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Health policy in the European Union

Abstract: The purpose of this article is to present the problem of medical law in European terms. This article discusses the topic of European Union health policy. The history of EU integration in terms of the law governing medical standards will be traced. Specific provisions of the treaties and the most important directives will be discussed as well as landmark cases decided by the CJEU. Another element of the article is a summary of the community's activities in terms of EU funding for health programmes through the European Health Plans. The change in funding and the emphasis on different is gradually transforming the way EU health policy is viewed. The article explains how the EU's solutions work and the phenomena occurring within it, and this translates into understanding and being able to create future solutions that are better for Europeans.

Key words: European Union, health policy, TFUE

Introduction

This article focuses on the analysis of the common health policy in the European Union. The aim is to illustrate the problem of European Union health policy on the basis of Article 168 TFEU. The author uses data analysis as well as legal analysis. Data analysis is utilized to explore prevailing trends, potential threats, and challenges in the context of public health within the EU. Legal analysis is employed to delve into the legal foundations of EU health policy, the division of competencies, and the role of the EU in supporting member states. These methodological approaches enable a comprehensive exploration of the subject, shedding light on the challenges and importance of regulating health policy in the European Union.

Basic concepts as well as systems of action and cooperation in EU are extensively discussed. This topic is relevant and crucial because, due to the high mobility of Europeans and the many freedoms provided by the

European Union, cross-border medical care should be regulated by law. The EU health strategy, as well as its predecessors, aims to promote the protection and improvement of the health of EU citizens and influence its improvement. UE should support the modernization of health infrastructure and improve preparedness and response measures to cross-border health threats (Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021). Its constant and growing proportion is of importance and has an impact on every Europe citizen, whether it be emergency care or specialised treatment.

The paper addresses the following research questions: why is it important to regulate health care law and to what extent action has already been taken on the EU level? Why should steps be taken to harmonise regulations, procedures and thus standardise the services provided? Why is cross-border healthcare so important in the context of international relations?

This paper is theoretical in nature, after an introductory and explanatory section, the author examines prevailing trends and possible threats and challenges for the future of Europe in the context of public health. The author presents definitions of frequently used terms and plans and policies of the European Union in the public health sector. In the following sections, the author analyses the legal basis of common health policy, mechanisms of shared competencies and financing of European health programs, which are the key factors in the topic.

Definitions

In order to have a good understanding of the issue under consideration, it is useful to understand definitions of the basic concepts. Public health, according to Ed Acheson, is “the science and art of preventing disease, prolonging life, and promoting health through organised social efforts” (Nutbeam, 1986, p. 113). Public health is a part of the domain of European social policies. It is an integral part of the Treaty on the Functioning of the European Union (TFUE, Art. 168). The guarantees, which are also pillars of the European Union, provide for the free movement of goods, services, persons and capital and apply to many spheres of life, including medical care, health protection and access to medical treatment.

Equally important in this context is the health system. Each Member State is fully responsible for the construction and functioning of its

national health system. The health system consists of the following elements:

- health care – medical activities and therapeutic medicine;
- health care – the set of public health activities carried out by different sectors of socio-economic life;
- health care and health care governance structures;
- sources and routes of financing overall health activities (Miller, Opol-ski, 2009, p. 282).

It can be deduced the concept of a health system is quite broad and includes not only strictly medical activities but also organisational and financial matters. In the case of public health, it focuses primarily on the aspect of health care, its quality, accessibility and health protection through, vaccination systems or preventive examinations and access to medicines.

When defining the scope of terms, it is worthwhile to look at the question of who the public health system is supposed to concern. According to the Treaty on the Functioning of the European Union, two significant concepts can be noted. One is the citizenship of the European Union, which is defined in Part II of the Treaty on the Functioning of the European Union (TFEU) as citizenship additional to the primary nationality – that of a Member State (TFUE, art. 9). Under the same treaty, citizens of the European Union are guaranteed freedom of movement. This has a significant impact on how EU citizens are perceived by the health care system in individual member states.

Medical care and the whole section of health-related policies are more broadly defined as one of the sections that make up social policies.¹ From the beginning of the creation of the first forms of cooperation in Europe after World War II, Europeans have been aware of the need to regulate social provisions for those who will actively take advantage of the newly created opportunities, such as freedom of movement.

These are: safeguarding citizens against life's risks and their consequences, in which we can distinguish the issue of social security – the core of social policy; improving the material situation of citizens, i.e. levelling out “drastic differences” through redistributive action, regulated by both social law (social security contributions) and tax law (scale and

¹ Social policies include: population and family policies, employment promotion and rehabilitation of disabled persons policies, wage and income formation policies of the population, labour protection policies, social work formation policies, housing policies, health protection policies, environmental protection policies and social security policies.

thresholds of taxation, the system of allowances, etc.); levelling out the life chances of socially and economically vulnerable groups – undertaking activation measures to prevent, for example, the occurrence of social risks.

The legislator knows and at the same time, points out the immense value of access to health care.² When considering the problem of cross-border and civilisational diseases, as well as the similar structure of the societies of the Member States, the question has to be answered to what extent countries are willing and able to cooperate. The European Union, as an international organisation under Article 47 TEU, should not exceed its competence in relation to the conduct of Member States' health policy.

The level of variation in healthcare across Europe is high. Similarly, there is much differentiation in the level of opinion about its quality among citizens in the Member States. Initially, the desire to develop a common health care policy in Europe had to and still has to do with levelling out the differences between the quality of the services offered and their sheer scope.

Interpretation of Article 168 TFUE

Titles X and XI touch directly on social policy issues. In detail, the desire to maintain a high level of employment, guarantees of social assistance, combating social exclusion, guarantees of a high level of education and health protection. The complementary elements of these titles are directives on more specific issues, for example, Directive 2011/24/EU, Directive 2019/1152 and Directive 2000/78/WE.

Title XIV is entirely devoted to public health. Article 168 sets out the way forward in understanding health policy as a separate policy within the European Union. This implies a division of competencies between the European Union and the Member States. In the field of health, the EU does not have legislative authority and cannot influence the exercise of these competencies by the member states other than by supporting, coordinating or supplementing their actions (TFUE). The exercise of such

² Referring to the rhetoric of the dictators of the twentieth century, it can be noted that they very often accused their opponents of spreading disease, lack of hygiene or source of the plague. This closed a vicious circle, as people were isolated, for example in ghettos, deprived of access to proper nutrition, hygiene or access to doctor became ill more and more often, which only confirmed the words of the totalitarian leaders.

competencies will therefore consist, on the one hand, in adopting recommendations, opinions, resolutions, conclusions, communications, and, on the other hand, of financing the actions of member states. The exclusive competence of states is the organization of the health system. In contrast, the provisions formulated in TFEU Article 168 concern quality and safety standards (Wrześniewska-Wal, 2016). In practice, it boils down to a division between health programmes carried out within national borders by individual members and super-national programmes coordinated by the EU (Witkowska, 2015).

The EU4Health programme runs during the same years as national health programmes in various member states. Undoubtedly, some of the objectives are not only similar but perhaps even identical, which might be mutually beneficial. A closer look into Poland (2021–2025) and EU (2021–2027) health programs indicate that they are converging in several areas. Within this scope is the afford to disease prevention, health promotion and increasing the availability of medical services (Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021; Rozporządzenie Rady Ministrów z dnia 30 marca 2021 r.).

Harmonization of cooperation between the Member States of the European Union can contribute to better, more effective action on health care and the delivery of top-quality medical care. The European Union cannot prescribe action on the Member States, just as it has no legislative authority in this area. However, health policy is not important only in the strict sense. People's health is influenced by many internal and external factors, which leads to other policies (e.g. the economy, energy, agriculture or the environment) being introduced with a view to maintain and improve Europeans' health and quality of life.

The very history of common health policy in post-war Europe begins with the signing of the first major treaty, the European Coal and Steel Community. With the further integration of the states of Europe (Treaties of Rome, 1957), the understanding of public health concerns widens. The 1957 treaties mention the free movement of persons and thus also of medical professionals. At this moment, article 36 of that treaty in part regulates sanitary provisions, equally important in the context of health protection. The Treaty establishing the European Atomic Energy Community (EAEC), more commonly associated with the acronym EURATOM, presumably devotes considerably more space to health and safety issues.

Successive agreements, creating the European Economic Community and later the Single European Act, to eventually create the European Un-

ion always devote a place in the treaty provisions to the protection of citizens' health. The SEA document was supposed to reform the previous appearance of the European Community. In addition, preparations were being made for the inclusion of Spain and Portugal.³ The provisions of the SEA set a new – high – level of health protection for Europe, in the sense of not only providing access to modern care but also in the broader context of nature protection, which has a direct bearing on the health of citizens (Bik, 2000, p. 217–223).

In the Maastricht Treaty, a direct substitute for the SEA, one can read in Article 129 that healthcare requirements will be an integral part of Community policy (TUE). One can conclude from this that health policy should be taken into account in the development of other policies. The change in approach evident in the 1997 Treaty of Amsterdam was a breakthrough (Treaty of Amsterdam, 1997). From being preventive and looking rather passively at the actions of individual states, the Community decided to move towards action, in terms of an understanding, closer to the World Health Organisation. Care was taken with food safety (a sectoral approach to the problem), and the perspective changed to seeing the issue as an important element of integration.

Article 168 of the TFEU itself largely replicates the content of Article 152 of the Amsterdam Treaty. Public health and health policy have always been an exclusive competence of states, Article 168 is therefore a signpost of the EU for member states. It sets out the main orientations and actions, coordinates and encourages Community action to implement the Treaty provisions through continuous action adapted to current needs and improving the quality of life, especially in the sense of helping the poorest.

The Treaty on the Functioning of the European Union is one of the most important documents for the entire organization (Paziewska, 2018, p. 135). As it encompasses in its content all the most important areas of cooperation between the associated states, among others, the internal market, the movement of persons, services and capital, economic and monetary policy and health policy, it provides the basis for understanding EU health policy. Aiming at deep integration between the states of the European Union, it emphasises the importance of the health security of its citizens.

³ Spain and Portugal have become the so-called “twelve” since 1986. The term refers to the first twelve founding states of the European Union. The symbolism of the number can be seen, for example, in the twelve stars on the Community flag.

Treaty provisions presuppose the removal of sources of physical and mental health hazards (TFUE, art. 168). Unlike previous treaties, this one also assumes monitoring of cross-border threats and a warning system combined with joint combating of the causes. The European Union's specialist agenda is the European Centre for Disease Prevention and Control (ECDC). Established in 2005, its task is to coordinate activities leading to the prevention of the spread of communicable diseases.⁴ The ECDC implements its pre-accession programme to prepare the country for a smooth transition when it joins the community. In addition, focal points are designated for coordinated information and cooperation development.⁵ The ECDC cooperates with countries participating in the European Neighbourhood Policy. The aim is to develop technological cooperation, but also to bring the standards of the countries concerned closer to the EU level and to seek harmonisation in legislation (ECDC, 2023).

European Union often concludes bilateral agreements between countries that are not in the organisation. This is partly a policy pursued through the implementation of the partnership policy, but surprisingly, the EU does not have such agreements with, for example, Ukraine or Belarus (Godła-Sobczak, 2020, p. 130). Instead, it has concluded them with Russia and such states from the post-Soviet sphere of influence as Azerbaijan, Armenia, Georgia, Kazakhstan, Kyrgyzstan, Moldova and Tajikistan. Four of these (Armenia, Azerbaijan, Georgia and Moldova) are covered by the ENP and the Partnership and Cooperation Agreements (Ibidem.). Also term “medical diplomacy” is a rather uncommon and sometimes unknown even to international relations specialists. It is a tool used to perfection by the Republic of Cuba, but also on a smaller scale within the EU (Feinsilver, 2010, p. 85–104).

European health programmes

The European Health Programme known as the European Union Health Programme (EU HP) has had three iterations to date (European Union Health Programme 2003–2007; 2008–2013; 2014–2020) and the third

⁴ The ECDC/OECD's new 2021–2027 action plan aims to improve the quality of health and life in Europe, but also globally, through better public information, health awareness, support for the organisation's activities and international cooperation.

⁵ It is up to the Member States to decide how many such points to set up and where to place them.

one is ongoing. There is no doubt that much has changed over these seventeen years, not only in medicine itself but also in the approach to health-related expenditure planning.

The 2003–2007 programme was the first document of its kind created after the signing of the Treaty of Nice. It was accused of a lack of logic and efficiency following a 2008 evaluation by the European Court of Auditors. Attention was drawn to the way finances were distributed. Eastern European countries with much smaller medical units and with relatively low financial resources were excluded from participating in the programme.

The three main points of the first EU HP were to promote EU citizens' knowledge of public health developments, to increase the capacity of EU countries to respond rapidly and corroded to health threats, and to promote health and prevent disease through the integration of health determinants into all EU policies and activities.

This time too, weaknesses were found in the programme, although overall it was positively received (Ex-post evaluation of the 2nd Health programme 2008–2013, 2016). Vague-specific objectives and the large scope covered were pointed out. There was also a lack of emphasis on innovation and adequate representation of cases in relation to cross-border health care and the free movement of persons. In contrast, improvements were noted in the search for the best practice and more effective decision-making. It should be noted that all actions taken by the EU in public health matters have an impact on the Member States, but their scale depends on the degree of implementation and the level of state health systems.

The 2014–2020 programme was already the third EU HP. Its structure is considerably more elaborate than that of the previous ones, which was intended to eliminate the lack of precise definition of specific objectives that existed in previous years. As a final area, the SMART (specific, measurable, attainable, relevant, time-bound) measure was chosen. The third EU HP has so far consumed the most money from the Union budget. As much as €449.4 million has been allocated to its implementation (Mid-term evaluation of the Third Health Programme, 2021). Conclusions from the deliberations touched on specific plans as well as the need to support national health systems as a whole. The provision of best practices to be followed at the national level: the sharing and exchange of practical experience, expertise and knowledge and the support of health issues on national policy agendas were pointed out (Commission staff working paper, 2021).

The fourth, and final, EU HP under the name EU4Health is not only once again an improved programme, but also an expression of the will to fight the prevailing COVID-19 pandemic in Europe since the beginning of 2020, which changed the normalcy of the European population but also became a test for the effectiveness of the implemented third public health programme. It cannot be overlooked that the Fourth Programme, announced in May 2020, was not directed at civilisational diseases and the protection of the health of the continent's ageing population only, but a significant part of the document was devoted to the theme of joint action to combat infectious and cross-border diseases.

The EU4Health planned for the next few years (2021–2027) discussed the restoration of adequate reserves, as well as increased surveillance of potential health risks. There is no shortage of space for the fight against cancer, diabetes and obesity. The Europe of the Union is supposed to be a place where citizens of all member states have equal rights in access to health care and affordable medicines.

European health programmes have been in place since 2003. The prevailing belief that investment in preventive examinations is the way to ensure high-quality and effective treatments for the population encourages investment in such undertakings. There is no doubt that the European Union have to deal with the social, medical and financial consequences of the COVID-19 pandemic, and this change its approach to its policies.

The post-COVID-19 report in Public Republic of China public information appeared first on 31 December 2019. Since then, further announcements related to the spread of the virus have gradually begun to appear. Initially, the virus was not expected to spread within the European Union, however as time passed and more cases were detected, the situation began to change. As early as 11 March 2020, the Director General of the Who declared COVID-19 a “global pandemic” (Director-General's Opening Remarks at the Media Briefing on COVID-19, 2020). The EU did not have the legal power to act as a whole organization since health policy is a shared competence. Its actions were limited to soft law, which does not mean a lack of response from the community.

On 28 January 2020, the EU Council activated the Integrated Political Crisis Response Mechanism (Goniewicz, 2020, p. 3). As a part of the UE Council's response to COVID-19, UE leaders decided to focus their response on public health, travel, transportation, research and innovation, economy and crisis management on 17 and 26 March 2020 (Moskal, Sobarnia, Pazera, Kopania, 2021, p. 89). European Commission purchased

personal protective equipment and has spent more than €4.5 billion on activities to support public health (Ibidem). A step that seemed obvious, but nevertheless surprised by its reality, was the closing of borders between member states. Although the legality of this decision is being questioned, at the time, countries paralyzed by fear of the disease decided to make drastic moves (Berry, Homewood, Bogusz, 2019, p. 522).

An important part of the European Union's efforts has been to take steps to protect the economy. The tranches approved in April 2020 included financial assistance to those affected by the pandemic. The next step the EU faced was the issue of vaccines and certification. On 17 June 2020, the EU Strategy for COVID-19 vaccines was approved, and the strategy also indicated that the EU takes responsibility for testing, treatment and vaccination in a spirit of solidarity and a desire to return to normalcy (Moskal, Sobarnia, Pazera, Kopania, 2021, p. 120).

At the end of July, the European Commission ordered a total of 300 million doses of the vaccine on behalf of the member states, which were distributed among the countries, ensuring that those willing have access to protection (European Commission, 2022).

Conclusion

Health policy is an extremely important topic combining not only medical topics. By utilizing data analysis and legal analysis, the author has shed light on the challenges and importance of regulating European Union health policy. The high mobility of Europeans and the freedoms provided by the European Union necessitate the regulation of cross-border medical care. The EU4Health strategy, along with its predecessors, aims to protect and improve the health of EU citizens, enhance health infrastructure, and strengthen preparedness and response measures to cross-border health threats. Harmonizing regulations and standardizing services in cross-border healthcare are crucial for effective international relations, especially in organization such as EU.

The EU's role in health policy is to support, coordinate, and supplement member states' actions, without legislative authority in the field of health. The level of variation in healthcare across Europe underscores the need for common health policy to level out differences in quality and scope of services. The interpretation of Article 168 TFUE provides guidance for member states, emphasizing the importance of health se-

curity and continuous action to improve the quality of life. European health programs, such as the EU Health Programme, have evolved over the years, aiming to promote public health knowledge, respond to health threats, and integrate health determinants into all EU policies and activities. While improvements have been made, challenges remain in defining specific objectives, emphasizing innovation, and addressing cross-border healthcare and the free movement of persons. Overall, the analysis highlights the ongoing efforts to harmonize and enhance health policy in the European Union for the benefit of its citizens.

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Polityka zdrowia Unii Europejskiej

Streszczenie

Celem artykułu jest przedstawienie problemu prawa medycznego w ujęciu europejskim. Poprzez analizę źródeł artykuł przedstawia temat polityki zdrowia Unii Europejskiej. Jest to jedna z polityk wchodząca w skład polityk dzielonych Unii. Prześledzona zostanie historia integracji UE pod względem przepisów prawa regulującego normy medyczne, a dodatkowo zostaną omówione konkretne zapisy traktatów oraz najważniejszych dyrektyw, takie jak przełomowe sprawy rozstrzygnięte przez TSUE. Kolejnym elementem artykułu jest podsumowanie działań wspólnoty w zakresie finansowania programów zdrowia przez UE poprzez Europejskiej Planu Zdrowotne. Zmiana sposobu finansowania i nacisk na różne aspekty stopniowo zmieniają obraz polityki zdrowia UE. Artykuł wyjaśnia sposób funkcjonowania rozwiązań unijnych i zachodzących w nim zjawisk, a to przekłada się na rozumienie i możliwość tworzenia przyszłych, lepszych dla Europejczyków rozwiązań.

Słowa kluczowe: Unia Europejska, polityka zdrowia, TFUE

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