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Legal and organizational aspects of the implementation of immunization in Poland after the COVID-19 pandemic

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Abstract:

Introduction. Reducing the transmission of infectious diseases both among vaccinated individuals and the general population is only possible with the introduction of mandatory vaccination. The **purpose** of this article is to analyze the normative acts in force in the territory of the Republic of Poland, regulating mandatory and recommended immunizations. *State of the art description.* In Poland, immunization is mandatory and carried out in accordance with the Immunization Program for children and adolescents up to the age of 19, and persons particularly vulnerable to disease are published annually as a communiqué of the Chief Sanitary Inspector in the Official Journal of the Minister of Health. The issue of recommended immunizations is clarified by the Regulation of the Minister of Health of September 16, 2010, on the list of recommended immunizations and how to finance and document recommended immunizations required by international health regulations. According to Article 17(6) of the Law, vaccination may be performed by a doctor, feldsher, nurse, midwife, and school hygienist, as long as they have the appropriate qualifications. These qualifications are described in detail in the Ordinance of the Minister of Health of August 18, 2011, on mandatory immunization. According to Article 16 of the Law on Patient Rights and Patient Ombudsman, every patient has the right both to consent and to refuse certain health services. *Conclusion.* Immunization on the territory of the Republic of Poland is mandatory and is subject to legal regulation in the form of laws, regulations, and announcements, cited above. The exceptions are recommended vaccinations and COVID-19 vaccination, which are voluntary but are also legally normalized.

Key Words: *Immunization, Poland, Health care, Health,*

Introduction and purpose of the work

Reducing the transmission of infectious diseases among both vaccinated individuals and the general population is only possible with the introduction of mandatory vaccination. According to the so-called theory of community immunity, when a significant percentage of the population is vaccinated, the non-immunized are also "protected." Each disease has a specific threshold of community immunity, above which the unvaccinated population is protected. In most infectious diseases, the value of this threshold is above 80% [1]. The phenomenon of community immunity applies only to diseases transmitted from person to person. In Poland, mandatory immunization was introduced about sixty years ago, which made it possible to reduce the spread and even eliminate many infectious diseases, such as poliomyelitis and diphtheria [2]. The stable epidemiological situation prior to the Coronavirus pandemic, as well as the spread of anti-vaccine movements, has resulted in the growing phenomenon of evasion of immunization, especially among young parents.

The purpose of this article is to analyze the normative acts in force in the territory of the Republic of Poland, regulating mandatory and recommended immunizations. In particular, the regulations on the obligation of doctors and vaccinators, as well as on adverse post-vaccination reactions. Ways of enforcing this obligation will also be considered, as well as issues concerning consent to immunization.

State of the art description

The obligation of immunization in Poland

In Poland, immunization is mandatory and carried out in accordance with the Immunization Program for children and adolescents up to 19 years of age and persons particularly exposed to the disease (medical personnel, students of medical universities, employees of veterinary services, post-exposure vaccination), published annually as a communication of the Chief Sanitary Inspector in the Official Journal of the Minister of Health. The main normative act regulating the implementation of vaccination is the Law of December 5, 2008, on the prevention and control of infections and infectious diseases in humans [3]. Article 5 of this Act indicates that every person residing on the territory of the Republic of Poland is obliged to undergo immunization; persons residing on the territory of the Polish state for less than 3 months are exempt from this obligation (the exceptions are post-exposure vaccinations, against rabies, tetanus, and diphtheria). Chapter 4 of the aforementioned law specifies the duties of physicians and vaccinators with regard to their implementation, maintenance of medical records, as well as proper patient education. However, it does not include a list of diseases against which vaccination is mandatory. It was not until the introduction of a supplementary act to the law - the Ordinance of the Minister of Health of August 18, 2011, on mandatory immunization, clearly defines the list of infectious diseases subject to mandatory vaccination (diphtheria, tuberculosis, invasive *Haemophilus influenzae* type b infection, invasive *Streptococcus pneumoniae* infection, whooping cough, parotid fever, measles, Sudden Infantile Palsy, rubella, tetanus, hepatitis B, rabies). The document also regulates, among other things, how immunization is carried out and documented, specifies the qualifications that the immunizer must have, and clarifies the groups of people required to undergo mandatory immunization, that is, specifies the age range and other circumstances that impose the obligation to be vaccinated.

The issue of recommended immunizations is clarified by the Decree of the Minister of Health of September 16, 2010, on the list of recommended immunizations and how to finance and document recommended immunizations required by international health regulations [4]. This act includes in an appendix a list of 22 recommended immunizations (including mandatory vaccinations). This is due to the fact that those who are not vaccinated according to the vaccination calendar have the opportunity to be vaccinated later with mandatory vaccines as part of the recommended vaccinations. The list includes vaccinations against hepatitis A, hepatitis B, parotitis, measles, rubella, chickenpox, influenza, rotavirus, diphtheria, tetanus, pertussis, *Streptococcus pneumoniae*, *Neisseria meningitidis*, *Haemophilus influenzae* type b, tick-borne encephalitis, cholera, typhoid fever, rabies, acute anterior myelitis, yellow fever, human papillomavirus, and tuberculosis.

According to Article 17 (11) of the Law of December 5, 2008, on the Prevention and Control of Infections and Infectious Diseases in Humans, the Chief Sanitary Inspector, by October 31 of the year preceding the realization of the program, is obliged to announce, in the form of a communiqué, in the official journal of the Minister of Health, the Immunization Program for a given year. However, the communiqué currently in effect is the Communiqué of the Chief Sanitary Inspector dated October 28, 2021, on the Immunization Program for 2022 [5]. This communiqué was preceded by the communiqué of October 21, 2021. In light of Annex 85 to the aforementioned communiqué, pneumococcal vaccination for the elderly, which was withdrawn for the pandemic period, is reintroduced into the list of recommended vaccinations. The current communiqué also clarifies the aspect of the implementation of immunization during the pandemic period, in the field of influenza vaccination separate recommendations are given for vaccination by injection preparation and by the intranasal route, and the rules for vaccination against selected infectious diseases are supplemented. However, the current legal act does not introduce any "revolution" in the immunization program in Poland.

The most important component of the Chief Sanitary Inspector's communiqué is the vaccination calendar, i.e. the list of mandatory vaccinations for children and adolescents by age, which includes 12 infectious diseases. Vaccination against rotavirus from 2021 is a mandatory vaccination, which became obligatory for children born after January 1, 2021, even though it was previously on the list of recommended vaccinations. The mandatory immunization calendar also lists the specific age at which a child must be vaccinated, starting from the child's birth until the age of 19, as well as by which route the vaccine against a particular disease must be administered.

At this point, it is also worth mentioning the inaccuracies that exist in Polish law regarding immunization. According to the current Constitution of the Republic of Poland of April 2, 1997 [6]. Communication is not a source of law in the constitutional sense. Article 87(1) of the Constitution states that "the sources of universally binding law of the Republic of Poland are: Constitution, laws, ratified international agreements and regulations." Accordingly, both the aforementioned Act and the Regulations are sources of the law in force in Poland. However, it is the communication of the Chief Sanitary Inspector, which is not formally a law-making act, that defines the age at which a child is to be vaccinated and discusses the rules for specific vaccinations.

Legal aspects governing the role of the doctor and vaccinators in their implementation

Article 17. of the Law on Prevention and Control of Infections and Infectious Diseases in Humans specifies the steps that must be carried out before the implementation of mandatory and recommended vaccinations. The doctor who provides preventive health care is obliged to inform the person undergoing vaccination, or his legal guardian, of the obligation to undergo such vaccinations. In addition, this doctor must inform about recommended vaccinations. Otherwise, he is subject to a fine. Immediately prior to performing preventive vaccinations, the doctor is required to conduct a medical qualifying examination to rule out any contraindications to a given vaccination. In a situation in which the doctor postpones vaccination for a long time, it is within his competence to refer the patient for a consultation with a specialist. This examination can only be carried out by a doctor who has the necessary qualifications in this area, as well as knowledge of the indications and contraindications to its implementation and possible adverse vaccine reactions. The duties of a doctor conducting a qualifying examination before both mandatory and recommended immunization also include issuing a certificate indicating the date and time of the examination. This is important because, according to the Law, immunization can be performed up to 24 hours after the date indicated in the certificate. After this time, the examination must be repeated, and the vaccination must be rescheduled.

According to Article 17(6) of the Law, vaccination can be performed by a doctor, feldsher, nurse, midwife, and school hygienist, as long as they have the appropriate qualifications. These qualifications are described in detail in the Ordinance of the Minister of Health of August 18, 2011, on compulsory immunization. Section 6 indicates three eventualities, at least one of which must be met in order for a healthcare worker to perform the vaccination. These include:

- completion of certified training or courses in the field of immunization, which can be confirmed by submitting appropriate documentation
- possession of a specialization in a medical field in which immunization is a framework component.
- the documented experience of at least six months in vaccination.

Recommendations for vaccination against SARS-CoV2 are slightly different. According to the Regulation of the Minister of Health of April 9, 2021, on the qualification of persons conducting qualification examinations and immunization against COVID-19, (Journal of Laws 2021.668). Eligible for qualification for vaccination against COVID-19 are:

- physicians, dentists, field persons, nurses and midwives, paramedics,
- laboratory diagnosticians, pharmacists, and physiotherapists after theoretical training,
- students of the last two years of medical faculties and the last year of the first degree program in nursing, who can qualify for vaccination under the supervision of a doctor and upon presentation of a certificate of completion, as part of their studies, of a course related to immunization.

In accordance with the Ministry of Health's Announcement on the Eligibility of Physicians to Conduct Vaccination Qualification Examinations and the above-mentioned regulation, the requirement of additional professional authorization by physicians, dentists, field persons, nurses and midwives, and paramedics to perform the COVID-19 vaccination qualification examination is not required [7].

It is the responsibility of the person performing the immunization to carefully maintain medical records of mandatory immunizations, including completing the child's immunization booklet. These persons are also required to keep immunization cards. Both documents are issued by those issuing the certificate of live birth. Immunizers are also required to prepare reports on the mandatory immunizations performed and the immunization status of the person. These reports are then submitted to the District Sanitary Inspector. If, on the other hand, a person who is qualified to perform immunizations performs a recommended immunization, then pursuant to Article 19(8) of the Law and pursuant to the Regulation of the Minister of Health of September 16,

2010, he or she is also obligated to keep the medical records mentioned earlier, i.e. the vaccination booklet and immunization card, if the person performing the recommended immunization has access to it. In addition to this, it is the duty of this person to issue a certificate that the recommended immunization was carried out, and he must inform the vaccinated person of the possibility of issuing a paid International Immunization Booklet, the model of which is provided in the aforementioned Decree. If the person carrying out the immunization fails to fulfill his obligation to complete the medical records, or if the immunization is carried out by a person who is not authorized to perform it, a fine may be imposed.

Consent to vaccinate

According to Article 16. of the Law on Patients' Rights and the Patients' Ombudsman [8], every patient has the right both to consent and to refuse certain health services. On the other hand, Article 15. of the same law reads that "the provisions of this chapter shall apply to the consent to the provision of health services or refusal of such consent if the provisions of separate laws do not provide otherwise." At this point, it seems appropriate to specify whether immunization is a health benefit. This information is given to us by Article 2 para. 10 of the Law of April 15, 2011, on medical activity [9], where we find a definition of a health benefit. According to this point, health benefits are "activities aimed at preserving, saving, restoring or improving health, as well as other medical action resulting from the process of treatment or separate regulations governing their performance." This means that immunization is a health benefit, as it serves to preserve health. In the Law on Prevention and Control of Infections and Infectious Diseases in Humans, there is no mention of obtaining consent for immunization. In the case of recommended immunization, the situation is quite clear, the mere fact of incurring the cost of the vaccine is informed consent to the vaccination procedure. However, in the context of compulsory immunization, the only mention of consent is found in § 7 of the Regulation on Compulsory Immunization. It indicates that the medical qualifying examination of children over 6 years of age, can be carried out without the presence of a guardian, provided that his written consent is obtained. During the examination of children under the age of 6, the presence of the person who has legal custody of the minor is required. The qualifying examination always precedes the immunization and without it, the vaccination cannot be performed. Thus, consent to vaccination also consents to the medical examination. This does not mean, however, that consent to the medical examination is sufficient for immunization.

In a situation where a guardian does not consent to a child's immunization, it is possible to legally enforce this obligation, which is aimed at forcing the guardian to comply, as discussed below. However, the fact that the obligation to undergo immunization is regulated by law does not take away anyone's ability to give, or not give, consent to the action in question.

For a patient's consent to be considered legally effective, the patient must have full knowledge of the health service to be performed. This means that consent must be taken knowingly. The doctor providing the service in question is obliged to inform the person concerned, in a comprehensive and accessible manner, about the service. The most important information to be provided concerns the type and scope of the health service, as well as the consequences of administering or not administering the vaccination. The provision of information to the patient is also regulated by law in Articles 9 - 12. of the Law of November 6, 2008, on Patient Rights and Patient Ombudsman. Focusing exclusively on immunization, it is worth informing the patient about the dose and type of vaccine used. The doctor must also not withhold information from the patient about the risk of an adverse vaccine reaction (NOP).

The age of the patient determines who can give consent for recommended or mandatory immunization. In the case of a minor, consent is given by the legal representative (parent, adoptee, guardian, custodian). Thus, if the child's legal representative is the parent, then if one parent reports for a vaccination with the child, the doctor is not required to obtain consent for this procedure from the other parent. However, if both parents report the child to the doctor, then in the event that one parent has consented and the other has not, the vaccination cannot be performed. The patient, who has reached the age of sixteen, also has the right to consent to the proposed vaccination. So, both the consent of the legal representative and the minor is required. In the case of immunization, consent does not have to be in writing, a verbal message is sufficient. If, on the other hand, consent to vaccination is not given, then according to Article 36. Law on Prevention and Control of Infections and Infectious Diseases in Humans: "a person who does not submit to mandatory vaccination, sanitary-epidemiological examination, sanitary treatment, quarantine or isolation, and in whom a particularly dangerous and highly contagious disease is suspected or diagnosed, posing a direct threat to the health or life of others, may be subject to a measure of direct coercion consisting of restraint, immobilization or forced administration of drugs." Hence, it might seem that direct coercion can be applied to people who do not submit to vaccination. However, it is clear from the rest of the article that only people diagnosed or suspected of having a dangerous infectious disease are subject to such coercion. The purpose of immunization is to prevent infectious diseases, and vaccination can only be performed on a healthy person. Thus, direct coercion does not apply to immunization. It can only be administered when cholera, plague, smallpox and viral hemorrhagic fever are suspected or diagnosed. The only coercive vaccination that was used in Poland was against smallpox, performed

in 1963 during an epidemic in Wrocław [10].

Funding for the purchase and administration of mandatory and recommended immunizations

On the territory of the Polish state, every person has the right and opportunity to undergo immunization. This follows from the supreme source of law, which is the Constitution of the Republic of Poland. In Article 68, we read that "citizens, regardless of their financial situation, the public authorities shall ensure equal access to publicly funded health care services." This means that both insured and uninsured persons have the opportunity to undergo immunizations. This rule also applies to foreigners who stay in Poland for more than 3 months and are subject to mandatory immunization. In the case of both of these groups, the qualifying examination, mandatory vaccinations, as well as any specialist consultations, are performed by providers who have a contract with the National Health Fund (NFZ) for these services. The costs of these services, in the case of insured persons, are covered by public funds. Those without health insurance, on the other hand, can rely on the state budget to cover them. However, if a person, whether insured or not, decides to have the above services performed at a facility that does not have a contract with the National Health Insurance Fund to provide them, he or she must cover all the costs, including the purchase of the vaccine, on his or her own.

The procurement of vaccines, in accordance with their annual requirements drawn up by the State Sanitary Inspection authorities, is carried out and financed by the Ministry of Health. The State Sanitary Inspectorate is also responsible for the distribution and storage of the preparations in accordance with the pharmaceutical law. Funds for the purchase of vaccines, in the case of insured persons, come from public funds, while those without health insurance are financed from the state budget. Vaccines other than those purchased by the Minister of Health must be financed by the individual purchaser.

In the case of recommended immunizations, the cost of the vaccination is borne by the person taking the vaccination, or his legal or actual guardian. If an insured person chooses to receive a recommended vaccination at a facility that has a contract with the National Health Service to provide these services, the performance of the vaccination and the medical qualifying examination are covered by public funds. In the case of uninsured persons or insured persons who wish to have a recommended immunization at a facility that does not have a contract with the National Health Fund, the cost of these services is borne by the person undergoing the immunization or his legal or actual guardian.

Adverse vaccine reaction

An adverse vaccination reaction, as defined in the Law of December 5, 2008, on the Prevention and Control of Infections and Infectious Diseases in Humans, is "an undesirable disease symptom that is temporally related to the protective vaccination performed." Fear of it is one of the main reasons for not consenting to protective vaccination. However, this fear does not absolve the obligation to undergo vaccination.

The legal act that defines the types of adverse vaccine reactions and how they are classified is the Decree of the Minister of Health of December 21, 2010, on adverse vaccine reactions and the criteria for their diagnosis [11]. According to the above regulation, we can divide NOP into severe, serious, and mild. A severe reaction threatens life and health and may require hospitalization or even end in death. Severe - is characterized by high fever, severe redness, and swelling of the limb, but does not pose a threat to the life or health of the vaccinated person. Mild NOP, during which there may be fever, swelling, or redness of the limb, has no apparent severity.

Adverse vaccine reactions can also be defined as swelling, enlargement of lymph nodes, abscess at the injection site, encephalopathy, febrile and non-febrile convulsions, flaccid paralysis, encephalitis, meningitis, Guillain-Barre syndrome, arthralgia, thrombocytopenia, high fever, septicemia, anaphylactic reaction, allergic reaction, generalized BCG mycobacterial infection, anaphylactic shock, testicular inflammation, salivary gland inflammation, brachial plexus palsy, incontinent continuous crying, and hypotensive-hyporeactive episode. However, we can consider as NOP any reaction of the body that occurred up to 4 weeks after vaccination.

The procedure for dealing with an adverse vaccine reaction is partially covered in the Law on the Prevention and Control of Infections and Infectious Diseases in Humans, while it is discussed more extensively in the Regulation on Adverse Vaccine Reactions and the Criteria for their Diagnosis. If a doctor suspects or recognizes the occurrence of an adverse vaccine reaction, he is obliged to report the case to the State District Sanitary Inspector, who analyzes the relationship between the vaccine and the symptoms that occur, within 24 hours of the diagnosis. It is also his responsibility to fill out the relevant form, samples of which are attached to the Ordinance. By the hour, the news of the occurrence of a severe or serious reaction is transmitted to the relevant State Regional Sanitary Inspector, who should then also inform the Chief Sanitary Inspector within the hour.

An important issue is the financing of the cost of health services, related to the treatment of NOP. Any person who develops an adverse vaccine reaction, whether or not they have health insurance, has the option of treatment. In the case of an insured person, the cost of treatment is covered by public funds, while for those without insurance, the cost is financed by the state budget.

Enforcement of vaccination obligation

The obligation of immunization is a legal obligation of a non-monetary nature and is enforced as such. The overriding act in the context of enforcement proceedings, in this case, is the Law of June 17, 1966, on Administrative Enforcement Proceedings [12]. According to Article 5. of the aforementioned Act, the entity authorized to carry out administrative enforcement is the institution directly interested in the performance of this duty, that is, in the case of immunization, it is the State Sanitary Inspectorate. It follows from Article 5 of the Law of March 14, 1985, on the State Sanitary Inspectorate [13] that the scope of this institution's activities includes, among other things, "determining the scope and timing of immunization and exercising supervision in this regard." Thus, it is the organs of the State Sanitary Inspectorate that have the authority to demand compliance with the obligation to vaccinate. However, since 2013, it is the competent provincial governor who is the enforcement authority in this regard.

In a situation where the deadline for compliance with this obligation has passed, the State District Sanitary Inspector should send a written reminder requesting compliance. Administrative proceedings may not be initiated until 7 days after the date of delivery, which is in accordance with Article 14 § 1. of the Law. This reminder contains an instruction to refer such a case to enforcement proceedings if the obligation is not fulfilled. It is important that this reminder be received by both parents with parental rights. After the expiration of 7 days from the date of delivery, the State District Sanitary Inspector shall immediately send a request to the competent governor to initiate enforcement proceedings [14]. Thus, the consequence of possible evasion of the obligation to vaccinate is the possibility of imposing a fine on the evader under the administrative procedure, i.e., under Article 26 of the Law of June 17, 1966, on Administrative Enforcement Proceedings. If despite the use of administrative enforcement, the admonished person still refuses to comply with this obligation, an offense occurs, which is regulated by the Code of Offenses. Article 115 § 1. of the same Code reads that "whoever, despite the use of administrative enforcement measures, fails to submit to mandatory immunization against tuberculosis or another contagious disease or to mandatory health examination aimed at detecting or treating tuberculosis, venereal diseases or another contagious disease, shall be subject to a fine of up to PLN 1,500 or a reprimand." In addition, in § 2. of the same article we can find information that the penalty described in § 1. is also subject to the guardians of a minor or helpless person.

However, the mere payment of the imposed fine does not end the enforcement proceedings. The purpose of these proceedings is to bring about the fulfillment of the obligation of immunization. It follows that if the child's guardians continue to postpone the vaccination, further fines may be imposed for the same reason, in the same or higher amount. However, Article 121. of the Law on Administrative Enforcement Proceedings indicates that the total amount of the fine imposed on legal entities, may not exceed 50 thousand zlotys [15].

Another form of the penalty imposed for failure to comply with the mandatory vaccination requirement is the penalty of reprimand, which is purely stigmatizing and thought-provoking, and ultimately aimed at bringing about the implementation of mandatory vaccination. This penalty is not subject to registration in the National Criminal Register and does not make the person on whom it is imposed "punishable" [16].

Conclusion

Immunization in the Republic of Poland is compulsory and regulated by law in the form of laws, regulations, and announcements, cited in the above study. The exceptions are recommended vaccinations and COVID-19 vaccination, which are voluntary but are also legally normalized. Due to a new regulation, as of February 1, 2022, they are to be mandatory for certain professional groups (including healthcare workers) [18]. There are a number of tools to help with enforcement proceedings against vaccine evaders, but restricting civil liberties and using forced vaccination seems a less effective form of action. The overriding goal of medical professionals, mainly in the PCP, seems to be to take on an educational role, making people aware of the benefits of vaccinations, and eradicating persistent misconceptions about vaccination in society, while not concealing possible NOPs [19].

The introduction of COVID-19 vaccination removes the need for quarantine, reduces the risk of disease, limits the transmission of infection within the workplace, and reduces sickness absence. The role of the occupational health service is to promote COVID-19 vaccination by providing reliable information on the safety and efficacy of vaccination, as well as organizing and carrying out vaccination at workplaces [20].

Mandatory vaccination applies to the entire population in only three countries - Tajikistan, Turkmenistan, and Vatican City. Other countries, including France, the United Kingdom, Italy, and Greece, have mandatory vaccinations for healthcare workers or certain professions requiring a high level of contact with people [17]. The United States has made vaccination against COVID-19 mandatory for companies with more than 100 employees and healthcare workers.

The United States on November 8, 2021, became the first in the world to introduce vaccination of children aged 5-11 years, with the BioNTech/Pfizer formulation (the vaccine was recommended by the federal government agency, the Centers for Disease Control and Prevention); and on June 19, 2022, Pfizer and Moderna

formulations were registered for children from 6 months to 5 years. The vaccine intended for them has the same qualitative composition as the vaccine used for adolescents over 12 and adults and differs only in dose size. The first countries in the world to allow the use of COVID-19 vaccines in children who are five years old and younger are China, Cuba, and the United Arab Emirates. As of December 13, 2021, this possibility also exists in Poland.

Conflicts of interest - The authors declare no conflict of interest.

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