for COVID-19 vaccination[419] or the introduction of a new procedure to facilitate and speed up the approval of vaccines adapted to the new COVID-19 variants can be identified[420].

4.2.2 COVID-19 pandemic statistics[421]

The peaks of global infection rates are referred to as the first and second waves of COVID-19. During the first wave, the highest number of reported daily infections were on 9 January 2021 (810,178 new cases) and 10 January 2021 (807,042 new cases)[422]. During the second wave, the highest number of newly reported cases were, in numerical order, on 23 April 2021 (895,018), 22 April 2021 (884,113), 29 April 2021 (875,969), and 30 April 2021 (870,756)[423].

In Europe, during the first wave of COVID-19, the highest daily increase in cases was found on 7 January 2021 (326,546 new cases), and during the second wave of COVID-19, the highest daily infections occurred on 1 April 2021 (288,657 new cases)[424]. Globally, France, Russia, Turkey, the UK, Italy, and Spain had the highest number of cases.. In France, 5,675,702 cases of SARS-CoV-2 infection were confirmed by 6 July 2021; the largest daily increase in new cases (69,989) occurred

417 Interim recommendations for the use of the Janssen Ad26.COV2.S (COVID-19) vaccine: interim guidance, 17 March 2021 (https://apps.who.int/iris/handle/10665/340203 – accessed 9.07.2021).

418 World Health Organization, 2021.

419 EU Digital COVID Certificate (https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/safe-covid-19-vaccines-europeans/eu-digital-covid-certificate_en#documents – accessed 9.07.2021.). As of this writing, all EU Member States are using this solution, as well as Iceland, Liechtenstein, Norway, and Switzerland. San Marino and the Vatican are in the preparatory phase of adopting it.

420 Coronavirus: new procedure to facilitate and speed up approval of adapted vaccines against COVID-19 variants (https://ec.europa.eu/commission/presscorner/detail/en/ip_21_1088 – accessed 9.07.2021.).

421 Due to the dynamic nature of the COVID-19 outbreak, it was necessary to define a cut-off date to determine the validity of the data contained in this subsection. This was taken as 6 July 2021.

422 WHO Coronavirus (COVID-19) Dashboard: Global Situation: Daily (https://covid19.who.int – accessed 7.07.2021).

423 WHO Coronavirus (COVID-19) Dashboard: Global Situation: Daily (https://covid19.who.int – accessed 7.07.2021).

424 WHO Coronavirus (COVID-19) Dashboard: Situation by WHO Region: Daily (https://covid19.who.int – accessed 7.07.2021).

on 1 November 2020, and 110,262 deaths were due to COVID-19[425]. In Russia, 5,658,672 cases of SARS-CoV-2 infection were confirmed by 6 July 2021; the largest daily increase in new cases (29,935) was reported on 24 December 2020, and 139,316 deaths were due to COVID-19[426]. In Turkey, 5,449,464 cases of SARS-CoV-2 infection were confirmed by 6 July 2021; the largest daily increment of new cases (63,082) were reported on 17 April 2021, and 49,959 deaths were due to COVID-19[427]. In the UK, 4,930,538 cases of SARS-CoV-2 infection were confirmed by 6 July 2021; the largest daily increment of new cases (81,519) occurred on 31 December 2020, and 128,231 deaths were due to COVID-19[428]. In Italy, 4,263,797 cases of SARS-CoV-2 infection were confirmed by 6 July 2021; the largest daily increment of new cases (40,902) were reported on 14 November 2020, and 127,680 deaths were due to COVID-19[429]. In Spain, 3,866,475 cases of SARS-CoV-2 virus infection were confirmed by 6 July 2021; the largest daily increment of new cases (42,772) were reported on 17 January 2021, and 80,934 deaths were due to COVID-19 disease[430]. It therefore became an international priority to develop a vaccine against the SARS-CoV-2 virus and medications to treat COVID-19[431].

4.2.3 Vaccination against SARS-CoV-2[432]

The discovery, testing, and introduction of the first vaccines against SARS-CoV-2, was a turning point in the pandemic. Four different vaccines[433] had been approved for circulation in the EU by 8 July 2021. These included two mRNA vaccines[434]

425 WHO Coronavirus (COVID-19) Dashboard: Global: France (https://covid19.who.int/region/euro/country/fr – accessed 7.07.2021.).
426 WHO Coronavirus (COVID-19) Dashboard: Global: Russian Federation (https://covid19.who.int/region/euro/country/ru – accessed 7.07.2021).
427 WHO Coronavirus (COVID-19) Dashboard: Global: Turkey (https://covid19.who.int/region/euro/country/tr – accessed 7.07.2021.).
428 WHO Coronavirus (COVID-19) Dashboard: Global: The United Kingdom (https://covid19.who.int/region/euro/country/gb – accessed 7.07.2021.).
429 WHO Coronavirus (COVID-19) Dashboard: Global: Italy (https://covid19.who.int/region/euro/country/it – 7.07.2021.).
430 WHO Coronavirus (COVID-19) Dashboard: Global: Spain (https://covid19.who.int/region/euro/country/es – accessed 7.07.2021.).
431 As of 10 December 2020, there were already 214 vaccines being tested worldwide, including 52 in clinical trials and 162 in pre-clinical trials (World Health Organization, 2020b).
432 Due to the dynamic nature of the COVID-19 pandemic, it was necessary to define a cut-off date to determine the validity of the data contained in this subsection. This was taken as 8 July 2021.
433 Safe COVID-19 vaccines for Europeans (https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response /safe-covid-19-vaccines-europeans_en – accessed 8.07.2021.).
434 According to the official website of the European Commission, vaccines based on mRNA technology 'contain part of the 'instructions' of the virus that causes COVID-19. This allows the cells of the human body to produce a protein that is specific to the virus. The immune system of the vaccinated person recognises that this specific protein should not be in the

(from BioNTech/Pfizer[435] and Moderna[436]) and two adenovirus vaccines[437] (from Johnson & Johnson/Janssen Pharmaceuticals[438] and

body, and responds by producing natural protection against COVID-19' (2021). (https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/safe-covid-19-vaccines-europeans/how-do-vaccines-work_pl – accessed 8.07.2021.).

435 On 21 December 2020, the European Medicines Agency recommended the marketing authorisation of this vaccine in the EU (European Medicines Agency, 2020). See also: Comirnaty (https://www.ema.europa.eu/en/medicines/human/EPAR/ comirnaty – accessed 8.07.2021.), Research Plan EMEA-002861-PIP02-20-M01 (https://www.ema.europa.eu/en/medicines/human/paediatric-investigation-plans/emea-002861-pip02-20-m01 #decision-section – accessed 8.07.2021.). BioNTech/Pfizer's vaccine was granted conditional marketing authorisation in the territory EU. It use was therefore approved based on less comprehensive data than is normally required. This choice was authorized by patients' urgent medical needs and under the belief that the available data demonstrate benefits outweighing associated risks and a commitment by the applicant for the authorisation in question to provide comprehensive clinical data in the future (European Medicines Agency, n.d.). The legal basis for conditional authorisation is Article 14(7) of the Medicinal Products Regulation. See the Evaluation Report of the Committee for Medicinal Products for Human Use of the European Medicines Agency: Assessment Report Comirnaty, 19 February 2021, EMA/707383/2020 Corr.1*1, Committee for Medicinal Products for Human Use (CHMP), Procedure No. EMEA/H/C/005735/0000.

436 On 6 January 2021, the European Medicines Agency recommended the marketing authorisation of this vaccine in the EU (EMA recommends COVID-19 Vaccine Moderna for authorisation in the EU) (https://www.ema.europa.eu/en/news/ema-recommends-covid-19-vaccine-moderna-authorisation-eu – accessed 8.07.2021). See also: Spikevax (2021) (previously COVID-19 Vaccine Moderna) (https://www.ema.europa.eu/en/medicines/human/EPAR/spikevax-previously-covid-19-vaccine-moderna – accessed 8.07.2021.), EMEA Research Plan-002893- PIP01-20 (https://www.ema.europa.eu/en/medicines/human/paediatric-investigation-plans/emea-002893-pip01-20 – accessed 8.07.2021.). Moderna's vaccine received conditional marketing authorisation in the territory EU. See European Medicines Agency's Committee for Medicinal Products for Human Use assessment report: Assessment report COVID-19 Vaccine Moderna, 11 March 2021, EMA/15689/2021 Corr.1*1, Committee for Medicinal Products for Human Use (CHMP), Procedure No. EMEA/H/C/005791/0000.

437 According to the official website of the European Commission, viral vector-based vaccines 'use a different, harmless virus to deliver the 'instructions' from the virus that causes COVID-19. This allows the body's own cells to make the protein unique to the COVID-19 virus. The person's immune system recognises that this unique protein should not be in the body and responds by producing natural defences against infection by COVID-19'. (https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/safe-covid-19-vaccines-europeans/how-do-vaccines-work_pl – accessed 8.07.2021.).

438 On 11 March 2021, the European Medicines Agency recommended the marketing authorisation of this vaccine in the EU (EMA recommends COVID-19 Vaccine Janssen for authorisation in the EU (https://www.ema.europa.eu/en/news/ema-recommends-covid-19-vaccine-janssen-authorisation-eu – accessed 8.07.2021.). See also: COVID-19 Vaccine Janssen (https://www.ema.europa.eu/en/medicines/human/EPAR/covid-19-vaccine-janssen – accessed 8.07.2021.), EMEA Test Plan-002880-PIP01-20 (https://www.ema.europa.eu/en/medicines/human/paediatric-investigation-plans/emea-002880-pip01-20 – accessed 8.07.2021.). The vaccine from Johnson & Johnson/Janssen Pharmaceuticals received a conditional marketing authorisation in the territory of the EU. See the assessment report of the

AstraZeneca[439]). In the United States, three vaccines were authorized (BioNTech/Pfizer, Moderna, and Johnson & Johnson/Janssen Pharmaceuticals) were authorized by 8 July 2021[440]. According to official WHO data, 1,229,404,475 people had received at least one dose of the vaccine globally by 7 July 2021. In Europe, the highest vaccination rates were in Germany, the UK, Turkey, Italy, France, and Spain. By 8 July 2021, 44,617,425 people had received at least one dose of the vaccine, representing 53.65% of the country's population[441]; in the UK, 44,454,511 (65.48%) people had been vaccinated[442]; in Turkey, 32,857,375 (38.9%) people had been vaccinated[443]. In Italy, 33,114,877 (55.52%) people had been vaccinated[444]; in France, 33,549,424 (49.84%) people had been vaccinated[445]; in Spain, 24,794,318 (53.8%) people had been vaccinated[446]. In Poland, 16,737,666 people had received at least one dose of the vaccine by 8 July 2021, but this represents 44.09% of the country's population, making its percentages similar to the other noted European countries[447].

The events of the pandemic dramatically reshaped and redetermined the actions of modern states, international organisations, and individuals. It is currently extremely difficult to assess the direction of the COVID-19 pandemic, despite

Committee for Medicinal Products for Human Use of the European Medicines Agency: Assessment report COVID-19 Vaccine Janssen, 11 March 2021, EMA/158424/2021, Committee for Medicinal Products for Human Use (CHMP), Procedure No. EMEA/H/C/005737/0000.

439 On 29 January 2021, the European Medicines Agency recommended marketing authorisation for this vaccine in the EU (EMA recommends COVID-19 Vaccine AstraZeneca for authorisation in the EU) (https://www.ema.europa.eu/en/news/ema-recommends-covid-19-vaccine-astrazeneca-authorisation-eu – accessed 8.07.2021.). See also: Vaxzevria (previously COVID-19 Vaccine AstraZeneca) (https://www.ema.europa.eu/en/medicines/human/EPAR/vaxzevria-previously-covid-19-vaccine-astrazeneca #assessment-history-section – accessed 8.07.2021.), study plan EMEA-002862-PIP01-20 (https://www.ema.europa.eu/en/medicines/human/paediatric-investigation-plans/emea-002862-pip01-20 – accessed 8.07.2021.). AstraZeneca's vaccine received conditional marketing authorisation in the territory EU. See European Medicines Agency's Committee for Medicinal Products for Human Use assessment report: Assessment report COVID-19 Vaccine AstraZeneca, 29 January 2021, EMA/94907/2021, Committee for Medicinal Products for Human Use (CHMP), Procedure No. EMEA/H/C/005675/0000.

440 See Center for Disease Prevention and Control, n.d.

441 WHO Coronavirus (COVID-19) Dashboard: Global: Germany (https://covid19.who.int/region/euro/country/de – accessed 8.07.2021.).

442 WHO Coronavirus (COVID-19) Dashboard: Global: The United Kingdom (https://covid19.who.int/region /euro/country/gb – accessed 8.07.2021).

443 WHO Coronavirus (COVID-19) Dashboard: Global: Turkey (https://covid19.who.int/region/euro/country/tr – accessed 8.07.2021.).

444 WHO Coronavirus (COVID-19) Dashboard: Global: Italy (https://covid19.who.int/region/euro/country/it – accessed 8.07.2021.).

445 WHO Coronavirus (COVID-19) Dashboard: Global: France (https://covid19.who.int/region/euro/country/fr – accessed 8.07.2021.).

446 WHO Coronavirus (COVID-19) Dashboard: Global: Spain (https://covid19.who.int/region/euro/country/es – accessed 8.07.2021.).

447 WHO Coronavirus (COVID-19) Dashboard: Global: Poland (https://covid19.who.int/region/euro/country/en – accessed 8.07.2021.).

numerous countermeasures being taken and a considerable amount of research on the subject[448].

4.3 The law in the face of the COVID-19 pandemic

4.3.1 Law as an instrument to combat the COVID-19 pandemic

The COVID-19 pandemic phenomenon is multidimensional and has affected numerous areas of human life. The spread of the SARS-CoV-2 virus unequivocally demonstrated the spectrum of problems, risks, and consequences of pandemics. To avoid the spread of COVID-19, rules regarding participant and functioning in society were changed. Other changes aimed at directly combating the COVID-19 pandemic should also be examined, such as the simplification of the procedure involved in marketing vaccines[449]. While this issue is important, from the perspective of legal conditioning of society, the changes required to combat the spread of the SARS-CoV-2 virus constitute a relevant point of reference. These changes were clearly justified by the COVID-19 pandemic.

Tools that can introduce and enforce specific transformations of the rules for participating and functioning in society should be determined. One of these tools is likely to be appealing to people's value of solidarity and the expectation that people belonging to a certain society will behave reasonably and responsibly[450]. Neverthe-

448 In terms of forecasting studies, it is worth noting, for example: Yuan, 2021, pp. 70-76.; Cowan et al., 2021, pp. 1-3.; Gaia, 2021, pp. 11-38.; Rafajlowicz, 2021, pp. 195-215.; Tran, 2021, pp. 280-292.; Dash and Chakraborty, 2021, pp. 8-23.; Alhashemi et al., 2021, pp. 3225-3234.; Pawar et al., 2021, pp. 253-266.; Sawant et al., 2021, pp. 133-155.; Do et al., 2021, pp. 737-752.; Liu et al., 2021, pp. 962-983.; Wang et al.; 2021, pp. 22-26.; Young et al., 2021, pp. 15-26.; Radlińska, 2020, pp. 113-126.; Niemczyk et al., 2020, pp. 19-27.; Stojczew, 2021, pp. 64-84.; Partyk, 2020, pp. 42-52.; Kruczalak-Jankowska, 2020, pp. 13-17. There are 187,206 entries in the LitCOVID database (a literature database of scientific publications on the SARS-CoV-2 virus or COVID-19 disease) as of this writing.

449 Conditional marketing authorisation (https://www.ema.europa.eu/en/glossary/conditional-marketing-authorisation – accessed 8.07.2021.); Article 14(7) of the Medicinal Products Regulation. See European Medicines Agency's Committee for Medicinal Products for Human Use Assessment report: Assessment report Comirnaty, 19 February 2021, EMA/707383/2020 Corr.1*1, Committee for Medicinal Products for Human Use (CHMP), Procedure No. EMEA/H/C/005735/0000.

450 'Solidarity' is defined as 'a sense of community and co-responsibility resulting from conformity of views and aspirations' (Słownik języka polskiego [Dictionary of the Polish language] *PWN*, https://sjp.pwn.pl/sjp/solidarnosc;2575796.html – accessed 9.07.2021.), 'collective and individual responsibility of a specific group of people for the whole of a common obligation' (Słownik języka polskiego [Dictionary of the Polish language] *PWN*, https://sjp.pwn.pl/sjp/solidarnosc;2575796.html – accessed 9.07.2021.), 'being in solidarity, conformity in conduct and aspirations, unanimity; supporting one another' (Słownik języka polskiego [Dictionary of the Polish language], ed. W. Doroszewski, https://sjp.

less, it seems that the tool that guarantees, in principle, the widespread adherence to the newly introduced standards of social distance is the law as a natural instrument that defines and enforces the powers and duties of the individual. In the EU forum, reality has confirmed this observation, as since the beginning of the COVID-19 pandemic, one can observe a significant increase in legal regulations providing for numerous prohibitions and injunctions in this respect[451]. It seems expedient to present a selection of legal regulations that illustrated the approaches from the EU Member States, which, as state bodies, reacted on an ongoing basis and adapted their legal state to the facts of the pandemic[452].

pwn.pl/doroszewski/solidarnosc; 5498841.html – accessed 9.07.2021.) or 'co-responsibility' (Słownik języka polskiego [Dictionary of the Polish language], ed. W. Doroszewski, https://sjp.pwn.pl/doroszewski/solidarnosc;5498841.html – accessed 9.07.2021.). In addition, one must remember that, for the law, solidarity is of momentous importance (see Wielec, 2017, pp. 93-94). For example, in the EU CFR, Title IV is called 'SOLIDARITY', and in the preamble to the EU CFR, one can read that 'Conscious of its spiritual and moral heritage, the Union is founded on the indivisible, universal values of human dignity, freedom, equality and solidarity; it is based on the principles of democracy and the rule of law. It places the individual at the heart of its activities, by establishing the citizenship of the Union and by creating an area of freedom, security and justice'. See also interesting studies thematically related to solidarity: Radzinska, 2014, pp. 58-68.; Bunikowski, 2013, pp. 757-765.; Hilpold, 2015, pp. 257-285.; Küçük, 2018, pp. 38-60.

451 An interesting and valuable database for legal measures taken against COVID-19 is maintained by the European Centre for Disease Prevention and Control, which is an independent EU agency based in Sweden (https://www.ecdc.europa.eu/en – accessed 19.07.2021), and the Community Research Centre, which is one of the European Commission's Directorates-General (https://ec.europa.eu/jrc/en/about/jrc-in-brief – accessed 19.07.2021.). The database under discussion is the Response Measures Database (European Centre for Disease Prevention and Control, n.d.). The Response Measures Database is regularly updated and contains information relating to legal measures against COVID-19 introduced by 30 countries belonging to the EU and the European Economic Area, including Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden. Additionally, the European Centre for Disease Prevention and Control publishes weekly national reviews on the management of the COVID-19 outbreak.

452 Although soft law acts are non-binding, those produced by the EU during the COVID-19 pandemic are worth mentioning as they are often a helpful instrument for both EU institutions and EU Member States. For example, these soft law acts have been produced within the EU eHealth network: Guidelines on the use of Digital COVID Certificates in traveller and online booking scenarios, V1.2.0 (https://ec.europa.eu/health/sites/default/files/ehealth/docs/covid-certificate_traveller-onlinebooking_en.pdf – accessed 1.08.2021.); Third Country EU Digital COVID certificate Equivalence Decision procedure, Version 1.0 (https://ec.europa.eu/health/sites/default/files/ehealth/docs/covid-certificate_equivalence-decision_en.pdf – accessed 1.08.2021.); Guidelines on Validation of the EU Digital COVID Certificates in the context of air transport, Version 1.0 (https://ec.europa.eu/health/sites/default/files/ehealth/docs/covid-certificate_air-transport_en.pdf – accessed 1.08.2021.); Commission Implementing Decision (EU) 2021/1073 of 28 June 2021 laying down technical specifications and rules for the implementation of the trust framework for the EU Digital COVID

4.3.2 Legal remedies against COVID-19 in selected EU Member States[453]

By analysing all 27 Member States of the EU, it clear that the COVID-19 pandemic period represents an extremely intensified period in terms of law-creating activity directed at the current problem. It is therefore necessary to provide an overview of the selected EU Member States characterising the impact of the pandemic on the legal operating conditions in the different societies. The number of infections identified between the beginning of the pandemic and the date when data were collected for this study was used to determine which specific Member States to examine. The highest number of infections in EU Member States during that time were in France, Italy, Spain, Germany, and Poland[454], so these states were analysed.

According to the European Commission, the legal measures introduced in these countries can be categorised into six main groups[455], including legal measures related to physical distance, international travel, intra-state travel, hygiene and safety rules, disease management and quarantine, and general matters.

Certificate established by Regulation (EU) 2021/953 of the European Parliament and of the Council (OJ of the EU L 230, 30.06.2021, pp. 32-53); Guidelines on Technical Specifications for EU Digital…; Guideline on the electronic exchange of health data under Cross-Border Directive 2011/24/EU, Patient Summary (https://ec.europa.eu/health/sites/default/files/ehealth/docs/ehn_guidelines_patientsummary_en.pdf – accessed 1.08.2021.); Guidelines on Paper version of the EU…; Guidelines on Technical Specifications for Digital Green…; Guidelines on Value Sets for Digital…; Guidelines on COVID-19 citizen recovery interoperable…; Guidelines on Verifiable Vaccination Certificates…; OUTLINE, Interoperability of Health Certificates…; European Interoperability Certificate Governance….; European Proximity Tracing…; Commission Implementing Decision (EU) 2020/1023…; eHealth Network Towards a Common Approach for the Use of…; Mobile Applications to Support Contact…; eHealth Network Guidelines to the EU Member States and the European Commission on Interoperability…; Interoperability guidelines for Approved Contact Tracing…; EU Health Preparedness: A Common List of COVID-19 Rapid Antigen Tests; A common standardised set of data to be included in COVID- 19 test result certificates; and A common list of COVID-19 laboratory-based antigenic assays (https://ec.europa.eu/health/sites/default/files/preparedness_response/docs/covid-19_rat_common-list_en.pdf – accessed 1.08.2021.).

453 Due to the dynamic nature of the COVID-19 outbreak, it was necessary to define a cut-off date to determine the validity of the data contained in this subsection. This was taken as 19 July 2021.

454 As of 19 July 2021, there had been 5,737,097 cases of SARS-CoV-2 infection in France, 4,284,332 in Italy, 4,069,162 in Spain, 3,744,681 in Germany and 2,881,424 in Poland since the beginning of the COVID-19 pandemic (WHO Coronavirus [COVID-19] Dashboard: situation by Region, Country, Territory & Area) (https://covid19.who.int/table – accessed 19.07.2021).

455 The breakdown was considered using the Response Measures Database (RMD) with a slight modification (https://covid-statistics.jrc.ec.europa.eu/RMeasures# – accessed 19.07.2021.). The Response Measures Database categorises legal measures into seven categories: 1) Physical distance; 2) Hygiene and safety rules; 3) Disease management and quarantine measures; 4) Ensuring treatment capacity; 4) General measures; 5) Internal travel; 6) International travel.

Based on this, 150 national legal measures were introduced in France by 19 July 2021; 13 currently have the status of applicable law[456], and the remaining legal measures have been repealed. Overall, 119 legal measures related to physical distance, 6 to international travel, 3 to intra-state travel, 8 to hygiene and safety rules, 4 to disease case management and quarantine, and 10 to general matters.

In Italy, 489 legal measures were introduced by 19 July 2021; 23 currently have the status of valid law[457]. A total of 389 legal measures related to physical distance, 24 to international travel, 39 to intra-state travel, 19 to hygiene and safety rules, eight to disease case management and quarantine, and 11 to general matters.

In Spain, 302 legal measures were introduced by 19 July 2021; 131 currently have the status of applicable law[458]. A total of 199 legal measures related to physical distance, 18 to international travel, 45 to intra-state travel, 16 to hygiene and safety rules, 8 to disease case management and quarantine, and 16 to general matters.

In Germany, 86 legal measures were introduced by 19 July 2021; 13 currently have the status of binding law[459]. A total of 54 legal measures related to physical distance, 19 to international travel, none related to intra-state travel, 7 covered hygiene and safety rules, 1 to disease case management and quarantine, and 5 to general matters.

In Poland, 129 legal measures were introduced by 19 July 2021; 27 currently have the status of binding law[460]. A total of 92 legal measures were related to physical distance, 15 to international travel, 1 to intra-state travel, 7 to hygiene and safety rules, 5 to disease case management and quarantine, and 9 to general matters.

Based on this, the COVID-19 pandemic clearly justified a period of intensive legislative activity in the analysed Member States. However, the number of legislative

456 Response Measures Database (RMD): Current Measures: France (https://covid-statistics.jrc.ec.europa.eu/RMeasures# – accessed 19.07.2021). For literature thematically related to the French experience of the COVID-19 outbreak only by way of example, see Attané et al., 2021, pp. 137-159.

457 Response Measures Database (RMD): Current Measures: Italy (https://covid-statistics.jrc.ec.europa.eu/RMeasures# – accessed 19.07.2021). For literature thematically related to the Italian experience of the COVID-19 outbreak only, see for example: Fabiani et al., 2021, pp. 1757-1771.

458 Response Measures Database (RMD): Current Measures: Spain (https://covid-statistics.jrc.ec.europa.eu/RMeasures# – accessed 19.07.2021.). For literature thematically related to the Spanish experience of the COVID-19 outbreak only, see for example: Díez-Gutiérrez and Espinoza, 2021, pp. 1-24.

459 Response Measures Database (RMD): Current Measures: Germany (https://covid-statistics.jrc.ec.europa.eu/RMeasures# – accessed 19.07.2021.). For literature thematically related to the German experience of the COVID-19 outbreak only see, for example: Pfeiffer-Ruiz and Schroder, 2021, pp. 46-49.

460 Response Measures Database (RMD): Current Measures: Poland (https://covid-statistics.jrc.ec.europa.eu /RMeasures# – accessed 19.07.2021.). For literature thematically related to the Polish experience of the COVID-19 outbreak only see, for example: Landmesser, 2021, pp. 539-556.

measures adopted in the selected countries only shows the intensity of national activity because the adopted grouping of the European Commission is hardly suggestive of the substantive content of legal solutions. It is therefore necessary to clarify the substantive layer of the legal measures in the specific thematic groups. In the group of legal measures concerning physical distance, it was decided to introduce restrictions on private gatherings and create injunctions in the workplace, recommendations to stay at home, injunctions to stay at home, solutions for a special category of the population, restrictions on public gatherings, closure or restrictions on the use of public transport, closure or restrictions on the use of public space, and closure or restrictions on the use of educational institutions[461]. Regarding legal measures concerning international travel, it was decided to introduce travel advisories, complete closure of state borders, quarantine for international travellers, specific border controls and entry bans for foreigners from selected countries[462]. In the legal measures regarding intra-state travel, travel restrictions, travel advisories, and quarantine for travellers were specifically introduced[463]. For legal measures on hygiene and safety rules, the measures were usually in favour of requiring or recommending the use of protective masks and other protective measures, air safety controls, disinfection orders, restrictions on blood donations, and animal surveillance and control[464]. Re-

461 Examples of such legal measures are as follows. On 16 March 2020, an order was introduced in Austria to stay at home unless conducting urgent and necessary work activities, essential grocery or medical shopping, assisting others, walking alone or walking in the company of persons living in the same household with a distance of 1 metre between them. On 13 March 2020, restrictions on the use of public spaces were introduced in Belgium in the form of restaurant and café closures. On 8 March 2021, Bulgaria introduced restrictions on public assemblies by banning cultural events, including the closure of cinemas, and made it mandatory for all sports events to take place without an audience (Source, 2021).

462 Examples of such legal measures are as follows. On 19 March 2020, Croatia closed its national borders. On 21 March 2020, Cyprus suspended international flights and imposed a travel ban for anyone who did not have a negative test for SARS-CoV-2 infection. On 1 July 2021, the Czech Republic banned all its citizens and any foreigners residing in the Czech Republic from travelling to countries at extreme risk of SARS-CoV-2 infection, including Botswana, Brazil, Eswatini, Republic of India, South Africa, Colombia, Lesotho, Namibia, Malawi, Mozambique, Nepal, Paraguay, Peru, Russia, Tanzania, Zambia, and Zimbabwe (Source, 2021).

463 Examples of such legislative measures are as follows. On 7 August 2020, Denmark issued a recommendation to avoid public transport. On 28 March 2020, Finland in the Uusimaa region (Helsinki) decided to impose travel restrictions except for daily commuting and other urgent needs. A ban on travel to and from the region was also introduced outside of situations that had compelling justifications. On 3 April 2021, France introduced travel restrictions in metropolitan areas by limiting relocation to a radius of 10 km from the place of residence. In addition, inter-regional travel was banned (Source, 2021).

464 Examples of such legislative measures are as follows. On 10 February 2020, a ban on the donation of blood, stem cells, or plasma by persons who had contact with a person infected with the SARS-CoV-2 virus was introduced in Germany, with the ban applying for 4 weeks from the date of such contact. It was then extended to persons recovering from COVID-19 disease, lasting for 8 weeks from the date of recovery. On 28 June 2021, Greece made mask-wearing indoors and outdoors mandatory when physical distance was not possible.

garding legal measures for case management and quarantine, the most common measures were the introduction of quarantine, isolation of infected cases, and tracking of human contact[465]. Finally, general legal measures mainly included risk assessment, rules for public communication, rules for communication with health services, and a crisis management system[466]. The correlation between the number of legal measures adopted by the selected Member States and their subject matter confirms the impact of the COVID-19 pandemic on the legal condition of society in the EU. This is because, as further confirmed by the European Commission data cited above, the approaches of France, Italy, Spain, Germany, and Poland are not specific; they represent a general trend found throughout the EU.

4.3.3 Exercise of the unit's rights during the COVID-19 pandemic

So far, this analysis suggests that the COVID-19 pandemic caused extensive changes in the law; a number of provisions were created that introduced new standards of functioning in society, and specific rules of conduct have been defined. Therefore, the impact of COVID-19 on the law, including on the conditions of participation in society, is far-reaching and of a direct nature. Nevertheless, the issue of the actual exercise of individual rights in practice is a different matter. In this context, it should be noted that the EU legal measures adopted by the Member States create a new legislative matter; they become a new normative standard as soon as they are introduced in the form of hard law or when they are the subject of guidelines in the form of soft law. They often form the basis for pioneering legal institutions that limit an individual's rights or introduce new types of obligations. The legal measures in question, however, theoretically concern a well-defined subject matter and have, as a rule, a clear and direct purpose and effect. In practice, however, some of these measures also strongly affect legal rights other than those directly mentioned. The right to a court trial and the right to education are two examples of this. During the pandemic, both of these entitlements were depleted due to the introduction of

On 1 October 2020, Hungary required all pupils and teachers to undergo temperature testing at the entrance to schools and kindergartens (Source, 2021).

465 Examples of such legislative measures are as follows. On 28 January 2020, isolation of confirmed cases of SARS-CoV-2 virus infection was made compulsory in Iceland. Infected persons were directed to live in isolation and that household members should quarantine in the same place and have limited contact with the infected person. On 14 March 2020, Ireland recommended that people with a fever or cough should stay at home regardless of their history of contact with the SARS-CoV-2 virus. On 22 January 2020, a 14-day quarantine and two negative tests for SARS-CoV-2 virus were made mandatory in Italy for infected persons to confirm the absence of further infection (Source, 2021).

466 Examples of such legal measures are as follows. A COVID-19 outbreak status was declared in Slovenia on 19 October 2020 for the entire territory of Slovenia. A state of emergency was declared in Spain on 14 March 2020. On 1 October 2020, a state of emergency was declared in Slovakia (Source, 2021).

successive legal regulations justified by the fight against the SARS-CoV-2 virus. The problems with the education[467] and justice systems[468] are only selected examples that confirm the indirect impact of the above-mentioned legal measures. In these cases, the intention of the legislator was not to deplete either of the mentioned rights, but to fight the pandemic. However, the entitlements of individuals in this areas were in fact reduced.

It is also important to note that, in some cases, the COVID-19 outbreak constitutes an independent source of a negative impact on the actual ability of individuals to exercise their powers, even without legal measures in place. A limitation in the exercise of individuals' powers may therefore result from a subsequent reaction of the legislature, as well as from the consequences of a changing factual situation. Access to health services in times of pandemics, where the exercise of the right to health may be jeopardised or even restricted, seems to be such a case, although there are potential remedies available. Factual conditions are a major source of risks and problems.

4.4 The right to health and cross-border healthcare during the COVID-19 pandemic

4.4.1 The right to health during the COVID-19 pandemic

As the subject and aspects of the right to health have been discussed earlier in this work[469], it is possible to focus directly on the problem of realising the right to health in times like those of the COVID-19 pandemic. It seems frustratingly true that the proper realisation of the right to health *in genere* depends on having an efficient, effective, efficient, fast, safe, and universal healthcare system to which all individuals

467 The problems associated with the delivery of traditional education, i.e., face-to-face learning, became a significant consequence of the COVID-19 pandemic. See, for example: Theoret and Ming, 2020, pp. 591-592.; Tarkar, 2020, pp. 3812-3814.; Rashid and Yadav, 2020, pp. 340-343.; Also noteworthy is the document published by the Polish Ministry of National Education entitled *Report of the Ministry of National Education. Ensuring the functioning of units of the education system during the COVID-19 pandemic* (2021).

468 For example, problems related to international cooperation in criminal matters or the proper fulfilment of national laws guaranteeing the rights of litigants. See: Gori and Pahladsingh, 2021, pp. 561-577.; Partyk, 2020, pp. 42-52.; Lipiński, 2020, pp. 37-47.; Traczyk, 2020, pp. 132-141.; Manikowski, 2021, pp. 105-122. In addition, the document from the European Commission (Directorate-General for Justice and Consumers), entitled 'The protection and support of victims of crime during COVID-19', is worth noting. Protection and support to victims of crime during COVID-19 pandemic – exchange of good practices on how to deal with victims of domestic violence, cybercrime and hate crime (https://e-justice.europa.eu/fileDownload. do?id=18cd46dc-ff63-4af4-a8d0-b35f5e01a04f – accessed 26.07.2021.).

469 See Chapter 2.2 The subject of the right to health protection.

have equal access[470]. Any modern state should be attempting to meet these features in their healthcare systems. It should be considered a natural state of affairs that, depending on their geographical location, economic development, and human and material resources, healthcare systems have varying levels of sophistication. The process of improvement is continuous and progressive in countries that respect the right to health for their citizens.

The emergence of the SARS-CoV-2 virus and the declaration of a global pandemic, which introduced a series of prohibitions, orders or restrictions in general, drastically affected individuals' ability to realise the right to health in the practice of the health system. The institutional core is primarily responsible for the day-to-day realisation of the right to healthcare services, but it has also been overburdened to a certain extent[471]. There are two primary reasons for this.

First, there was an extraordinary increase in the number of people requiring medical or healthcare assistance, including specialised approaches. A significant number of people who did not normally need health interventions began to need them overnight. The second reason for the overloading of national health systems was that they were not prepared for the sudden increase in the number of people needing health or medical assistance. These two situations caused national healthcare systems to become inefficient. The consequence of their simultaneous materialisation during the peak phases of the COVID-19 pandemic[472] is far from the protective standard of the right to health, including the right to health protection and healthcare services.

In Poland, for example, several health service problems can be pointed out: lack of available beds in hospitals; shortages in medical equipment, intensive care health personnel, other staff, and personal protective equipment; inadequate coordination of emergency ambulance services; insufficient oxygen supplies; and

470 Lach, 2011, p. 178.; Baka, 2010, pp. 124-125.; Dercz and Rek, 2012, p. 41.; Jarosz-Żukowska, 2014, p. 660.; Jończyk 2005, p. 110.

471 See: Chapter 2.2.4 Correlation of the essence of the right to health protection and healthcare services. It notes in particular that: 'It seems rational, therefore, to theorise that the right to health protection is a substantive guarantee of the right to health, while the right to healthcare services is more executive in nature […] the right to health has its material aspect […]. The subjective aspect is of a personal normative nature and materialises in the form of the right to health protection, the material core of the right to health […] the right to health also has an executive aspect, in which both the legally protected good in the form of equal access to health care that effectively protects health and guarantees access to treatment regardless of the material situation of the beneficiary and the contingent subjective scope are evident this aspect has a social normative character, concretising itself in the form of the right to healthcare services, which constitutes an institutional guarantee for the realisation of the material aspect of the right to health, being the most essential means for the realisation of the main objective, i.e. health protection.'

472 See Chapter 4.2.2 COVID-19 pandemic statistics.

insufficient training[473]. These problems, created by the simultaneous occurrence of the above-mentioned premises, illustrate the huge impact the COVID-19 pandemic had and continues to have on the realisation of the right to health in practice.

In the interest of fairness, other reasons for these inefficiencies can be mentioned. For example, the legal measures against COVID-19 that were previously mentioned were aimed at providing protective procedures in healthcare, such as introducing procedures making access to healthcare services conditional on an asymptomatic patient showing a negative test result, or the limited access of seniors to health services may have been factors[474]. Nevertheless, if it were not for the primary reasons noted above, these legal measures would not have constituted a real problem that affected the ability to realise the right to health; an efficient health service would offset difficulties resulting from legal measures.

To address the core of the identified issue, however, it seems clear that the drastic overloading of the state health service by the COVID-19 pandemic caused inefficiencies in the health system, making it impossible to practically realise the right to health in its full or existing form. The issue at the root of the problem is therefore reconciling the increased number of patients with the current capacity of the health service in a particular state.

4.4.2 Cross-border healthcare during the COVID-19 pandemic

As with the right to health, the issue of cross-border healthcare in the EU *in genere* has already been presented in this work. Fundamentally[475], it is necessary at this

473 These problems were highlighted in the Ombudsman's letter of 12 November 2020 with the reference V.7013.145.2020.ET/GH/PM to the Minister of Health (https://bip.brpo.gov.pl/sites/default/files/WG_to_MZ_ws_problemow_sluzby_zdrowia_w_epidemii_12.11.2020.pdf – accessed 27.07.2021.), in which the Ombudsman asked for their clarification. The explanations in question were contained in a comprehensive reply of the Minister of Health of 18 January 2021 with the mark MMI.704.1.2020.TM to the Ombudsman's letter of 12 November 2020 with the mark V.7013.145.2020.ET/GH/PM to the Minister of Health (https://bip.brpo.gov.pl/sites/default/files/odpowiedź%20z%20Ministerstwa%20Zdrowia%20z%2018.02.2021%20-sent%2011.03.2021%20ws%20situation%20in%20service%20health.pdf – accessed 27.07.2021.).

474 These problems were highlighted in the Ombudsman's letter of 12 November 2020 with the reference V.7013.145.2020.ET/GH/PM to the Minister of Health (https://bip.brpo.gov.pl/sites/default/files/WG_to_MZ_ws_problemow_sluzby_zdrowia_w_epidemii_12.11.2020.pdf – accessed 27.07.2021.), in which the Ombudsman asked for their clarification. The explanations in question were contained in a comprehensive reply of the Minister of Health of 18 January 2021 with the mark MMI.704.1.2020.TM to the Ombudsman's letter of 12 November 2020 with the mark V.7013.145.2020.ET/GH/PM to the Minister of Health (https://bip.brpo.gov.pl/sites/default/files/odpowiedź%20z%20Ministerstwa%20Zdrowia%20z%2018.02.2021%20-sent%2011.03.2021%20ws%20situation%20in%20service%20health.pdf – accessed 27.07.2021.).

475 See Chapter 3 Cross-border healthcare provision in the European Union.

point in the work to focus on the problem of cross-border healthcare during the COVID-19 pandemic. To do so, it is necessary to define the criteria required for the proper functioning of cross-border healthcare in the EU. In other words, the conditions that are critical for cross-border healthcare to fulfil its functions need to be identified; without them, cross-border healthcare cannot be effectively applied. These conditions appear to have been included to define patients' rights in cross-border healthcare and in the legal definition of the concept[476]. It should be stressed again that the aim of this work is to establish rules that can facilitate access to safe and high-quality cross-border healthcare, ensure patient mobility in accordance with the principles established by CJEU, and promote cooperation in healthcare between Member States, in full respect of their competencies[477]. According to Article 3(e) of the DPRCH, cross-border healthcare refers to healthcare provided or prescribed in an EU Member State other than the Member State of affiliation.

Based on the two premises mentioned above, the first condition for the proper functioning of cross-border healthcare is facilitating equal access for insured persons to a well-organised healthcare system of a Member State of the EU other than the Member State of affiliation. The second condition is ensuring the mobility of patients in accordance with the rules established by CJEU so that the patients can receive healthcare provided or prescribed in a Member State other than the Member State of affiliation. The third condition is cooperation on healthcare between Member States of the EU, and the fourth condition is full respect for the public health competences of Member States. These conditions are, to some extent, identical to the premises of the DPRCH objective already discussed in this academic work[478].

The COVID-19 pandemic, including its effects and consequences, did not affect all of the above conditions equally. The third and fourth conditions appear to be effectively fulfilled during the pandemic[479]. The first condition, however, will not be fulfilled until the problems in realising the right to health during the COVID-19 pandemic are solved because its fulfilment depends on the functioning of an

476 This problem is already beginning to be noticed by some doctrine representatives: Byszek, 2021, pp. 747-757.; Neergaard, 2021, pp. 213-217.; Gołda-Sobczak, 2020, pp. 127-142.; Sobczak, 2020, pp. 7-22.

477 Hervey and Mchale, 2015, pp. 184-211.; Goscinska, 2014, pp. 1-40.; McLean, 2013, pp. 35-40.; Meyer, 2013, pp. 83-103.

478 See Chapter 3.4.1Purpose of defining cross-border patients' rights.

479 First, it appears that cooperation between EU Member States regarding healthcare can be undertaken under the conditions of the COVID-19 pandemic. This does not mean that the pandemic has not influenced the forms and methods of this cooperation, but the objective behind this cooperation can be achieved during a pandemic. Second, the public health competences for EU Member States can and should be fully respected, regardless of the realities of the COVID-19 pandemic. This is because such a state of affairs derives from a clear normative basis, in particular Article 168(7) TFEU, Article 35 EU CFR and recital 10 and Article 1 of the DPRCH. The current situation may justify a number of actions by EU institutions to combat the COVID-19 outbreak, but these should be consistent with full respect for the public health competences of the Member States of the EU.

efficient, effective, prompt, safe, and universal healthcare system to which all individuals have equal[480]. This is the source of the same problem in terms of the right to health[481]. It therefore becomes legitimate to examine the impact of the COVID-19 pandemic on the second condition, i.e. the provision of patient mobility.

Based on the analysis already conducted regarding the legal measures against the SARS-CoV-2 virus issued by Member States of the EU, a certain proportion of these measures concern international travel, including travel advisories, complete closure of national borders, quarantine for international travellers, specific border control, and entry bans for foreigners from selected countries. A large majority of Member States of the EU[482] decided to introduce some of these legal measures. This suggests that the problems caused by making it difficult or impossible for patients to cross borders to receive healthcare are directly linked to the COVID-19 pandemic. This allows the relevant problem to be named. Considering all the issues raised, this

480 Lach, 2011, p. 178.; Baka, 2010, pp. 124-125.; Dercz and Rek, 2012, p. 41.; Jarosz-Żukowska, 2014, p. 660.; Jończyk, 2005, p. 110.

481 See Chapter 4.4.1 The right to health during the COVID-19 pandemic.

482 To date: Austria has introduced 11 legal measures on international travel, of which 3 are currently in force; Belgium has introduced 8 legislative measures on international travel, of which 3 are currently in force; Bulgaria has introduced 13 legal measures on international travel, of which 2 are currently in force; Croatia has introduced 10 legal measures on international travel, of which 4 are currently in force; Cyprus has introduced 11 legislative measures on international travel, of which 3 are currently in force; the Czech Republic has introduced 11 legal measures on international travel, of which 5 are currently in force; Denmark has introduced 8 legal measures on international travel, of which 5 are currently in force; Estonia has introduced 18 legal measures on international travel, of which 6 are currently in force; Finland has introduced 15 legislative measures on international travel, of which 11 are currently in force; France has introduced 7 legislative measures on international travel, of which 3 are currently in force; Germany has introduced 19 legal measures on international travel, of which 3 are currently in force; Greece has introduced 9 legislative measures on international travel, of which 3 are currently in force; Hungary has introduced 8 legal measures on international travel, of which 1 is currently in force; Ireland has introduced 5 legislative measures on international travel, of which 2 are currently in force; Italy has introduced 25 legislative measures on international travel, of which 3 are currently in force; Latvia has introduced 14 legal measures on international travel, of which 5 are currently in force; Lithuania has introduced 15 legal measures on international travel, of which 2 are currently in force; Luxembourg has introduced 5 legislative measures on international travel, of which 2 are currently in force; Malta has introduced 13 legislative measures on international travel, of which 3 are currently in force; the Netherlands has introduced 28 legal measures on international travel, of which 11 are currently in force; Poland has introduced 14 legal measures on international travel, of which 3 are currently in force; Portugal has introduced 18 legal measures on international travel, none of which are currently in force; Romania has introduced 9 legislative measures on international travel, of which 1 is currently in force; Slovakia has introduced 8 legal measures on international travel, of which 1 is currently in force; Slovenia has introduced 6 legislative measures on international travel, of which 3 are currently in force; Spain has introduced 13 legislative measures on international travel, of which 3 are currently in force; Sweden has introduced 14 legal measures on international travel, of which 6 are currently in force (Source, 2021).

appears to be a restriction or, in some cases, even a paralysis of the traditionally understood mobility of the EU population which is directly linked to the realisation of the freedom of movement of persons within the internal EU market; this restriction either significantly impedes or prevents the use of cross-border healthcare in the EU its full or current form. The root issue is therefore reconciling the need to ensure patient mobility with the restrictions that may occur during the physical crossing of traditionally understood national borders, which was justified in this case because of the COVID-19 pandemic.

4.4.3 The negative impact of COVID-19 on the operation of cross-border healthcare in the EU

Given the above considerations, it is important to bear in mind EU's attempts to counteract the negative impact of the COVID-19 pandemic on the functioning of cross-border healthcare. For this exact purpose, the European Commission issued the already referred to communication entitled Guidelines for EU emergency assistance on cross-border healthcare cooperation related to the COVID-19 pandemic crisis (hereinafter: Guidelines on EU Emergency Assistance on Cross-Border Cooperation in Healthcare related to the COVID-19 crisis)[483]. This document makes it clear that its goal is to create a more coordinated approach in cross-border healthcare due to the occurrence of an emergency. One proposed solutions is the full use of the medical infrastructure in each EU Member State so that countries in a better situation relieve the burden on those in a worse situation. The European Commission declared that it would support Member States of the EU by, for example, providing clarity on the reimbursement of healthcare[484] or arrangements for cross-border patient mobility.

483 Communication from the Commission Guidelines on EU Emergency Assistance on Cross-Border Cooperation in Healthcare related to the COVID-19 crisis 2020/C 111 I/01, C/2020/2153

484 The Guidelines on EU Emergency Assistance on Cross-Border Cooperation in Healthcare related to the COVID-19 crisis state: '1. The coverage of healthcare costs will be governed by the Social Security Coordination Regulations (Regulation 883/2004); 2. Patients who have to be transported to a hospital in a neighbouring or another Member State offering assistance should normally be in possession of a prior authorisation from the competent social security institution. This is not practical in view of the COVID-19 pandemic and the emergency situation.; 3. The Commission calls on the Member States to take a pragmatic approach for patients requiring urgent care and in view of the public emergency to consider a general prior authorisation to ensure the coverage of all the expenses incurred by the hosting health care provider; 4. It is recommended that it should be sufficient for the competent Member State to ensure that the patient carries a document attesting that s/he is covered at the time of hospital admission or any other practical arrangements that the Member States involved may agree upon. This guidance applies to emergency healthcare only in the context of the COVID-19 pandemic.; 5. For patients still able to access

The latter designator is extremely interesting considering the research aims of this work. In this context, the European Commission points out that, for citizens of the EU, the principles set out in Directive 2004/38/EC of the European Parliament and of the Council of 29 April 2004 on the right of citizens of the Union and their family members to move and reside freely within the territory of the Member States continue to apply, amending Regulation (EEC) No 1612/68 and repealing Directives 64/221/EEC, 68/360/EEC, 72/194/EEC, 73/148/EEC, 75/34/EEC, 75/35/EEC, 90/364/EEC, 90/365/EEC and 93/96/EEC[485]. On this basis, the Communication from the Commission Guidelines on EU Emergency Assistance on Cross-Border Cooperation in Healthcare related to the COVID-19 crisis that patients requiring urgent state that patients requiring urgent care in a healthcare facility in another Member State of the EU cannot be refused entry, but also say that patients going to another Member State of the EU for non-emergency treatment should check whether border controls will allow them to travel. This solution, however, raises an interpretative problem related to the definition of urgent versus non-urgent care in a healthcare facility setting[486]. In this context, linguistic interpretation directives can be used, and the designators under consideration can be linked to a life-threatening condition. Nevertheless, this proposition is incomplete as there may be cases where patients require urgent healthcare in another Member State of the EU, but the treatment is not life-threatening for that patient. For this reason, *prima facie,* it seems that a possible solution would be replacing the criteria of urgent and non-urgent with an objective criterion in the form of a life-threatening condition. In such a case, patients in a life-threatening condition would not be denied entry into the

non-urgent planned healthcare the usual procedures apply in principle for healthcare treatment in another Member State.'

485 Directive 2004/38/EC of the European Parliament and of the Council of 29 April 2004 on the right of citizens of the Union and their family members to move and reside freely within the territory of the Member States, amending Regulation (EEC) No 1612/68 and repealing Directives 64/221/EEC, 68/360/EEC, 72/194/EEC, 73/148/EEC, 75/34/EEC, 75/35/EEC, 90/364/EEC, 90/365/EEC and 93/96/EEC (OJ.Official Journal EU L 158 of 30.04.2004, pp. 77-123.).

486 The dictionary definition of 'urgent' is 'requiring immediate execution', 'dealing with something zealously' (Słownik języka polskiego [Dictionary of the Polish language] *PWN*, https://sjp.pwn.pl/slowniki/pilne – accessed 29.07.2021) or 'requiring immediate execution; immediate, sudden, not necessary, necessary' (Słownik języka polskiego [Dictionary of the Polish language] pod ed. W. Doroszewskiego, https://sjp.pwn.pl/doroszewski/pilny;5472062.html – accessed 29.07.2021). Meanwhile, 'nagły' means 'appearing suddenly', 'not impatiently delayed' (Słownik języka polskiego [Dictionary of the Polish language] *PWN*, https://sjp.pwn.pl/sjp/nagly;2486088.html – accessed 29.07.2021) or 'zjawiający się znienacka; znienacka, unexpected, raptowny' and 'impatient of delay; urgent, pressing, burning, immediate' (Słownik języka polskiego [Dictionary of the Polish language] under ed. W. Doroszewskiego, https://sjp.pwn.pl/doroszewski/nagly;5454979.html – accessed 29.07.2021). The created law should avoid the use of terms of a general nature that do not have a strictly defined meaning and both increase the decision-making freedom of legitimate entities and reduce the predictability and comprehensibility of the law by the final beneficiaries.

territory of another Member State of the EU to receive care in a healthcare facility. However, it should be stressed that the solution proposed here, as noted above, has a smaller personal scope of application compared to that identified by the European Commission. This means that the use of the objective criterion of a life-threatening condition may not fully realise the objective of the COVID-19 Guidelines for cross-border cooperation in healthcare. The European Commission should therefore objectify its proposed criteria by specifying the distinction between urgent care and non-emergency care in the created document. In the COVID-19 Guidelines for cross-border healthcare cooperation itself, there is no clear indication of such an objective criterion that distinguishes between the two concepts. For this reason, there is a high risk that the boundary between cases requiring urgent care and non-urgent cases will be determined by a subjective criterion[487].

Another problem with the COVID-19 Guidelines for cross-border healthcare cooperation is that their name, rationale, and purpose concern cross-border healthcare cooperation related to the COVID-19 pandemic crisis. There is, therefore, a direct link between the subject matter of the document under consideration and the pandemic state, which significantly narrows its scope of application[488]. In addition, it should not be forgotten that these Guidelines are a typical example of soft law. The interpretation of the EU provisions contained therein regarding the right of EU citizens and their family members to move and reside freely within the territory of Member States of the EU is not binding[489]. This interpretation should be treated

487 The risk of relying on a subjective criterion when deciding on whether requires care at a healthcare facility in another Member State of the EU should be assessed negatively. When regulating a human health issue, the law should use as precise criteria as possible. In practice, a subjective criterion is likely to be determined based on the decision-maker's sense of equity, compassion, and individual experience. That does not mean that application will be unjust; however, a subjective criterion is more likely to cause undesirable consequences or even abuse. For this reason, the use of well-considered objective criteria that reflect the essence and purpose of the regulated solution is highly recommended.

488 It should be proposed that the scope of subjects and objects of created and enacted legal acts, including those with non-binding status (so-called soft law), justified by the fight against and mitigation of the negative effects of the COVID-19 pandemic should not be narrowed only to the COVID-19 pandemic. It seems reasonable to define these scopes more broadly and to relate them to the state of threat that occurs during an pandemic. Such a procedure will not negatively affect the fight against and the levelling of the negative effects of the COVID-19 pandemic, but will prepare a normative system for possible future pandemic threats.

489 Guidelines on EU Emergency Assistance on Cross-Border Cooperation in Healthcare related to the COVID-19 crisis do not have a binding character in the EU's legal system, making them a typical example of so-called soft law. However, one should not lose sight of the fact that the author and issuer of this communication was the European Commission. The communication therefore presents the viewpoint and legal interpretations of one of the most relevant EU institutions. The non-binding legal nature of the COVID-19 Guidelines on cross-border healthcare cooperation should therefore be combined with the authority and power of the European Commission. In practice, it appears that such circumstances may effectively encourage Member States of the EU to apply soft law acts. An additional

by Member States of the EU as a valuable guide to how the relevance of the EU law rules should be understood and applied at this level. Notwithstanding the above dilemmas, however, the solution proposed in this document by definition applies only to patients requiring urgent care in a healthcare facility in another Member State of the EU. Only this group of patients cannot be refused the ability to cross the border due to the restrictions caused by the COVID-19 pandemic; persons travelling to another Member State for treatment in non-urgent cases are outside the scope of this recommendation. The solution presented in the COVID-19 Guidelines for Cross-Border Healthcare Cooperation should therefore be treated as a half-measure that clarifies the legal status of a specific group of patients; other patients, as *expressis verbis* stated in the document under review, should check whether border controls will allow them to travel. The lack of universal applicability is a definite drawback to this solution.

Notwithstanding these reservations, however, such solutions proposed by EU should be viewed positively as counteracting the negative impact of the COVID-19 pandemic on the functioning of cross-border healthcare in the EU. This positive view is justified because the application of the Communication from the Commission Guidelines on EU Emergency Assistance on Cross-Border Cooperation in Healthcare related to the COVID-19 crisis is clearly a partial solution to the problem defined above. However, as this solution indicated above only applies to patients whose cases are classified as urgent and is contained in a soft law document, another solution that either supports patients in urgent cases or experience with non-urgent cases is valuable in moving towards a more complete solution to the defined problem of cross-border healthcare in the COVID-19 pandemic.

4.5 Proposal for the implementation and use of telemedicine solutions during the COVID-19 outbreak

4.5.1 Telemedicine as a solution to the right to health during a pandemic

To propose a solution to this problem, it is necessary to refer to five fundamental premises which, based on the conclusions already discussed, justify the demand put forward.

First, the burden caused by the COVID-19 pandemic on the state health service must be relieved, improving health system efficiently and making it possible to

argument in favour of complying with the provisions of the COVID-19 cross-border healthcare cooperation guidelines is the fact that they were issued in an emergency situation and provide a helpful tool to combat the negative effects of an pandemic.

practically realise the right to health[490]. The underlying issue is finding a solution that reconciles the increased number of patients with the current capacity of the health service in a particular state[491].

Second, telemedicine is predisposed to acting as a new guarantor of the substantive core of the right to health, and thus to act as a guarantor of the right to health protection, especially given the inefficiency of the traditional health system[492].

Third, telemedicine seems to have the qualities necessary to act as a new institutional guarantor of the material aspect of the right to health. It thus constitutes the most essential means for the realisation of the main objective, i.e. the protection of health[493].

Fourth, the use of telemedicine brings a number of benefits, such as: improving the efficiency of the healthcare system *sensu largo*, supporting the work of doctors by increasing their efficiency, increasing the trust and satisfaction of final beneficiaries or improving the availability, speed, equity, safety, quality of medical services and reducing their costs[494].

Fifth, since the essence of telemedicine is that it provides care in a remote setting and is therefore independent of movement restrictions or geographical barriers, it can improve health outcomes and support clinics through the use of modern ICT[495].

For these reasons, it seems reasonable to state that the use and implementation of the instrumentality of telemedicine constitutes a solution to the drastic overloading of the national health service by the pandemic state, which is causing inefficiencies in the healthcare system and making it impossible to fully realise the right to health. Based on the above-mentioned characteristics and the specificity of telemedicine, it can be assumed that it is better able to reconcile the increased number of patients with the current capacities of the health service than its traditional counterpart. Definitely, *de lege ferenda* postulates the implementation and use of telemedicine solutions as those which, during pandemics and regardless of the impediments to movement, ensure the preservation of the efficiency of the healthcare system by increasing the efficiency of doctors, more completely realising the right to health protection and a stable and effective realisation of the right to healthcare services[496]. Telemedicine allows a single unit of medical staff to attend to the health of a larger number of patients in real time or asynchronously.

490 See Chapter 4.4.1 The right to health during the COVID-19 pandemic.
491 See Chapter 4.4.1 The right to health during the COVID-19 pandemic.
492 See Chapter 2.5.1 Telemedicine as a new guarantor of the right to health protection.
493 See Chapter 2.5.2 Telemedicine as a modern tool for the realisation of the right to healthcare services.
494 See Chapter 1.5.1 Benefits of telemedicine.
495 See Chapter 1.4.2 Essence of telemedicine.
496 Author's suggestion is based on: Argy and Caputo, 2001, p. 227.; Shaw, 2009, pp. 13-18.; McAuley, 2014, pp. 373-401.; Heus and Sartawi, 2014, pp. 193-229.; France, 2014, pp. 335-352.; Arras, 1984, pp. 23-45.; Childress, 1984, pp. 47-70.; Kluge, 2002, pp. 29-48.; Green, 2004, pp. 203-221.; Halper, 1991, pp. 135-168.; Gunn, 2008, pp. 3-7.; Ryś, 2017, p. 119.;

4.5.2 Telemedicine as a solution to the problem of cross-border healthcare in the EU during a pandemic state

The problem of cross-border healthcare during the COVID-19 pandemic requires a solution that ensures patient mobility within the EU regardless of restrictions on movement, including crossing traditionally understood state borders, and enables the full or existing use of cross-border healthcare in the EU[497]. The need to ensure patient mobility given the restrictions that may occur when physically crossing traditionally understood national borders during an pandemic state is crucial[498]. The solution proposed in the Communication from the Commission Guidelines on EU Emergency Assistance on Cross-Border Cooperation in Healthcare related to the COVID-19 crisis ensures mobility only for patients whose cases will be classified as urgent. In the analysis to this point, telemedicine appears to be an appropriate, supplemental proposal to the solution proposed in the Communication from the Commission Guidelines on EU Emergency Assistance on Cross-Border Cooperation in Healthcare related to the COVID-19 crisis.

Telemedicine *ex definitione* provides remote healthcare, which is therefore free from restrictions on movement or geographical barriers due to its use of modern ICT[499]. Geographical limitations of the traditionally understood healthcare system are irrelevant for telemedicine, allowing barriers due to distance between patient and medical staff to be overcome. This suggests that telemedicine and its services, when properly implemented, ensure the efficient, fast, safe, and effective digital mobility of patients. This type of mobility, like its traditional counterpart, can effectively fulfil the normatively defined objective of the DPRCH[500]. It can also provide immediate and remote access to cross-border healthcare without changing physical geographic location either in real time or asynchronously.

In summary, it is reasonable to argue that telemedicine should be regarded as a proposal that supports and complements the solution set out in the Communication from the Commission Guidelines on EU Emergency Assistance on Cross-Border Cooperation in Healthcare related to the COVID-19 crisis. In this regard, *de lege ferenda* telemedicine, particularly due to the specificity of its concept, should be considered as a direct remedy for patients seeking cross-border healthcare in the EU whose cases are classified as non-urgent by the COVID-19 Cross-Border

Zoll, 2000, p. 8.; Pestova, 2014, pp. 341-372.; Surówka, 2009, p. 395.; Wu, 2019, pp. 457-469.; Raskas et al., 2017, p. 206.; Piechota, 2010, pp. 137-142.; Adelakun and Garcia, 2019, p. 85.; Daniels, 1991, pp. 201-212.; Jain, 2018, pp. 139-173.; Montgomery, 1992, pp. 184-203.; Otto, 2001, p. 106.; Zimpfer, 1999, p. 77.; Buchanan, 1991, pp. 169-184.; Mpedi, 2020, pp. 77-100.; Tu, 2019, pp. 59-84.; Rawaf and Hassounah, 2014, pp. 135-163.; Linkous, 2001, p. 226.; Piechota, 2012, pp. 93-102.; Waldenström et al., 1972, pp. 117-182.; Iguiñiz, 2014, pp. 313-337.; Simmons et al., 2008, p. 163.

497 See Chapter 4.4.2 Cross-border healthcare during the COVID-19 pandemic.

498 See Chapter 4.4.2 Cross-border healthcare during the COVID-19 pandemic.

499 See Chapter 1.4.1 Definition of telemedicine.

500 See Chapter 3.4.1 Purpose of defining cross-border patients' rights.

Healthcare Cooperation Guidelines[501]. Telemedicine can ensure digital mobility, avoiding movement restrictions, including crossing traditional national borders; this fully enables the use of cross-border healthcare in the EU[502]. The ability to reconcile the need to ensure the mobility of patients whose cases are non-urgent with the restrictions that may occur when physically crossing traditionally understood national borders during an pandemic state can be resolved. Telemedicine can also support the solution set out in the COVID-19 Guidelines for cross-border cooperation in healthcare for patients with urgent cases to some degree, especially in terms of meeting highly advanced forms of telepresence or tele-operations using specialised robotics. The correlation of telemedicine with the solution proposed by the European Commission provides a more complete answer to the defined problem of cross-border healthcare during the COVID-19 pandemic.

4.6 Summary

This chapter addressed the issues related to difficulties in realising the right to health and the function of cross-border healthcare in the EU during the COVID-19 pandemic.

In the introduction, the development of the COVID-19 pandemic and its general characteristics were discussed. To do so, the most important pandemic-related events were presented along with statistical data and analyses of the COVID-19 vaccination process. This led to three important conclusions. First, the SARS-CoV-2 virus has an unprecedentedly rapid rate of spread. Second, given the high rate of contagiousness and the high risk of life-threatening symptoms for a significant proportion of the population, it became an international priority to invent a vaccine for the SARS-CoV-2 virus or a drug to treat COVID-19. Third, these developments caused states, international organizations, and individuals to dramatically re-evaluated their actions and adjust them, including in the legal dimension. At present it is extremely difficult to assess the direction of the pandemic caused by the SARS-CoV-2 virus, despite numerous countermeasures and a significant amount of research on the topic.

Next, attention was turned to the impact of the COVID-19 pandemic on the legal system, including how laws had been issued as instruments to combat the spread of SARS-CoV-2. It was established that the tool guaranteeing, in principle, widespread compliance with the newly introduced standards of social distancing

501 Author's proposal is based on: Dafoulas et al., 2017, p. 340.; Mohr et al., 2019, p. 255.; Lynn, 2019, p. 107.; Raskas et al., 2017, p. 206.; Adelakun and Garcia, 2019, p. 85.; Otto, 2001, p. 106.; Cohendet et al., 1998, p. 191.; Argy and Caputo, 2001, p. 227.; Shaw, 2009, pp. 13-18.; Bhattacharyya, 2017, p. 6.; Spradley, 2001, p. 291.; Reynolds, 2019, p. 4.; Klar and Pelikan, 2011, p. 1119.; Zimpfer, 1999, p. 77.; Linkous, 2001, p. 226.; de Lucena et al., 2013, p. 129.; Melton et al., 2019, p. 253.; Simmons et al., 2008, p. 163.; European Commission, 2018, p. 25.

502 Ibid.

was the law that naturally defined and enforced the rights and obligations of individuals. The legal measures passed in relation to the COVID-19 in selected Member States were discussed, and the correlation of their number and substantive subject matter unequivocally confirmed the impact of the COVID-19 pandemic on the legal conditions of European society as a whole. This means that, in a relatively short period of time, the legal system was normatively adapted to the new state of affairs through implementing a number of prohibitions, injunctions or, in general, strictures or restrictions. It follows that the impact of the COVID-19 pandemic on the law, including on the conditions of participation in society, is far-reaching and direct nature. This analysis shows that due to the pandemic, extensive changes have taken place in the law, mainly through the creation of a series of standards defining new rules for functioning in society.

This matter was complemented by considering the issue of the actual exercise of the individual's powers in practice during the COVID-19 pandemic. It was noted that the legal measures analysed form the basis for new legal institutions that limit the individual's powers or introduce previously unknown types of obligations. These restrictions or obligations in specific cases strongly affect not only the legally defined entitlements directly affected; they also have indirect effects on other entitlements, including the right to a court trial or education. Indeed, in practice, it appears that a side effect of the EU legal measures adopted by Member States is limiting the actual possibility of exercising the rights of individuals in the realities of the COVID-19 pandemic, which are not the direct object of regulation. Significantly, it was then noted that the pandemic, in some cases, negatively affected the actual ability of individuals to exercise their rights. It follows that a limitation in the exercise of the individuals' powers can also arise from the consequences of a changing factual situation. Threats and problems related to realising the right to health were identified as such a limitation. This remark was crucial to further consider the definition of problems related to realising the right to health and the functioning of cross-border healthcare in the reality of the COVID-19 pandemic, which was the main aim in this chapter. Accordingly, the problem of the right to health during the COVID-19 pandemic was presented and named. After applying appropriate interpretative techniques and considering the issues raised so far, it was proposed that the problem was the drastic overloading of the state health service by COVID-19, resulting in inefficiencies in the healthcare system that made it impossible in to practically realise the right to health in its full or existing form. It was emphasised that the root of this problem is how to reconcile the increased number of patients with the current capacities of the health service in a particular state.

An identical analysis was then performed related to the proper definition of the problem of the functioning of cross-border healthcare under the same conditions. After presenting a carefully chosen rationale, it was proposed that this problem be defined as a restriction or, in some cases, even a paralysis of the traditionally understood mobility of the population of the EU directly linked to the realisation of the freedom of movement of persons within the internal market of the EU, which

either significantly impedes or prevents the use of cross-border healthcare in the EU in its full or existing form. It was then highlighted that the underlying requirement is reconciling the need to ensure patient mobility with the restrictions that may occur during the physical crossing of traditionally understood national borders as justified by the pandemic situation.

These considerations were complemented by the proposal to counteract the negative impact of the COVID-19 pandemic on the functioning of cross-border healthcare in the EU. An in-depth examination of the nature of this measure led to the conclusion that its application partially, due to its coverage of only some patients, solved the problem laid out in this chapter. Any proposal that supports or complements the steps taken by EU is therefore considered to be valuable in moving towards a more complete solution to the defined problem.

Based on these results, the final chapter of this work proposed concepts for the implementation and use of telemedicine solutions during the COVID-19 pandemic. First, after additional analysis, it was proposed *de lege ferenda* the implementation and use of telemedicine solutions as they remove the impediments related to movement, preserve the efficiency of the healthcare system by increasing the efficiency of doctors, more fully realise the right to health protection, and offer a stable and effective realisation of the right to healthcare services, all of which are critical in a pandemic situation. Second, this work proposed that *de lege ferenda* telemedicine should be considered as a direct remedy for patients wishing to receive cross-border healthcare in the EU whose cases are not considered urgent according to the provisions of the Communication from the Commission Guidelines on EU Emergency Assistance on Cross-Border Cooperation in Healthcare related to the COVID-19 crisis. In addition, the provision of digital patient mobility has the advantage of being more independent of the will of the state authorities than is the case with the solution proposed by the EU. As this discussion is around digital crossing of the border by the service, the non-interference of the EU Member States is sufficient. The situation in question is of a different nature than the one proposed by the EU, where EU Member States already have a positive obligation to guarantee the possibility of traditional border crossing. As part of these considerations, it has also been suggested that, in terms of patients whose cases are urgent, telemedicine can support the EU solution when technology allows, including highly advanced forms of telepresence.

As a whole, this chapter suggests that it is currently legitimate to put solutions based on modern technologies into practice to tackle the negative effects of the COVID-19 pandemic in the context of realising the right to health and the functioning of cross-border healthcare. This observation justifies the main proposal of the chapter in the form of a more widespread deployment and use of telemedicine solutions, considering the benefits and potential and being attentive to certain real risks, such as, for example, cybercrime[503].

503 See Chapter 1.5.2 Risks of telemedicine.

5

Telemedicine cybercrimes as a threat to the realisation of the right to health in telemedicine

5.1 Introduction

The chapter aims to identify solutions to level the phenomenon of telemedicine cybercrime that threatens the realisation of the right to health in telemedicine. It is mainly concerned with identifying how to respond before and after a telemedicine cybercrime is committed with the goal of protecting and strengthening telemedicine's realisation of the right to health. Accordingly, insights related to the theoretical characteristics of telemedicine cybercrime are presented, and attention is drawn to the impact of telemedicine cybercrime on the right to health, the concept of cybercrime, and the term telemedicine cybercrime.

After a theoretical introduction, the types of telemedicine cybercrimes that can be interpreted on the basis of relevant public international law standards are analysed. A method for identifying specific types of telemedicine cybercrimes is discussed. Subsequently, the issue of evidentiary acts in telemedicine cybercrimes that are also possible to interpret on the basis of the relevant norms of public international law are considered. Here, too, a method for defining telemedical evidentiary acts is presented, and specific types of such acts are identified. As a result, the standardisation of telemedicine systems is proposed, including two specific demands. The first is standardising telemedicine service IT systems based on the types of telemedicine cybercrimes, and the second is standardising of telemedicine service IT systems based on types of telemedicine evidentiary acts.

The chapter concludes with a summary containing the author's observations on the matter under discussion and an outline of *de lege ferenda* proposals for the legislator.

5.2 Theoretical characteristics of telemedicine cybercrime

5.2.1 The impact of telemedicine cybercrime on the right to health

One of the threats of the application of modern technologies for use in the practice of medicine in the form of telemedicine solutions is telemedicine cybercrime. The act of cybercrime[504] is directly related to the specificity of telemedicine services, as highlighted above, as they serve the right to health[505]. It is also worth noting that the legally protected good harmed by telemedicine cybercrime is also, if only indirectly, the right to health. This occurs because every telemedicine cybercrime, irrespective of the directly infringed legal good (such as personal data) always simultaneously infringes the legal good of realising the right to health in digital form by limiting the actual possibility of caring for patients' health or causing them to fear a modern form of treatment due to the harm suffered. There is therefore a condition of simultaneous obligatory existence between the directly infringed legal good and the right to health, unless the directly infringed legal good is directly and exclusively the right to health. However, it must be emphatically emphasised that the means by which the cybercriminal induces a violation of the actual possibility of realising the right to health using digital medicine solutions, particularly telemedicine, is not as important as the effect of his action. There may therefore be a specific objectification of the infringement in this respect, where what matters above all is the effect of limiting the realisation of the right to digital health[506]. In addition, due to the presence of the already repeatedly emphasised permanent digital element, the environment in which telemedicine cybercrime may occur, develop, and negatively affect the proper realisation of the material and enforcement aspect of the right to health is telemedicine[507], and more precisely, telemedicine

504 Following the literature on the subject, it can be reiterated that the object of the executive act is 'such an asset protected by the provisions of criminal law on which the criminal act is performed, i.e. according to the intention of the perpetrator it is directly attacked or (in the case of unintentionality) in relation to which the principles of safe handling of the given asset are violated,' Filar, 2002, p. 25., quoted by Tarapata, 2009, p. 133.

505 Recall that telemedicine services are services performed by a doctor, related to an actual medical need, having a positive impact on the general state of health, implementing the material and executive aspect of the right to health, and performed at a distance using telepresence techniques, usually for remuneration to the extent that they are not covered by the provisions on free movement of goods, capital, and persons (see Chapter 3.5.1 Services in telemedicine).

506 The main reference here is to telemedicine, but we should not lose sight of other types of modern technologies put into practical use in medicine, so, for example, eHealth or mHealth (See Chapter 1.2 Systematics of the application of modern technology for practical use in medicine).

507 See Chapter 1.4 The concept of telemedicine.

services. These observations justify the thesis that telemedicine cybercrimes pose a real threat to realising the right to health during the practical use of modern telemedicine technologies[508].

This chapter aims to demonstrate how to respond to and counter telemedicine cybercrime. However, to do so, it is necessary to define cybercrime and telemedicine cybercrime and to identify telemedicine cybercrime risks.

The methodology in the following section is based on the premise of logical reasoning. As telemedicine cybercrime is a risk affecting the full or more complete realisation of the right to health in the form of telemedicine, the types of telemedicine cybercrime are types of possible risks to realising the right to health through the use of telemedicine. This suggests that the evidentiary steps of procedural criminal law that are possible in the context of a telemedicine cybercrime are either a reaction to the commission of a criminal act in cyberspace *post factum*, i.e. when the aforementioned risks materialise, or are actions aimed at detecting that a telemedicine cybercrime has been committed. Appropriate standardisation of telemedicine service software can prevent the risk of telemedicine cybercrime *ex ante*.

5.2.2 The concept of cybercrime

There is generally no legal definition of the terms cybercrime or cybercrime in national legal systems[509]. However, cybercrime seems to belong to a broader semantic category perceived as the general phenomenon of committing cybercrimes[510]; the notion of cybercrime is therefore key for an effective presentation of the matter at hand[511]. Intuitively, one may point out that a cybercrime is a criminal act committed in cyberspace. From a substantive point of view, this definition can be considered appropriate. This proposal is overwhelmingly subject to a particular type of logical error, however, namely the logical fallacy of *ignotum per ignotum*[512]. For this reason, more elaborate semantic proposals are presented in the literature. One emphasises that cybercrime is an activity where computers, phones, mobile

508 See also Frumento and Freschi, 2016, pp. 237-258.; Pollard et al., 2017, pp. 308.; Luna et al., 2016, pp. 1-9.; Basile and Amate, 2011, pp. 486-490.

509 Such a situation exists, for example, in the Polish normative system: Wróbel, 2014, p. 75.; Siwicki, 2012, pp. 246-250.; Wasilewski, 2016, p. 149.; Chałubińska-Jentkiewicz, 2021, pp. 15-16. A valuable bibliographic position for legislators who wish to introduce a legal definition of cybercrime is Gordon and Ford, 2006, pp. 13-20.

510 Such a conclusion can be reached by reading, for example, Jaroszewska, 2017, pp. 10-13.; Zbrojewska et al., 2016, pp. 64-65.; Golonka, 2016, pp. 63-64.

511 Many scholarly works refer to and use the concept of cybercrimes directly, which is particularly noticeable in the foreign literature, such as Gruodytė and Bilius, 2014, pp. 217-249.; Ghosh, 2011, pp. 341-362.; Saini, Rao and Panda, 2012, pp. 202-209.; Jaishankar, 2007, pp. 7-9.; Wall, 2004, pp. 20-21.; Kshetri, 2006, pp. 33-39.; Abdullah, 2019, pp. 1540-1546.; Padmaavathy, 2019, pp. 1-9.; Boukemidja, 2018, pp. 34-44.

512 Lewandowski et al., 2003, p. 61.; Szymanek, 2004, p. 83.; Nieznański, 2011, pp. 108-114.

equipment, and other technological devices are used for illegal purposes, such as fraud, theft, electronic vandalism, infringement of intellectual property rights, and hacking and entering into computer systems and networks[513]. It is rightly noted that the devices are not always technologically advanced; in some cases, it is not necessary to have a device that does more than access the ICT network[514].

Still elsewhere, cybercrime is defined as committing a criminal act using the Internet or another ICT network, where a digital machine is either the object of the criminal act or an instrument thereof[515]. Electronic use of user information is often considered to be an essential element of cybercrime[516].

There is no consensus in the literature on a single universally accepted definition of the concept of cybercrime[517], meaning that there are many different semantic proposals, which are also supplemented by proposals from selected international organisations[518]. The EU is one international organisations that has proposed a definition of cybercrime. The Communication from the Commission to the European Parliament, the Council and the Committee of the Regions Towards a general policy on the fight against cybercrime of 22 May 2007[519] stresses that, for the purposes of that document only, cybercrime should be understood as criminal acts committed using or targeting electronic communications networks and information systems. Considering the above-described fragment of how the concept of cybercrime is defined, the multiplicity of meaning proposals is considered a kind of semantic chaos. This chaos is, in part, the lack of a legal definition of the concept of cybercrime in legal systems; however, this is true only if a direct definition of the term is sought in legal acts. It is important to remember that the Council of Europe adopted the Convention on Cybercrime of 23 November 2001[520] (hereinafter: Convention on Cybercrime or Budapest Convention) or the function of a legal definition of cybercrime in the Polish normative system. This is notable as the application of appropriate techniques of legal interpretation should indicate how the notion of cybercrime can be understood. However, the two areas of interpretation indicated are quite

513 Speer, 2000, pp. 259-273
514 Wall, 2017, p. 537.
515 Hołyst and Pomykała, 2011, p. 17.
516 Jibril et al., 2020, p. 149.
517 Warren et al, 2017, p. 541.
518 For example, the United Nations has developed a proposal that the concept of cybercrime should be understood as either a series of actions directly striking at the security of computer systems and the data they process (cybercrimes *sensu stricto*) or as any illegal action committed using or concerning computer systems and networks (cybercrimes *sensu largo*), see Suchorzewska, 2010, p. 152.
519 Communication from the Commission to the European Parliament, the Council and the Committee of the Regions – Towards a general policy on the fight against cyber crime {SEC(2007) 641} {SEC(2007) 642}/* COM/2007/0267 final */.
520 Council of Europe Convention on Cybercrime…; See Clough, 2012, pp. 363-391.; Cangemi, 2004, pp. 165-171.; Weber, 2003, pp. 425-446.; Young, 2004, pp. 346-421.; Csonka, 2000, pp. 329-330.; Carr and Williams, 2002, pp. 83-90.; Moise, 2017, pp. 28-38.

different regarding how universal they are; the analysis of the Budapest Convention refers to the international legal order, while the analysis of the Polish legal system is of a domestic nature.

The Convention on Cybercrime does not explicitly indicate a definition of cybercrimes, but it does typify them. Thus, breaking down the term appears to show a definition[521]. This observation is confirmed by the Explanatory Report to the Convention on Cybercrime adopted on 23 November 2001 in Budapest, where it can be read that 'cyber-space offences' are committed against the integrity, availability, and confidentiality of computer systems and telecommunications networks, or involve the use of such networks and their services to commit traditional offences, where the cross-border nature of such offences stands in opposition to the territoriality of national law enforcement[522]. In turn, the Budapest Convention itself identifies cybercrime as a crime of illegal access, illegal interception of data, violation of data integrity, violation of system integrity, misuse of devices, computer forgery, computer fraud, related to child pornography, or in violation of copyright and related rights[523]. In the Polish normative system, two legal definitions are relevant. First, pursuant to Article 115 §1 of the Act of 6 June 1997 – Penal Code[524] (hereinafter: PC), a prohibited act is a behaviour incorporating the features specified in the penal act. Second, according to Article 2(1b) of the Act of 29 August 2002 on martial law and the competences of the Commander-in-Chief of the Armed Forces and the principles of his subordination to the constitutional bodies of the Republic of Poland[525], cyberspace is understood as the space used to process and exchange of information created by ICT systems, as defined in Article 3(3) of the Act of 17 February 2005 on informatisation of the activity of entities performing public tasks[526], together with the links between them and the relations with users. In turn, in accordance with the aforementioned Article 3(3) of the Act of 17 February 2005 on Informatisation of the Activity of Entities Performing Public Tasks, an ICT system is a set of cooperating IT devices and software ensuring processing and storage, as well as sending and

521 An extremely interesting study on the issue of division is Jonkisz, 2017, pp. 95-109.
522 Council of Europe, 2021.
523 The normative definition of the types of cybercrimes should be viewed positively. On the one hand, it is a recognition of the efforts of the doctrinal representatives who published their works in this thematic area before the Budapest Convention was enacted, while on the other hand, this fact provided a stimulus for authors to undertake more far-reaching analyses (for examples, see Speer, 2000, pp. 259-273.; Walden, 2004, pp. 321-336.; Brenner and Schwerha, 2004, pp. 111-114.; Wang, 2007, pp. 216-223.; Gercke, 2009, pp. 409-42.0; Hilley, 2005, pp. 171-174.; Moitra, 2005, pp. 435-464.; Chung et al., 2006, pp. 669-682.; Clough, 2014, pp. 698-736.; Katyal, 2001, pp. 1003-1114.; Hancock, 2000, pp. 306-307.; Boni, 2001, pp. 18-19.; Wible, 2003, pp. 1577-1623.; Simon, 1998, pp. 1015-1048.; Nuth, 2008, pp. 437-446.; Sinrod and Reilly, 2000, pp. 1-53.).
524 Act of 6 June 1997 – Penal Code (consolidated text; Journal of Laws 2021, item 1023, as amended).
525 Law of 29 August 2002 on martial law….
526 Act of 17 February 2005 on the computerisation of the activities of entities performing public tasks (consolidated text; Journal of Laws 2021, item 2070).

receiving data via telecommunication networks using a telecommunication terminal device appropriate for a given type of network, within the meaning of the provisions of the Telecommunications Law of 16 July 2004[527]. The proper interpretation of the notion of cybercrime in Poland is therefore complemented by the legal definition contained in Article 2(43) of the Telecommunications Act of 16 July 2004. According to this definition, a telecommunications terminal device is a telecommunications device intended to connect directly or indirectly to network terminals.

Relying on the simplest definition, which is certainly substantively correct, the meaning of cybercrime in Poland is that a cybercrime is a prohibited act committed in cyberspace. The combination of prohibited acts and cyberspace in the Polish normative order is sufficient. According to the cited Polish legal norms, therefore, a cybercrime may be a behaviour with the features specified in the criminal act, including international agreements, that is committed in the space for processing and exchange of information created by a set of cooperating IT devices and software that are ensuring processing and storage, as well as sending and receiving data through telecommunication networks using a telecommunication device that is appropriate for a given type of network and which is intended to connect directly or indirectly to the network, creating links between different points and relationships with the users[528]. However, in view of the quality of the obtained product of the legal interpretation in question, this solution deserves recognition as it shows the features of completeness, clarity and semantic unconditionality[529]. Accordingly, *de lege ferenda* the Polish legislator should first consider the introduction of a legal definition of the concept of cybercrime in the presented form; second, *de lege ferenda* the international legislator should consider the introduction of such a definition, with amendments as necessary based on international regulations.

This definition could be supplemented by a specification of the types of cybercrimes, which is currently present in the Convention on Cybercrime[530], as well as a

527 Telecommunications Act of 16 July 2004 (consolidated text; Journal of Laws 2021, item 576.).

528 The presented definition of cybercrime is a direct result of an interpretation process based on Polish law, but it does not derive directly from Polish law. As already noted, this is because the Polish legislator has not chosen to introduce a legal definition of the concept of cybercrime into its normative system.

529 Nevertheless, these features are only demonstrated by the fully defined content of the definition of cybercrime, where one of its components, in addition to the theoretical definition of cybercrime and the legal definition of the criminal act, is the legal definition of cyberspace. It should be noted that the systemic reference contained in the legal definition of cyberspace, implying further references of this kind, is not conducive to the clarity and comprehensibility of the law. For this reason, *de lege ferenda,* the Polish legislator should consider amending the legal definition of cyberspace in such a way that it does not contain references to other legislative acts.

530 According to the Budapest Convention, a cybercrime is an offence of illegal access, illegal interception of data, violation of data integrity, violation of system integrity, misuse of equipment, computer forgery, computer fraud or involving child pornography, or violation of copyright and related rights.

description of cybercrime offences, which in turn are included in the Explanatory Report to the Convention on Cybercrime[531]. The Budapest Convention therefore appears to provide a suitable matrix for introducing a direct legal definition of cybercrime through, for example, the Additional Protocol procedure.

5.2.3 The term telemedicine cybercrime

However, to properly define the title problem and propose a solution, a semantic analysis of telemedicine cybercrime is necessary. It becomes important to identify an answer to the question of the fundamental concept that constitutes the main research aim of this work. In other words, from a methodological point of view, the meaning of telemedicine cybercrime must be established.

When posed this way, the research question requires that two broad conglomerates of designators in the concept must be examined. The first is cybercrime, and the second is telemedicine services. Identifying these two suppositions should lead to a definition of the concept of telemedicine cybercrime. This is crucial for the further considerations in this chapter as it determines the shape, form, and content of future conclusions.

The analysis already carried out has established how the concept of cybercrime itself should be understood. The same is true for telemedicine services, as this follows from the findings already made in relation to the definition of the location of telemedicine services in cross-border healthcare in the EU[532]. It therefore becomes necessary at this point to appropriately combine the developed and presented definition of cybercrime with selected components of the concept of telemedicine services; a telemedicine cybercrime is a cybercrime that is committed within the framework of a telemedicine service, or that appears to be substantially related to such a service. Telemedicine services are the target, source, or environment of the attack, i.e., they are the object of the telemedicine cybercrime. It is also worth noting that the concept of telemedicine services has already been established as a service provided by a medical practitioner, related to an actual medical need, having a positive effect on the general state of health, implementing the material and executive aspect of the right to health, and provided at a distance using telepresence techniques, usually for remuneration to the extent that it is not covered by the provisions on free movement

531 According to the Explanatory Report to the Convention on Cybercrime, 'cybercrime offences' are committed against the integrity, availability and confidentiality of computer systems and telecommunications networks or involve the use of such networks and their services to commit traditional crimes, where their cross-border nature stands in opposition to the territoriality of national law enforcement authorities.

532 See Chapter 3.5.1 Services in telemedicine.

of goods, capital, and persons[533]. In a situation where the two essential components of the concept of telemedicine cybercrime have been identified, i.e., the concept of cybercrime and telemedicine services, it is appropriate to combine them in a methodologically appropriate manner. Thus, considering the arguments raised and the assertions presented, *de lege ferenda* the term of telemedicine cybercrime should be understood as behaviour with the characteristics set out in the criminal law, including international agreements, committed in the space of information processing and exchange created by a set of cooperating IT devices and software ensuring the processing, storage, and sending and receiving of data through telecommunication networks by means of a telecommunication device appropriate for a given type of network intended to be connected directly or indirectly to the network, together with the links between points and the relationship with users, the object of which is the provision of services by a medical practitioner which are related to an actual medical need, which have a positive effect on the general state of health, which implement the material and executive aspect of the right to health, and which are provided at a distance using telepresence techniques usually for remuneration insofar as they are not covered by the provisions on free movement of goods, capital, and persons[534]. This definition is supplemented by the description of cybercrime offences in the Explanatory Report to the Convention on Cybercrime and the normatively defined types of cybercrimes in the Budapest Convention, which, when appropriate interpretative techniques are applied, identify specific types of telemedicine cybercrimes. This is tantamount to defining a basic catalogue of risks possible when using modern technology in medical practice in the form of telemedicine services. This will form the foundation for further analysis related to telemedical evidence activities and the standardisation of telemedicine systems.

533 Author's proposal is based on Jasudowicz, 2010, pp. 161-172.; Jamar, 1994, pp 17-35.; Tu, 2019, pp. 59-84.; Kirchner, 2018, pp. 141-151.; de Lucena et al., 2013, p. 129.; Buchanan, 1991, pp. 169-184.; Beauchamp, 1991, pp. 53-81.; Merrill, 1994, pp. 99-128.; Evans, 2014, pp. 233-257.; Heus and Sartawi, 2014, pp. 193-229.; Qiu, 2014, pp. 97-120.; Argy and Caputo, 2001, p. 227.; Shaw, 2009, pp. 13-18.; Spradley, 2001, p. 291.; Piechota, 2010, pp. 137-142.; Reynolds, 2019, p. 4.; Dafoulas et al., 2017, p. 340.; Mohr et al., 2019, p. 255.; Lynn, 2019, p. 107.; Ryś, 2017, p. 119.; Surówka, 2009, p. 395.; Montgomery, 1992, pp. 184-203.; Pestova, 2014, pp. 341-372.; Cohendet et al., 1998, p. 191.; Klar and Pelikan, 2011, p. 1119.; Leary, 1994, pp. 24-56.; Wiberg, 2014, p. 20.; van de Gronden, 2013, p. 125.; McAuley, 2014, pp. 373-401.; Walker, 2014, pp. 165-192.; Daniels, 1991, pp. 201-212.; Engelhardt, 1991, pp. 103-111.; Melton et al., 2019, p. 253.; Raskas et al., 2017, p. 206.; Rawaf and Hassounah, 2014, pp. 135-163.; Wu, 2019, pp. 457-469.; Mohr et al., 2019, p. 255.; Lynn, 2019, p. 107.; Ryś, 2017, p. 395.; Sass, 1991, pp. 243-255.; Halper, 1991, pp. 135-168.; T. Marmor, 1991, pp. 23-49.

534 The author's proposal is based on the developed notion of cybercrime and telemedicine services; the following items were particularly inspiring: Tu, 2019, 59-84.; Leary, 1994, pp. 24-56.; Beauchamp, 1991, pp. 53-81.; Engelhardt, 1991, pp. 103-111.; Heus and Sartawi, 2014, pp. 193-229.; Sass, 1991, pp. 243-255.; Klar and Pelikan, 2011, p. 1119.; Evans, 2014, 233-257.; Melton et al., 2019, p. 253.; Qiu, 2014, pp. 97-120.; Wu, 2019, pp. 457-469.; Surówka, 2009, p. 395.; Merrill, 1994, pp. 99-128.; Jamar, 1994, pp 17-35.; Jasudowicz, 2010, p. 227.; de Lucena et al., 2013, p. 129.; Montgomery, 1992, pp. 184-203.; Daniels, 1991, pp. 201-212.

Regarding the proposed definition of telemedicine cybercrime, it should be noted that, from a substantive, logical, and methodological point of view, the definition appears to be appropriate. It also appears to be clear, direct, unconditional, and complete. An advantage of the definition presented is that it is based on already developed conclusions, and the concept of telemedicine services was also established based on previously examined premises. This observation means that proposing a definition of telemedicine cybercrime in this form should be read as a consistent step in analysing the main research aim of this monograph.

5.3 Types of telemedicine cybercrimes

5.3.1 Method of identifying types of telemedicine cybercrimes

Current Polish and international law lacks a direct definition of the types of telemedicine cybercrimes. Nevertheless, these crimes can be interpreted based on other norms. In this context, the observation that the concept of telemedicine cybercrime has a narrower scope of meaning than the notion of cybercrime becomes important. There is a one-way relationship between these terms, i.e., every telemedicine cybercrime is a cybercrime, but not every cybercrime is a telemedicine cybercrime. This is because, and this is worth emphasising, telemedicine cybercrimes are mostly a translation of ordinary cybercrimes enriched with a telemedicine feature. Telemedicine cybercrimes are, therefore, a specific category of cybercrimes, meaning that they have much in common with other cybercrimes. The vast majority of the normatively envisaged types of cybercrimes, therefore have a telemedicine component when telemedicine services are added as their object of infringement; most cybercrimes could be transformed into telemedical [535].

535 This means, however, that there are types of cybercrimes whose transformation into telemedicine cybercrimes is not advisable. An example of this phenomenon is the child pornography offence provided for in Article 9 of the Budapest Convention. According to this provision, '1. Each Party shall adopt such legislative and other measures as may be necessary to establish as criminal offences under its domestic law, when committed intentionally and without right, the following conduct: a. producing child pornography for the purpose of its distribution through a computer system; b. offering or making available child pornography through a computer system; c. distributing or transmitting child pornography through a computer system; d. procuring child pornography through a computer system for oneself or for another person; e. possessing child pornography in a computer system or on a computer-data storage medium. (2) For the purpose of paragraph 1 above, the term 'child pornography' shall include pornographic material that visually depicts: a. a minor engaged in sexually explicit conduct; b. a person appearing to be a minor engaged in sexually explicit conduct; c. realistic images representing a minor engaged in sexually explicit conduct. (3 For the purpose of paragraph 2 above, the term 'minor' shall include all persons under 18 years of age. A Party may, however, require a lower age-limit, which shall be not less than 16 years. 4. Each Party may reserve the right not to apply, in whole or in part, paragraphs

The relevant source material for this analysis is the material legal section of the Budapest Convention, which is an example of an international law that typifies selected types of cybercrimes; this will be the basis for interpreting the correct translation of these types of cybercrimes into specific telemedicine cybercrimes.

5.3.2 Types of telemedicine cybercrimes

Based on the current content of the Budapest Convention, it should be emphasised again that it provides for specific types of cybercrimes. From Articles 2 to 10 of the Convention on Cybercrime, it is clear that the types in question are the offences of illegal access, illegal interception of data, violation of data integrity, violation of system integrity, misuse of devices, computer forgery, computer fraud, related to child pornography, or violation of copyright and related rights[536]. Most of these cybercrimes have characteristics that could transform them into telemedicine cybercrimes. For example, a child pornography-related cybercrime is characterised by its autonomous specificity. However, if it were committed in the context of or within a telemedicine system, the subject of such a cybercrime would not be telemedicine services. A similar conclusion can also be reached by analysing the content of the Additional Protocol to the Convention on Cybercrime concerning the criminalisation of acts of a racist or xenophobic nature committed using computer systems[537].

According to the presented method of defining specific telemedicine cybercrimes and the above remarks, the first type of telemedicine cybercrime is illegal access to the information system of telemedicine services. Based on Article 2 of the Budapest Convention, this type of cybercrime can be understood as intentional and unlawful access to all or part of the information system of telemedicine services[538].

1, sub-paragraphs d and e, and 2, sub-paragraphs b and c.' This is because, due to the subject matter of the criminal act, child pornography cybercrime is characterised by its own autonomous specificity. This is explained later in this monograph.

536 See Clough, 2012, pp. 363-391.; Weber, 2003, pp. 425-446.; Csonka, 2000, pp. 329-330.; Carr and Williams, 2002, pp. 83-90.; Moise, 2017, pp. 28-38.

537 Additional Protocol to the Convention on Cybercrime concerning the criminalisation of acts of a racist or xenophobic nature committed through computer systems, drawn up in Strasbourg on 28 January 2003 (OJ 2015, item 730).

538 Proposal based on the original text of Article 2 of the Cybercrime Convention: 'Each Party shall adopt such legislative and other measures as may be necessary to establish as criminal offences under its domestic law, when committed intentionally, the access to the whole or any part of a computer system without right. A Party may require that the offence be committed by infringing security measures, with the intent of obtaining computer data or other dishonest intent, or in relation to a computer system that is connected to another computer system.' It is further worth noting that the original wording of Article 2 of the Cybercrime Convention may make it clear that the telemedicine cybercrime of illegal access to an IT system of telemedicine services may be enriched by the requirement that it must be committed through a breach of security, with the intent to obtain IT data of telemedicine services, with other fraudulent intent, in relation to an IT system, or in relation to an IT

For the sake of clarity, it should be emphasized that Article 1 of the Budapest Convention allows for the interpretation that an information system for telemedicine services should be understood as any device or group of interconnected or associated devices, one or more of which, according to a programme, performs automatic data processing for the provision of telemedicine services[539]. On the same basis, it can be stated that data of telemedicine services can be understood as any representation of facts, information, or concepts related to telemedicine services in a form suitable for processing in a computer system, including the corresponding program causing the IT system of telemedicine services to perform its functions[540].

The second type of telemedicine cybercrime is the unlawful interception of data of telemedicine services. Translating Article 3 of the Budapest Convention correctly, the article refers to the intentional and unlawful interception by means of technical devices of non-public transmissions of data of telemedicine services to, from, or within the IT system of telemedicine services, including electromagnetic emissions originating from the IT system of telemedicine services transmitting such data[541].

The third type of telemedicine cybercrime is violation of the data integrity of telemedicine services. Based on Article 4 of the Budapest Convention, it can be understood to be the intentional or unlawful destruction, erasure, damage, alteration, or deletion of data from telemedicine services[542].

system for telemedicine services that is connected to another IT system for telemedicine services. In the Polish legal system, cybercrime, as defined in Article 2 of the Convention on Cybercrime, is provided for in Articles 267 § 1 and 2 PC. In this context, however, one should bear in mind the content of Article 269c PC, which provides for the counterparty of acting to detect errors in the security of IT systems.

539 Proposed from the original text of Article 1(a) of the Cybercrime Convention: '"computer system" means any device or group of interconnected or related devices, one or more of which, pursuant to a program, performs automatic processing of data.'

540 Suggestion is based on the original text of Article 1(b) of the Cybercrime Convention: '"computer data" means any representation of facts, information or concepts in a form suitable for processing in a computer system, including a program suitable to cause a computer system to perform a function.'

541 Proposal is based on the original text of Article 3 of the Cybercrime Convention: 'Each Party shall adopt such legislative and other measures as may be necessary to establish as criminal offences under its domestic law, when committed intentionally, the interception without right, made by technical means, of non-public transmissions of computer data to, from or within a computer system, including electromagnetic emissions from a computer system carrying such computer data. A Party may require that the offence be committed with dishonest intent, or in relation to a computer system that is connected to another computer system.' Like Article 2 of the Cybercrime Convention, Article 3 provides for the possibility of introducing the requirement that the illegal interception of IT data of telemedicine services must be committed with fraudulent intent or in connection with an IT system or an IT system of telemedicine services that is connected to another IT system for telemedicine services. In the Polish legal system, cybercrime as defined in Article 3 of the Convention on Cybercrime is provided for in Article 267 § 3 PC.

542 Proposal is based on the original text of Article 4 of the Cybercrime Convention: '(1) Each Party shall adopt such legislative and other measures as may be necessary to establish as

The fourth type of telemedicine cybercrime, which can be interpreted on the basis of Article 5 of the Budapest Convention, is the violation of the integrity of the information system of telemedicine services. It can be understood as the intentional, unlawful, and serious interference with the functioning of the information system of telemedicine services by introducing, transmitting, destroying, erasing, damaging, altering, or deleting information data from telemedicine services[543].

The fifth type of telemedicine cybercrime is the misuse of devices. This type is general in nature and, with reference to Article 6 of the Budapest Convention, has two aspects[544]. The first consists of the act of manufacturing, selling, obtaining with intent to use, importing, distributing or otherwise making available two types of items. The first type referenced is devices, including computer programs, that

criminal offences under its domestic law, when committed intentionally, the damaging, deletion, deterioration, alteration or suppression of computer data without right. (2) A Party may reserve the right to require that the conduct described in paragraph 1 result in serious harm.' The original wording of Article 4 of the Cybercrime Convention therefore suggests that it is possible to introduce a requirement into the telemedicine cybercrime of a breach of data integrity of telemedicine services that the telemedicine cybercrime must result in serious damage. In the Polish legal system, cybercrime as defined in Article 4 of the Cybercrime Convention is provided for in Articles 268 and 268a PC.

543 Proposal is based on the original text of Article 5 of the Cybercrime Convention: 'Each Party shall adopt such legislative and other measures as may be necessary to establish as criminal offences under its domestic law, when committed intentionally, the serious hindering without right of the functioning of a computer system by inputting, transmitting, damaging, deleting, deteriorating, altering or suppressing computer data.' In the Polish legal system, cybercrime as defined in Article 5 of the Convention on Cybercrime is provided for in Articles 269 and 269a PC. In this context, however, it is important to bear in mind the content of Article 269c PC, which provides for the counter-crime of acting to detect errors in the security of IT systems.

544 Proposal is based on the original text of Article 6 of the Cybercrime Convention: '(1) Each Party shall adopt such legislative and other measures as may be necessary to establish as criminal offences under its domestic law, when committed intentionally and without right: a. the production, sale, procurement for use, import, distribution or otherwise making available of: i. a device, including a computer program, designed or adapted primarily for the purpose of committing any of the offences established in accordance with Articles 2 through 5; ii. a computer password, access code, or similar data by which the whole or any part of a computer system is capable of being accessed,; and b the possession of an item referred to in paragraphs a.i or ii above, with intent that it be used for the purpose of committing any of the offences established in Articles 2 through 5. A Party may require by law that a number of such items be possessed before criminal liability attaches. (2) This article shall not be interpreted as imposing criminal liability where the production, sale, procurement for use, import, distribution or otherwise making available or possession referred to in paragraph 1 of this article is not for the purpose of committing an offence established in accordance with Articles 2 through 5 of this Convention, such as for the authorised testing or protection of a computer system. (3) Each Party may reserve the right not to apply paragraph 1 of this article, provided that the reservation does not concern the sale, distribution or otherwise making available of the items referred to in paragraph 1 a.ii of this article.' In the Polish legal system, the cybercrime defined in Article 6 of the Cybercrime Convention is provided for in Article 269b PC.

are designed or adapted primarily for the purpose of committing a telemedicine cybercrime of illegal access to the IT system of telemedicine services, illegal interception of data of telemedicine services, violation of the integrity of the data of telemedicine services or violation of the integrity of the IT system of telemedicine services. The second type is related to computer passwords, access codes, or similar data by which all or part of the telemedicine services IT system is accessed, with the purpose of committing the telemedicine cybercrimes mentioned in the first situation. In contrast, the second aspect of telemedicine cybercrime that involves misuse of a device consists of the mere possession of the items from the first aspect with the intention of using for them to commit telemedicine cybercrimes, such as illegal access to the telemedicine services IT system, illegal interception of the telemedicine services data, violation of the integrity of the telemedicine services data, or violation of the integrity of the telemedicine services IT system.

A sixth type of telemedicine cybercrime is telemedicine forgery. Drawing on Article 7 of the Budapest Convention, telemedicine forgery should be understood as the intentional and unlawful insertion, alteration, deletion, or concealment of data from telemedicine services, resulting in inauthentic data that the perpetrator intends to be recognised or used for the purpose of legal proceedings as authentic, regardless of whether it is directly readable and intelligible[545].

The seventh telemedicine cybercrime is telemedicine fraud, which, with reference to Article 8 of the Budapest Convention, can mean the intentional and unlawful causing of loss of property to another person by entering, altering, or deleting data of telemedicine services, or by any interference with the functioning of the IT telemedicine system, with the intent to defraud or to obtain economic benefits for oneself or another person[546].

The eighth telemedicine cybercrime is the infringement of copyright and related rights in the context of the information system of telemedicine services. Based on Article 10 of the Budapest Convention, this telemedicine cybercrime, like

545 Proposal is based on the original text of Article 7 of the Cybercrime Convention: 'Each Party shall adopt such legislative and other measures as may be necessary to establish as criminal offences under its domestic law, when committed intentionally and without right, the input, alteration, deletion, or suppression of computer data, resulting in inauthentic data with the intent that it be considered or acted upon for legal purposes as if it were authentic, regardless whether or not the data is directly readable and intelligible. A Party may require an intent to defraud, or similar dishonest intent, before criminal liability attaches.' Based on the original wording of Article 7 of the Cybercrime Convention, it is possible to introduce a requirement into the cybercrime of telemedicine forgery stating that criminal liability applies to acting with fraudulent intent or similar dishonest intent. In the Polish legal system, the cybercrime defined in Article 7 of the Cybercrime Convention is provided for in Article 270 PC.

546 Proposal is based on the original text of Article 8 of the Cybercrime Convention: 'Each Party shall adopt such legislative and other measures as may be necessary to establish as criminal offences under its domestic law, when committed intentionally and without right, the causing of a loss of property to another person.' In the Polish legal system, cybercrime as defined in Article 8 of the Convention on Cybercrime is provided for in Article 287 PC.

the telemedicine cybercrime related to misuse of devices, has two aspects[547]. The first is the infringement of copyright as provided for in national law in accordance with the obligations undertaken by the specific State under the Paris Act and relating to the Berne Convention for the Protection of Literary and Artistic Works[548], the Agreement on Trade-Related Aspects of Intellectual Property Rights[549] and the World Intellectual Property Organisation Copyright Treaty[550], to the exclusion of moral rights provided for by these acts, if the act is committed intentionally, on a commercial scale, and by means of an information system for telemedicine services. The second aspect is the related rights aspect, which consists of the infringement of related rights as defined in national law in accordance with the obligations undertaken by the specific State under the International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organisations[551], the Agreement on Trade-Related Aspects of Intellectual Property Rights, and the World Intellectual Property Organisation Treaty on Performances and Phonograms[552], to the exclusion of the moral rights provided for by these acts, if the act is committed

547 Proposal is based on the original text of Article 10 of the Cybercrime Convention: '1. Each Party shall adopt such legislative and other measures as may be necessary to establish as criminal offences under its domestic law the infringement of copyright, as defined under the law of that Party, pursuant to the obligations it has undertaken under the Paris Act of 24 July 1971 revising the Bern Convention for the Protection of Literary and Artistic Works, the Agreement on Trade-Related Aspects of Intellectual Property Rights and the WIPO Copyright Treaty, with the exception of any moral rights conferred by such conventions, where such acts are committed wilfully, on a commercial scale and by means of a computer system. 2. Each Party shall adopt such legislative and other measures as may be necessary to establish as criminal offences under its domestic law the infringement of related rights, as defined under the law of that Party, pursuant to the obligations it has undertaken under the International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organisations (Rome Convention), the Agreement on Trade-Related Aspects of Intellectual Property Rights and the WIPO Performances and Phonograms Treaty, with the exception of any moral rights conferred by such conventions, where such acts are committed wilfully, on a commercial scale and by means of a computer system. (3) A Party may reserve the right not to impose criminal liability under paragraphs 1 and 2 of this article in limited circumstances, provided that other effective remedies are available and that such reservation does not derogate from the Party's international obligations set forth in the international instruments referred to in paragraphs 1 and 2 of this article.' In the Polish legal system, the cybercrime defined in Article 10 of the Convention on Cybercrime is provided for in the Act of 4 February 1994 on Copyright and Related Rights' (consolidated text; Journal of Laws of 2021, item 1062.).

548 Paris Act relating to the Berne Convention for the Protection of Literary and Artistic Works, completed at Paris on 24 July 1971 (Journal of Laws 1990, No. 82, item 474.).

549 Agreement on Trade-Related Aspects of Intellectual Property Rights (OJ of the EU L 336, 23.12.1994, pp. 214-233.).

550 World Intellectual Property Organisation Copyright Treaty (OJ 2005 No. 3, item 12).

551 International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organisations (OJ 1997, No. 125, item 800.).

552 World Intellectual Property Organisation Treaty on Performances and Phonograms (OJ 2004, No. 41, item 375.).

intentionally, on a commercial scale and by means of an information system for telemedicine services.

The catalogue of telemedicine cybercrimes outlined above is open, which is clearly emphasised by the Budapest Convention in Article 14. According to this provision as well as paragraph 2, the vast majority of evidentiary steps provided for in the procedural part of this international instrument are applicable not only to the cybercrimes identified therein, but also to all other offences committed with the use of an information system[553]. It leads to the conclusion that the offences provided for in Articles 2 to 10 of the Budapest Convention fall into the category of cybercrimes *sensu stricto*, while all other offences committed with the use of an information system fall into the category of cybercrimes *sensu largo*. All the proposals presented above for the transformation of specific types of cybercrimes into types of telemedicine cybercrimes are dogmatic in nature. The main objective was to identify and name the basic catalogue of risks possible when using modern technology for practical use in medicine in the form of telemedicine services. It was not, however, to make *de lege ferenda* demands for the legislator to introduce hard law. Doing so is unnecessary because criminal provisions explicitly typify telemedicine cybercrimes as they are also cybercrimes. It should therefore be highlighted that, if a more general category is criminalised, it becomes redundant to criminalise a specific category, as it already falls within the general category provided; this assumes that the identity of the sanction is maintained. In this particular semantic case, particularly in view of the relatively high level of similarity between the designations of cybercrime and telemedicine cybercrime, this is also justified by considerations of proper legislation. Nevertheless, there is nothing to prevent *de lege ferenda* a prudent legislator from designating the types of telemedicine cybercrimes defined above in the form of soft law for the information of the general public. This would seem to be likely to increase the level of public confidence in telemedicine, particularly in view of the emphasis by state or international bodies that they are aware of certain risks and intend to counter them.

5.4 Telemedical evidence activities

5.4.1 Method for defining types of telemedical evidentiary acts

As with telemedicine cybercrimes, the current law lacks a definition of the specific types of evidentiary acts used against telemedicine cybercrimes. This should not

553 Article 14(2) of the Convention on Cybercrime: 'Except as specifically provided otherwise in Article 21, each Party shall apply the powers and procedures referred to in paragraph 1 of this article to: a. the criminal offences established in accordance with Articles 2 through 11 of this Convention; b. other criminal offences committed by means of a computer system; and c. the collection of evidence in electronic form of a criminal offence.'

come as a surprise as it stems from the lack of normative typification of telemedicine cybercrimes. However, it is important to note that current international law, and more specifically Part Two of the Budapest Convention, entitled Procedural Law, provides for specific types of evidentiary steps that should be used to search for, disclose, or control evidence[554] in cases of ordinary cybercrimes. It is also important to recall that telemedicine cybercrimes are, for the most part, a translation of ordinary cybercrimes enriched with a telemedicine feature. A similar interpretation can therefore be made in the context of evidentiary actions.

It seems that, if it was possible to define the types of telemedical cybercrimes based on the types of cybercrimes defined in the Budapest Convention, it is equally possible to propose evidentiary steps that should be used against telemedical cybercrimes based on the evidentiary steps defined in the Budapest Convention, after adding the telemedicality feature to them. In other words, if cybercrimes have defined evidentiary steps, telemedicine cybercrimes also have them. The source material, as a direct consequence of the above assumptions, for such a defined analysis will be the criminal procedural part of the Cybercrime Convention, which is the basis for determining the types of telemedical evidentiary acts[555].

5.4.2 Types of telemedical evidentiary acts

The purpose of specifying the types of telemedicine evidentiary activities, as with the identification of types of telemedicine cybercrimes, is not to recommend their introduction in the form of hard law. Instead, the purpose is to consider proper legislation; therefore, if a more general category is provided for by law, it becomes unnecessary to define a specific category due to the relatively high level of similarity between the designations of evidentiary acts of traditional cybercrimes and telemedical evidentiary acts. However, it is recommended that the legislator *de lege ferenda* present the named and described telemedical evidentiary acts below in the form of soft law as information to the general public[556]. Such a measure would

554 Waltoś and Hofmański, 2015, p. 357.

555 However, it cannot be ruled out that a particular type of evidentiary act provided for in the Budapest Convention will not exhibit the semantic properties that enable the translation of such an evidentiary act into a telemedical evidentiary act.

556 This can take the form of a handbook, guidelines, recommendations, good practice or national policy relating to telemedicine evidence. Examples for these types of documents can be found in the so-called 'soft law' instruments that have already been created in the field of telemedicine (Communication from the Commission to The European Parliament, The Council, The European Economic and Social Committee and the Committee of the Regions on the benefits of telemedicine…; Commission Staff Working Document of 21 December 2007 Action Plan on…; Communication From The Commission To The European Parliament, The Council, The European Economic And Social Committee And The Committee Of The Regions on enabling the digital traansformation of health and care in the Digital Single Market…; Communication From The Commission To The Council, The European

increase the level of public confidence in telemedicine by making citizens aware that state or international authorities know how to detect and prove certain types of telemedicine cybercrimes and how to attribute legal responsibility to a specific perpetrator.

However, the aim of the analysis in this subsection is to determine either the appropriate response to the commission of a telemedicine cybercrime or the appropriate means of detecting that it has occurred. The analytical effect of this subsection will therefore be indicate what detection or evidentiary measures should be taken in the context of the possibility that a telemedicine cybercrime is either committed or has been committed.

Based, therefore, on the method outlined above for defining the types of telemedicine evidentiary acts, it should be noted that the first such act is the immediate preservation of the stored data of telemedicine services. According to Article 16 of the Budapest Convention, this evidentiary step can be understood as enabling the competent authorities to order or obtain by similar methods the immediate preservation of the specified data of the telemedicine services, including traffic data, stored using a telemedicine service's IT system, particularly when there are grounds for believing that they are particularly vulnerable to the risk of loss or modification[557]. The concept of traffic data of telemedicine services is relevant in the context of this evidentiary exercise. A proper interpretation of Article 1(d) of the Budapest Convention, traffic data of telemedicine services can be understood as any data

Parliament, The European Economic And Social Committee And The Committee Of The Regions – e-Health -making healthcare better.…; Communication from the Commission to The European Parliament, The Council, The European Economic and Social Committee and the Committee of the Regions: eHealth Action Plan on…; Council conclusions on Health in the Digital Society – making progress in data-driven innovation in the field of health…; Question to the Commission on enabling the transformation of…; European Parliament Resolution of 18 December 2019 on enabling the transformation of…; Commission Recommendation (EU) 2019/243 of 6 February 2019 on a European Electronic Health Record…; Commission Recommendation of 2 July 2008 on cross-border.…).

557 Proposal is based on the original text of Article 16 of the Cybercrime Convention: '(1) Each Party shall adopt such legislative and other measures as may be necessary to enable its competent authorities to order or similarly obtain the expeditious preservation of specified computer data, including traffic data, that has been stored by means of a computer system, in particular where there are grounds to believe that the computer data is particularly vulnerable to loss or modification (2) Where a Party gives effect to paragraph 1 above by means of an order to a person to preserve specified stored computer data in the person's possession or control, the Party shall adopt such legislative and other measures as may be necessary to oblige that person to preserve and maintain the integrity of that computer data for a period of time as long as necessary, up to a maximum of ninety days, to enable the competent authorities to seek its disclosure. A Party may provide for such an order to be subsequently renewed. (3) Each Party shall adopt such legislative and other measures as may be necessary to oblige the custodian or other person who is to preserve the computer data to keep confidential the undertaking of such procedures for the period of time provided for by its domestic law. (4) The powers and procedures referred to in this article shall be subject to Articles 14 and 15.'

from telemedicine services relating to communication using a telemedicine service's IT system, generated by an a telemedicine service's IT system that was part of the communication chain, indicating its origin, destination, path, time, date, size, duration, or type of service concerned[558].

The second telemedicine evidentiary measure is the immediate preservation and partial disclosure of telemedicine service traffic data, which is a refinement of the immediate preservation of stored data from telemedicine services regarding telemedicine service traffic data. From Article 17 of the Budapest Convention it follows, therefore, that the medical evidentiary act in question may have two meanings with regard to telemedicine service traffic data: first, ensuring that it is possible to secure telemedicine service traffic data without delay, regardless of whether only one or more telemedicine service providers were involved in the transmission of this information, and ensuring that sufficient telemedicine traffic data is disclosed without delay to the competent authority or the person designated by such authority to enable the identification of the telemedicine service providers and the channels through which the transmission took place[559]. In the light of this, it is necessary to draw attention to the term telemedicine service provider. In terms of the paper's main research aim and the content of Article 1(c) of the Budapest Convention, it can be concluded that the provider of telemedicine services is any private or public entity that enables users to use telemedicine services by means of the telemedicine services IT system, or any entity that processes or stores telemedicine-related data generated by the telemedicine services' IT system[560].

The third telemedical evidentiary act is the order to provide data of telemedicine services or provide information relating to the subscriber of telemedicine services. Based on Article 18 of the Budapest Convention, the indicated medical evidentiary act can be understood in two dimensions[561]. First, an order for the

558 Proposal based on the original text of Article 1(d) of the Cybercrime Convention: '"traffic data" means any computer data relating to a communication by means of a computer system, generated by a computer system that formed a part in the chain of communication, indicating the communication's origin, destination, route, time, date, size, duration, or type of underlying service.'

559 Proposal is based on the original text of Article 17 of the Cybercrime Convention: '(1) Each Party shall adopt, in respect of traffic data that is to be preserved under Article 16, such legislative and other measures as may be necessary to: a: ensure that such expeditious preservation of traffic data is available regardless of whether one or more service providers were involved in the transmission of that communication; and b: ensure the expeditious disclosure to the Party's competent authority, or a person designated by that authority, of a sufficient amount of traffic data to enable the Party to identify the service providers and the path through which the communication was transmitted.'

560 Proposed from the original text of Article 1(c) of the Cybercrime Convention: '"service provider" means: i. any public or private entity that provides to users of its service the ability to communicate by means of a computer system, and ii. any other entity that processes or stores computer data on behalf of such communication service or users of such service.'

561 Proposal based on the original text of Article 18(1) and (2) of the Cybercrime Convention: '(1) Each Party shall adopt such legislative and other measures as may be necessary to

provision of data of telemedicine services may mean ordering a person present on the territory of a particular State to provide certain data of telemedicine services that are in his possession or control and are stored in a telemedicine services' IT system or similar medium. Second, an order to communicate information relating to a subscriber to a telemedicine service may imply an order to the provider of a telemedicine service offered on the territory of a particular State to provide information relating to a subscriber to a telemedicine service which is in its possession or control. In addition, it is necessary to emphasise that, based on Article 18(3) of the Budapest Convention, information relating to a subscriber of telemedicine services can be interpreted as any information in the form of data from telemedicine services or in any other form, in the possession of a provider of telemedicine services and relating to users of telemedicine services, other than traffic or content data; this makes it possible to identify three essential data sets[562]. The first is the type of communication services used by the user, applied in connection with the technical solutions used and the period of the telemedicine service. The second is the user's identity, postal or geographical address, telephone or other access number, list of calls, and payment information available under the contract or arrangements for the telemedicine service. The third set is any other information related to the location of the communication equipment available under the contract or arrangements for the telemedicine service.

The fourth telemedicine evidentiary act that can be interpreted based on Article 19 of the Budapest Convention is the search and seizure of stored data from telemedicine services[563]. It can be understood as a search or access to the telemed-

empower its competent authorities to order: a. a person in its territory to submit specified computer data in that person's possession or control, which is stored in a computer system or a computer-data storage medium; and b. a service provider offering its services in the territory of the Party to submit subscriber information relating to such services in that service provider's possession or control. (2) The powers and procedures referred to in this article shall be subject to Articles 14 and 15.'

562 Proposal is based on the original text of Article 18(3) of the Cybercrime Convention: 'For the purpose of this article, the term "subscriber information" means any information contained in the form of computer data or any other form that is held by a service provider, relating to subscribers of its services other than traffic or content data and by which can be established: a. the type of communication service used, the technical provisions taken thereto and the period of service; b. the subscriber's identity, postal or geographic address, telephone and other access number, billing and payment information, available on the basis of the service agreement or arrangement; c. any other information on the site of the installation of communication equipment, available on the basis of the service agreement or arrangement.'

563 Proposal is based on the original text of Article 19 of the Cybercrime Convention: '(1) Each Party shall adopt such legislative and other measures as may be necessary to empower its competent authorities to search or similarly access: a. a computer system or part of it and computer data stored therein; and b. a computer-data storage medium in which computer data may be stored in its territory. (2) Each Party shall adopt such legislative and other measures as may be necessary to ensure that where its authorities search or similarly access a specific computer system or part of it, pursuant to paragraph 1.a, and have grounds

icine services' IT system or parts thereof, to the telemedicine services; data stored therein, and to the storage medium for the telemedicine services' data, which is located on the territory of a specific State. In addition, in certain cases, it is possible to immediately extend a search to another IT system or to a telemedicine services' IT system. However, a condition for such an action is that, when carrying out a search to a specific information system of telemedicine services or part thereof, a normatively prescribed ground exists. Based on Article 19 of the Budapest Convention, specifically paragraph 2, it may be concluded that such a basis is provided by the reasonable belief that the telemedicine service' data sought is stored in another IT system, and that this data can be lawfully accessed from or is accessible to the primary system. Meanwhile, the telemedicine evidentiary act of search and seizure of stored data from telemedicine services regarding the seizure of telemedicine services' data can be equated with the seizure or securing of data accessed on the basis of a search of stored data of telemedicine services through the execution of legally prescribed actions. Based on Article 19 (3) (a) to (d), it may be interpreted that both the seizure or securing of a telemedicine services' IT system or of a storage medium used for storing telemedicine services' data, making and retaining copies of telemedicine services' data, retaining the entirety of the relevant stored telemedicine services' data, and making the telemedicine services' data inaccessible or deleting it from the systems in question are feasible actions.

The fifth telemedical evidentiary act is the collection of real time data on the telemedicine service's traffic[564]. This telemedical evidentiary act may, on the basis

to believe that the data sought is stored in another computer system or part of it in its territory, and such data is lawfully accessible from or available to the initial system, the authorities shall be able to expeditiously extend the search or similar accessing to the other system. (3) Each Party shall adopt such legislative and other measures as may be necessary to empower its competent authorities to seize or similarly secure computer data accessed according to paragraphs 1 or 2. These measures shall include the power to: a. seize or similarly secure a computer system or part of it or a computer-data storage medium; b. make and retain a copy of those computer data; c. maintain the integrity of the relevant stored computer data; d render inaccessible or remove those computer data in the accessed computer system. (4) Each Party shall adopt such legislative and other measures as may be necessary to empower its competent authorities to order any person who has knowledge about the functioning of the computer system or measures applied to protect the computer data therein to provide, as is reasonable, the necessary information, to enable the undertaking of the measures referred to in paragraphs 1 and 2. (5) The powers and procedures referred to in this article shall be subject to Articles 14 and 15.'

564 Proposal is based on the original text of Article 20 of the Cybercrime Convention: '(1) Each Party shall adopt such legislative and other measures as may be necessary to empower its competent authorities to: a. collect or record through the application of technical means on the territory of that Party, and b. compel a service provider, within its existing technical capability: i. to collect or record through the application of technical means on the territory of that Party; or ii. to co-operate and assist the competent authorities in the collection or recording of, traffic data, in real-time, associated with specified communications in its territory transmitted by means of a computer system. (2) Where a Party, due to the established principles of its domestic legal system, cannot adopt the measures referred to in paragraph

of Article 20 of the Budapest Convention, be interpreted as, first, the real time collection or recording, by means of available technical means, of data on the traffic of telemedicine services relating to specific transmissions carried out by means of the telemedicine service's IT. It can also be understood as an opportunity to require a telemedicine service provider to cooperate with and assist the competent authorities or to collect or record, by means of the technical means available, in real time, data on the traffic of telemedicine services which are related to specific transmissions carried out by means of the IT means of telemedicine services.

The sixth and final telemedical evidentiary activity that can be Interpreted based on the Budapest Convention is the interception of data relating to the content of telemedicine services. This activity, which has its origin in Article 21 of the Budapest Convention, can mean the possibility, with regard to serious telemedicine cybercrimes[565], of collecting or recording real time data regarding the content of telemedicine services, using the available technology to determine specific transmissions carried out using the IT means[566]. In addition, in the framework of this telemedicine evidentiary action, there is also the possibility of requiring the telemedicine service provider to cooperate with and assist the competent authorities with collecting and recording data to the extent technically possible on the content

1.a, it may instead adopt legislative and other measures as may be necessary to ensure the real-time collection or recording of traffic data associated with specified communications transmitted in its territory, through the application of technical means on that territory. (3) Each Party shall adopt such legislative and other measures as may be necessary to oblige a service provider to keep confidential the fact of the execution of any power provided for in this article and any information relating to it. (4) The powers and procedures referred to in this article shall be subject to Articles 14 and 15.'

565 The Cybercrime Convention does not indicate how the term 'serious crimes' should be understood. However, according to the Explanatory Report to that Convention, serious crimes should be identified in national law either by name or by specifying the level of punishment that may be imposed for their commission.

566 Proposal based on the original text of Article 21 of the Cybercrime Convention: '(1) Each Party shall adopt such legislative and other measures as may be necessary, in relation to a range of serious offences to be determined by domestic law, to empower its competent authorities to: a. collect or record through the application of technical means on the territory of that Party, and; b. compel a service provider, within its existing technical capability: i. to collect or record through the application of technical means on the territory of that Party, or; or ii. to co-operate and assist the competent authorities in the collection or recording of content data, in real-time, of specified communications in its territory transmitted by means of a computer system. (2) Where a Party, due to the established principles of its domestic legal system, cannot adopt the measures referred to in paragraph 1.a, it may instead adopt legislative and other measures as may be necessary to ensure the real-time collection or recording of content data on specified communications in its territory through the application of technical means on that territory. (3) Each Party shall adopt such legislative and other measures as may be necessary to oblige a service provider to keep confidential the fact of the execution of any power provided for in this article and any information relating to it. (4) The powers and procedures referred to in this article shall be subject to Articles 14 and 15.'

of the telemedicine services of specific transmissions carried out using the service's IT. The Budapest Convention itself lacks a definition of the concept of content data. Nevertheless, appropriate interpretative guidance is provided in the Explanatory Report to the Convention on Cybercrime. On the basis of its paragraph 209, it can be determined that content data from telemedicine services can mean communication data, other than traffic data, which make it possible to see the content of transmitted messages to determine the meaning or purpose of the message itself or the information transmitted by it[567]. It may be concluded that, based on the concept of the Budapest Convention in the context of telemedicine cybercrimes and telemedicine evidence, there are two types of telemedicine service data that can be collected: traffic data and content data. It follows from the meaning of these two terms that their subject scopes are conjugated because, as noted, the normatively prescribed definition of telemedicine service traffic data determines the subject scope of telemedicine service content data. This is because content data include all collectible data that are not telemedicine service traffic data. In this respect, both terms simultaneously appear to contain the complete range of designations of collectible data within the meaning of the Budapest Convention.

The above-mentioned possible interpretations of telemedical evidentiary acts based on the current wording of the Budapest Convention constitute, as highlighted above, a second premise, in addition to the types of telemedical cybercrimes, for proposing the standardisation of telemedical systems for the prevention of telemedical cybercrime. However, it should be emphasised that the potential scope for abuse and the form and the severity of telemedical evidentiary activities should be significant. It is important to remember the possible negative consequences of using telemedical evidentiary measures, which are directly provided for by the Budapest Convention. First, Article 14 of the Budapest Convention defines the scope of application of the procedural rules and, on this basis, each State Party to this international agreement may avail itself of the possibility to make reservations[568] limiting the application of both the evidentiary act of real-time collection of traffic data and the interception of content data[569]. These evidentiary steps seem to provide a clear example where serious negative consequences of their use are possible.

567 Original text of paragraph 209 of the Explanatory Report to the Cybercrime Convention: 'The type of data that can be collected is of two types: traffic data and content data'. 'Traffic data' is defined in Article 1 d as any computer data relating to a communication that is made using a computer system, is generated by the computer system, and forms part of the chain of communication, indicating the communication's origin, destination, route, time, date, size and duration or the type of service. 'Content data' is not defined in the Convention but refers to the communication content of the communication, i.e., the meaning or purport of the communication, or the message or information being conveyed by the communication (other than traffic data).

568 See Staszków, 2004, pp. 129-138.

569 Article 14 of the Convention on Cybercrime states: '(1) Each Party shall adopt such legislative and other measures as may be necessary to establish the powers and procedures provided for in this section for the purpose of specific criminal investigations or proceedings.

Second, in the light of Article 15 of the Budapest Convention, it should be noted that each State or authority empowered therein, when establishing, implementing, and applying telemedical evidentiary operations interpreted based on the relevant provisions of the Convention on Cybercrime, is obligated to ensure that the conditions and guarantees provided by national law which should adequately protect human freedoms and rights are implemented, including specifically the rights under the Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950[570], the International Covenant on Civil and Political Rights of 19 December 1966[571], and other applicable international human rights instruments[572]. These conditions and guarantees should be based on the principle of proportionality and adapted to the specific case. For example, reference is made to judicial or other independent scrutiny, justification for the use of telemedical evidence, and restrictions on the scope and duration of its use. In addition, on the basis of Article 15 of the Budapest Convention, specifically paragraph 3, it should be emphasised that, insofar as it is in the public interest, particularly in the interest of justice, the state or a body empowered by it should consider the effect of the applicable evidence-gathering act on the rights, obligations, and legitimate interests of third parties.

Third, it is important to note that the layout and wording of the Budapest Convention as a whole unequivocally determines that it is an unenforceable

2. Except as specifically provided otherwise in Article 21, each Party shall apply the powers and procedures referred to in paragraph 1 of this article to: a. the criminal offences established in accordance with Articles 2 through 11 of this Convention;; b. other criminal offences committed by means of a computer system; and c. the collection of evidence in electronic form of a criminal offence. 3. a. Each Party may reserve the right to apply the measures referred to in Article 20 only to offences or categories of offences specified in the reservation, provided that the range of such offences or categories of offences is not more restricted than the range of offences to which it applies the measures referred to in Article 21. Each Party shall consider restricting such a reservation to enable the broadest application of the measure referred to in Article 20. b. Where a Party, due to limitations in its legislation in force at the time of the adoption of the present Convention, is not able to apply the measures referred to in Articles 20 and 21 to communications being transmitted within a computer system of a service provider, which system: i. is being operated for the benefit of a closed group of users, and ii. does not employ public communications networks and is not connected with another computer system, whether public or private that Party may reserve the right not to apply these measures to such communications. Each Party shall consider restricting such a reservation to enable the broadest application of the measures referred to in Articles 20 and 21.'

570 Convention for the Protection of Human Rights and Fundamental Freedoms drawn up in Rome on 4 November 1950, subsequently amended by Protocols Nos. 3, 5 and 8 and supplemented by Protocol No. 2 (Journal of Laws 1993, No. 61, item 284.).

571 International Covenant on Civil and Political Rights opened for signature in New York on 19 December 1966 (OJ 1977, No. 38, item 167.).

572 The scope depends on the catalogue of other international human rights instruments ratified by individual states. For example, from Poland's perspective, EU CFR can be given as an example.

international agreement. This means that the Convention on Cybercrime creates an obligation to bring national law into line with its provisions for countries that have chosen to ratify it. In other words, once the ratification procedure has taken place, the state is legally obligated to take the appropriate legislative action and implement the provisions of the Budapest Convention into its normative system. It is therefore relevant that the Convention on Cybercrime obliges State Parties to confer on the 'competent authorities'[573] the powers or competences to carry out the evidentiary acts specified therein. It follows that the evidentiary measures in question, including those related to telemedicine, should be carried out by competent state authorities with the legitimacy to do so. This is because the Budapest Convention, by using the term 'competent authorities', has not given free rein to the arbitrary determination of the authorities authorised to carry out evidentiary measures, but has respected the diversity represented by the legal systems of the Member States of the Council of Europe. This is clearly confirmed in paragraph 138 of the Explanatory Report to the Cybercrime Convention, according to which the use of the term 'competent authorities' was justified by the diversity in question[574].

However, it is also emphasised that the term refers to a judicial, administrative, or other law enforcement authority which is empowered under national law to take the procedural measures provided for in formal criminal law[575]. This unequivocally prejudges that the last guarantee provided for in the Budapest Convention limiting the possible negative consequences of the use of evidentiary measures is that the power to carry out these measures is reserved exclusively to the 'competent authorities' in the sense outlined above. Considered as a whole, the above analysis has demonstrated a response to the risk of committing, or to the commission of, a telemedicine cybercrime, as specific detection or evidentiary actions that may be taken in the context of the possibility of a telemedicine cybercrime have been established.

573 The original Cybercrime Convention uses the English term 'competent authorities'.

574 Paragraph 138 of the Explanatory Report to the Cybercrime Convention reads: 'All the articles in the Section refer to "competent authorities" and the powers they shall be granted for the purposes of specific criminal investigations or proceedings. In certain countries, only judges have the power to order or authorise the collection or production of evidence, while in other countries prosecutors or other law enforcement officers are entrusted with the same or similar powers. Therefore, "competent authority" refers to a judicial, administrative or other law enforcement authority that is empowered by domestic law to order, authorise or undertake the execution of procedural measures for the purpose of collection or production of evidence with respect to specific criminal investigations or proceedings.'

575 Ibid.

5.5 Proposal for standardising telemedicine systems

5.5.1 Proposal for standardising telemedicine services' information systems based on types of telemedicine cybercrime

When the types of telemedicine cybercrimes as interpreted based on the types of cybercrimes normatively provided for in the Budapest Convention are known, it becomes possible to realise the next step of the conducted analysis, i.e., to propose a standardisation of telemedicine services' IT systems so that they are built considering the developed catalogue of risks that may occur during the use of modern technologies in the form of telemedicine services used during the practice of practicing medicine. This aspect of standardisation is extremely important to prevent telemedicine cybercrime as it addresses the medical informatics professionals who are responsible for creating a properly programmed information system for telemedicine services that can adapt to the types of risks that arise directly from the types of telemedicine cybercrime. It would be sufficient to require the telemedicine service provider to obtain a certificate confirming that the telemedicine service IT system it uses meets the premise of resilience against the possibility of committing a telemedicine cybercrime. This prerequisite should be understood as effectively preventing or significant impeding known types of telemedicine cybercrimes from being committed. In turn, significantly impeding the possibility of committing a telemedicine cybercrime should mean the use of technologically available solutions, including those from medical informatics[576], that effectively prevent telemedicine cybercrime. This form of standardisation presupposes that the telemedicine services provider demonstrates the willingness to prevent or mitigate the potential risks as much as possible[577].

However, it should also be noted that the aspect of standardisation described at this point is based on a non-legal basis, and when carried out by a non-normatively designated entity, it may not be an effective measure. It is therefore necessary to create a normative basis for the standardisation of IT systems for telemedicine services that consider the known types of telemedicine cybercrimes. Reviewing the analysis already conducted on the certification of digital medicine solutions[578], it seems that the appropriate legal act where such a basis could be found is the Medical Device Regulation, more specifically Chapters V, VI, VII of the Medical Device Regulation, which could involve an amendment of Article 51 of this legal act. Such a legislative intervention would unify the process of qualifying digital medicine

576 See Chapter 1.2.6 Medical informatics.

577 However, it should be sufficient for the telemedicine provider to demonstrate that it has taken all reasonable and technologically up-to-date steps to limit the possibility of known telemedicine cybercrimes.

578 See Chapter 1.3 Certification of digital medicine solutions.

solutions as medical devices with the standardisation of information systems for telemedicine services based on types of telemedicine cybercrimes in a single action. It would also unify the entity authorised to assess and issue the relevant case decision. However, it should be noted that, in the current state of the law, it is debatable whether every telemedicine service IT system is a medical device as not every telemedicine service IT system is used for at least one medical purpose[579]. It therefore becomes important to consider the demands made *de lege ferenda* when considering the certification of digital medicine solutions. We are talking here about the inclusion of either a either full[580] or balanced[581] postulate. However, it should be stipulated that if a postulate with a balanced character is implemented, the standardisation itself, regardless of the character of the qualification of digital medical solutions, should be obligatory. Otherwise, the proposed solution would not fulfil its purpose due to inefficiency.

In summary, *de lege ferenda* a methodologically appropriate and, from the point of view of the coherence of the legal system, desirable solution would be an amendment to the Regulation on medical devices, where the possibility of qualifying digital medicine solutions as medical devices, provided for therein, among other things, could be enriched by an obligatory standardisation of IT systems of telemedicine services on the basis of criteria that consider the risks arising directly from specific types of telemedicine cybercrimes[582]. In this context, it should be specified that the sources of risk are: the possibility of committing a telemedicine cybercrime, such as illegal access to the telemedicine service IT system, illegal interception of telemedicine service data, violation of integrity for telemedicine service data or IT system, misuse of devices, telemedicine forgery, telemedicine fraud, violation of copyright and related rights in the context of the telemedicine service IT system, or other telemedicine cybercrime or cybercrime. It appears that the demands made

579 Recitals 16 and 17 of the Judgment of the Court of Justice of the European Union of 22 November 2012 in Case C-219/11….

580 According to a *de lege ferenda* postulate of a complete nature: 'as it would in fact be most effective *de lege ferenda* to have a mandatory system of certification as a medical device for any digital medicine solution, whether tangible or intangible, and irrespective of the premise of direct medical use'. See Chapter 1.3.3 Digital medicine solutions as medical devices.

581 According to a *de lege ferenda* postulate of a balanced nature: 'In this context, the *de lege ferenda* system of certification of digital medicine solutions in the form of their qualification as medical devices should be two-pronged. First, any digital medicine solution, whether directly used for one or more medical purposes, should be optionally admitted to the certification system as a medical device. Secondly, those digital medicine solutions that are used for one or more medical purposes should be mandatorily referred to this certification scheme.' See Chapter 1.3.3 Digital medicine solutions as medical devices.

582 The author's proposal based on the considerations is discussed in earlier sections of this chapter (see: Chapters 5.2 Theoretical characteristics of telemedicine cybercrime and 5.3 Types of telemedicine cybercrime) together with the referenced sources, where the following in particular were inspiring to the author: Clough, 2012, pp. 363-391.; Weber, 2003, pp. 425-446.; Csonka, 2000, pp. 329-330.; Carr and Williams, 2002, pp. 83-90.; Moise, 2017, pp. 28-38.

are comprehensive and take into account the requirement to preserve the coherence of the normative system. However, it is possible that its implementation would be impossible or significantly impeded, in particular by interfering with the content of the EU regulation. Mainly for this reason, the legislator should alternatively consider *de lege ferenda* the postulate that, within the framework of national law, a legal obligation to standardise information systems for telemedicine services, as already described above, may be necessary[583]. It should be further emphasised that, if the scope of the analysis is the Member States of the EU, there is a one-way relationship between the full and the alternative postulate. This is because, within this scope, implementing the full postulate also implements the alternative postulate due to the direct effect of EU law enacted in the form of a regulation[584]. The implementation of the alternative postulate, on the other hand, only affects the national law of the specific state and does not affect the legal order of EU.

The postulates indicated are examples of a solution, either complete or partial, to the problem of committing cybercrimes, including telemedicine cybercrimes, in the context of providing of telemedicine services. The essence of the suggested standardisation is the protection and strengthening of the certainty of telemedicine's implementation of the right to health from the perspective of cybercrime threats. Creating a legal obligation to ensure that all information systems for telemedicine services are programmed in accordance with legally stipulated criteria, which should mean that they have been prepared for known types of telemedicine cybercrime or cybercrime in general to an acceptable degree[585]. It is also important that, irrespective of how this standardisation is introduced, it should be mandatory and a prerequisite for allowing IT systems for telemedicine services to be used. In should also be remembered that cybercrime, including telemedicine, is constantly evolving. It is therefore necessary to constantly update the catalogue of possible risks in providing telemedicine services using IT systems, which directly derive from known types of cybercrimes, including telemedicine cybercrimes[586].

583 The alternative postulate was made on the same basis as the main postulate.

584 For example, see Wójtowicz, 2004, pp. 43-70.

585 The degree of preparedness required for a specific telemedicine service IT system to address the possible risks of committing known types of telemedicine cybercrimes should be based on objective and feasible criteria proposed by medical informatics specialists.

586 It is worth noting that the catalogue of known types of cybercrimes should not be equated exclusively with the types of cybercrimes provided for in the Convention on Cybercrime. The possibility of the systematic emergence of new types of cybercrimes, which will simultaneously pose new risks, should be considered as a natural consequence of the development of cybercrime.

5.5.2 Proposal for standardising telemedicine services' information systems based on telemedical evidentiary acts

The demand related to the standardisation of telemedicine services' IT systems based on telemedical evidentiary acts is of a different nature. It aims to require that an IT system used for telemedicine services can enable competent authorities to carry out evidentiary steps to detect and prove that a telemedicine or cybercrime has been committed. As the information system of telemedicine services enables telemedical evidentiary acts interpretable under the Budapest Convention to be carried out quickly and efficiently directly influences the public's awareness that acts deemed to be telemedicine cybercrimes will be effectively prosecuted and their perpetrators held legally accountable. It is therefore highly recommended that IT systems for telemedicine services that are put into public use provide, beginning in the design phase, features enabling telemedical evidentiary actions that can be taken to immediately safeguard stored data related to telemedicine services. Systems should also have features that efficient secure and partial disclose telemedicine service traffic data, enabling relevant data or information related to a subscriber easy to search and seize if necessary, as well as allowing for real-time data collection relating to telemedicine services traffic or data interception related to the content of telemedicine services. All of the aforementioned telemedicine evidentiary actions have their counterpart provided for by the Cybercrime Convention[587]. This observation is of momentous importance; the attitudes of this act are currently being implemented into public international law, and a legal obligation to standardise information systems *in genere* based on the types of evidentiary acts provided for in the Budapest Convention could and should have been introduced into national law. Such an action would have to be assessed as a desirable adaptation of the IT infrastructure to the new competences of the authorities assigned to perform evidentiary acts; simply equipping the relevant authorities with a spectrum of new powers, without interfering with the technological layer, may prove to be an insufficient measure[588].

An information system, and, as far as the subject matter is concerned, an information system for telemedicine services, must provide a platform for legally defined

587 The catalogue presented is not closed and may be supplemented by other and currently unforeseen evidentiary steps in the Convention on Cybercrime. Cybercriminals are constantly evolving, using new instruments and learning new ways to commit cybercrimes. This means that law enforcement or Convention competent authorities cannot remain passive and should also develop and improve their skills, including expanding the types of evidentiary acts that can be carried out. In this context, it is worth mentioning the adoption of the Second Additional Protocol to the Convention on Cybercrime on enhancing cooperation and disclosure of electronic evidence by the Committee of Ministers of the Council of Europe on 17 November 2021. See Convention on Cybercrime, 2021.

588 It could even be argued that equipping the competent authorities with the powers provided for in the Cybercrime Convention without giving them the actual possibility to act within an appropriate timeframe would have to be assessed as illusory.

evidence-gathering measures. In other words, if the authority competent for telemedicine evidence has a normatively justified basis for taking the action required by law, the telemedicine IT system and the provider of telemedicine services should, for example, use access keys to cooperate fully with authorities and enable them to swiftly, effectively, and efficiently obtain information or carry out other actions. Otherwise, the authority carrying out the telemedicine evidentiary act will be forced to act on its own, thereby significantly increasing the time required, which is important in terms of effectively detecting and proving a telemedicine cybercrime and attributing legal responsibility to the perpetrator. It appears that, the faster the competent authorities act, the more likely it is that the perpetrator will be efficiently detected and held legally liable, which in turn significantly increases the effectiveness of telemedicine cybercrime prevention as potential perpetrators will be aware that their act will be detected and proven, and they will be brought to justice.

For these reasons, if no obligation for the above-described standardisation of IT systems for telemedicine services has been stipulated in a specific legal system, it is proposed *de lege ferenda* to introduce a legal obligation that will standardise all IT systems with a view to possessing functionalities enabling the efficient, fast, and effective performance, on a normatively justified basis, of the evidentiary acts provided for in the Budapest Convention[589]. This request is of a general nature, and its scope covers not only IT systems for telemedicine services, but also all others. This is because its implementation, on the one hand, enhances the effectiveness of certain provisions of the Convention on Cybercrime and, on the other hand, further applies to information systems of telemedicine services. Accordingly, countries that have ratified the Budapest Convention should consider the possibility of implementing the reported demand into their normative order.

Alternatively, a combination of the previously postulated standardisation of IT systems for telemedical services based on types of telemedical cybercrimes with the currently postulated standardisation of telemedical services' IT systems, referring to types of telemedical evidentiary activities[590], could also be submitted for *de lege ferenda* consideration. In such a case, it would be necessary to standardise the proposed legislative solutions, either in the Medical Device Regulation or within the relevant national law standards. However, this demand is made in the second instance, as the first one seems to be a natural complement to a more effective implementation by states of their international obligations under the Budapest Convention. It must be emphasised that the choice of the means leading to the effect does not appear to be as important as the effect itself, which is the introduction of

589 The author's proposal is based on the considerations presented in earlier sections of this chapter (see Chapters 5.2 Theoretical characterisation of telemedicine cybercrime and 5.4. Telemedical evidence activities) combined with the sources referenced in those chapters. The follow articles were particularly inspiring: Clough, 2012, pp. 363-391.; Weber, 2003, pp. 425-446.; Csonka, 2000, pp. 329-330.; Carr and Williams, 2002, pp. 83-90.; Moise, 2017, pp. 28-38.

590 The alternative postulate was made on the same basis as the main postulate.

the legally required standardisation of information systems of telemedicine services based on the types of telemedical evidentiary activities. This standardisation, by preventing telemedicine cybercrime, will protect and strengthen the realisation of the object of the right to health by telemedicine services.

5.6 Summary

This chapter analyses the issue of telemedicine cybercrime as a threat to realising the right to health in telemedicine. The main objective of the chapter was to identify ways to respond to the phenomenon of telemedicine cybercrime. Importantly, it can encapsulate actions taken both before and after a telemedicine cybercrime is committed. The methodology of the argument contained in this section of the monograph is also important. It is based on the premise of logical reasoning, according to which telemedicine cybercrime constitutes a threat affecting the full or more complete realisation of the right to health in the form of telemedicine. This implies further conclusions. First, the specific types of telemedicine cybercrimes represent the types of possible threats when telemedicine is used as it is meant to, including the right to health. Second, the legally prescribed evidentiary steps of procedural criminal law that are possible in the context of a telemedicine cybercrime are either a reaction to the commission of a criminal act in cyberspace *post factum*, i.e., at the moment when said threats materialise, or they are actions aimed at detecting the fact that a telemedicine cybercrime has been committed. Third, appropriate standardisation of the software providing telemedicine services is a solution that can prevent the threat of committing telemedicine cybercrimes *ex ante,* i.e., it protects and strengthens the telemedicine's benefits in realising the right to health.

Given the above assumptions, an overview was given of the topics related to the theoretical characteristics of telemedicine cybercrime. The chapter began with a discourse related to the impact of telemedicine cybercrime on the realisation of the right to health. The thesis that telemedicine cybercrimes pose a real threat to the realisation of the right to health in use of modern telemedicine technologies in medical practice was argued. Next, the outline of a definition of the concept of cybercrime was presented. Various definitions of this phenomenon were presented, and a specific *de lege ferenda* postulate was put forward. According to this, the Polish legislator should consider introducing a legal definition of the concept of cybercrime in the form presented, and the international legislator should also consider introducing the definition in question in the Budapest Convention in the form presented, with amendments necessary given the nature of the international regulation.

These considerations provided the basis for further analysis related to determining the proper meaning of the term telemedicine cybercrime. As part of this discourse, it was pointed out that the term contains two broad sets of designators. It refers first to cybercrime and second to telemedicine services. After combining

the meanings of the aforementioned components into the term telemedicine cybercrime, a definition was proposed.

The above theoretical introduction to the issue under analysis, following the presentation of the method adopted, made it possible to identify specific types of telemedicine cybercrimes based on the relevant standards of the Budapest Convention. A basic catalogue of potential risks caused by the use of modern technologies during the practice of medicine in the form of telemedicine services were identified and named. A *de lege ferenda* postulate was also made on this occasion to provide information to the general public. This was followed by a similar analysis; after the method of this interpretation had been presented, telemedical evidentiary acts were interpreted based on the relevant provisions of the Budapest Convention. The aim of these considerations was to determine either the appropriate response to the commission of a telemedicine cybercrime or the appropriate means of detecting that it had been committed. The analytical effect of this chapter of the monograph was to indicate which detection or evidentiary actions should be taken if a telemedicine cybercrime was being or had been committed. As part of these remarks, a *de lege ferenda* postulate was also made to provide information to the general public. Following the above observations, based on the conclusions developed, a proposal for the standardisation of telemedicine systems was made that includes two main *de lege ferenda* postulates. The first concerns the standardisation of IT systems for telemedicine services on the basis of the types of telemedicine cybercrimes. The aim of this solution is to ensure that the IT systems available on the market to conduct telemedicine are developed in accordance with the mandatory legal requirements arising from the basic catalogue of risks possible when using modern technology for practical medical use in the form of telemedicine services. This should mean that these systems are prepared for known types of telemedicine cybercrimes or cybercrimes in general to an acceptable degree. Meanwhile, the second *de lege ferenda* postulate concerns the standardisation of IT systems for telemedicine services based on the types of telemedicine evidence activities. The aim of this is to require that the telemedicine service's IT system has the functionality to enable the competent authorities to carry out evidentiary steps to detect and prove that a telemedicine cybercrime has been committed. This should have a direct impact on the public's awareness that acts deemed to be telemedicine cybercrimes will be effectively prosecuted and their perpetrators held legally accountable. In the first and second cases, the essence of the standardisation advocated is the protection and strengthening of the certainty of the realisation by telemedicine of the subject of the right to health.

Overall, this chapter has met its objective of identifying solutions to address the phenomenon of telemedicine cybercrime. Implementing the suggestions made should lead to a more complete and certain realisation of the right to health in telemedicine.

Final issues

Summary of findings

The analysis of the right to health from the perspective of the cross-border provision of telemedicine services in the EU has clearly shown the potential of telemedicine solutions to strengthen the realisation of the right to health more fully, or at least to the present extent, from the chosen and presented research perspective. In this research monograph, the possibilities offered by applying telemedicine to protect, support and strengthen the realisation of the right to health were established. In addition, the question of the meaning, place, systematics, role, essence, goals, characteristics, specificity, and functions of telemedicine within the subject of the main research aim was answered, and the threats or problems associated with implementing the right to health through the use of telemedicine were determined. The research results showed that, at the current stage of civilizational, technical, technological, and legal development, telemedicine can be treated as a new and modern means of supporting the realization of the right to health in a fuller scope, or if certain difficulties occur, at least maintaining the current scope. This means that, not only has the main objective of this monograph been completed, its key scientific dilemma has also been clarified.

This would not have been possible without examining the individual subsidiary objectives of the study, which, while marking a logical path towards achieving the monograph's main objective, also provided valuable conclusions and insights. The realisation of each subsidiary objective constituted an important step toward verifying the methodological assumptions of the monograph. First, within the framework of the analysis of the subsidiary objectives, the terminology used in the context of using modern technologies during the practice of medicine was semantically defined or approximated, including the possibility of certifying digital medicine solutions and presenting the basic benefits and risks of telemedicine. Second, the scope and meanings of the right to health in the EU were indicated and the concept of the right to health *in genere* was presented. Third, the conditions, principles, and interpretation of the law in the context of the cross-border provision of healthcare services in the EU were analysed, and the results showed that telemedicine services could be qualified as services within the meaning of EU law. Fourth, a solution to the problems of realising the right to health and the operation

of cross-border healthcare in the EU during the COVID-19 pandemic was proposed, and finally, solutions were suggested to address the phenomenon whereby of telemedicine cybercrime posed a threat to realising the right to health in telemedicine. Completing these subsidiary objectives brought together the information needed to address the key research question of this monograph.

The insights contained in the study supported the thesis of monograph, that: 'telemedicine should be understood as a new and modern means of supporting the realisation of the right to health in a more complete or at least hitherto existing scope'. This thesis was supported by the analysis of three fundamental issues that were first described in detail and then thoroughly investigated through the monograph's framework. These issues were modern technologies put to practical use in medicine, the concept of the right to health, and the cross-border provision of healthcare services in the EU. Together, they formed a capacious conglomerate of information to complete a rich, diverse, and constructive scientific analysis.

Referring to basic concepts, problems, opinions of other researchers, and jurisprudence or various types of documents, including acts of so-called soft law, was required. It was necessary to both present the avant-garde possibilities, such as the characteristics of modern solutions put to practical use in medicine, and to analyse issues that were more traditionally legal in nature, such as the right to health or cross-border provision of healthcare services in the EU.

The remarks and assumptions made in the introduction to this work, including the definition of the main objective, the key dilemma of the scientific study, the subsidiary objectives, and the adopted scientific methods determined the structure of the monograph. Chapter One detailed with modern technologies in medicine, proposing a systematic of modern technologies as used in the practice of medicine, presenting possible ways to certify digital medicine solutions, interpreting the concept of telemedicine, and identifying its basic risks and benefits. Chapter Two addressed with the concept of the right to health in the EU, interpreted the subject matter of the right to health, drew valuable conclusions from the presented historical outline of the right to health in the original EU law, established manifestations of the right to health in the current EU law, and presented a picture of the right to health in telemedicine. Chapter Three examined the cross-border provision of healthcare services in the EU, took a closer look at the EU's internal market in light of the free movement of services, established the conditions for the free movement of healthcare services, presented patients' rights in cross-border healthcare, and proposed the role of telemedicine services in cross-border healthcare. Chapter Four considered the implementation of the right to health and the functioning of cross-border healthcare in the EU during the COVID-19 pandemic; the general characteristics of the pandemic were presented, legal changes dictated by the fight against COVID-19 were indicated, problems facing the right to health and cross-border healthcare in the reality of the COVID-19 pandemic were presented, and a proposal was offered regarding how the implementation and use of telemedicine could solve these problems. Chapter Five addressed telemedicine cybercrimes as a threat

to the implementation of the right to health in telemedicine. Within this issue, the theoretical characteristics of telemedicine cybercrime were approximated, types of telemedicine cybercrimes were proposed, telemedicine evidentiary actions were interpreted, and solutions were proposed to offset the negative phenomenon of telemedicine cybercrime by introducing standardisation of telemedicine systems.

The analysis carried out within the framework of the monograph showed that, while it is indisputable that part of science deals with the application of modern medical technologies for practical use, the concept of the right to health, or the cross-border provision of services in the EU, including healthcare services, there are few in-depth and well-considered reflections in the current body of research linking the aforementioned considerations and referring to the right to health from the perspective of the cross-border provision of telemedicine services in the EU.

Several final observations can be made against the background of the analysis conducted in this paper. First, while there are many terms in circulation to describe the phenomenon of applying modern technology in the practice of medicine, there is no unambiguous decision regarding the definitions of the terminology, such as digital medicine, eHealth, mHealth, telehealth, telemedicine, telecare, sensory health, or medical informatics. These terms are often used interchangeably and without reference to their actual scope. It is necessary to create, implement, and consistently use a system of terms referring to the practical application of modern medical technologies. This would bring order to the nomenclature and indicate the differences, similarities, and relationships between these terms and their actual subject scopes.

Second, the ongoing process of technical, technological and civilisational advances is strongly influencing the image of medicine today. Many healthcare services are being digitally enhanced to improve the quality, safety, efficiency, equity, universality, or speed of healthcare, which is causing widespread and eager implementation. However, the law should provide mechanisms to check these assumptions about modern medical technologies to ensure that the new technologies actually serve their declared purposes. Introducing legal regulations requiring mandatory certification of digital medicine solutions seems necessary.

Third, there is currently no universally accepted concept of telemedicine in the academic literature or in documents from governments, international organisations, or NGOs. Most authors propose their own definitions, which even leads to a specifically understood semantic chaos. An important and timely task in this area would be to create a single, well-considered definition of telemedicine based on the many available proposed definitions.

Fourth, when discussing new or modern technologies, including modern medical technologies, it is important to analyse not only the benefits that their implementation may bring, but also any problems or risks. Only an objective examination of both the positive and negative aspects provides a reasonable basis for a determination regarding whether the solution is actually useful.

Fifth, it is important to continuously enrich the concept of the right to health and its key elements, namely the rights to health protection and healthcare services; research is regularly deepening the understanding of these matters and can lead to new conclusions or different perspectives than what is currently present in the literature. It is important for the right to health to be considered a determinant of modern technologies in medicine, which both legitimises the implementation of such solutions and justifies the creation of a new legal framework.

Sixth, by referring to historical EU primary legislation, it is possible to find provisions that refer to the right to health either directly or indirectly. It is important to remember that EU law evolved from an early European integration that was initially purely economic to the current situation where political and social integration elements have been introduced. Through proper analysis, it can be seen how interest in human health issues developed in the EU and how the first legal regulations in this area were created and introduced. While the TEC, TECSC, and the Merger Treaty did not contain legal norms correlating with the right to health, the SEA contained such provisions and represented a significant re-framing of the idea of European integration by opening the possibility of social and political cooperation among EU Member States. The enactment of the SEA is therefore of major importance for the right to health in the EU, as it is a treaty that lays the foundations for a new, previously undefined area of EU activity, one which was made more specific by the Maastricht Treaty.

Seventh, in the current law of the EU, one can find legal norms that refer directly or indirectly to the subject matter of the right to health. In the provisions of primary law of the EU, EU CFR, TFEU, and TEU are crucial; in secondary law of the EU, the right to health is concretised. Some examples include the Directive on Patients' Rights in Cross-Border Healthcare, the Decision on Serious Cross-Border Health Threats, the Tobacco Products Directive, the Human Blood Directive, the Human Tissues and Cells Directive, the Medicinal Products Regulation, as well as the Medical Device Regulation; although these items take a different sectoral approach to the right to health in the EU, they do detail treaty provisions that contain general orientations, objectives, or principles related to the right to health. It is important to realise the significant level of the above provisions in the EU law system. This leads to the conclusion that the right to health, its concept, and its subject matter are now a priority element of current EU law. From the Maastricht Treaty through to the Treaty of Amsterdam, the Treaty of Nice, and the Treaty of Lisbon, one can observe an increasingly fuller, more complete, and more effective handling of the issues of both health protection and access to healthcare services, and thus, *in genere*, the right to health in the EU.

Eighth, the current changes dictated by the process of technical, technological, and civilisational advances not only force a discussion on the transformation of traditional medicine into a modern state, but also encourage conversation on the right to health in a non-traditional environment. In light of the main research aim of this paper, insights on the right to health in telemedicine are relevant. The analysis in

this work has determined that telemedicine can be regarded as a new guarantor of the right to health and a modern tool for realising the right to healthcare services. Telemedicine also supports a more complete realisation of equal access to health services. It seems reasonable to argue that there is theoretical legitimacy for the use of telemedicine as a subsidiary instrument to the traditional healthcare system, where the two systems could operate in parallel.

Ninth, the idea of an internal market of the EU should be taken as a kind of foundation for the cross-border provision of healthcare services in the EU because the treaty norms regarding the freedom of movement of services provide a source for analysis related to this topic. One of the most important legal norms in this respect is the legal definition of the EU service. What is important here is the observation that the drafting of the provision that contains the legal definition of a service in EU law unambiguously determines the material enumeration of the notion of service as contained in TFEU is merely exemplary and serves to adopt the correct line of interpretation. From this perspective, it is also important to determine the normative character of the Treaty norms regarding the freedom of movement of services. It should be noted that both Articles 56 TFEU and 57 TFEU meet the formal criteria for the attribution of direct effect, but this does not preclude the enactment of relevant secondary legislation.

Tenth, it is necessary to adopt a definition of healthcare services. This concept should probably be understood through the lens of correlating the EU definition of service and the term healthcare with the purpose of healthcare services. Normative regulation of this issue would seek to bring order to the free movement of healthcare services. It would also reinforce the observation that it becomes possible to qualify healthcare services as internal market services of EU. This conclusion appears to be true notwithstanding the possibility of introducing restrictions on the free movement of healthcare services. The principle that there are no restrictions under Article 56 TFEU, and that exceptions must be justified and are subject to careful analysis, become important in this light.

Eleventh, to preserve the entitlements under the internal market rules of the EU on the free movement of healthcare services, the EU legislator decided to adopt the DPRCH. This is a sign of sensitivity to the political will of the Member States of the EU found when adopting the Services Directive; it is also an expression of the realisation of the right to health in the EU cross-border situations. This can be seen as an alternative to make the freedom of movement of healthcare services more of a reality.

Twelfth, patients' rights in cross-border healthcare are key to a proper understanding and presentation of the principles and conditions for the movement of cross-border healthcare services in the EU. In this context, the observation that the standards of Articles 4, 5, and 6 of the DPRCH emphasise the indispensable role of the EU Member States in effectively guaranteeing cross-border healthcare in the EU is important, as it means that, without their proactive action and cooperation, achieving the objective of the DPRCH may be significantly hindered or even be

impossible. This leads to the further conclusion that the national law of the Member States of the EU assumes the position of the first and primary means to implement the provisions of the DPRCH. It is also important to note that, within the provisions of the DPRCH, the EU legislator chose to explicitly indicate that telemedicine may be one form of cross-border healthcare provided. On the basis of the relevant legal norms, it can be seen that, under EU law, the telemedicine mode of healthcare provision is considered equivalent with the traditional type, specifically in regards to the payment rules.

Thirteenth, there is currently no clear indication in the academic literature or relevant documents from governmental, international, or non-governmental organisations addressing how the concept of telemedicine services should be understood. Finding a well-considered, balanced, and meaningful definition for this term is necessary. This study's results suggest that telemedicine services should benefit from the EU's freedom of movement of services on the same basis as healthcare services. This observation is critical to final results of the study in this monograph.

Fourteenth, the rate of development and spread of SARS-CoV-2, the virus that causes COVID-19 has been and generally continues to be unprecedentedly rapid. Due to the high rate of contagiousness and the high risk of life-threatening symptoms for a large part of the population, at a certain point in the pandemic's timeline, the international priority became developing a vaccine for the SARS-CoV-2 virus or a drug that could treat COVID-19. This caused dramatic re-evaluation and redetermination of actions in modern states, international organisations, and individuals, including in legal terms. The COVID-19 pandemic caused specific problems for the realisation of the right to health and the function of cross-border healthcare. The difficulty in realising the right to health is the drastic overloading of the state health service, which caused inefficiencies in the healthcare system that made it impossible for the right to health to be realized fully, or even in the previously existing form. The issue at the root of this problem is the discrepancy between the increased number of patients needing medical care and the capacity of the health service in a particular state. In turn, the problem of the operation of cross-border healthcare during the COVID-19 pandemic is linked to the reduction or, in some cases, the paralysis of the traditionally understood mobility of the EU population that was directly linked to the realisation of the freedom of movement of persons within the internal EU market; this either significantly hindered or prevented the use of cross-border healthcare in the EU, either in full or in its previous form. The issue at the root of this problem is reconciling the need to ensure patient mobility with the necessary restrictions regarding physical crossing of traditionally understood national borders due to the COVID-19 pandemic state. Proper implementation and use of telemedicine solutions may provide a solution to these concerns during a pandemic situation.

Fifteenth, telemedicine cybercrimes represent a current and serious threat to the realisation of the right to health in telemedicine. It is therefore important to determine both the definition of the concept of telemedicine cybercrime and the

types of telemedicine cybercrimes and telemedicine evidentiary acts based on appropriate interpretative techniques. This is necessary because the specific types of telemedicine cybercrimes represent the types of possible risks when telemedicine functions as designed, including the right to health. Meanwhile, the legally foreseeable evidentiary steps of procedural criminal law that are possible in the context of a telemedicine cybercrime are either a reaction to the commission of a criminal act in cyberspace *post factum*, i.e., when the aforementioned risks materialise, or are actions aimed at detecting that a telemedicine cybercrime has been committed. In this context, it was proposed that appropriate standardisation of the software facilitating telemedicine services can prevent the risk of telemedicine cybercrimes *ex ante*, and is thus a solution that protects and strengthens telemedicine's realisation of the right to health, making it important in this context.

Conclusions for the future

The analysis of the right to health from the perspective of the cross-border provision of telemedicine services in the EU was carried out within the framework of this monograph, and the presented summary of findings makes it possible to present opportunities for future action that follow directly from the study's results. These may be of interest both to national and international legislators and to representatives of legal theory and practice.

First, it should be considered whether the concept of digital medicine should be equated with all manifestations of the application of modern technologies used in the practice of medicine along with the disciplines supporting its functioning. In this view, it may even be appropriate to determine that digital medicine is a mirror image of traditionally understood medicine with a necessary digital element. This proposal may provide material for the legislator, whose aim should be to introduce a legal definition of the concept of digital medicine, for example within the framework of Article 2 of the Medical Device Regulation.

Second, eHealth should be identified with the external layer of digital medicine, i.e., it would represent its services to stakeholders, both medical staff and patients. Therefore, within the concept of eHealth, there is the possibility of defining further, narrower subject terms, such as mHealth, telehealth, and sensory health. This proposal may provide material for the legislator, whose aim should be to introduce a legal definition of the concept of eHealth, for example, within the framework of Article 2 of the Medical Device Regulation.

Third, mHealth should be understood as a segment of eHealth, in which modern mobile technologies enable medical personnel to manage the improvement of a patient's health by using mobile tools, such as mobile phones, tablets, medical apps, or others. Defining the subject scope of mHealth allows a precise distinction from other terms used in the context of the application of modern technologies in medicine and an understanding that mHealth is part of the overall concept of eHealth.

This proposal may provide material for the legislator, whose aim should be to introduce a legal definition of the concept of mHealth. This could be done, for example, within the framework of Article 2 of the Medical Device Regulation.

Fourth, telehealth should be equated with the provision of medical services at a distance using telepresence techniques. This concept includes eHealth services that take place remotely with the direct participation of medical personnel in both real time and asynchronously. This proposal may provide material for the legislator, whose aim should be to introduce a legal definition of the concept of telehealth within, for example, the framework of Article 2 of the Medical Device Regulation.

Fifth, telemedicine should be understood as the part of telehealth responsible for the provision of medical services by doctors at a distance using telepresence techniques. This proposal may provide material for the legislator, whose aim should be to introduce a legal definition of the concept of telemedicine, for example, within the framework of Article 2 of the Medical Device Regulation. In addition, it would seem that the semantic proposals presented in this work about the concept of telemedicine, particularly those put forward by the WHO, EU, and the American Telemedicine Society, could support the attempt to adopt an essential and correct legal definition of telemedicine. The essence of telemedicine should be understood as the provision of medical services by doctors at a distance using telepresence techniques by transmitting medical data using ICT to improve the health of the patient. Defined in this way, the essence of telemedicine clarifies that this application of modern technology in medicine does not aim to dehumanise healthcare, but instead functions as a tool to help improve the accessibility, speed, equity, safety, quality, and cost reduction of medical services.

Sixth, the term telecare should refer to the provision of medical services by non-physicians using telepresence techniques. The difference between this term and telemedicine will therefore be based on the level of sophistication of the healthcare provided, determined by what type of medical personnel is involved. This proposal may provide material for the legislator, whose aim should be to introduce a legal definition of the term telecare, for example, within the framework of Article 2 of the Medical Device Regulation.

Seventh, sensory health should be treated as a separate segment of the overall eHealth concept as it is responsible for the wireless care of patients by means of medical sensors that enable the collection and transmission of medical data, regardless of the patient's mobility. It should be postulated that the criterion presented differentiates mHealth and sensor-based health in a sufficiently precise manner, indicating that they are essentially different. This proposal may provide material for the legislator, whose aim should be to introduce a legal definition of the concept of sensory health, for example, within the framework of Article 2 of the Medical Device Regulation.

Eighth, medical informatics should be understood as the use of advanced information and communication technologies and programming methods to create the technical infrastructure necessary to apply modern technologies to medical

practice. This proposal may provide material for the legislator, whose aim should be to introduce a legal definition of the concept of medical informatics, for example, within the framework of Article 2 of the Medical Device Regulation.

Ninth, a certification system for digital medicine solutions can be followed by their qualification as medical devices in the Medical Device Regulation. This certification system should be two-fold. First, any digital medicine solution, whether directly used for one or more medical purposes, should be optionally admitted to the certification system as medical devices. Second, those digital medicine solutions that are used for one or more medical purposes should be mandatorily referred to this certification scheme. However, it should be emphasised that this is a balanced option as, in essence, a mandatory certification system as a medical device would be most effective for any digital medicine solution, whether it be tangible or intangible and irrespective of the premise of direct medical use. This is important because the safety of patients, consumers, and medical staff is at stake; there are also a number of legal standards provided medical devices to digital medicine solutions.

Tenth, at least three basic building blocks of the concept of telemedicine are apparent. The first is the medical data that transmit an electronic medical record, which is a digital reproduction of traditional medical records with functionalities adapted to the current technical, technological, and social progress, via ICT. Second is the use of an ICT network by doctors for medical purposes. It is crucial to use an ICT network that is properly designed and accessible to all beneficiaries. This also implies the need to address the cross-border nature of telemedicine services. Third, and most importantly from an axiological point of view, the basic design element of telemedicine is the improvement of the patient's health, which should be identified with realising of this right to health protection and healthcare services, including medical care.

Eleventh, the criteria of universality, accessibility, and permanent substitutability can be considered adaptation criteria for telemedicine. The first is determined by the extent to which telemedicine is used, e.g., for the entire population, a group of inhabitants, or specific individuals. The second evaluates the actual ability and possibility of using the implemented solutions by the final beneficiaries. The criterion of permanent substitutability, on the other hand, assesses whether a traditional solution, if it exists, remains permanently and irrevocably replaced by a modern alternative. The combination of universality, accessibility and permanent substitutability gives rise to the identification of actual directives for the adaptation of telemedicine. From a theoretical point of view, these may lead to a situation in which it becomes impossible or significantly more difficult to fully implement telemedicine for practical use. For example, these criteria may imply that telemedicine can be implemented with different types of coverage:

- global (e.g. entire population) with full availability, together with permanent substitution,
- global (e.g. entire population) with limited availability and no permanent replacement,

- regional (e.g. community groups) with full accessibility, together with permanent substitution,
- regional (e.g. community groups) with limited availability but no permanent replacement,
- non-universal (e.g. selected and informed individuals) with limited availability, together with permanent substitution.

The main objective of these criteria is to prevent the deployment of telemedicine that is not adapted to the realities of the specific society for whom it is designed.

Twelfth, the rights to health protection and healthcare services, including medical care, are integral and key elements of the right to health as understood through the lens of the research analysed in this work.

Thirteenth, from a theoretical point of view, any modern technology put into practical use should be created, implemented, and used for and by human beings. The main goal of innovation should be to make everyday life easier, possibly followed by an increase in the efficiency of the results of the processes carried out. Different assumptions seem pointless. This implies, in turn, that modern technologies used in medical practice in the form of telemedicine services must comply with a number of standards in the field of human rights protection and, particularly and primarily, with those whose core is directly related to the essence of telemedicine, understood as correlating the universal priority of telemedicine with its proper terminological meaning. It seems indisputable that such rights are those relating to human health, and which should constitute an essential element of the test for legitimising the authorisation of a particular type of modern technology in medicine.

Fourteenth, the right to health, as understood within the semantic boundaries presented, should be classified as a personal right, constituting a material guarantee of health protection. The latter should at the same time be regarded as a kind of nucleus of the right to health. In addition, the right to health should oblige public authorities to take positive action guaranteeing the essence of the good to be protected by law, and thus it should be treated as a subjective right. However, this should include the proviso that the claims made will only fall within the subjective limits of the right to health as presented.

Fifteenth, the material scope of the concept of healthcare is much broader than that of medical care. This is because, in principle, the latter should be determined by actual medical need understood through the lens of clinical, hospital, or pharmacological services. Healthcare, on the other hand, also encompasses all non-clinical, non-hospital, or non-pharmacological health services that have a positive impact on the general state of health. The relationship between these concepts is governed by the unidirectional principle of the inclusion of medical care in healthcare, according to which every medical care service is also a healthcare service, but not every healthcare service is also a medical care service.

Sixteenth, the right to healthcare services does not meet the premise of the subjective premise of a personal right. For this reason, this right has a social normative character, which directly influences the definition of its essence. The essence, which should be founded on guaranteeing the realisation of the right to health in institutional terms, being a means of realising the main objective, i.e. the protection of health.

Seventeenth, the subject matter of the right to health as understood within the semantic boundaries set should be identified primarily with the correlation of the essence of the right to health and the right to healthcare services. The above is a fundamental component of the right to health. In addition, the thesis that the right to health protection is a substantive guarantee of the right to health and the right to healthcare services is more of an executive nature seems reasonable. First, this means that the right to health has its material aspect, where there is both the legally protected good of health taken in its own right, the abstractly understood possibility for individuals to care for their own health and the indirect protection of the right to life, and the unconditional subjective scope, according to which every human being, regardless of his or her qualities, should have such a right simply because he or she is a human being. The subjective aspect is of a personal normative nature and materialises in the form of the right to health protection, i.e., the material core of the right to health. Second, the right to health also has an executive aspect, in which both a legally protected good in the form of equal access to healthcare that effectively protects health and guarantees access to treatment regardless of the material situation of the beneficiary and a contingent subjective scope are evident. This means that the right in this respect *ex definitione* does not belong to every person just because he or she is a human being; additional conditions must be met. Consequently, this aspect has a social normative character, concretised in the form of the right to healthcare services, which constitutes an institutional guarantee that realising the material aspect of the right to health is one of the most essential means to realising the main objective, i.e. health protection. It therefore follows that the right to health defines the objective and the right to healthcare services is the principal means for its realisation. Consequently, it is not possible to speak fully of the right to health without discussing both of its aspects, material and executive.

Eighteenth, the function of telemedicine in the right to health protection should be seen through the lens of materially guaranteeing a normatively defined personal right of every human being, ensuring the possibility of independently caring for health in a substantive aspect, and having a duly defined legally protected good and subjective scope, thanks to the provision of medical services by doctors at a distance using telepresence techniques by means of the transmission of medical data using ICT to improve the health of the patient. Telemedicine is therefore fully predisposed to act as a new guarantor of the substantive nucleus of the right to health, i.e., to act as a guarantor of the right to health. The EU is not the only

place this can occur, although this paper does establish that the EU has available elaborate legal bases referring to the right to health.

Nineteenth, the function of telemedicine in the right to healthcare services should be seen through the lens of the executive realisation of a normatively envisaged human social entitlement, ensuring equal enjoyment of universally available healthcare services and having a duly defined legally protected good and subjective scope. This is available because of doctors providing medical services at a distance using telepresence techniques and ICT to transmit medical data and improve the patient's health. Telemedicine, therefore, seems to have the appropriate qualities to act as a new institutional guarantor for the realisation of the material aspect of the right to health, constituting the most relevant means for the realisation of the main objective, i.e., health protection. This therefore leads to the conclusion that telemedicine should be viewed at the operational level as a modern tool for realising the right to healthcare services. In addition, the functions of telemedicine in the right to health as they are defined in this paper, i.e., in the context of both the right to health protection and the right healthcare services, may lead to the conclusion that access to telemedicine, just as access to healthcare services, should be regarded as a human right and, specifically, a patient right. Such a conclusion should lead to the recognition of access to telemedicine as a human right both internationally (e.g., amendment of Article 3 of the Convention on Human Rights and Biomedicine) and domestically (e.g., amendment of the Act of 6 November 2008 on Patient Rights and Patient Ombudsman).

Twenty-first, apply modern technology to the practice of medicine in the form of telemedicine can lead not only to increased speed, safety, quality, or reduced costs, but also to improved equity in access to health services. However, for this to be possible, it proves necessary to ensure that barriers caused by the distance between patient and provider can be freely overcome. A factor supporting the achievement of the outlined objective is the guarantee of a well-defined, cross-border nature of healthcare services, and thus also of telemedicine services. Telemedicine, with its cross-border characteristics, is seen as an even more powerful instrument for increasing equality of access to health services *in genre,* where distance and travel time will become globally irrelevant.

Twenty-second, the concept of service as contained in TFEU is merely illustrative and serves to adopt the correct line of interpretation. Therefore, considerations regarding the classification of other activities as services under EU law are open to analysis. According to case law CJEU, both Articles 56 TFEU and 57 TFEU fulfil the formal criteria for the attribution of direct effect and can therefore form the legal basis of parties to proceedings before the courts of Member States of the EU. This further reinforces the interest in analysing the classification of activities other than those listed in Article 57 TFEU as EU services benefiting from the freedom of movement of services in the EU.

Twenty-third, healthcare services should be understood as provisions that are related to a factual medical need, particularly clinical, hospital, or pharmacological

services; complemented by any non-clinical or non-hospital or non-pharmacological health service that has a positive impact on the general state of health; implements the material and legal aspect of the right to health; and is normally provided for remuneration insofar as it is not covered by the provisions on the free movement of goods, capital, and persons. The proposed semantic meaning of the concept of healthcare service has the advantage of both indicating as precisely as possible its material boundaries and being characterised by its open character; it does not omit any essential service profile while referring to the right to health.

Twenty-fourth, any healthcare service, irrespective of conditions beyond its usual provision for remuneration, should be treated as a service within the meaning of Articles 56 and 57 TFEU with the fullest possible recognition of professional qualifications and respect for patients' rights in cross-border healthcare.

Twenty-fifth, the adoption of the directive on patients' rights in cross-border healthcare has to be seen as an alternative to make the free movement of healthcare services more feasible. This is necessary because the reason for the definition of patients' rights in cross-border healthcare was both the normatively defined exclusion of healthcare services from the scope of application of the Services Directive and the jurisprudence of the CJEU in the context of Articles 56 and 57 TFEU, which developed single rules for cross-border healthcare. These considerations, in view of the need for the EU to ensure that the principles of freedom of movement of services within the EU internal market are fully realised, and that the right to health, i.e., the rights to health protection and healthcare services, is effectively guaranteed throughout the EU, led to the issuance of the Directive on patients' rights in cross-border healthcare.

Twenty-sixth, the national law of the Member States of the EU plays a primary role in the realisation of the right to health for every EU citizen, in particular in the light of Article 168 TFEU. In addition, the norms of Articles 4, 5, and 6 of the DPRCH unequivocally emphasise the indispensable role of the Member States of the EU in effectively guaranteeing cross-border healthcare in the EU. This means that, without their proactive action and cooperation, the achievement of the DPRCH objective may be either impossible or significantly hampered. It is therefore clear that the national law of the Member States of the EU plays a key role in cross-border healthcare, assuming the position of the main and first means to implement the provisions of the DPRCH. This leads to the conclusion that the legislation of the Member States of the EU is the determinant premise for the actual possibility for patients to exercise their rights in cross-border healthcare in the EU.

Twenty-seventh, both the Commission Implementing Decision on the eHealth Network and the Commission Implementing Decision on COVID-19 Data Exchange and Alerting, a number of acts issued in the framework of the e-Health Network, as well as the very establishment of such a network in accordance with the empowerment provided for in the DPRCH, clearly show that e-Health services, including telemedicine services, are gaining recognition as priorities for action by policy makers of the EU. In addition, in light of Article 7(7) of the DPRCH, it can be concluded that

the EU legislator considers telemedicine to be a mode of healthcare delivery that is equivalent to the traditional prototype.

Twenty-eighth, the concept of a telemedicine service should be identified as a service provided by a medical practitioner in relation to a genuine medical need, having a positive effect on the general state of health, exercising a material and executive aspect of the right to health, and provided at a distance using telepresence techniques, usually for remuneration insofar as it is not covered by the provisions on free movement of goods, capital, and persons. In the light of the above, the modern legislator should consider introducing into its normative system a legal definition of telemedicine services with content that is identical or as close as possible to the proposal made. Telemedicine services in the sense presented should be qualified as services benefiting from the freedom of movement of services within the internal market of the EU.

Twenty-ninth, the implementation and use of telemedicine provides a solution to the problems outlined in this work for realising the right to health and the operation of cross-border healthcare during a state of pandemic. First, the use and implementation of telemedicine instruments solves the problem of drastic overloading of the national health service by the pandemic, which has caused severe inefficiencies in the health system that make it impossible in practice to realise the right to health in its full or current form. Based on the above-mentioned features and the specificity of telemedicine, it is better able to reconcile the increased number of patients with the current capacities of the health service of a particular state than its traditional counterpart. The implementation and use of telemedicine solutions is advocated as those which, in times of pandemics, regardless of the impediments to movement, ensure that the efficiency of the healthcare system is maintained by increasing the efficiency of doctors, offering a fuller realisation of the right to health protection and stable and effective realisation of the right to healthcare services. Telemedicine provides a means by which a single unit of medical staff is able to attend to the health of a larger number of patients in real time or asynchronously. Second, telemedicine should be seen as a proposal that both supports and complements the solution presented in the Communication from the Commission Guidelines on EU Emergency Assistance on Cross-Border Cooperation in Healthcare related to the COVID-19 crisis. Due to the specificity of its concept, telemedicine should be seen as a direct remedy for patients seeking cross-border healthcare in the EU whose cases are classified as not urgent according to the provisions of the Communication from the Commission Guidelines on EU Emergency Assistance on Cross-Border Cooperation in Healthcare related to the COVID-19 crisis. A remedy to ensure digital mobility, irrespective of restrictions on movement, including crossing traditional national borders, will enable cross-border healthcare in the EU to be used in its full or existing form. There will thus be a reconciliation of the need to ensure the mobility of patients whose healthcare needs are not urgent with the restrictions that may occur when physically crossing traditionally understood national borders during an pandemic state. Regarding patients with urgent healthcare needs, telemedicine can support the solution

set out in the Communication from the Commission Guidelines on EU Emergency Assistance on Cross-Border Cooperation in Healthcare related to the COVID-19 crisis as far as technological possibilities allow, including using highly advanced forms of telepresence. For example, teleoperation may be possible using specialised robotics. It therefore appears that the correlation of telemedicine with the solution proposed by the European Commission provides a more complete answer to the defined problem of the functioning of cross-border healthcare during the COVID-19 pandemic state. It is therefore currently justified to see solutions based on modern technologies put into practice as a practical role for telemedicine as a means of combating the negative effects of the COVID-19 pandemic in the context of realising the right to health and the functioning of cross-border healthcare.

Thirtieth, the term telemedicine cybercrime should be understood as behaviour with the characteristics set out in the criminal law, including international agreements, that is committed in the space of information processing and exchange created by a set of cooperating IT devices and software ensuring the processing, storage, and the sending and receiving of data. The crime occurs telecommunication networks by means of a telecommunication device that is appropriate for the type of network and is designed to connect directly or indirectly to the network terminations, including the links between them and the relationship with users. The object of this communication is the provision of services by a medical practitioner which are related to a genuine medical need, which have a positive effect on the general state of health, which implement the material and executive aspects of the right to health, and which are provided at a distance using telepresence techniques usually for remuneration in so far as they are not covered by the provisions on the free movement of goods, capital and persons. This suggests that the vast majority of the normatively envisaged types of cybercrimes, when telemedicine services are added as their object of infringement, have a telemedical counterpart.

Thirty-first, proposing appropriate standardisation of the software providing telemedicine services can reduce the risk of telemedicine cybercrimes. First, a methodologically appropriate and, from the point of view of the coherence of the legal system, desirable solution would be an amendment to the Medical Device Regulation. The possibility of qualifying digital medical solutions as medical devices could be enriched by a mandatory standardisation of information systems for telemedicine services based on criteria that consider the risks that arise directly from specific types of telemedicine cybercrimes. These risks include the possibility of committing several types of telemedicine cybercrime, including illegal access to the telemedicine service IT system or interception of telemedicine service data, violation of telemedicine service data or system integrity, misuse of devices, telemedicine forgery or fraud, or the violation of copyright and related rights in the context of the telemedicine service's IT system or other cybercrime, either related to telemedicine or general. Alternatively, the legislator should consider that, within the framework of national law, there may be a legal obligation to standardise telemedicine service information systems on the basis of criteria that consider the

risks arising directly from specific types of telemedicine cybercrimes. The essence of the standardisation postulated is the protection and strengthening of the certainty of telemedicine's implementation of the right to health from the perspective of the threat of cybercrime. There can be a legal obligation to ensure that all telemedicine services IT systems are developed in accordance with legally prescribed criteria, which should mean that they are prepared to deal with known types of telemedicine cybercrime or cybercrime in general to an acceptable degree. It is also important that, irrespective of the way in which this standardisation is introduced, it should be mandatory and be a prerequisite for the acceptance of IT systems for telemedicine services. In addition, it should also be remembered that cybercrime, including telemedicine cybercrime, is constantly evolving. It is necessary to continuously update the catalogue of possible risks for the provision of telemedicine services using IT systems that are directly derived from the known types of cybercrimes. Second, it is proposed that a legal obligation be introduced to standardise all information systems with the goal of having functionalities that enable the efficient, rapid, and effective performance, on a normatively justified basis, of the evidentiary acts provided for in the Budapest Convention. Alternatively, the standardisation of information systems for telemedicine services on the basis of the types of telemedicine-related crimes, as postulated earlier, and the standardisation of information systems for telemedicine services on the basis of the types of telemedicine evidentiary acts, as currently postulated, could be combined in a single measure. In this case, it would be necessary to standardise the proposed legislative solutions either in the Medical Device Regulation or within the relevant national law standards. However, this is a second demand, as the first one seems to be a natural complement to a more effective implementation by states of their international obligations under the Budapest Convention. It should be emphasised that the choice of the means leading to the effect is not as important as the effect itself, which is the introduction of the legally required standardisation of the information systems of telemedicine services on the basis of the types of telemedical evidentiary activities. This standardisation can prevent telemedicine cybercrime, allowing it to protect and strengthen the realisation of the right to health by telemedicine services. The implementation of the demands made above should lead to a more complete and secure realisation of the right to health in telemedicine.

In conclusion, telemedicine can play an important role from the perspective of the right to health. The considerations, observations, and conclusions contained in this paper make it clear that telemedicine should be understood as a new and modern means of supporting the realisation of the right to health in a more complete manner or, in the case of certain difficulties, at least maintaining the existing scope. The implementation of telemedicine solutions brings with it a number of possible benefits, problems, or risks. The role of a wise legislator is to balance these and make informed decisions. It seems that his only decision is whether the problems and risks of telemedicine will be properly exploited.

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