
EUROPEAN UNION REGULATIONS CONCERNING VACCINATION AS A MEANS OF PREVENTING INFECTIOUS DISEASES IN THE FACE OF COVID-19/SARS-COV-2 PANDEMIC

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The outbreak of the COVID-19 global pandemic caused by the coronavirus SARS-CoV-2 resulted in fierce criticism of the European Union accused by the EU Member States' mass media of being unprepared to counteract the situation.¹ The opinions were accompanied by numerous statements made by politicians first in Italy

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¹ Z. Krasnodebski, *Unia kompletnie nieprzygotowana do pandemii*, Rzeczpospolita, 17.4.2020, <https://www.rp.pl/Koronawirus-SARS-CoV-2/200419407-Zdzislaw-Krasnodebski-Unia-kompletnie-nieprzygotowana-do-pandemii.html> (accessed 6.6.2020); A. Turczyn, *Zwalczanie chińskiego #koronawirus jest odbieraniem ludziom wolności przez rządy przy pomocy strachu bez wystrzału*, 17.5.2020, <https://trybun.org.pl/2020/05/17/zwalczanie-chińskiego-koronawirus-jest-odbieraniem-ludziom-wolności-przez-rządy-przy-pomocy-strachu-bez-wystrzału> (accessed 6.6.2020); R. Grochal, *Rząd robi dobrą minę, ale jest nieprzygotowany na koronawirusa*, Newsweek Polska, 22.5.2020; S. Stodolak, *Koronawirus wywoła gospodarczy kryzys. Nie gasić pożaru benzyną*, Dziennik.pl, 18.3.2020, <https://wiadomosci.dziennik.pl/opinie/artykuly/6464480,koronawirus-kryzys-gospodarczy-opinia.html> (accessed 6.6.2020); S.L. Greer, *How Did the EU Get the Coronavirus so Wrong? And What Can it do Right Next Time?*, The New York Times, 6.4.2020, <https://nytimes.com/2020/04/06/opinion/europe-coronavirus.html> (accessed 6.6.2020); D.M. Herszenhorn, S. Wheaton, *How Europe Failed the Coronavirus Test. Contagion's Spread is a Story of Complacency, Overconfidence and Lack of Preparation*, Politico, 7.4.2020, <https://www.politico.eu/article/coronavirus-europe-failed-the-test> (accessed 6.6.2020); R. Stavrinou, *Europe is Unprepared to Face Future Deadly Disease Outbreaks*, New Europe, 17.12.2019, <https://www.neweurope.eu/article/europe-is-unprepared-to-face-future-deadly-disease-outbreaks> (accessed 6.6.2020); M. Pierini, *Caught Unprepared by Pandemic, Europe Must Relearn Tough Lessons*, Carnegie Europe, 18.3.2020, <https://carnegieeurope.eu/2020/03/18/caught-unprepared-by-pandemic-europe-must-relearn-tough-lessons-pub-81315> (accessed 6.6.2020).

and then in other EU countries. The criticism also concerned the World Health Organisation (WHO) accused of failure to satisfy people's expectations. The US president expressed particularly harsh criticism of the situation and threatened to withdraw the United States' funding for the organisation.² Those attacks were undoubtedly aimed at shifting responsibility for failure to prepare the infrastructure and coordinate activities in particular states. It was ignored that for years the WHO and the European Union bodies even to a greater extent, developing the foundations of health policy, have been drawing attention to the need to work out the rules of preventing a pandemic in many normative acts. It was argued that it was not possible to develop vaccines against a pandemic. However, it was indicated that states should prepare for such a hazard. Concerns were also voiced in relation to anti-vaccination movements which influence Member States' societies with the use of the freedom of speech and communications media.³

Article 168 placed under Title XIV Public health of the Treaty on the Functioning of the European Union (hereinafter TFEU) in seven successive paragraphs determines the European Union powers to act in the sphere of public health, specifies its objective and indicates activities that should be undertaken in order to achieve those aims, at the same time defining measures that can be used.⁴ Obviously the

² It finally happened on 20 May 2020. See C. Finnegan, *Trump Escalates Fight Against World Health Organization, Threatens to Permanently cut US Funds*, ABC News, 20.5.2020, <https://abcnews.go.com/Politics/trump-escalates-fight-world-health-organization-threatens-permanently-story?id=70771446> (accessed 6.6.2020); *Coronavirus: What are President Trump's Charges Against the WHO?*, BBC, 1.6.2020, <https://www.bbc.com/news/world-us-canada-52294623> (accessed 6.6.2020); B. Lovelace Jr., *Trump Says the U.S. will cut Ties with World Health Organization*, CNBC, 29.5.2020, <https://www.cnbc.com/2020/05/29/trump-says-the-us-will-cut-ties-with-world-health-organization.html>; A. Wolska, *Trump: USA zrywają relacje ze Światową Organizacją Zdrowia*, Euractiv.pl, 31.5.2020, <https://www.euractiv.pl/section/bezpieczenstwo-i-obrona/news/trump-usa-who-zerwane-relacje-chiny-pandemia-koronawirus> (accessed 6.6.2020).

³ *Ruchy antyszczepionkowe jednym z największych zagrożeń dla zdrowia*, Medycyna Praktyczna, 17.1.2019, <https://www.mp.pl/szczepienia/aktualnosci/202357,ruchy-antyszczepionkowe-jednym-z-najwiekszych-zagrozen-dla-zdrowia> (accessed 6.6.2020); N. Sayegh, *Europe's Anti-vaxxers Could Lead to a Public Health Crisis*, TRT World, 5.11.2019, <https://www.trtworld.com/opinion/europe-s-anti-vaxxers-could-lead-to-a-public-health-crisis-31141> (accessed 6.6.2020); H. Larson, A. de Figueiredo, E. Karafllakis, M. Rawal, *State of Vaccine Confidence in the EU 2018*, European Commission, Luxembourg 2018, https://ec.europa.eu/health/sites/health/files/vaccination/docs/2018_vaccine_confidence_en.pdf (accessed 6.6.2020); K. Jennings, *48 Percent of Europeans Believe False Claims on Vaccines. While Most People Agree Vaccines are Important, a Relative Majority Incorrectly Believe they Often Cause Serious Side Effects*, Politico, 26.4.2019, <https://www.politico.eu/article/poll-48-percent-of-europeans-believe-false-claims-on-vaccines> (accessed 6.6.2020); Ph. Oltermann, *Europe's Covid Predicament – How do you Solve a Problem Like the Anti-vaxxers?*, The Guardian, 23.5.2020, <https://www.theguardian.com/world/2020/may/23/europes-covid-predicament-how-do-you-solve-a-problem-like-the-anti-vaxxers> (accessed 6.6.2020); K. Juničić, S. Michalopoulos, *Measles hit Zagreb as Social Media Join Fight Against Anti-vaccination*, Euractiv, 24.9.2019, <https://www.euractiv.com/section/health-consumers/news/measles-hit-zagreb-as-social-media-join-fight-against-anti-vaccination> (accessed 6.6.2020).

⁴ The founding treaties did not contain regulations granting the European Community institutions powers in the field of public health. The European Communities founding treaties did not deal with the sphere of public health at all. Integration was designed to have only an economic dimension. The concept of health was used in Article 69 Treaty establishing the European Coal and Steel Community (hereinafter TECSC), in which the Member States were obliged to eliminate any limitations to employment in coal and steel industry, with the exception

powers of the European Union in the field of public health support, coordinate and supplement the activities of the Member States. However, Article 168 para. 6 TFEU stipulates that the Council, on a proposal from the Commission, may also adopt recommendations for the purposes set out in Article 168 TFEU. Certainly, the recommendations cannot lead to harmonisation of national statutory and implementing provisions, nevertheless Article 168 makes it possible to undertake normative actions aimed at ensuring high quality standards and security of

of those that result from the need to protect health and public order. Not earlier than in the Treaty establishing the European Atomic Energy Community (hereinafter TEAEC), were there declarations concerning the need to create the conditions of safety necessary to eliminate hazards to the life and health of the public (recital 4 of the Preamble). Article 30 of Chapter 3 of the Treaty grants the Commission and the Council powers to establish basic standards for the protection of the health of workers and the general public, however, only against the dangers arising from ionizing radiations. Similar solutions can be found in the Treaty establishing the European Economic Community (hereinafter TEEC). Article 56 TEEC allows issuing national regulations concerning special treatment of foreign nationals on grounds of public health. Article 57 TEEC envisages progressive abolition of limitations and coordination of national provisions concerning medical and allied professions, including pharmaceutical ones, in order to make it easier for citizens of one Member State to take up and pursue activities as self-employed persons in another Member State. Article 118 TEEC obliges the Commission to promote close cooperation between the Member States in the field of protection against occupational accidents and diseases by conducting studies, delivering opinions and arranging consultations (D. Bach-Golecka, *Pomiędzy solidarnością a wspólnym rynkiem. Uwagi na tle orzecznictwa ETS dotyczącego usług medycznych*, [in:] S. Biernat, S. Dudzik (eds), *Przeptyw osób i świadczenie usług w Unii Europejskiej. Nowe zjawiska i tendencje*, Warszawa 2009, p. 287; A. Krajewska, *Ochrona zdrowia w Unii Europejskiej*, [in:] J. Barcz (ed.), *Polityki Unii Europejskiej: polityki społeczne, aspekty prawne*, Warszawa 2010, p. 67). The issue concerning the protection of health occurred in recital 4 TEAEC and Article 36 TEEC. The latter normative act admits the application of prohibitions or restrictions on imports, exports or goods in transit justified on grounds of health and life of humans. Article 129 Treaty on European Union (the Maastricht Treaty) introduced a clear competence of the Community in the field of public health. A successive change was introduced by the Treaty of Amsterdam, which recognised public health as one of the priorities of the European Community. Article 152 of the Treaty establishing the European Community (TEC) imposed an obligation to maintain a high level of human health protection and the Community action should be directed towards improving public health, preventing human illnesses and diseases, and obviating sources of danger to human health. It was aimed at fighting against the major health scourges by promoting research into their causes, their transmission and prevention, as well as health information and education (see M. Malczewska, [in:] K. Kowalik-Bańczyk, M. Szwarc-Kuczer, A. Wróbel (ed.), *Traktat o Funkcjonowaniu Unii Europejskiej*, Vol. II, Warszawa 2012, pp. 1048–1053). The Single European Act added Article 118a to TEEC obliging the Member States to pay particular attention to encouraging improvements, especially in the field of health protection. On the other hand, the amended Article 108 TEEC recommended that the Community institutions adopt high level of standards for health protection in the field of healthcare. It corresponded to Article 130r added to TEEC, indicating that one of the Community's aims in the field of natural environment is to contribute to the protection of human health. Further changes in this respect were introduced in the Maastricht Treaty, where the content of Article 129 TEC was changed, and ensuring a high level of human health protection was indicated as one of the aims of the Community, feasible by encouraging cooperation between the Member States. The Treaty recommended that health protection requirements should form a constituent part of the Community's other policies. Article 129 TEC was amended by means of the Treaty of Amsterdam, which recognised public health as one of the European Community's priorities. In accordance with the amended Article 152 para. 1 TEC, the Community action in the area should take into account improvement of public health, prevention of human illnesses and diseases, and obviating sources of danger to human health. The action should cover the fight against

therapeutic and medicinal products and health protection. Article 168 para. 4 TFEU provides that the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee for the Regions, can adopt relevant measures. The measures may be designed to protect and improve human life, in particular to combat the major cross-border health scourges. They may also concern monitoring serious cross-border threats to health, early warning of such threats and combating them. The direct objective of those measures should be the protection of public health, especially regarding tobacco and the abuse of alcohol. The events in recent weeks, the occurrence of the coronavirus (SARS-CoV-2)⁵ causing the COVID-19 disease, prove that Europe is in fact one organism and great mobility of its citizens indicates that health protection should be treated as a category concerning the continent and even the whole world.

The European Union's health policy, although it seems to result only from Article 168 TFEU, is based on quite detailed regulations adopted later. They concern prevention of human diseases and illnesses, elimination of the sources of threats to physical and mental health, prevention and combat of infectious diseases, and reduction of the harmful consequences of addictions (especially drug addiction, abuse of alcohol and tobacco). In addition, cross-border cooperation between Member States in the field of provision of health services and cooperation with non-EU countries became subject to regulation.⁶ Within its health policy, the EU

the major health scourges by complementing national policies. Article 152 para. 5 TEC recognised exclusive responsibilities of the Member States for the organisation and delivery of health services and medical care. Although the Treaty of Nice did not introduce any changes in the field of public health, Article 3 of the Charter of Fundamental Rights adopted then recognised everyone's right to respect for his or her physical and mental integrity, indicating that in the field of medicine and biology, the following must be respected in particular: the free and informed consent of a person concerned, according to the procedures laid down by law. Article 35 of the Charter of Fundamental Rights formulates what constitutes the basis of patients' rights by stating that: 'Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities.' The content of Article 35 is based on the text of Article 152 TEC and Article 11 of the European Social Charter. For more on the issue, see A. Świątkowski, *Karta Praw Społecznych Rady Europy*, Warszawa 2006, pp. 369–376; *idem*, *Prawo socjalne Rady Europy*, Kraków 2006, pp. 152–157.

⁵ K. Pyró, *Ludzkie koronawirusy*, Postępy Nauk Medycznych XXVIII (4B), Borgis, 2015, pp. 48–54. See Projekt ustawy o szczególnych rozwiązaniach związanych z zapobieganiem, przeciwdziałaniem i zwalczaniem COVID-19, innych chorób zakaźnych oraz wywołanych nimi sytuacji kryzysowych [Bill on special solutions related to prevention, counteracting and combating of COVID-19, other communicable diseases and the resulting crisis situations], Sejm paper No. 265, Sejm of IX term; *Getting your workplace ready for COVID-19* of 27 February 2020, available at https://www.who.int/docs/default-source/coronaviruse/getting-workplace-ready-for-covid-19.pdf?sfvrsn=359a81e7_4 (accessed 8.3.2020, 13:03).

⁶ What may be particularly interesting in connection with that are agreements on partnership and cooperation with Russia and former Soviet republics. Such agreements were signed, inter alia, with Azerbaijan, Armenia, Georgia, Kazakhstan, Kyrgyzstan and Moldova, as well as Tajikistan. On the other hand, there are no such agreements with Ukraine and Belarus. The European Union conducts the so-called European Neighbourhood Policy, which covers three- to five-year bilateral Action Plans agreed with Belarus and Ukraine, as well as fourteen

establishes standards of quality and security of human organs and blood, thoroughly regulating the issue of blood donation, and the rules of dealing with blood and human tissues. In this area, there are also regulations concerning therapeutic and medicinal products, pharmaceutical policy, including the development of the therapeutic products market, and the regulation of medicinal products trade.⁷

The content of Article 168 TFEU,⁸ Title XIV,⁹ stipulates that a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities. The Union action, which must complement national policies, is directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action must cover the fight against the major health scourges, by promoting research into their causes, transmission and prevention, as well as health information and education, and monitoring, early warning and combating serious cross-border threats to health.¹⁰

Article 168 para. 2 TFEU stipulates that:

The Union shall encourage cooperation between Member States in the areas referred to in this Article and, if necessary, lend support to their action. It shall in particular encourage cooperation between Member States to improve complementarity of their services in cross-border areas. Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation. The European Parliament shall be kept fully informed.

other states, including Algeria, Egypt, Georgia, Israel, Morocco and Tunisia, and offering the analysis of the directions of reform of national healthcare systems, exchange of best practices, research and statistical methods and information, participation in the network of control of infectious diseases, and cooperation between research laboratories. It is interesting that the European Neighbourhood Policy as well as agreements on partnership and cooperation cover Armenia, Azerbaijan, Georgia, and Moldova.

⁷ The issues concerning the scope of health policy are thoroughly analysed by M. Malczewska, [in:] A. Wróbel (ed.), *supra* n. 5, pp. 1056–1085.

⁸ The text of Article 168 was amended and given the present number by Article 2 para. 26 and Article 12 paras 1 and 2 of the Treaty of Amsterdam amending the Treaty on European Union, the Treaties establishing the European Communities and some other related acts – Dz.U. 2004, No. 90, item 864/31 – in connection with Poland's accession to the European Union. A successive change was introduced through Article 2 para. 2(a), (c), (d) and para. 127, and Article 5 paras 1 and 2 of the Treaty of Lisbon amending the Treaty on European Union, the Treaties establishing the European Community and some related acts, entering into force on 1 December 2009, OJ C 306, 17.12.2007, p. 1.

⁹ Title XIV was added by Article G(D) para. 38 of the Treaty on the Functioning of the European Union, Dz.U. 2004 No. 90, item 864/30, in connection with Poland's accession to the European Union. The number of the Title was determined in Article 12 para. 1 of the Treaty of Amsterdam amending the Treaty on European Union, the Treaties establishing the European Communities and some related acts, Dz.U. 2004 No. 90, item 864/31 – in connection with Poland's accession to the European Union. The present numbers were determined in Article 5 para. 1 the Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community, OJ C 306, 17.12.2007, p. 1 – entering into force on 1 December 2009.

¹⁰ J. Sobczak, *Prawo a medycyna*, Poznań 2018, pp. 33–48.

It is also declared that the Union and the Member States should foster cooperation with third countries and the competent international organisations in the sphere of public health. Further on, it is laid down that the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee for the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet common safety concerns: measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures; measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health; measures setting high standards of quality and safety for medicinal products and devices for medical use (Article 168 para. 4 TFEU).¹¹

It is also emphasised that the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee for the Regions, may also adopt incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health, and measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol, excluding any harmonisation of the laws and regulations of the Member States (Article 168 para. 5 TFEU). Finally, it is emphasised that Union action must respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States include the management of health services and healthcare and the allocation of resources assigned to them. The measures referred to in Article 168 do not affect national provisions on the donation or medical use of organs and blood (Article 168 para. 7). It is also indicated that the Council, on a proposal from the Commission, may adopt recommendations for the purposes set out in that Article, designed to improve public health in order to combat the major health scourges and monitor, early warn of and combat serious cross-border threats to health.¹²

It should be emphasised that, as it is indicated in literature, diseases that can be prevented with the use of vaccination are recognised as the most serious health

¹¹ I. Wrzeźniewska-Wal, *Wspólnotowe regulacje prawne w obszarze zdrowia publicznego*, *Prawo i Medycyna* 4, 2004, p. 101 et seq.; P. Saganek, *Ochrona zdrowia*, [in:] J. Barcz (ed.), *Prawo Unii Europejskiej. Prawo materialne i polityki*, Vol. II, 2nd edn, Warszawa 2006, p. 585; *idem*, *Dostęp do usług medycznych w innych państwach członkowskich w świetle orzecznictwa Europejskiego Trybunału Sprawiedliwości*, *Przeegląd Prawa Europejskiego i Międzynarodowego* 2, 2008, p. 59; M. Malczewska, [in:] A. Wróbel (ed.), *supra* n. 5, pp. 1048–1049.

¹² On this issue, see J. Sobczak, *Zdrowie publiczne a prawa pacjentów w transgranicznej opiece zdrowotnej*, [in:] M. Urbaniak, R. Staszewski (eds), *Aktualne problemy przemian systemu ochrony zdrowia w Polsce*, Poznań 2017, pp. 9–29; *idem*, *Poważne transgraniczne zagrożenie zdrowia w systemie prawa unijnego*, [in:] T. Gardocka, A. Fiutak, D. Jagiełło (eds), *Aktualne problemy prawne w psychologii i medycynie*, Warszawa 2018, pp. 117–134.

scourges. The European Union has drawn attention to the significance of vaccination for the protection of public health many times on various occasions.

Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work,¹³ which determines the minimum requirements designed to guarantee the safety of workers, including the necessity to offer preventive vaccination to workers who have not been already immune, is an example.

In 2000, the Global Alliance for Vaccines and Immunisation (GAVI) was formed. The Commission donated 83 million euros to the Alliance until 2015, which contributed to the immunisation of 277 million children in the period 2011–2015. The Commission declared to donate successive 200 million euros for the period 2016–2020, planning to vaccinate 300 million children in this period. It should be added that during the World Health Assembly 2012, the ministers for health approved the Global Vaccine Action Plan (GVAP) in order to ensure access to important vaccines for everyone by 2020. In 2014, the WHO Regional Office for Europe endorsed the European Vaccine Action Plan for 2015–2020. In 2018, the common Union vaccination activities co-financed within the EU Third Health Programme started, first of all to exchange the best practice in the field of national vaccination and to determine technical requirements concerning electronic systems of information in the field of immunisation used to programme vaccination, set priorities in the field of research and development concerning vaccination and to do research aimed at resolving the problem of evading vaccination.¹⁴

It is worth mentioning that the Resolution 70/1, Transforming our world: the 2030 Agenda for Sustainable Development, adopted by the UN General Assembly on 25 September 2015, aims to guarantee all people at any age health and to promote welfare, and emphasises the importance of vaccines in protecting people against diseases. At the same time, the European Union and its Member States adopted the European Consensus on Development ‘Our World, our Dignity, our Future’.¹⁵

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use¹⁶ and Regulation (EC) No 726/2004 of the European Parliament and

¹³ OJ L 262, 17.10.2000, p. 21.

¹⁴ See Regulation (EU) No 282/2014 of the European Parliament and of the Council on the establishment of a third Programme for the Union’s action in the field of health (2014–2020) and repealing Decision No 1350/2007/EC (OJ L 86, 21.3.2014, p. 1). It is worth mentioning that the first Programme for the Union’s action in the field of health 2003–2008 was adopted through the Decision of the European Parliament and of the Council of 23 September 2002 (OJ L 271, 9.10.2002, p. 1). The second Programme for Union’s action in the field of public health 2008–2013 was adopted through the Decision of the European Parliament and of the Council of 23 October 2007 (OJ L 301, 20.11.2007, p. 3). Both programmes did not directly concern the issue of vaccination. However, it should be remembered that on 24 September 1998, the Decision 2119/98/EC of the European Parliament and of the Council set up a network for the epidemiological surveillance and control of communicable diseases in the Community (OJ L 268, 3.10.1998, p. 1).

¹⁵ Joint statement by the Council and the representatives of the governments of the Member States meeting within the Council, the European Parliament and the Commission, *The New European Consensus on Development ‘Our World, our Dignity, our Future’* (OJ C 210, 30.6.2017, p. 1).

¹⁶ OJ L 311, 28.11.2001, p. 67.

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 Agency¹⁷ authorised regulatory organs to promote and protect public health by granting authorisation for safe and efficient vaccines and by continuous assessment of benefits resulting from vaccination in relation to the risk arising from authorisation for marketing.

Council Directive 2010/32/EU of 10 May 2010 implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector concluded by the European Hospital and Healthcare Employers' Association (hereinafter HOSPEEM) and the European Federation of Public Service Unions (hereinafter EPSU)¹⁸ stipulates that if the assessment reveals that there is a risk to the safety and health of workers due to their exposure to biological agents for which effective vaccines exist, workers must be offered vaccination.

The Council of the European Union in Council conclusions on childhood immunisation: success and challenges of European childhood immunisation and the way forward of 8 July 2011 asked the Member States and the Commission to prepare common action in order to exchange the best practices in the field of vaccination policy.¹⁹

Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for disease prevention and control (hereinafter ECDC)²⁰ states that the Member States must provide information on communicable diseases in accordance with Article 4 of Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community.²¹ The annex to the decision provides a list indicating categories of communicable diseases, including diseases preventable by vaccination. The decision was repealed by Article 20 para. 1 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.²² The European Parliament in its Resolution of 8 March 2011 and the Council in its Conclusions of 13 September 2010 stressed the need to introduce a common procedure for the joint procurement of medical countermeasures, and in particular of pandemic vaccines, to allow the Member States, on a voluntary basis, to benefit from such group purchases, e.g. by obtaining advantageous prices and order flexibility with regard to a given product. With regard to pandemic vaccines, in the context of limited capacities at the global level, such a procedure would be undertaken with the aim of enabling more equitable access to vaccines for the Member States involved, to help them to better meet the vaccination needs of their citizens, in line with vaccination policies in the Member States. It is also indicated that the Commission will strengthen cooperation

¹⁷ OJ L 136, 30.4.2004, p. 1.

¹⁸ OJ L 134, 1.6.2010, p. 6.

¹⁹ OJ C 202, 8.7.2011, p. 4.

²⁰ OJ L 142, 30.4.2004, p. 1.

²¹ OJ L 268, 3.10.1998, p. 1.

²² OJ L 293, 5.11.2013, p. 1.

with the European Medicines Agency and the WHO to improve the methods and processes through which information related to the coverage of vaccine-preventable diseases is provided.

Decision of 22 October 2013 emphasises that in case of a pandemic situation involving human influenza, it is possible to apply accelerated marketing of certain medicinal products as well as a human influenza vaccine even where certain non-clinical or clinical data are missing.²³ It is emphasised that the occurrence of an event that is linked to serious cross-border threats to health and likely to have Europe-wide consequences could require the Member States concerned to take particular control or contact-tracing measures in a coordinated manner to identify those persons already contaminated and those persons exposed to risk.

Before recognising a situation of public health emergency at the Union level, the Commission should liaise with the WHO in order to share the Commission's analysis of the situation of the outbreak and to inform the WHO of its intention to issue such a decision. Where such a decision is adopted, the Commission should also inform the WHO thereof. The occurrence of an event that is linked to serious cross-border threats to health and likely to have Europe-wide consequences could require the Member States concerned to take particular control or contact-tracing measures in a coordinated manner to identify those persons already contaminated and those persons exposed to risk. Such cooperation could require the exchange of personal data through the system, including sensitive information related to health and information about confirmed or suspected human cases of disease, between those Member States directly involved in the contact-tracing measures.

The Council conclusions of 6 December 2014 on vaccinations as an effective tool in public health²⁴ draw attention to the fact that vaccines are medicinal products subject to the rules and procedures adopted at the Union level, authorised by national authorities or by the Commission on the basis of an assessment carried out by the European Medicines Agency and subject to post-marketing monitoring. The document reminds one about the WHO European Region Vaccine Action Plan 2015–2020, which was approved in response to the Decade of Vaccines, setting a course through a regional vision and goals for immunisation and control of vaccine-preventable diseases. It is pointed out that post-marketing studies carried out by marketing authorisation holders are important for the evaluation of vaccine products and should be carried out in a transparent way. The Member States are encouraged to carry out independent studies. It is indicated that some re-emerging

²³ This concerns situations envisaged in the Commission Regulation (EC) No 507/2006 of 29 March 2006 on the conditional marketing authorisation for medicinal products for human use within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 92, 30.3.2006, p. 6), as well as the Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 334, 12.12.2008, p. 7). The texts of Articles 12 and 13f of the last Regulation concerning human influenza vaccines indicate rules concerning the departure from the procedure of examination of such vaccines. For more on the issue, see K. Kumala, J. Piecha, R. Stankiewicz, *Procedura zmian istotnych typu II*, [in:] R. Stankiewicz (ed.), *Instytucje rynku farmaceutycznego*, Warszawa 2016 (Chapter 4.3.3).

²⁴ OJ C 438, 6.12.2014, p. 3.

communicable diseases still present a public health challenge. It is recognised that vaccination programmes are the responsibility of the individual Member States, while various vaccination schemes exist in the EU. This results in the necessity of strengthening cooperation. It is recognised that many vaccines used in community vaccination programmes have been able to prevent disease in individuals and the herd immunity phenomenon contributed to a healthier global society. This type of immunity may be considered an objective in national vaccination plans. It is observed that in the demographic structure of the European population, there must be a greater focus on preventing infectious diseases by means of vaccination of all age groups. The conclusions emphasise the importance of the general public understanding of the value of vaccination and note the occasional lack of awareness of the benefits of some vaccines and the increasing refusal of vaccination in some Member States. This may lead to under-vaccination in some populations, resulting in public health problems and costly outbreaks.

It is recognised that the public should be aware of the value of vaccination and the crucial role of healthcare professionals in informing and educating the population about the benefits of vaccination is underlined. It is recognised that effective vaccination campaigns are useful in preventing the spread of communicable diseases and they should be absolutely carried out. It is pointed out that some Member States should inform their citizens travelling abroad about the risk of communicable diseases that are not present in the Union. It is emphasised that some viruses can cause chronic pathologies, some even of a neoplastic nature. It is considered necessary that an analysis and evaluation of the safety, effectiveness and impact of vaccines to prevent distinct communicable diseases in the European Union be carried out. It is also regarded as useful that the Member States collaborate and exchange best practices concerning the prevention of communicable diseases through vaccination. It is expected that policies to encourage research, including clinical studies, in the field of vaccination should be supported within the Union, and it is observed that as a result of the success in reducing the spread of a number of serious communicable diseases due to widespread use of vaccinations, the population may believe that these diseases no longer represent a threat to public health.

It is also considered appropriate, in order to react to inaccurate information regarding vaccinations in some Member States, that communication campaigns continue to be carried out to educate the public about the risks related to communicable diseases preventable by vaccination. Then, the Member States are encouraged to: continue to improve epidemiological surveillance and evaluation of the situation concerning communicable diseases in their territories, including diseases preventable by vaccination; improve national vaccination programmes and to strengthen national capacity for carrying out evidence-based, cost-effective vaccination, including the introduction of new vaccines where considered appropriate; develop plans and standard operating procedures in collaboration with the ECDC and the WHO to ensure a timely and effective response to vaccine-preventable diseases during outbreaks, humanitarian crises and emergencies; develop comprehensive and coordinated approaches within vaccination

programmes, following the Health in All Policies approach creating synergies with broader health policies and pro-actively working with other preventive sectors; ensure transparency with regard to the post-marketing evaluations of vaccines and of studies on the impact of vaccination programmes in order to provide reliable information for both governments, medicine regulators and manufacturers; actively offer appropriate vaccination to population groups considered to be at risk in terms of specific diseases and consider immunisation beyond infancy and early childhood by creating vaccination programmes with lifelong approach. It is considered necessary that the Member States work with health professionals on risk communication in order to maximize their role in informed decision-making, further increase activities aimed at expanding, where necessary, the immunology and vaccinology components of the basic medical training curricula for students of medical and health sciences and provide health professionals with relevant in-service training opportunities, and inform the population in order to raise its trust in vaccinations programmes, using appropriate tools and communication campaigns, also by engaging opinion leaders, civil society and relevant stakeholders (e.g. academia).

Council Recommendation of 7 December 2018 on strengthened cooperation against vaccine-preventable diseases is undoubtedly the summing-up of the Union activities.²⁵ It is stated in it that vaccination is one of the most powerful and cost-effective public health measures developed in the 20th century and remains the main tool for primary prevention of communicable diseases. The Recommendation adopted by the Council in accordance with Article 168 para. 6 TFEU aims to improve public health. And it is indicated that although vaccination programmes are the responsibility of the Member States, the cross-border nature of vaccine-preventable diseases and the common challenges faced by national immunisation programmes would benefit from the more coordinated EU action and approaches to preventing or limiting the spread of epidemics and diseases with a cross-border dimension. It is emphasised in the Recommendation (recital 5) that the rapid spread of misinformation through social media and by vocal anti-vaccination activists has fuelled misconceptions that are shifting the public focus away from the individual and collective benefits of vaccination and the risks posed by communicable diseases. Anti-vaccination movements focus towards increased distrust and fears of unproven adverse events. That is why, action is needed to strengthen dialogue with citizens to understand their genuine concerns and doubts about vaccination and to adequately address issues, on the basis of individual needs. It is pointed out that it is necessary to improve vaccination coverage rates, which is the healthcare workers' task. That is why, they should be offered opportunities for continuing education and training on vaccination in accordance with national recommendations.

The Recommendation points out that the differences in vaccination schedules between the Member States, the number of doses administered and timing increase the risk that citizens, particularly children, miss a vaccination while moving from one Member State to another. In such a situation there is a need to bring immunisation services closer to citizens and increase efforts to reach out to the most vulnerable

²⁵ OJ C 466, 28.12.2018, p. 1; hereinafter Recommendation.

in society. It is indicated that the European Structural Funds, in particular the European Social Fund (ESF) and the European Regional Development Fund (ERDF), offer significant opportunities for the Member States to strengthen vaccine-related training of healthcare staff and to reinforce health infrastructure capacities in the area of vaccination. It is reminded that demographic changes, mobility of people, climate change and waning immunity are contributing to epidemiological shifts in the burden of vaccine-preventable diseases, which require vaccination programmes with a life-course approach beyond childhood years. This will ensure adequate lifelong protection and contribute to healthy living and healthy aging as well as the sustainability of healthcare systems (recital 10).

The Recommendation points out that vaccine shortages have direct consequences for the delivery and implementation of national vaccination programmes. The Member States face various vaccine supply disruptions, production capacities in the EU remain limited and difficulties persist in sharing vaccines across borders, while the lack of coordinated forecast planning contributes to demand uncertainty. In this context, the European Union and its citizens remain vulnerable in the event of outbreaks of communicable diseases. Thus, there is a need to rapidly advance research and development of new vaccines and improve or adapt existing ones.

Having noticed that considerable proportion of population in the Member States evades vaccination, the authors of the Recommendation point out that the present situation requires innovative partnerships and platforms, high-level expertise and stronger links between disciplines and sectors, as well as investment in social (sic!) and behavioural science research to improve understanding of context-specific determinants underpinning vaccine-hesitant attitudes (recital 12).

In the conclusions of the Recommendation it is stated that the Member States should develop and implement vaccination plans at national and/or regional level, as appropriate, aimed at increasing vaccination coverage with a view to reaching the goals and targets of the WHO's European Vaccine Action Plan by 2020. It is emphasised that the plans could include, for example, provisions for sustainable funding and vaccine supply, a life-course approach to vaccination, capacity to respond to emergency situations, and communication and advocacy activities. It is pointed out that they should aim to achieve by 2020, for measles in particular, a 95% vaccination coverage rate, with two doses of the vaccine for the targeted child population, and work towards closing the immunity gaps across all other age groups, with a view to eliminating measles in the EU. It is indicated that it is necessary to introduce routine check of vaccination status and regular opportunities to vaccinate across different stages of life through routine visits to the primary healthcare system and through additional measures taken, for example when beginning (pre-)school, in the workplace or in care facilities.

The Member States should also facilitate access to national and/or regional vaccination services, by simplifying and broadening opportunities to offer vaccination, leveraging community-based providers, and ensuring targeted outreach to the most vulnerable groups, including socially excluded groups, so as to bridge inequalities and gaps in vaccination coverage. Their task should also be to encourage higher education institutions and relevant stakeholders to consider

including and strengthening training on vaccine-preventable diseases, vaccinology, and immunisation in national medical curricula and any continuing medical education programmes for healthcare workers across all sectors whenever advisable, to strengthen their key role in achieving higher vaccination coverage rates.

It is recognised necessary for the Member States to make use of the opportunities offered by the ESF and the ERDF in order to support the training and skills development of healthcare workers on vaccine-preventable diseases, vaccinology, and immunisation and to reinforce national and regional healthcare infrastructure capacities, including electronic immunisation information systems. It is emphasised that it is imperative to increase communication activities and awareness-raising on the benefits of vaccination by presenting scientific evidence in a form understandable to laypersons, using different context-based strategies, to counter the spread of misinformation, including, for example, through digital tools and partnerships with civil society and other relevant stakeholders. It is also recognised appropriate to engage with and offer training for relevant actors, such as healthcare workers, education stakeholders, social partners and the media as multipliers, to fight complacency and increase trust in immunisation.

It is also pointed out that the Member States must explore the possibility of developing the capacity of health and healthcare institutions to have electronic information on the vaccination status of citizens, for example based on information systems providing reminder functionalities, capturing up-to-date vaccination coverage data across all age groups, and allowing data linkages and exchanges across the healthcare systems. It is recognised that, where appropriate, they should increase support for vaccine research and innovation so that sufficient resources are available for rapid advancement of new or improved vaccines, and facilitate uptake of vaccine research for better-informed national and regional vaccination programmes and policies.²⁶

²⁶ The Recommendation indicates that the Commission intends to take actions in close cooperation with the Member States aiming to establish a European Vaccination Information Sharing (EVIS) system, coordinated by the ECDC, in order to: examine the feasibility of establishing, by 2020, guidelines for a core EU vaccination schedule taking into account the WHO recommendations for routine immunisation, aiming to improve the compatibility of national schedules and promote equity in the Union citizens' health protection, as well as the feasibility of creating a common vaccination card; strengthen consistency, transparency, and methodologies in the assessment of national and regional vaccination plans, by sharing scientific evidence and tools with the support of National Immunisation Technical Advisor Groups (NITAGs); design the EU methodology and guidance on data requirements for better monitoring of vaccination coverage rates across all age groups, including healthcare workers, in cooperation with the WHO and collect such data and share them at the EU level; establish, by 2019, a European vaccination information portal, with the support of the European Medicines Agency, to provide objective, transparent and updated evidence on vaccination and vaccines, their benefits and safety, and the pharmacovigilance process; counter online vaccine misinformation and develop evidence-based information tools and guidance to support the Member States in responding to vaccine hesitancy, in line with the Commission Communication on tackling online disinformation; continuously monitor the benefits and risks of vaccines and vaccination, at the EU level, including through post-marketing surveillance studies; work towards developing methodologies and strengthen capacities to assess the relative effectiveness of vaccines and vaccination programmes. The general aim is to strengthen the effective application of the Union rules on the protection of workers

The analysis of the EU regulations, in particular the content of the Recommendation, indicates that the Council is evidently concerned about the occurrence of a series of communicable diseases in Europe, which were, as it has turned out, too early considered to have been completely combated. Their return can be associated with sensational information about the alleged risks resulting from vaccination that may cause other dangerous diseases, lead to impairment, developmental delays, etc. Another reason can be the inflow of refugees from Africa and Asia, who may be carriers of some infectious diseases, which has not been given due attention for a long time. This last problem seems to be particularly difficult to solve and undoubtedly also very costly. Not ignoring humanitarian issues, the need to take care of people seeking refuge from war, looking for a home to go to and an opportunity to earn a living, the EU Member States must remember about the need to protect their citizens and, as a result, the necessity of examining immigrants and vaccinating them, and even keeping them in quarantine. The European Union legal acts lack attention drawn to this aspect. However, the European Union citizens' unexpected vulnerability to gossip, rumours, and false information about the alleged harmfulness of vaccination has been rightly ascertained. The issue should become an interesting research area for sociologists, political studies specialists, and anthropologists of culture. Indeed, legal regulations cannot change the awareness of their addressees, and dispel myths, stereotypes and superstitions.

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EUROPEAN UNION REGULATIONS CONCERNING VACCINATION AS A MEANS OF PREVENTING INFECTIOUS DISEASES IN THE FACE OF COVID-19/SARS-COV-2 PANDEMIC

Summary

The emergence of the coronavirus proves that Europe is essentially one organism, and the considerable mobility of its inhabitants indicates that health protection should be thought of in terms of the entire continent or even globally. Therefore, the health policy was rightly considered in the Treaty on the Functioning of the European Union, in Article 168, to be a separate policy of the European Union. However, it is also supported by later quite detailed regulations. These regulations stress the importance of vaccination for the protection of public health, and the need to provide information on infectious diseases. An epidemiological surveillance and control network has also been established in the EU. It was also noted that accelerated marketing of medicinal products, including vaccines, is possible even when some clinical data are not available. Vaccines were considered to be medicinal products that are subject to regulations and procedures adopted at the European Union level. It was pointed out that the whole society should be aware of the value of vaccination. It is necessary, in the face of false and inaccurate information, to conduct information campaigns on the dangers of infectious diseases that are preventable by vaccination. Attention was also paid to the negative effects of anti-vaccination movements, stating that as a result of their actions a significant part of the population in the EU countries evades vaccination.

Keywords: World Health Organization, pandemic, coronavirus, European Union, Treaty on the Functioning of the European Union, cross-border epidemic, cross-border health threat, European Union health policy, vaccination, global alliance for vaccines and vaccination, public health, diseases preventable by vaccination

REGULACJE UNIJNE W ZAKRESIE SZCZEPIEŃ JAKO ŚRODEK ZWALCZANIA CHOROÓB ZAKAŹNYCH W OBLICZU PANDEMII COVID-19/SARS-COV-2

Streszczenie

Pojawienie się koronawirusa dowodzi, że Europa jest w gruncie rzeczy jednym organizmem, a olbrzymia mobilność jej mieszkańców wskazuje, że o ochronie zdrowia należy myśleć w kategoriach całego kontynentu czy nawet globalnie. Słusznie więc polityka zdrowotna w Traktacie o Funkcjonowaniu Unii Europejskiej została potraktowana w art. 168 jako samodzielna polityka Unii Europejskiej. Oparta jest ona jednak także o dość szczegółowe późniejsze regulacje. W treści tych regulacji zwrócono uwagę na znaczenie szczepień dla ochrony zdrowia publicznego oraz konieczność przekazywania informacji dotyczących chorób zakaźnych. Powołano także sieć nadzoru i kontroli epidemiologicznej w UE. Zauważono, że możliwe jest przyspieszone wprowadzenie do obrotu produktów leczniczych, w tym także szczepionek, nawet wtedy, gdy brak jest w odniesieniu do nich niektórych danych klinicznych. Uznano, że szczepionki są produktami leczniczymi, które podlegają przepisom i procedurom przyjętym na szczeblu Unii Europejskiej. Wskazano, że ogół społeczeństwa powinien być świadom wartości szczepień, a wobec nieprawdziwych i nieprecyzyjnych informacji konieczne jest prowadzenie kampanii informacyjnych o zagrożeniach związanych z chorobami zakaźnymi, które są możliwe do uniknięcia dzięki szczepieniom. Zwrócono także uwagę na negatywne skutki ruchów antyszczepionkowych, konstatując, że na skutek ich działań znacząca część populacji w państwach unijnych uchyla się od szczepień.

Słowa kluczowe: Światowa Organizacja Zdrowia, pandemia, koronawirus, Unia Europejska, Traktat o Funkcjonowaniu Unii Europejskiej, epidemia transgraniczna, transgraniczne zagrożenie dla zdrowia, polityka zdrowotna Unii Europejskiej, szczepienia, globalny sojusz na rzecz szczepionek i szczepień, zdrowie publiczne, przeciwdziałanie chorobom zwalczanym drogą szczepień

REGULACIÓN COMUNITARIA DE VACUNAS COMO MEDIDA DE LUCHA CONTRA ENFERMEDADES CONTAGIOSAS EN EL MARCO DE PANDEMIA COVID-19/SARS-COV-2

Resumen

La aparición de coronavirus demuestra que Europa en general es el un único organismo. La gran movilidad de sus habitantes indica que hay pensar sobre la protección de salud en la categoría de todo el continente o incluso globalmente. Con razón, la política sanitaria en el Tratado de Funcionamiento de la Unión Europea está regulada en el art. 168 como política independiente de la Unión Europea. Se basa, sin embargo, en la regulación posterior. Esta regulación presta la atención a la importancia de las vacunas para la protección de la salud

pública, a la necesidad de transmisión de la información relativa a las enfermedades contagiosas. Se ha establecido también la red de supervisión y control epidemiológico en la UE. Se observa también, que es posible acelerar la introducción al tráfico de productos médicos, incluyendo las vacunas, incluso cuando carecen de algunos datos clínicos. Se considera que vacunas son productos médicos sometidos a la normativa y procesos aprobados por la Unión Europea. Se indica que la sociedad ha de ser consciente de la importancia de vacunas y en cuanto a la información falsa e imprecisa, es necesario llevar a cabo campaña de información sobre riesgos relacionados con enfermedades contagiosas que se pueden evitar gracias a las vacunas. Se presta también atención a los efectos negativos de movimientos antivacunas, llegando a la conclusión que por su actividad una parte importante de la población en los países comunitarios no se vacuna.

Palabras claves: Organización Mundial de la Salud, pandemia, coronavirus, Unión Europea, Tratado de Funcionamiento de la Unión Europea, epidemia transfronteriza, peligro transfronterizo para la salud, unión global a favor de vacunas y vacunación, salud pública, prevención ante enfermedades combatidas con vacunas

ЗАКОНОДАТЕЛЬСТВО ЕС ОТНОСИТЕЛЬНО ВАКЦИНАЦИИ КАК СРЕДСТВА БОРЬБЫ С ИНФЕКЦИОННЫМИ ЗАБОЛЕВАНИЯМИ В КОНТЕКСТЕ ПАНДЕМИИ КОВИД-19/SARS-COV-2

Аннотация

Распространение нового коронавируса показало, что Европа, по сути, представляет из себя единый организм. Ввиду значительной мобильности ее жителей проблемы здравоохранения следует рассматривать с точки зрения всего континента и даже в глобальном масштабе. Неслучайно в ст. 168 Договора о функционировании Европейского союза отдельно определена политика ЕС в области здравоохранения. Более детально политика в области здравоохранения регулируется последующими нормативными актами. Среди прочего, в нормативных актах ЕС особое внимание уделено важности вакцинации для охраны общественного здравоохранения, а также необходимости обмена информацией, касающейся инфекционных заболеваний. Кроме этого, в ЕС создана сеть учреждений эпидемиологического надзора и контроля. Законодательством ЕС предусмотрена возможность ускоренного выпуска на рынок лекарственных средств, в том числе вакцин, даже если по ним отсутствуют некоторые клинические данные. Вакцины относятся к лекарственным средствам, на которые распространяются правила и процедуры, принятые на уровне Европейского союза. Автор указывает, что широкая общественность должна осознавать важность вакцинации, и что ввиду распространения ложной и неточной информации необходимо проводить разъяснительные кампании о рисках, связанных с инфекционными заболеваниями, предотвратимых посредством вакцинации. Кроме этого, автор обращает внимание на негативные последствия деятельности движений против вакцинации и констатирует, что в результате их действий значительная часть населения в странах ЕС уклоняется от вакцинации.

Ключевые слова: Всемирная организация здравоохранения; пандемия; коронавирус; Европейский Союз; Договор о функционировании Европейского Союза; трансграничная эпидемия; трансграничные угрозы для здоровья; политика Европейского Союза в области здравоохранения; вакцинация; Глобальный альянс по вакцинам и иммунизации; здравоохранение; предотвращение заболеваний, против которых имеются вакцины

EU-VORSCHRIFTEN ZUR IMPFUNG ALS MASSNAHME ZUR BEKÄMPFUNG VON ANSTECKENDEN KRANKHEITEN MIT BLICK AUF DIE COVID-19/SARS-COV-2-PANDEMIE

Zusammenfassung

Die Ausbreitung des sogenannten Coronavirus zeigt, dass Europa im Grunde als ein Organismus betrachtet werden kann und die enorme Mobilität seiner Bewohner macht deutlich, dass über den Schutz der öffentlichen Gesundheit im Hinblick auf den Kontinent als Ganzes oder auch aus globaler Sicht nachgedacht werden sollte. So wurde die Gesundheitspolitik in Artikel 168 des Vertrages über die Arbeitsweise der Europäischen Union zu Recht als eigenständige EU-Politik behandelt. Sie stützt sich darüber hinaus aber auch auf spätere spezifische gesetzliche Regelungen. In diesen Rechtsvorschriften wird auf die Bedeutung von Impfungen für den Schutz der öffentlichen Gesundheit hingewiesen und die Notwendigkeit, Informationen über Infektionskrankheiten bereitzustellen, herausgestellt. Es wurde entschieden, in der EU ein Netz für die epidemiologische Überwachung und die Kontrolle übertragbarer Krankheiten aufzubauen. Außerdem wird festgestellt, dass auch wenn einige klinische Daten nicht verfügbar sind, ein beschleunigtes Inverkehrbringen von Arzneimitteln, einschließlich Impfstoffen, möglich ist. Es wird ausgeführt, dass Impfstoffe Arzneimittel sind, die den auf EU-Ebene erlassenen Vorschriften und Verfahren unterliegen. Betont wird, dass die Allgemeinheit sich über den Wert der Immunisierung durch Impfung bewusst sein sollte und dass angesichts der vielen kursierenden Falschinformationen und ungenauen Auskünfte Informationskampagnen über die Gefahren von Infektionskrankheiten notwendig sind, die sich durch Schutzimpfungen verhüten lassen. Es wird daneben auf die negativen Folgen der Impfgegnerschaft hingewiesen, und der Autor kommt zu dem Schluss, dass als Resultat der Aktivität der impfkritischen Bewegung ein erheblicher Teil der Bevölkerung in den EU-Ländern impfskeptisch ist.

Schlüsselwörter: Weltgesundheitsorganisation (WHO), Pandemie, Coronavirus, Europäische Union, Vertrag über die Arbeitsweise der Europäischen Union, grenzüberschreitende Epidemie/weit verbreitete schwere länderübergreifende Krankheit, grenzüberschreitende Gesundheitsbedrohung, Gesundheitspolitik der Europäischen Union, Impfungen, Globale Allianz für Impfstoffe und Immunisierung (GAVI), öffentliche Gesundheit, Bekämpfung von durch Impfung verhütbaren Krankheiten

RÉGLEMENTATION DE L'UE SUR LA VACCINATION COMME MOYEN DE LUTTE CONTRE LES MALADIES INFECTIEUSES FACE À LA PANDÉMIE COVID-19/SARS-COV-2

Résumé

L'émergence de soi-disant le coronavirus prouve que l'Europe est essentiellement un organisme, et l'énorme mobilité de ses habitants indique que la protection de la santé doit être envisagée en termes de tout le continent, et même globalement. Par conséquent, la politique de la santé a été traitée à juste titre dans le Traité sur le fonctionnement de l'Union européenne à l'art. 168 en tant que politique indépendante de l'Union européenne. Cependant, elle est également basé sur des réglementations ultérieures assez détaillées. Dans le contenu de ces réglementations, l'attention a été attirée sur l'importance de la vaccination pour la protection de la santé publique,

la nécessité de fournir des informations sur les maladies infectieuses. Un réseau de surveillance et de contrôle épidémiologiques a également été mis en place dans l'UE. Il a également été noté qu'une accélération de la mise sur le marché des médicaments, y compris des vaccins, est possible même lorsque certaines données cliniques ne sont pas disponibles. Les vaccins étaient considérés comme des médicaments soumis aux réglementations et procédures adoptées au niveau de l'Union européenne. Il a été souligné que le grand public devrait être conscient de la valeur des vaccinations, et étant donné les informations fausses et inexacts, il est nécessaire de mener des campagnes d'information sur les dangers des maladies infectieuses qui peuvent être évitées grâce à la vaccination. Une attention particulière a également été accordée aux effets négatifs des mouvements anti-vaccination, déclarant qu'en raison de leurs actions, une partie importante de la population des pays de l'UE échappe à la vaccination.

Mots-clés: Organisation mondiale de la santé, pandémie, coronavirus, Union européenne, Traité sur le fonctionnement de l'Union européenne, épidémie transfrontalière, menace sanitaire transfrontalière, politique de santé de l'Union européenne, vaccination, alliance mondiale pour les vaccins et la vaccination, santé publique, prévention des maladies contrôlées par la vaccination

NORME COMUNITARIE NELL'AMBITO DELLE VACCINAZIONI COME MEZZO DI LOTTA ALLE MALATTIE INFETTIVE DI FRONTE ALLA PANDEMIA COVID-19/SARS-COV-2

Sintesi

L'apparizione del cosiddetto coronavirus dimostra che l'Europa è in effetti un unico organismo e l'enorme mobilità dei suoi abitanti indica che la protezione della salute va pensata nelle categorie di intero continente e addirittura a livello globale. Giustamente quindi la politica sanitaria nel Trattato sul funzionamento dell'Unione europea è stata considerata nell'art. 168 come politica autonoma dell'Unione Europea. È basata tuttavia anche su successive norme abbastanza dettagliate. In tali norme si è posto l'accento sull'importanza delle vaccinazioni per la protezione della salute pubblica e sulla necessità di trasmissione delle informazioni riguardanti le malattie infettive. È stata istituita una rete di sorveglianza epidemiologica e di controllo delle malattie trasmissibili nell'UE. Si è notato anche che è possibile un'immissione accelerata sul mercato di medicinali, tra cui anche i vaccini, anche quando mancano nei loro confronti alcuni dati clinici. Si è riconosciuto che i vaccini sono medicinali soggetti alle norme e alle procedure assunte a livello di Unione europea. Si è indicato che in generale la società dovrebbe essere consapevole dell'importanza delle vaccinazioni, e nei confronti delle informazioni false e imprecise è necessario condurre campagne informative sui rischi legati alle malattie infettive, evitabili grazie alle vaccinazioni. Si sono fatte anche notare le conseguenze negative dei movimenti antivaccinisti, constatando che in seguito alle loro attività una parte significativa della popolazione negli stati comunitari evita le vaccinazioni.

Parole chiave: Organizzazione Mondiale della Sanità, pandemia, coronavirus, Unione europea, Trattato sul funzionamento dell'Unione europea, epidemia transfrontaliera, rischio sanitario transfrontaliero, politica sanitaria dell'Unione europea, vaccinazioni, Alleanza globale per i vaccini e l'immunizzazione, salute pubblica, lotta contro le malattie prevenibili da vaccino

Cytuj jako:

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