Teka Komisji Prawniczej PAN Oddział w Lublinie, vol. XVIII, 2025, no. 1, pp. 291-301
https://doi.org/10.32084/tkp.9695

THE EU4HEALTH PROGRAMME WITH REGARD TO THE CURRENT NEEDS FOR MEDICAL EQUIPMENT IN THE POLISH HEALTH CARE SYSTEM

Dr. Ryszard Pankiewicz

Academy of Zamość, Polska
e-mail: ryszard.pankiewicz@akademiazamojska.edu.pl; https://orcid.org/0000-0003-2574-0550

Abstract. The European Union Health Programme is a response to the crisis caused by the COVID-19 pandemic. The impact of the pandemic was felt by all the health systems of individual European countries, affecting both patients and medical and administrative staff. The fundamental premise of the programme is to strengthen the resilience of the health systems of the EU member states by undertaking activities strongly focused on long-term health problems. In this respect, one key activity is the European Commission's recommendation on using only safe medical equipment, which is to be achieved by 2028. This article presents the objectives of the aforementioned programme and, more specifically, the guidelines concerning medical infrastructure and apparatus in the context of the current needs of the Polish health care system.

Keywords: medical law; health care financing; quality of health care; patient safety; health care system; participants in the health care system.

INTRODUCTION

One of the key advantages of the European Union Health Programme is its acceleration of the process in which the efficiency of the health systems of EU countries is improved, in particular in the post-pandemic period, which cannot be achieved through activities undertaken at national level alone.[1] In addition, the programme supports and complements national policies to promote and improve human health and safety in Europe, and ensures that health is protected across all EU activities, in line with the 'One Health' approach, according to which human health is closely connected with animal health and the environment (Article 2(5)). This approach also promotes the elimination of bad practices found in national health systems of the EU

[1] Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014. O.J. L 107/1, vol. 64, 26 March 2021, https://eur-lex.europa.eu/legal-content/PL/TXT/?uri=CELEX:32021R0522 [accessed: 24.03.2025].

ISSN 1899-7694
e-ISSN 2719-7379

countries by standardising and strengthening the protection and improvement of human health and life in the European Union [Marcinkowski 2024, 218].

In the described context, it is necessary to point out the basic legal regulations and documents concerning health care in Poland, in which the creators of the system outlined its course of development and strategic goals, as well as the tools used to attain them. From the point of view of this article, special attention should be paid to the document entitled "Healthy Future: Strategic Framework for the Development of the Health Care System for 2021-2027, with an Outlook to 2030."[2] Being part of the government's policy,[3] this document is a follow-up to the document entitled "Policy Paper for Health Care 2014-2020: National Strategic Framework,"[4] which, importantly enough, covers the whole system and not only European Union funds. Therefore, it should also be noted that the entry into force of the Medical Fund Act of 7 October 2020[5] played a key role in the improvement of the quality of health care and patient safety in Poland. Within the framework of the implemented financial mechanism, investments in Polish health care may be made in the following areas: "1) prevention, early detection, diagnosis and treatment of civilisation diseases, including cancer, infectious diseases and rare diseases; 2) health care infrastructure influencing the quality and availability, as well as safety, of the health care services provided; 3) access to high-quality health care services; 4) development of the health care system by focusing on patients' needs, with particular emphasis on improving the quality of life of patients and their families; 5) provision of health care services to persons up to the age of 18; 6) provision of health care services to beneficiaries outside the country" (Article 3 of the resolution).

In the light of the above, it is legitimate to ask whether the implementation of the EU4Health Programme for 2021-2027 and national solutions, including public policy and an additional financial mechanism in Poland, after more than halfway through its operation, has proved effective in terms of medical facilities' provision of medical equipment that guarantees high quality of health care services and patient safety. In order to answer this question, in addition to identifying the objectives of the EU Programme for Health and selected aspects of the Polish health care system, available data

---

[2] The document was adopted by Resolution No. 196/2021 of the Polish Council of Ministers of 27 December 2021 on the Establishment of a Relevant Public Policy. See *Zdrowa Przyszłość. Ramy strategiczne rozwoju systemu ochrony zdrowia na lata 2021-2027, z perspektywą do 2030 r.*, https://www.gov.pl/web/zdrowie/zdrowa-przyszlosc-ramy-strategiczne-rozwoju-systemu-ochrony-zdrowia-na-lata-2021-2027-z-perspektywa-do-2030 [accessed: 24.03.2025].

[3] See Article 4(1) and Article 4(7b) of the Resolution of 6 December 2006 on the Principles of Development Policy, Journal of Laws of 2021, item 1057.

[4] See https://www.zdrowie.gov.pl/uploads/pub/pages/page_846/text_images/Krajowe%20ramy%20strategiczne%20www.pdf [accessed: 24.03.2025].

[5] Journal of Laws of 2020, item 1875.

from analyses carried out by public law entities, including recent inspections carried out by the Supreme Chamber of Control (NIK), will be examined.[6]

1. THE OBJECTIVES OF THE EU HEALTH PROGRAMME

The EU4Health Programme was established by Regulation 2021/522 of the European Parliament and of the Council (Article 3),[7] which defines the general (Article 3) and specific (Article 4) objectives as well as the rules and regulations of EU funding for the period 2021-2027.

Among the general objectives, the EU legislators list four main activities: (1) improving and promoting health in the EU; (2) protecting EU citizens from serious cross-border health threats; (3) improving medical products and devices, including crisis-relevant ones; (4) strengthening health systems by improving their resilience and resource efficiency. The programme aims to achieve these general objectives through specific objectives.

The first specific objective is to improve and promote health in the EU. In this respect, the programme supports disease prevention and health promotion activities as well as international health initiatives and cooperation.

The second specific objective is to work towards strengthening the capacity of the EU member states and the European Union itself to respond to cross-border health threats. Through this objective, the programme shall support the prevention of, preparedness for and rapid response to cross-border health threats, along with complementation of national stockpiling of essential crisis-relevant commodities and creation of reserves of medical staff, health professionals, and auxiliary personnel.

The third specific objective is to contribute to activities undertaken in response to increasing demand for health care and to support more equitable protection of public health by promoting greater availability, supply and affordability of medical products and devices, including crisis-relevant ones.

The final objective set out in EU law is to improve the resilience and resource efficiency of the health systems of the member states. To this end, the EU Health Programme supports actions contributing to the strengthening of health databases and digital tools and services, also fostering the digital transformation of the health systems. In addition, it envisages increased access to health care, the development and implementation of EU health legislation, along with effective health policies pursued at a trans-European level.

---

[6] The Supreme Chamber of Control (NIK) is the most important and independent instrument of state control, whose activities are regulated by the Act of 23 December 1994 on the Supreme Chamber of Control, Journal of Laws of 2022, item 623.

[7] O.J. L 107/1.

Consequently, the adoption and implementation of the EU Health Programme should be considered an important and welcome step towards the standardisation of the health systems of the European Community countries.

2. SELECTED ASPECTS OF FINANCING THE HEALTH CARE SYSTEM IN POLAND

Due to the different level and scope of the health care services provided in the EU countries, which mainly results from different financing of the health care systems in individual member states, it is necessary to implement community programmes in order to eliminate significant disproportions in this sector.

In Poland, as in other countries of the European Community, there is a system of public health insurance.[8] According to official data, in 2021, total expenditure on health care in Poland amounted to 6.4% of GDP, which is one of the lowest rates in Europe and much lower than the EU average of 11.0%.[9] In these statistics, Poland is only ahead of Bulgaria and Romania.[10]

The low financing of health care in Poland is reflected in the per capita expenditure on health care. In 2021, this indicator stood at EUR 1,733 (adjusted for the difference in purchasing power) – one of the smallest amounts in the EU.[11] In comparison, in 2021, health care expenditure in Germany was the highest in the EU and significantly higher than the EU average, at EUR 5,159 per capita.[12]

According to the amendment to the Act on Publicly Funded Health Care Services, in 2027 health care expenditure in Poland will be no less than 7% of GDP.[13] However, given the steady growth of health care spending in European countries, this will not bring Poland's funding levels closer to the European average.

Discussing the financing of the health care system in Poland in comparison with other European countries, it should be emphasised that this system is essentially oriented towards hospital care, as evidenced by the high number of hospital beds. In 2019, there were 6.2 beds per 1,000 inhabitants, with the

---

[8] Such a system is also to be found, for example, in Norway, Portugal, Slovenia, and Hungary.

[9] For example, in Germany it is 12.9%. See *Germany: Country Health Profile 2023*, State of Health in the EU, OECD Publishing, Paris, p. 9, https://doi.org/10.1787/21dd4679-en [accessed: 24.03.2025].

[10] See *Polska: Profil systemu ochrony zdrowia 2023*, OECD Publishing, Paris, p. 9, https://doi.org/10.1787/b12d3d03-pl [accessed: 24.03.2025].

[11] Ibid.

[12] See *Germany: Country Health Profile 2023*, p. 3.

[13] See Article 131c of the Act of 27 August 2004 on Health Care Services Financed from Public Funds, Journal of Laws of 2024, item 146.

EU average being 4.9 beds.[14] In this context, special attention should be paid to the medical equipment used in Poland's health care facilities, which, in the case of hospital treatment, is an essential tool in the diagnosis and treatment of patients, corresponding to the quality of the health care services provided and patient safety. Undoubtedly, the low level of financing of Polish health care results not only in the limited possibilities of medical institutions to purchase modern medical equipment, but also, among others, the performance of diagnostic tests on worn-out equipment in need of replacement, which, in turn, may be the cause of medical mistreatment [Kunert 2019, 168-69]. Therefore, it is vital to implement the EU Health Programme in order to support the domestic activities in the health sector.

It should be noted that the significant difference between the financing of health care in Poland and other EU countries has a negative impact on the process of integrating the member states' health care systems. In order to attempt to develop common health measures in the EU, it would be necessary to equalise the financing of health care systems in all the countries of the European community. An effective solution, for example, would be for the European Commission to set a percentage of GDP expenditure on health care, which would oblige the countries of the European community to maintain a minimum level of health care provision.

In conclusion, health care should be a priority within the European community, especially bearing in mind the freedom of movement and residence of EU citizens within the territory of the member states.

3. MEDICAL EQUIPMENT

The public strategy entitled "Healthy Future: Strategic Framework for the Development of the Health Care System for 2021-2027, with an Outlook to 2030" identified, among other things, the problem of aging equipment, resulting from health care institutions' underinvestment and the high cost of specialised medical apparatus, as well as the frequent inability to install it due to the limitations of the existing building infrastructure.[15] In addition, it was pointed out that the amount, as well as the quality, of medical equipment in use was unsatisfactory,[16] because "the age and technical condition

[14] See *Polska: Profil systemu ochrony zdrowia 2023*, p. 16.

[15] Ibid., p. 104.

[16] As stated by the authors of the document while referring to the study "Map of Health Needs for 2022-2026": Announcement of the Minister of Health of 27 August 2021 on the Map of Health Needs. Journal of Ministry of Health 2021, item 69, "In 2019, The Republic of Poland was below the average for selected European countries in terms of the density of CT scanners, MRIs and angiographs. It can be observed that for CT scanners and angiographs, the Republic of Poland is ranked 14th among the countries listed. The situation is much worse for MRI and PET scanners – in these cases the Republic of Poland is ranked 18th and 19th respectively. Ibid.

of the equipment owned by hospitals is likely to generate substantial additional costs, both in terms of repair service and operational downtime. Using worn-out equipment negatively affects the quality, effectiveness, and efficiency of the health care services provided, as well as the financial efficiency of medical facilities."[17] The authors of the report also pointed to the need for investment in new equipment, which is related, among other things, to the continuous development of medical technology, the implementation of new procedures and therapies, and legal requirements. They were also right to note the correspondence between the use of worn-out and old medical equipment and the risk of making diagnostic errors and using inappropriate and expensive therapies.[18] Additionally, taking into account the forecast contained in the document "Map of Health Needs for 2022-2026," the percentage of equipment to be replaced in 2025 due to being classified as "old" ranges from 65% for linear accelerators to 90% for sonographs.[19]

The data cited above, which include a forecast of the state of medical equipment, make it possible to analyse the extent to which the objectives set in the strategy have been achieved, taking into account the inspections of safe medical equipment carried out by the NIK.

In 2024, the NIK examined the functioning of voivodship hospitals in Poland.[20] Narrowing down the results of the inspection to the subject of the hospitals' observance of the rules of safe use of medical equipment in their provision of health services, it should be noted that, despite the existence of legal regulations of statutory character on this subject,[21] several irregularities were found. Having scrutinised a sample of 160 pieces of equipment of the highest value that constituted the apparatus of hospital wards with the highest number of beds in a given hospital, with the aim to inspect the two largest wards (five pieces of equipment from each ward), the NIK discovered that the inspections of nine pieces of equipment in four hospitals had been performed with a delay of up to eight months.[22] In the subsequent report, the following delays were specified: a mobile defibrillator with a cardiometer (14 days), a chest compression system (14 days), an immunochemical analyser (22 days), a neuronavigation system (8 months), an X-ray machine (3 months), a neurosurgical navigation system (11 days), a surgical microscope (3 days), an echocardiogram (7 days), and an operating table

[17] Ibid.

[18] Ibid.

[19] See *Mapa potrzeb zdrowotnych na lata 2022-2026*, p. 503.

[20] See the report on the results of the inspection entitled "The Functioning of Voivodship Hospitals", P/24/044, 20.02.2025, https://www.nik.gov.pl/kontrole/wyniki-kontroli-nik/kontrole,25052.html [accessed: 11.03.2025].

[21] See Article 63 of the Act of 7 April 2022 on Medical Products, Journal of Laws of 2022, item 974.

[22] See information on the inspection in "The Functioning of Voivodship Hospitals", p. 22.

(38 days). The hospitals accounted for those shortcomings, among other things, by changes in the administrative and technical staff responsible for the medical apparatus, as well as the implementation of new systems for keeping records of such apparatus.[23] What was the most important, however, was the fact that, despite those shortcomings, the abovementioned equipment was used in the provision of health services, jeopardising the patients' health and life.[24] Undoubtedly, the irregularities identified in the operation of medical equipment alone constituted a risk of medical (diagnostic) error, or, more precisely, organisational error [Zoll 1988, 72-73].

Indeed, the obligation to secure the efficiency of all the equipment used in the examination of the patients rests with managers of health care facilities, who also bear responsibility for failing to do so [Marek 2007, 98]. However, in practice, it is difficult to assess the performance of the workers of the Polish health care sector with regard to their observance of organisational procedures due to the lack of management standards [Dudek and Dudek 2012, 21]. Moreover, from the patient's perspective, it is difficult to imagine a situation in which they are diagnosed by means of apparatus that is not technically checked and approved for use. Any gaps in the technical passports of medical devices, including the date from which they may be used or the date of their next technical inspection, are unacceptable and should be identified and filled by managers of health facilities. Accordingly, a health facility that conducts specialised examinations should have adequate technical and human resources [Guzik-Makaruk, Truskolaska, and Wojewoda 2021, 174]. In modern medicine, the starting point for the doctor to make a diagnosis of the patient, to be followed by a suggested course of suitable medical treatment, which depends on the patient's consent, is most often preceded by an examination with the use of appropriate and technically advanced medical equipment. Allowing situations in which doctors diagnose their patients using uncertified medical apparatus not only endangers the patients' health and life but also violates the basic principle of providing health services in accordance with the current standards and requirements of medical practice.[25] Such a violation may result in civil liability for damages caused to patients as a consequence of using faulty medical equipment [Wąsik 2020, 67].[26]

---

[23] Ibid., p. 10.

[24] "In 2024, the technical inspection of the device with inventory number 802/003542 was found to have been delayed by 13 days, resulting in 78 patient examinations being performed with this device without a valid technical inspection," ibid., p. 22.

[25] See the Decision of the Supreme Court of 11 May 1983, ref. no. No. IV CR 118/83, OSNCPiUS 1983, No. 12, item 201.

[26] For more on this subject see Nesterowicz 2012 and the Lex System of Legal Information at https://sip.lex.pl/komentarze-i-publikacje/glosy/glosa-do-wyroku-sn-z-dnia-11-maja-1983-r-iv-cr-118-83-386107484 [accessed: 12.03.2025].

In another report, entitled "Oncological Treatment,"[27] the NIK identified, among other things, an unreliable inventory of medical apparatus,[28] including equipment which had been withdrawn from use and written off the fixed asset register,[29] in the attachment to a contract for the provision of health services with a branch of the National Health Fund (the resources section), as well as erratic technical documentation for the laminar chamber in a cytostatic laboratory.[30] The report also states that inspections carried out in the medical facilities offering radiological treatment protection revealed that basic quality control tests for X-ray apparatus or auxiliary equipment had not been carried out to the full extent.[31]

In addition, according to a survey of the Polish health care system within the framework of the 2nd edition of the Safe Hospital is Safe Patient certification,[32] almost half of the hospitals admit that safe equipment constitutes less than 50% of the total equipment they have, and only 13% of the hospitals admit that they have more than 90% of safe equipment.[33] Moreover, 11% of the hospitals do not use safety equipment at all in the drug preparation procedure. At the same time, it should be emphasised that determining the actual status of safe medical equipment is difficult, as 29% of Polish medical facilities do not keep relevant inventories.[34]

In the light of the above, it can be concluded that, despite the implementation of long-term financial programmes that enable health care facilities to retrofit and replace worn-out medical equipment, a level of complete safety similar to that of the developed countries of the European Community has still not been achieved.

4. GENERAL TERMS AND CONDITIONS OF HEALTH CARE CONTRACTS WITH REGARD TO SAFE MEDICAL EQUIPMENT

In the context of the subject under analysis, it should be noted that according to Article 7(1) of the Regulation of the Minister of Health

---

27 See *Informacja o wynikach kontroli „Leczenie onkologiczne"*, KZD.430.005.2023, No. 111/2023/P/23/044/KZD, Warszawa 2024, https://www.nik.gov.pl/plik/id,30368,vp,33408.pdf [accessed: 11.03.2025].

28 Ibid., p. 77 and 80.

29 Ibid., p. 78.

30 Ibid.

31 Ibid., p. 66.

32 See *Bezpieczny Szpital To Bezpieczny Pacjent. Podsumowanie II Edycji Programu Certyfikacyjnego Koalicji Na Rzecz Bezpieczeństwa Szpitali*, Koalicja na rzecz Bezpieczeństwa Szpitali, Warszawa 2023, https://deklaracja-bezpiecznyszpital.pl/wp-content/uploads/2023/11/Koalicja-na-rzecz-Bezpieczenstwa-Szpitali_Raport_2023_HR.pdf [accessed: 11.03.2025].

33 Ibid., p. 17.

34 Ibid., p. 18.

of 8 September 2015 on General Terms and Conditions of Contracts for the Provision of Health Care Services (GTCs),[35] the providers are obliged to offer their services in premises that meet the requirements set out in the regulations issued on the basis of the Act of 27 August 2004 on Health Care Services Financed from Public Funds,[36] regulations on medical practice, and the detailed terms and conditions of contracts defined by the President of the Fund pursuant to Article 146(1) and (2) and Article 159(2) of the aforementioned act. These premises should be equipped with certified medical apparatus inspected by authorised entities on a regular basis. Referring to the regulation in question, it should be emphasised that health care services must be provided with due diligence (Article 3(2) CTE), ensuring their high quality (Article 3(4) CTE), as illustrated by the mandatory use of a quality questionnaire defined by the President of the National Health Fund (NFZ) pursuant to Article 146(1) and (2) and Article 159(2) of the Health Services Act, as well as perioperative documentation referred to in regulations issued pursuant to Article 30(1) of the Act of 6 November 2008 on Patient Rights and Patient Ombudsman.[37]

In conclusion, it should be emphasised that in a situation in which a health care facility does not have at its disposal safe medical equipment, it not only jeopardises the patient's health and life but also exposes itself to the risk of legal liability for failing to comply with the general terms and conditions of contracts on the provision of health care services. It is more than obvious that all the people and institutions responsible for provision of health care services in Poland and the medical entities providing health care services in Poland should first of all be guided by the fundamental constitutional principle of the citizens' right to health care.

CONCLUSION

The analysis carried out in this paper has led the author to the following conclusions:

1. The general level of health care financing in Poland is below the European average, which has a direct impact on the level of financing the replacement of worn-out equipment and the purchase of new medical equipment in health care facilities.
2. The legal regulations concerning the provision of health services financed from public funds with respect to the obligation of health care

[35] Journal of Laws of 2023, item 1194.
[36] Journal of Laws of 2024, item 146.
[37] Journal of Laws of 2024, item 581.

facilities to be equipped with safe medical equipment are appropriate. Nevertheless, these regulations are not always observed.

3. The results of the most recent inspections of health care facilities carried out by the NIK clearly show that current state of medical equipment in Poland is far from satisfactory, as evidenced by the fact that the medical apparatus used in those facilities is often outdated or uncertified, endangering patients' health and life.
4. The irregularities identified by the NIK confirm that the inspected health care facilities breached legal regulations, including the general terms and conditions of contracts for the provision of health care services (GTCs). The violations in question included the use medical equipment that did not have all the necessary certificates or/and was not inspected by authorised entities on a regular basis, which made it unfit for use. The health care facilities at which such irregularities were found not only acted unlawfully but also negligently, failing to ensure the suitable quality of the services provided and patient safety.

In the light of the conclusions drawn above, it is reasonable to ask the question about the actual retrofitting and replacement of medical equipment in Polish health care facilities entities as specified in the European Commission's guidelines, according to which the medical apparatus of the member states is to be entirely safe by 2028. Answering this question, one should advocate taking full advantage of the opportunities offered by the EU Health Programme for 2021-2027, for example by securing to the greatest extent possible investment in this area. Furthermore, the level of public funding of health care in Poland should be raised to at least the European Union average as soon as possible.

REFERENCES

Dudek, Katarzyna, and Krzysztof Dudek. 2015. "Organizacyjny błąd medyczny jako czynnik oceny ryzyka funkcjonowania ośrodków opieki zdrowotnej." *Prace Naukowe Uniwersytetu Ekonomicznego we Wrocławiu* 410:13-23. http://dx.doi.org/10.15611/pn.2015.410.01.

Guzik-Makaruk, Ewa, Emilia Truskolaska, and Ewelina Wojewoda. 2021. *Odpowiedzialność za błędy medyczne w Polsce i Republice Federalnej Niemiec – wybrane aspekty*. Warszawa: Instytut Wymiaru Sprawiedliwości.

Kunert, Ireneusz. 2019. "Błąd organizacyjny w działaniach służby zdrowia jako przedmiot spraw o tzw. błędy medyczne z perspektywy praktyki prokuratorskiej." *Prokuratura i Prawo* 7-8:164-80.

Marcinkowski, Tomasz. 2024. "Program UE dla zdrowia w europejskiej debacie parlamentarnej." *Politeja* 1(88/3):213-28. https://doi.org/10.12797/Politeja.20.2024.88.1.01

Marek, Zdzisław. 2007. *Błąd medyczny. Odpowiedzialność etyczno-deontologiczna i prawna lekarza*. Kraków: Wydawnictwo Medyczne.

Nesterowicz, Mirosław. 2012. "Glosa do wyroku SN z dnia 11 maja 1983 r., IV CR 118/83." In Mirosław Nesterowicz, *Prawo medyczne. Komentarze i glosy do orzeczeń sądowych*, 3rd ed., 444-48. Warszawa: Wolters Kluwer.

Wąsik, Natalia. 2020. *Błąd organizacyjny podmiotu leczniczego. Aspekty prawnokarne*. Toruń: Wydawnictwo Naukowe Uniwersytetu Mikołaja Kopernika.

Zoll, Andrzej. 1988. *Odpowiedzialność karna lekarza za niepowodzenie w leczeniu*. Warszawa: Wydawnictwo Prawnicze.