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The legal aspects of compulsory vaccinations

Prawne aspekty obowiązkowych szczepień ochronnych

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Abstrakt: Aspekty prawne szczepień ochronnych są jednym z elementów zarówno szeroko pojętego prawa sanitarnego, jak i prawa medycznego. Z kolei same szczepienia ochronne jako jedno z podstawowych narzędzi w ochronie zdrowia publicznego są bezspornie niezwykle efektywną metodą walki z wieloma chorobami zakaźnymi. Skuteczne realizowanie nałożonego przez ustawodawcę powszechnego obowiązku szczepień ochronnych zapewnia wysoki stopień uodpornienia populacji i zapobiega epidemicznemu rozprzestrzenianiu się chorób zakaźnych.

Słowa kluczowe: obowiązek szczepień, zdrowie publiczne, uchylanie się od szczepień, prawa pacjenta, egzekucja administracyjna, niepożądane odczyny poszczepienne (nop)

Abstract: The legal aspects of preventive vaccinations are one of the elements of broadly understood sanitary law and medical law. Protective vaccinations, as one of the fundamental measures in the protection of public health, are undoubtedly an extremely efficient method for battling numerous infectious diseases. The effective implementation of the universal vaccination obligation, imposed by the legislator, ensures a high level of the population immunization and prevents the epidemic spread of infectious diseases.

Keywords: vaccination obligation, public health, avoiding obligation, patients' rights, administrative enforcement, adverse event following immunization (aeft)

1. Introduction

Prophylaxis of epidemic diseases is, in compliance with Art. 68 para. 4 of the Polish Constitution,¹ the basic obligation of public authorities. Compulsory vaccination, being one of the greatest achievements of contemporary medicine, is a method of prophylaxis of fundamental significance for public health. Legal aspects of preventive vaccinations are one of the elements of broadly understood sanitary law² and medical law.³ At present, the most significant is the matter of distinguishing between the public and individual nature of health, since only treating health as a public good enables the introduction of restrictions on constitutionally guaranteed rights, including restrictions on the patient's right to consent to a medical service of protective vaccination.⁴ Effective implementation of a universal vaccination policy imposed by the legislator ensures a high degree of herd immunity and prevents an epidemic spread of infectious diseases.⁵

The aim of this paper is to assess whether the current vaccination system permits the maintenance of the population's vaccination coverage at a safe level through effective implementation of compulsory preventive vaccinations. As a rule, this analysis fits within the system of administration law, although some issues go beyond this system and fall under other areas of legal practice (e.g. civil law).

2. Obligatory protective vaccinations

In Art. 5 para. 1 item 1 b) in connection with Art. 17 para. 1,⁶ the Act on prevention and combating infections and infectious diseases among humans imposes on people residing on the territory of the Republic of Poland the obligation to undergo specific vaccinations. The list of mandatory protective vaccinations as well as the group of people obliged to undergo them has been set forth in Art. 17 of the above act and in the Regulation of the Minister of

¹ The Constitution of the Republic of Poland of 2 April 1997, (OJ of 1997 No. 78, item 483) hereinafter referred to as the Constitution

² T. Bojar-Fijałkowski, *Prawo sanitarne w systemie ochrony prawnej środowiska w Polsce*, Bydgoszcz 2019, p. 35-39.

³ R. Tymiński, *Prawo medyczne dla lekarzy i studentów wydziałów lekarskich*, Warszawa 2014.

⁴ A. Augustynowicz, I. Wrześniewska-Wal, *Aspekty prawne obowiązkowych szczepień ochronnych u dzieci*, *Pediatrics Polska* 2013, p. 120-126.

⁵ *Kontrowersje wokół szczepień ochronnych*, Kancelaria Senatu, Biuro Analiz, Dokumentacji i Korespondencji, Marzec 2018, p. 7-8.

⁶ Act on preventing and combating infections and infectious diseases in humans (OJ of 2019, item 1239 as amended), hereinafter: APCIID.

Health of 18 August 2011 on mandatory vaccination,⁷ issued on the basis of the authorization contained in Art. 17 para. 10 of the Act. The universal obligation of preventive vaccination applies to such infectious diseases as tuberculosis, hepatitis B, poliomyelitis, invasive infection with *Haemophilus influenzae* type B, invasive infection with *Streptococcus pneumoniae*, diphtheria, tetanus, pertussis, measles, rubella, epidemic parotitis (mumps) and rabies.

The supplement of the above-mentioned legal regulations is constituted by the Preventive Vaccination Plan (hereinafter: PVP) announced annually by the Chief Sanitary Inspector, pursuant to Art. 17 clause 11 of the Act, through a Communication. PVP is a technical document intended for implementers of mandatory vaccinations and contains information as well as guidelines in accordance with current medical knowledge as to the manner of implementing the obligation of preventive vaccination, including the age, premises resulting from the health status and epidemiological premises, according to which individual vaccinations should be carried out.

A valid concern, which raises legal doubts, is that although the Communication of the Chief Sanitary Inspector has its statutory legitimacy as well as the character of a legal regulation, it does not fit into the catalog of constitutional sources of law and may constitute the basis for raising accusation as to the obligation to vaccinate children, which is specified in a document that does not fall under the catalog of sources of law.⁸ Consequently, the issue of whether detailed due dates of vaccinations defined in the PVP are binding for the persons liable has already been the subject of the judiciary's considerations in administrative jurisprudence, an example of which is constituted by the judgment of the Voivodeship Administrative Court in Gorzów Wielkopolski of 9 September 2015, in which the Court stated that "In accordance with Art. 87 para 1 of the Constitution, the act and regulation are the source of universally binding law." In considering the above, the Court concluded that: "Indeed, as such cannot be named the terms in the communication of the so-called immunization schedule, i.e. resulting from medical reasons – the time of administering subsequent doses of vaccines in relation to the age of children during the period (up to 19 years of age) of the statutory obligation to undergo these vaccinations, which undoubtedly serves only the effectiveness of the protective measures applied."⁹

⁷ Regulation of the Minister of Health of 18 August 2011 on compulsory vaccinations (OJ of 2018, item 753 as amended).

⁸ N. Szczęch, *Problematyka przymusowych szczepień ochronnych u dzieci na tle orzecznictwa sądów administracyjnych*, *Roczniki Administracji i Prawa*, 2016, 16/1, p. 187-211.

⁹ Judgment of the Voivodeship Administrative Court in Gorzów Wielkopolski of 9 September 2015, file No. II Sa/Go 331/15.

Various legal solutions are used by other countries to increase the level of vaccination; and so, in addition to financial penalties, in 2017 Italy introduced changes that allow the admission to kindergarten institutions (including nurseries, kindergartens, pre-school institutions) of exclusively children who have undergone a complete compulsory vaccination plan, and the possession of certificates confirming having undergone the required vaccinations is verified in schools.¹⁰ In turn, Australia has introduced a tax benefit program for families, which significantly increased the vaccinations of children aged 1 and 5.¹¹

3. Patients' rights

Protective vaccination is a medical service within the meaning of the Act on healthcare services financed from public funds.¹² Article 15 of the Act on Patients' Rights and Patients' Rights Ombudsman¹³ obliges the healthcare provider to obtain the consent of the patient or his statutory representative to provide certain medical services. In accordance with Art. 17 clause 2 of the APRPRO, in the case of a minor patient, consent is given by the legal representative, and in the absence of such a consent, it may be expressed by the actual guardian. However, as indicated by the Voivodeship Administrative Court in Białystok in the judgment of 16 April 2013, the responsibility of parents to subject children to compulsory vaccinations is a legal obligation in Poland,¹⁴ and in accordance with the ruling of the Supreme Administrative Court:

[...] calling on the constitutional guarantee of human rights and freedoms, including Art. 31 section 1 and 2 of the Polish Constitution has no justification. Contrary to the applicant's arguments, the obligation to undergo protective vaccination is strongly based on the provisions of the Constitution of the Republic of Poland, and above all of Art. 31 section 3 which states that restrictions on the exercise of constitutional freedoms and rights may be established only by statute and only when necessary in a democratic state for its security or public order, or for the protection of the environment, public health and morality, or the freedom and rights of other people. The relationship between preventive vaccinations and the protection of public health is obvious, primarily

¹⁰ F. D'Ancona, C. D'Amario, F. Maraglino, G. Rezza, W. Ricciardi, S. Iannazzo, *Introduction of new and reinforcement of existing compulsory vaccinations in Italy: first evaluation of the impact on vaccination coverage in 2017*, European Communicable Disease Bulletin, May 2018.

¹¹ J. Leask, M. Danchin, *Imposing penalties for vaccine rejection requires strong scrutiny*, Journal of Paediatrics and Child Health, Feb 2017; <https://doi.org/10.1111/jpc.13472> (25.03.2020).

¹² A. Agustynowicz, *op. cit.*

¹³ Act of November 6, 2008 on Patients' Rights and Patients' Rights Ombudsman (OJ of 2019, item 1127 as amended), hereinafter: APRPRA.

¹⁴ Judgment of the Voivodeship Administrative Court in Białystok of 16 April 2013, file No. II SA/Bk 18/13.

other people who are exposed in this way to the spread of infectious diseases should be protected (cf. the Supreme Administrative Court judgments cited above on April 17, 2014 and February 4, 2015, as well as judgments of the Supreme Administrative Court of June 12, 2012, II OSK 1312/13 and II OSK 97/13, *orzeczenia.nsa.gov.pl*).¹⁵

Only specific medical contraindications for vaccinating a child may constitute exemption from this obligation. At the same time, the Voivodeship Administrative Court in Białystok stated that in the case of compulsory preventive vaccinations, the patient's right to consent to the provision of services is excluded.¹⁶ The Court stressed that "failure to undergo compulsory vaccination, despite the use of administrative enforcement measures, gives rise to criminal and administrative liability as provided for in Art. 115 § 1 of the Petty Offences Code."¹⁷ However, in the case of a lack of consent to perform vaccination, a doctor cannot perform vaccination since the performance of a medical procedure without the consent of a patient, i.e. with the use of force is, according to Art. 36 of the APCIID, admissible only for a person suffering from a particularly dangerous and highly contagious disease that poses a direct threat to the health or life of others.

4. Qualification for vaccination

Pursuant to the APCIID, performing a protective vaccination must be preceded by a medical qualification test aimed at excluding the existence of possible contraindications. This examination must be carried out no earlier than 24 hours before the planned vaccination by a properly qualified doctor. In the case of discovering a long-term contraindication, the doctor refers the child to a specialist vaccination clinic for detailed diagnostics and establishing an individual immunization schedule. Only the acknowledgement of a permanent contraindication to one or several types of vaccination can be the basis for exemption from the statutory obligation.

Pursuant to the APRPRA, the patient has the right to: information on the type and scope of services provided to a given healthcare provider and persons providing these services, information about their health condition, diagnosis, diagnostic and therapeutic methods, foreseeable consequences of their use or omission, results of treatment and prognosis. This information should be conveyed in the most comprehensible and accessible way possible. It may

¹⁵ Judgment of the Supreme Administrative Court of 15 January 2019, file No. II OSK 370/17.

¹⁶ Judgment of the Voivodeship Administrative Court in Białystok of 16 April 2013, file No. II SA/Bk 18/13.

¹⁷ Act of 20 May 1971, Petty Offences Code (OJ of 2019, item 821 as later amended), hereinafter: POC.

be noted that the right to information is a constitutional right contained in Art. 61 of the Constitution. Therefore, it is the physician's duty to inform those obliged to vaccinate about disease hazards and on liability for any evasion of the obligation. The information should also include: type of vaccination, available preparations, number of vaccinations in a given cycle, time intervals at which subsequent vaccinations must be carried out, the most common consequences and complications after vaccination.

5. Adverse event following immunization (AEFI)

Like all medicinal products, vaccine preparations undergo detailed quality control. However, it is not possible to guarantee 100% efficacy either in terms of immunization effects or in predicting possible adverse vaccination reactions.¹⁸

The issue of side effects of vaccination is regulated by the Regulation of the Minister of Health of 21 December 2010 about adverse post-vaccination reactions and criteria for their recognition.¹⁹ The doctor or surgeon who recognizes an undesirable vaccination reaction is obliged to report it to the sanitary inspector appropriate for the reaction recognition site.

Moreover, as part of the AEFI voluntary supervision system, any person interested, including, e.g. a child's parent/guardian, may report a suspected AEFI directly to the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, where they are collected and analyzed in the Department for Monitoring Adverse Reactions of this Office, and then transferred to the European database, the so-called Eudra Vigilance (European Union Drug Regulating Authorities Pharmacovigilance) regulated by the European Medicines Agency, or EMA. This method of reporting AEFI does not require confirmation by a healthcare professional.²⁰

The AEFI registration and assessment system is the second, apart from clinical trials, way for monitoring the quality of vaccine preparations. It permits elimination of faulty vaccines or some of their series from the market. Furthermore, the supervision of undesirable vaccination reactions allows competent state authorities to take immediate action upon the identification of a potentially dangerous situation.²¹

¹⁸ K.M. Malone, A.R. Hinman, *Vaccination Mandates: The Public Health Imperative and Individual Rights*, https://www.cdc.gov/vaccines/imz-managers/guidespubs/downloads/vacc_mandates_chptr13.pdf (24.03.2020).

¹⁹ Regulation of the Minister of Health of 21 December 2010 about adverse post-vaccination reactions and criteria for their recognition (OJ of 2010, No. 254, item 1711 as amended).

²⁰ <https://szczepienia.pzh.gov.pl/faq/jak-w-polsce-mozna-zglaszac-nop/> (22.03.2020).

²¹ S. Dziwisz, *Prawne aspekty przeprowadzania i egzekwowania szczepień Obowiązek szczepień ochronnych*, Państwo i Społeczeństwo, 2015, No. 2.

The costs of health services provided in connection with AEFI treatment for insured persons are financed on the principles set out in the provisions on health care benefits financed from public funds, while in the case of persons without health insurance entitlements, they are financed from the state budget, that is from the part at the disposal of the Minister of Health.

Seeking compensation for damage caused by AEFI may take place on general principles before a common court in civil procedure as a claim against entities responsible for such damage. The only way to seek compensation and satisfaction in the event of complications related to the administration of the vaccine, which is the result of either a medical error or adverse effects caused by the vaccine, remains in civil court proceedings.

In the case of vaccine producers, the provisions of the Act of 23 April 1964 of the Civil Code will apply regarding the so-called liability for a dangerous product based on strict liability (Article 449 of the Civil Code).²² This also applies if the adverse event is not related to the fault of the vaccine manufacturer, but only because of an unpredictable individual patient's response to the vaccine.

The doctor shall be held responsible on general principles of non-contractual liability. Liability arises upon the occurrence of an event with which the Act combines the sanction of indemnity (i.e. committing a tort); the tort causes harm to another entity, there is an adequate causal relationship between the tort and damage and the offense was committed through the fault of the wrongdoer.²³

It is also worth noting in this regard the judgment of the Court of Justice of the European Union of 21 June 2017 in the case C-627/15, which interprets the provision of Art. 4 of Directive 85/374/EEC1 imposing on the injured person the burden of proof before the court, regarding the conditions for the producer's liability for damage caused by a defect in their product, i.e. proof of damage, defect and causal link between the defect and damage. The CJEU issued this ruling in response to the questions of the French Court of Cassation before the substantive settlement of the case to hold the producer of the hepatitis B vaccine responsible for the death of a patient who received 3 doses of this vaccine (26 December 1998,²⁴ 29 January 1999 and 8 July 1999), and who within two years of receiving the first dose contracted multiple sclerosis (November 2000) and died less than a year later (30 October 2011).²⁵ In the Court's view, requiring patients to provide scientific evidence in any case may in practice prevent them from enforcing their rights. In the case described above,

²² Act of 23 April 1964 Civil Code (OJ of 2019, item 1145 as amended) hereinafter: CC

²³ R. Tymiński, *op. cit.*, p. 74.

²⁴ <https://www.mp.pl/szczepienia/prawo/zapytajprawnika/176018,wplyw-orzecznictwa-trybunalu-sprawiedliwosci-ue-na-roszczenia-pacjentow-zwiazane-z-nop>.

²⁵ *Ibidem*.

it was crucial that scientific studies did not confirm and also did not exclude a link between hepatitis B vaccination and multiple sclerosis. The directive was reflected in the provisions of the Polish Civil Code. The judgment of the CJEU, issued on the basis of reference to the preliminary ruling (i.e. the question of the national court to the CJEU in connection with doubts regarding EU law), is binding on all courts of the Member States, including Poland – they are therefore obliged to take into account such rulings, interpreting the provisions of the CC in analogous matters. However, it should be noted that the judgment is of a general nature and does not determine the substance of the dispute itself. In the justification of the CJEU ruling, it stated that in case C-627/15 such elements as the coincidence of time between vaccine administration and the occurrence of the disease, the lack of personal and family history of the occurrence of this disease and the recording of many cases of this condition after taking such vaccines seem to constitute grounds that may lead the national court to consider that the injured party has met the burden of proof under Art. 4 of Directive 85/374/EEC. The general rule of evidence under Art. 6 of the CC stipulates that “the burden of proving a fact lies with the person who draws legal effects from that fact” and complies with the provision of the directive. In practice, this implies that in the course of submission and evaluation of the evidence, the party convinces the court of the truthfulness of facts. However, the role of the court is to assess their reliability and strength according to their own beliefs based on the collected material.

6. Administrative enforcement

The service provider with whom the child’s immunization card is stored is, in accordance with the provisions of the Regulation of the Minister of Health of 18 August 2011 on mandatory preventive vaccinations,²⁶ obliged to notify the competent State Poviats Sanitary Inspector (SPSI) about the fact of evading the obligation to vaccinate, by placing information in the quarterly report on the implementation of preventive vaccinations, the specimen of which is set out in Annex 3 to the Regulation.

As ruled by the Supreme Administrative Court in the judgment of 1 August 2013, the obligation to undergo protective vaccinations results from statutory provisions and its non-performance results in the initiation of enforcement proceedings, which will result in the child being given mandatory protective vaccinations.²⁷

²⁶ Regulation of the Minister of Health of 18 August 2011 on compulsory vaccinations (OJ of 2018, item 753 as amended).

²⁷ Judgment of the Supreme Administrative Court of 1 August 2013, file No. II OSK 745/12.

Measures of administrative enforcement in proceedings regarding non-pecuniary obligations are specified in the Act on the enforcement proceedings in administration²⁸ and include, inter alia a fine for enforcement that may be imposed on the child's legal guardians. The creditor of the obligation to undergo vaccination is the territorially competent State Poviats Sanitary Inspectorate. In accordance with Art. 1a point 13 of the Act on the enforcement proceedings in administration, a creditor is an entity entitled to demand that the obligation be fulfilled or secured in administrative enforcement or security proceedings.

In accordance with Art. 5 point 1 of the Act of 14 March 1985 on State Sanitary Inspection,²⁹ the scope of activity of the State Sanitary Inspection (SSI) in the field of prevention and combating, among others, infectious diseases, includes setting the scope and dates of preventive vaccinations and exercising supervision in this respect. The act on the SSI, in Art. 12 para 1 is a presumption of competence of poviats sanitary inspectors in matters falling within the tasks and competences of the SSI.

In turn, the enforcement body by law is the territorially competent voivode (which results directly from Art. 20 § 1 point 1 of the Act on the enforcement proceedings in administration), who initiates administrative enforcement upon a request, based on an executive title issued by the SPSI. Administrative execution is initiated upon delivery of a copy of the enforceable title to the obligated party. The voivode may impose a fine on an obligated person in order to force them to comply with the statutory obligation to vaccinate. A fine in order to force the entity may be imposed several times at the same or a higher amount. Each fine imposed may not exceed PLN 10,000. Fines imposed repeatedly may not jointly exceed the amount of PLN 50,000. Persons who refrain from vaccination are entitled, in accordance with Art. 122 § 3. EPA, the right to lodge an objection to the voivode, regarding an administrative execution and the right to appeal against the decision imposing a fine to the Minister of Health. Reported allegations are considered by the voivode after obtaining the final stance of the SPSI regarding the accusations made. The SPSI takes the stand in the form of a resolution to which the obligated persons may appeal to the State Voivodeship Sanitary Inspector (SVSI). In response to the complaint, the SVSI also takes a position in the form of a resolution. After obtaining the above position of creditor, the voivode issues a decision on the allegations. The governor's decision may be appealed by the Minister of Health through the voivode.

²⁸ Act of 14 March 1985 on State Sanitary Inspection (OJ of 2019, item 1239 as amended), hereinafter: ASSI.

²⁹ Act of 17 June 1966 on the enforcement proceedings in administration (OJ of 2019, item 1438 as amended), hereinafter: EPA.

7. Conclusions

Protective vaccinations, as one of the fundamental measures in the protection of public health, undoubtedly offer an extremely efficient method of eradicating numerous infectious diseases. Vaccinations have allowed humans to significantly decrease the number of cases of infectious diseases and deaths caused by these conditions. The percentage of deaths caused by infectious diseases, which in Poland was above 20% in the interwar period, currently remains below 1%.³⁰ States where all citizens without medical contraindications are subject to compulsory vaccinations record by an 86% lower incidence of infectious diseases than countries where vaccinations are not compulsory.³¹

Despite these successes, infectious diseases that seemed to no longer pose a major problem are once more becoming a threat. At this point it is worth recalling the concept of herd (population) immunity, i.e. the protection of nonimmunized people as a result of vaccinating a high percentage of a given population. Herd immunity provides protection for people who, due to their medical contraindications, cannot be vaccinated.³² The basic condition guaranteeing the maintenance of herd (population) immunity is to vaccinate a minimum of 95% of the country's population.

In recent years, we have been observing a systematic increase in the number of refusals to vaccinate in Poland; and so in 2010 there were 3,437 people evading vaccination, in 2014 – 12,681 people, and in the period from 1 January to 31 October 2019 – as many as 44,475 people.³³ Furthermore, the large number of foreign citizens from countries with unstable epidemiological situation, who have recently arrived in Poland, remaining completely beyond the control of the SSI authorities, pose an additional threat to the public health in our country.

The growing number of refusals to vaccinate in Poland necessitates the creation of effective enforcement of this obligation. The existing enforcement proceedings, despite the long and time-consuming administrative procedure, do not lead to vaccination of children, and the fines imposed on legal guardians do not have the expected effect. In view of the above, it seems reasonable to consider introducing legal solutions enabling the possible minimization of the

³⁰ J. Bzdęga, A. Gębska-Kuczerowska, *Epidemiologia w zdrowiu publicznym*, PZWL, Warszawa 2010, p. 302-303.

³¹ O.M. Vaz, K.M. Ellingson, P. Weiss, S.M. Jenness, A. Bardají, R.A. Bednarczyk, S.B. Omer, *Mandatory Vaccination in Europe*, PEDIATRICS Vol. 145, No. 2, February 2020; downloaded from www.aappublications.org/news by guest on 25 March 2020.

³² W. Magdzik, D. Naruszewicz-Lesiuk, A. Zieliński, *Wakcynologia*, α-medica press, Bielsko-Biała 2007, p. 19-58.

³³ <https://szczepienia.pzh.gov.pl/faq/jaka-jest-liczba-uchylen-szczepien-obowiazkowych/> (26. 03. 2020).

number of refusals to vaccinate, such as giving a preventive vaccination plan the form of a regulation or introducing a legal obligation to present a document confirming submission to compulsory vaccinations when admitting children to care or educational facilities. It can therefore be concluded that the existing system of legal measures occurring in the field of preventive vaccinations ensures an optimal level of protection of public health, and a correction is necessary at the level of implementing and enforcement provisions.

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