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LEGAL REGULATIONS GOVERNING THE PAYMENT OF COMPENSATION IN CONNECTION WITH VACCINATIONS AGAINST COVID-19

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Abstract. From a medical point of view, vaccinations are the only effective method of protection against the spread of infectious diseases. The aim of the study is to present legal regulations governing the payment of compensation in connection with vaccinations against Covid-19. The experience of other countries shows that compensation payments fulfill their intended function to a greater or lesser extent. While civil court proceedings remain an alternative, due to their lengthy nature, many people choose to submit an application to the Patient Ombudsman. However, it should be remembered that court proceedings – unlike the Patient Ombudsman procedure – provide the opportunity to obtain much larger amounts as compensation, or compensation and pension.

Keywords: compensation; infectious diseases; vaccinations.

INTRODUCTION

From a medical point of view, vaccinations are the only effective method of protection against the spread of infectious diseases. They are rightfully considered one of the greatest achievements of medicine and the most effective known method of preventing infectious diseases [Radlak 2018, 27-28]. Protective vaccinations against Covid-19 during the pandemic offered the much-awaited solution for preventing and combating the infectious disease caused by the SARS CoV-2 virus. After their wide adoption, the next

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challenge was to reach citizens with vaccinations as widely as possible. The widespread use of vaccinations has contributed to reducing the incidence of Covid-19. The aim of these vaccinations was to expand the public's belief that the only effective way to protect against Covid-19 was to achieve the highest possible level of vaccination. On the other hand, compensation payments for the adverse effects of vaccinations, i.e. the so-called vaccine adverse events, are legally considered to be compensation paid from the Vaccination Compensation Fund. The aim of the study is to discuss legal regulations governing the payment of compensation in connection with vaccinations against Covid-19. In connection with this aim, the study explored the problem of the legal regulations governing the payment of compensation. In addition, other specific questions were investigated: What are the conditions for the payment of compensation? What authority administers the Vaccination Compensation Fund? What is the obligatory condition for the payment of the compensation? What are the revenues of the Vaccination Compensation Fund? What actions are taken by the Patient Ombudsman to consider an application for compensation? Is the patient's consent to vaccination a prerequisite for the legality of a medical intervention?

1. CONDITIONS FOR THE PAYMENT OF COMPENSATION

Pursuant to Article 17a of the Prevention Act,[1] if, as a result of protective vaccination against Covid-19, the person who received the vaccination suffered from the side effects listed in the Summary of Product Characteristics (SmPC) referred to in the Act of September 6, 2001 – Pharmaceutical Law within five years from the date of administration of the vaccine or vaccines, such person is entitled to compensation paid from the Vaccination Compensation Fund. For such a benefit to be paid, at least one of the following two conditions must be met: the person concerned either required hospitalization for a period of not less than 14 days or suffered from anaphylactic shock and required observation in a hospital emergency department or an acute admissions ward, or hospitalization for a period of less than 14 days.

To start with, it should be noted that it is characteristic that the causal relationship between the vaccination of a person and the side effects listed in the SmPC may be both direct and indirect. This means that in accordance with Article 17a(1) of the Act on preventing and combating infections and infectious diseases in humans (for convenience, the Act will further be referred to as the "Prevention Act"). Side effects may appear both shortly after receiving the vaccination and later as a consequence of other

[1] Act of 5 December 2008 on preventing and combating infections and infectious diseases in humans, Journal of Laws of 2023, item 1284 as amended.

disturbances in the functioning of the body resulting from the administration of the vaccine. This interpretation of the provision in question is primarily determined by the five-year period adopted by the legislators as the time required for the occurrence of side effects listed in the Summary of Product Characteristics. This means that compensation is not due only in a situation that does not raise any doubts, i.e. where any relationship (direct or indirect) between the vaccination and an adverse event can be excluded.[2] This solution should be considered the aptest due to the justification for seeking compensation. *De lege ferenda*, the five-year period could be extended, if this is justified by an increase in the number of medical cases related to vaccination.

Although the five-year period is long enough to assume an indirect causal relationship between vaccination and the side effect [Serwach 2022, 115], the argument in favor of such an interpretation of Article 17a(1) of the Prevention Act. is provided by the justification for the draft act amending the Prevention Act. The Prevention Act clearly stipulates that compensation will be awarded both when the vaccine's side effects were the direct cause of hospitalization and when the side effects resulted in a deterioration of health requiring hospitalization for a period of not less than 14 days.[3]

Before this discussion continues, a brief description of the amount of compensation [Sałbut 2021, 67-77] is needed. The amount of compensation generally depends [Piecha 2021, 45-56] on the duration of hospitalization: in the case of observation in a hospital emergency department or an acute admissions ward due to anaphylactic shock, it is PLN 3,000, and in the event of hospitalization due anaphylactic shock for less than 14 days, it is PLN 10,000. Moreover, if the hospitalization period lasted 14 to 30 days, the compensation will range from PLN 10,000 to PLN 20,000, in proportion to the hospitalization period, and if the hospitalization lasted 31 to 50 days, it will range from PLN 21,000 to PLN 35,000, in proportion to the hospitalization period. In the case of hospitalization lasting 51 to 70 days, the compensation will range from PLN 36,000 to PLN 50,000, in proportion to the hospitalization period, and in the case of hospitalization lasting from 71 to 90 days – from PLN 51,000 to PLN 65,000, in proportion to the hospitalization period. For hospitalization lasting from 91 to 120 days – the compensation will amount from PLN 66,000 to PLN 89,000, in proportion to the hospitalization period. If hospitalization lasted more than 120 days, the compensation is PLN 100,000. As R. Budzisz rightly notes, "such an interpretation would lead to the conclusion that if the applicant received the amount of PLN 100,000 (for hospitalization lasting longer than 120 days), they would no longer be eligible for

[2] Judgment of the Provincial Administrative Court in Warsaw of 9 February 2024, ref. no. V SA/Wa 808/23, Lex no. 3709486.

[3] Amendment to the Act of 5 December 2008 on preventing and combating infections and infectious diseases in humans, Journal of Laws of 2021, item 2069.

any additional compensation. However, it seems that the legislators' intention was to grant the applicant an additional amount in connection with treatment or rehabilitation" [Budzisz 2023, 23]. Therefore, *de lege ferenda*, this regulation needs to be changed so as to ensure the quickest possible recovery by granting funds to the aggrieved party, and if this is not possible, at least reduce the nuisance caused by the vaccine adverse event.

2. PATIENT OMBUDSMAN AS THE ADMINISTRATOR OF THE VACCINATION COMPENSATION FUND

Compensation is granted by the Patient Ombudsman [Karkowska and Kmieciak 2021, Article 3]. It should also be emphasized that the proceedings for granting compensation are extrajudicial and are conducted under administrative procedures [Matan 2005, 572-80].

The Vaccination Compensation Fund was established on the basis of the amendment to the Prevention Act [Serowaniec 2022, 24-37], introduced by the Act of December 17, 2021 amending the Act on preventing and combating infections and infectious diseases in humans and certain other acts, which entered into force on January 27, 2022.[4]

The first of the above-mentioned Acts clearly stipulates that compensation is granted by the Monetary Policy Council (MPC) (Article 17a(6)) following an explanatory procedure (Article 17d(1) of the Prevention Act). This procedure results in an opinion being issued by the Panel for Benefits from the Vaccination Compensation Fund. The opinion concerns the occurrence of an adverse event listed in the Summary of Product Characteristics (Article 17d(2)). Moreover, the Monetary Policy Council and the members of the Panel authorized by it have, pursuant to Article 17f of the Prevention Act, access to medical documentation necessary to consider the application for compensation. It is worth emphasizing that a member of the Panel may be excluded on the terms and in the manner specified in Article 24 of the Code of Administrative Proceedings [Przybysz 2021, 25]. Such a situation may occur, for example, when the applicant is a party to the proceedings or is in such a legal relationship with the applicant that the outcome of the case may affect his or her rights and obligations.

However, in Article 17d(13) of the Prevention Act, the legislators provided a very broad definition of the group of persons subject to exclusion. This is a commendable approach given the possible conflicts of interest. A Panel member is also excluded if the case concerns their spouse, relatives or in-laws up to the second degree, or persons related to them by virtue of adoption,

[4] Act of 17 December 2021 amending the Act on preventing and combating infections and infectious diseases in humans and certain other acts, Journal of Laws of 2022, item 64.

care, or guardianship. Moreover, a Panel member is also excluded if the above conditions apply to an entrepreneur conducting business activity in the field of vaccine production or sales, provided that the side effects of these vaccines are the subject of the procedure for awarding compensation. *De lege ferenda*, it would be advisable to extend the exemptions also when the side effects of vaccines manufactured by this entrepreneur concern not only this specific procedure for awarding compensation, but in general, due to the biased nature of such affiliations. Therefore, following *a minori ad maius* reasoning, this postulate should be defined through the prism of impartial behavior that could negatively influence the outcome of the proceedings.

Next, after obtaining the opinion of the above-described Panel (Article 17g(1) of the Prevention Act), the Patient Ombudsman issues a decision on the application for compensation (grants the compensation and determines its amount, or refuses to grant the compensation) within two months of receipt of the complete application, and this decision may be appealed against to the administrative court (Article 17g(3) of the Prevention Act). This decision is final (Article 17g(1) of the Prevention Act). Taking into account the local jurisdiction, a complaint should be filed with the Provincial Administrative Court in Warsaw, and a cessatory complaint against the judgment of this court may be filed with the Supreme Administrative Court.

In addition, the MPC has the right to request that the applicant or medical provider submit medical documentation within a specified period of time (Article 17g(4) of the Prevention Act).[5] Here, it should be emphasized that compensation is additionally increased depending on the duration of hospitalization, or the need for surgery. In the case of: 1) surgery under general anesthesia – by PLN 15,000; 2) a surgical procedure other than specified in point 1, or a method of treatment or diagnosis posing an increased risk – by PLN 5,000; 3) hospitalization in an intensive care unit or intensive medical care department lasting at least 7 days – by PLN 10,000; 4) hospitalization in an intensive care unit or intensive medical care department lasting longer than 30 days – by PLN 20,000. It should also be noted that compensation also includes reimbursement of the costs of further treatment or rehabilitation after observation or hospitalization, in an amount not exceeding PLN 10,000. The total amount of compensation may not exceed PLN 100,000.

For the present discussion, it is important to note that the judgments from 2017-2022 regarding health disturbances or bodily injuries to the patient (data from an online resource of common-court rulings in Poland[6]) show that the average amount awarded to the aggrieved party was PLN

[5] Judgment of the Provincial Administrative Court in Warsaw of 28 April 2023, ref. no. V SA/Wa 1748/22, Lex no. 3570961.

[6] See https://orzeczenia.ms.gov.pl/search/advanced [accessed: 15.02.2025].

116,000. Although the proposed amounts regarding compensation fully correspond to the amounts of compensation that the patient could receive in a lawsuit, due to the costs associated with the recovery, they are still insufficient. Therefore, *de lege ferenda*, it is necessary to postulate an increase in the amounts paid from the Vaccination Compensation Fund, so that they would compensate the aggrieved party's for the suffered adverse health consequences more fairly.

3. VACCINE ADVERSE EVENTS AS A PRE-REQUIREMENT FOR THE PAYMENT OF COMPENSATION

Prima facie, the types and criteria of vaccine adverse events are included in Annex No. 1 to the Regulation of the Minister of Health of December 21, 2010 on vaccine adverse events and the criteria for their recognition.[7]

A vaccine adverse event is classified as a serious adverse reaction if it is life-threatening and may: require hospitalization to save health, lead to permanent loss of physical or mental fitness, or result in death. However, a vaccine adverse event is classified as a serious adverse reaction if it is characterized by severe symptoms such as significant swelling of the limb, severe redness, high fever, but: does not usually require hospitalization to save health; does not lead to permanent damage to health; does not pose a threat to life. A mild vaccine adverse event is an undesirable post-vaccination reaction that is not particularly severe and is characterized by local swelling of the limb and strong local redness or fever.

This brings us to the changes introduced by the Regulation of December 21, 2010, which was amended by the Regulation of the Minister of Health of December 31, 2020,[8] including the form in which the notification regarding vaccine adverse events should be submitted. Pursuant to para. 1 of the Regulation of December 31, 2020, the wording of para. 4(1)(1-2) of the Regulation of December 21, 2010 is as follows: "Reporting a vaccine adverse event by a doctor or medic: 1) prepares and sends in electronic form, with the direct use of the information exchange system as part of the information exchange systems within the remit of the State Sanitary Inspectorate referred to in the regulations issued pursuant to Article 8a(2) of the Act of March 14, 1985 on the State Sanitary Inspection [...], or with the use of an IT tool cooperating with this system, made available by a unit subordinate to the minister

[7] Annex No. 1 to the Regulation of the Minister of Health of 21 December 2010 on vaccine adverse events and the criteria for their recognition, Journal of Laws No. 254, item 1711.

[8] Regulation of the Minister of Health of 31 December 2020, including the form in which the notification regarding vaccine adverse events should be submitted, Journal of Laws of 2021, item 13.

responsible for health matters, responsible for health care information systems as part of the IT system referred to in Article 7(1) of the Act of April 28, 2011 on the health care information system [...], taking into account the scope of data resulting from the vaccine adverse event reporting card, or 2) prepares an electronic document – a vaccine adverse event reporting card – and sends it via electronic means of communication in an encrypted form if the technical capabilities of the sender and recipient allow it."

Vaccine adverse event reports sent in the manner specified above must be signed with a trusted signature, a qualified electronic signature, or a personal signature. It is also worth noting that corrections to vaccine adverse event reports can be made electronically – in the form of an electronic document, by telephone, fax, or using another data transmission device. Correction of a vaccine adverse event report made by telephone should be immediately confirmed in writing in the form of an electronic document [Król-Całkowska 2021, 45].

Against this backdrop, according to Article 21(1) of the Prevention Act, a doctor or medic who suspects or identifies the occurrence of a vaccine adverse event is obliged, within 24 hours from first suspecting such occurrence, to report the case to the state district sanitary inspector responsible for the area in which the event is suspected or identified. Moreover, the competent state sanitary inspector is obliged to: first, supplement the report of a vaccine adverse event with information collected at the place of vaccination, or immediately forward the report to the competent state district sanitary inspector, and secondly, keep a register of vaccine adverse event reports.

The register of vaccine adverse event reports may be kept in paper form, or in an electronic system. This means that the data collected in the register of vaccine adverse event reports are made available by the Chief Sanitary Inspector [Kowalska-Mańkowska 2018, Article 97] to the Patient Ombudsman to the extent necessary to conduct proceedings for the award of compensation.

According to legal commentators and jurisprudence, it is assumed that fault occurs when the perpetrator can be accused of objective and subjective misconduct.[9] Therefore, only after these conditions have been met will the payment of compensation be justified. However, there is no need to prove the culpable party's fault, and compensation is granted as a lump sum. Liability for adverse effects caused by the administration of the vaccine may be borne by the doctor, medical provider, or manufacturer. A vaccine defect results in strict liability under Article 449(1) et seq. of the Civil

[9] Judgment of the Court of Appeal in Warsaw of 5 September 2019, ref. no. V ACa 450/19, Lex no. 2978510.

Code.[10] And the actions of the doctor and medical staff violating the requirements of diligence under Article 355(2) of the Civil Code entail ex delicto liability (Articles 415, 430 of the Civil Code). In practice, the application of Article 417 of the Civil Code requires the patient to demonstrate, in addition to the damage sustained and the causal relationship, the circumstances that the action of the medical provider was objectively unlawful in terms of the administrative actions taken. As stated above, in certain cases, these culpable parties may be doctors and medical staff. In this context, the judgment of the Supreme Court in Gdańsk of May 31, 2016 is distinctive. According to it, "unlawful conduct of doctors and medical staff is one that violates the legal order, principles of professional ethics, standards of medical knowledge, or principles of social coexistence. In order to find them liable, it is therefore necessary to conclude that in a given situation, their conduct was evidently inappropriate. This may take the form of ignorance, carelessness, inattention, or negligence, consisting in failure to exercise a certain measure of diligence. The conduct of doctors and other medical staff must be objectively unlawful and subjectively culpable. It is the responsibility of all medical staff of the healthcare provider to exercise due diligence in the treatment of every patient."[11] Therefore, doctors and other medical professionals [Michałowska 2021, 54] will also be liable if they do not comply with the principles of due diligence, provided that their actions or omissions are objectively unlawful and subjectively culpable.

A problematic situation occurs when none of the above-mentioned providers is at fault, and the adverse event is a consequence of the body's reaction. In that event, the culpable party is the state, and culpability is assessed on the basis of risk or equity [Nesterowicz 2017, 57].

4. REVENUES OF THE VACCINATION COMPENSATION FUND

Expressis verbis, Article 17b of the Prevention Act stipulates that due to the criteria contained in Article 29 of the Public Finance Act, the Fund is a public special purpose fund created for the purpose of paying compensation. However, there are some doubts as to whether the concept of "another body" under the provision of Article 29(4) of the Public Finance Act should be interpreted to include only public administration bodies [Zimmermann 2008, 176-177] (in its subjective meaning). Although this is a broader category of administrative bodies, i.e. bodies with a much more diverse legal status that perform administrative functions in the objective sense, the Patient

[10] Act of 23 April 1964, the Civil Code, Journal of Laws of 2023, item 1610 as amended.

[11] Judgment of the Court of Appeal in Gdańsk of 31 May 2016, ref. no. V ACa 877/15, Lex no. 2144729.

Ombudsman, who is the administrator of the Vaccination Compensation Fund, is a central government administration body [Jagielski 2022, 27-34].

Before moving on to further discussion, it should be noted that the Fund's revenues come from many independent sources. First, these are obtained from payments by entities that have concluded an agreement with the State Treasury for the supply of protective vaccines and which are obliged, within 21 days from the date of this agreement, to make a payment to the Fund's bank account in the amount of 1.5% of the gross value of this agreement. Another source of revenue is the interest earned on the Fund's bank account. Third, the Fund's revenues include interest on late payments from entities that have concluded an agreement with the State Treasury. The fourth source are fees for compensation applications. These amount to PLN 200. The fifth source are payments from the state budget transferred in a given financial year, if it is necessary to supplement the Fund for the payment of awarded compensation. The Fund also obtains its financial resources from inheritances, bequests, and donations, among others.

It is characteristic that the Fund's revenues come from entities supplying vaccines for the purposes of mandatory protective vaccinations against diseases listed in the regulation issued under the authorization arising from Article 17(10) of the Prevention Act – currently in the Regulation of the Minister of Health of August 18, 2011 on mandatory vaccinations.[12]

Therefore, the obligation to make payments applies to suppliers of vaccines [Bosek 2021, 105-18] delivered for the prevention of selected diseases, in the event of a risk of their spread, and for ad hoc vaccination campaigns. They are indicated in the implementing regulations issued pursuant to Article 46(4)(7) of the Prevention Act This authorization exhausted the scope of the regulation of the Minister of Health of March 20, 2020 on the declaration of an epidemic on the territory of the Republic of Poland, which introduced the obligation to undergo protective vaccinations against Covid-19,[13] applicable to groups of people listed in this regulation (e.g. people practicing a medical profession). Vaccine suppliers are, therefore, obliged to make a payment to the Fund to provide preventive vaccinations to these professionals.

The diseases are listed in the implementing rules issued under the delegation contained in Article 3(4)(2) of the Prevention Act. Currently, such calculation is included in the following regulations of the Minister of Health: 1) of April 6, 2009 on methods of preventing meningococcal infections;[14] 2)

[12] Regulation of the Minister of Health of 18 August 2011 on mandatory vaccinations, Journal of Laws of 2018, item 753 as amended.

[13] Regulation of the Minister of Health of 20 March 2020 on the declaration of an epidemic on the territory of the Republic of Poland, Journal of Laws item 491, act repealed.

[14] Regulation of the Minister of Health of 6 April 2009 on methods of preventing

of September 6, 2016 on the methods of preventing measles;[15] 3) of December 31, 2020 on the methods of preventing Covid-19;[16] 4) of March 25, 2022 on the methods of preventing infections or infectious diseases constituting a particular threat to public health in connection with the armed conflict on the territory of Ukraine.[17]

It is worth noting that the first system for compensating adverse events caused by compulsory vaccinations was established in France in 1964, followed by Germany in 1971, Japan in 1976, the UK in 1979, and the USA in 1988. In Europe, the Fund's revenues also come from various sources. In Finland, for example, the vaccination compensation fund is financed from health insurance contributions. However, there are models in which compensation is paid directly by hospital facilities financed from the state budget, as well as ones in which the fund is operated by insurance companies. As an example, the system in Denmark was established in 1992 and initially covered only hospitals owned by the state or local governments. Primary health care was included in the compensation system only in 2004, and as of 2021, it expanded covers cases from other European countries. In Belgium, which had an ambitiously designed system covering all health care, the compensation system became inefficient from the very beginning. A vaccination compensation fund has also been in place in the Czech Republic since 2020 [Budzisz 2023].

5. ACTIONS TAKEN BY THE PATIENT OMBUDSMAN TO EXAMINE COMPENSATION APPLICATIONS

Pursuant to Article 17(f) of the Prevention Act, the Ombudsman has access to medical documentation necessary to consider a compensation application, including documentation regarding vaccination entitling to submit compensation application and the applicant's treatment [Haberko 2021, 298-99] collected in the electronic medical records system, as well as data and information contained in medical registers. Panel members are authorized to access the documentation by the Ombudsman. This means that the Panel processes the documentation collected in connection with the procedure for granting compensation to the extent necessary to prepare an opinion on the occurrence

meningococcal infections, Journal of Laws No. 56, item 465.

[15] Regulation of the Minister of Health of 6 September 2016 on the methods of preventing measles, Journal of Laws item 1418.

[16] Regulation of the Minister of Health of 31 December 2020 on the methods of preventing COVID-19, Journal of Laws of 2021, item 10.

[17] Regulation of the Minister of Health 25 of March 2022 on the methods of preventing infections or infectious diseases constituting a particular threat to public health in connection with the armed conflict on the territory of Ukraine, Journal of Laws item 681.

of an adverse event listed in the Summary of Product Characteristics after the administration of a vaccine or vaccines, and the effects of such an event.

Moreover, the data provided include: name and surname, date of birth, national identification number, and if the person has not been assigned this number – the series and number of the passport, or the identification number of another document with personal details – address of residence, health data, and other information necessary to supervise the occurrence of vaccine adverse events, according to the up-to-date medical knowledge. Documentation collected or prepared for the purposes of, or in connection with, the procedure for granting compensation is kept by the Patient Ombudsman for a period of ten years, starting from the end of the calendar year in which the compensation application was submitted. Moreover, it should be emphasized that the Patient Ombudsman is the controller of the data contained in the documentation collected and prepared for the purposes of, or in connection with, the procedure for granting compensation.

A solution where the Patient Ombudsman decides on the substantive issues regarding compensation is clearly preferable, and for a number of reasons. First, the institution is undoubtedly a specialized body and has, ab initio, comprehensive empirical knowledge due to the exercise of its powers. Second, it also makes decisions within the framework of the Code of Administrative Procedure, which provides appropriate guarantees of the procedural rights of the interested party. Third, it guarantees expediency and limits mistakes. Therefore, the powers of the Patient Ombudsman in substantive issues regarding compensation are absolutely justified and necessary. It is difficult to imagine another authority having equivalent powers. Such a solution would certainly not be beneficial or desirable for applicants.

6. THE REQUIREMENT FOR THE PATIENT'S CONSENT TO UNDERGO VACCINATION AGAINST COVID-19 AS A PREREQUISITE FOR THE LEGALITY OF A MEDICAL INTERVENTION

The patient's consent [Świderska 2007, 56] to vaccination is a prerequisite for the legality of such a medical intervention. In the absence of consent, medical practitioners may face criminal liability under Article 192 of the Penal Code. In this context, however, we may recall the view that "The issue of consent to vaccination is debatable." The courts indicate that in this case, the patient cannot exercise the right to refuse health care services under Article 16 of the Act[18] because this right is excluded in cases

[18] Act of 6 November 2008 on Patients' Rights and Patients' Ombudsman, Journal of Laws of 2024, item 581.

where separate provisions provide otherwise (Article 15 of the Prevention Act). This is the case, among others, in relation to mandatory vaccinations under the Prevention Act.[19] Although according to the literature, the Prevention Act is silent on this subject, one could hardly say that it stipulates otherwise in relation to the Act on patients' rights and the Patient Ombudsman [Augustynowicz and Wrześniewska-Wal 2013, 122-23].

Nevertheless, this is a specific regulation whose purposive interpretation allows for the conclusion that it excludes the patient's right [Bagińska 2013, 3] to refuse consent to vaccination. Legal commentators even present the view – in my opinion, too far-reaching, such as the one offered by N. Karczewska-Kamińska [Karczewska-Kamińska 2018, 5] – that "in the case of compulsory vaccinations of minors, the consent of the legal representative is not required, as it is about fulfilling an obligation" [Boratyńska 2013, 74]. However, it is difficult to agree with this view, since vaccinations [Safjan 2004, 27] are, according to the Family and Guardianship Code, important matters for the child and therefore the consent of statutory representatives is required.

Moreover, this thesis is justified by the existing legal regulations, according to which, as provided for in the Regulation of the Minister of Health on mandatory preventive vaccinations, a medical qualification examination and mandatory protective vaccinations for a person who is under six years of age are performed in the presence of a person who has legal custody of that person or an actual guardian within the meaning of Article 3(1)(1) of the Regulation. In the case of minors over six years of age, the presence of the above-mentioned persons is not necessary, provided that their written consent and information on health conditions that may constitute a contraindication to vaccination have been obtained (para. 7(1) and (2) of the Regulation). *A contrario*, accepting such a view as valid would constitute a denial of the applicable legal regulations referred to above.

The group of people without full legal capacity includes both minors (as a rule, up to 18 years of age) and people who have already reached the age of majority [Bączyk-Rozwadowska 2013, 182] but have been incapacitated. Those responsible for fulfilling the discussed obligation to undergo vaccinations [Paszkowska 2006, 15-21] will usually be the parents of the minor (if they have the so-called parental authority), a legal guardian appointed by the court, or the actual guardian. The subjective scope of the concept of actual guardianship was defined in the Act of November 6, 2008 on patient rights and the Patient Ombudsman. An actual guardian is a person who, without being statutorily obliged to do so, provides permanent care to a patient who requires such care due to their age, health, or mental

[19] See judgments and see judgment of the Provincial Administrative Court in Krakow of 16 April 2013, ref. no. III SA/Kr 1104/12, Lex no. 1326297.

condition. For example, it may be a family member [Jaworska 2017, 60-72] (grandmother, aunt) who takes care of the minor when their parents cannot be the caregivers. It is important, however, that this care should be permanent and not incidental or short-term. What is more, pursuant to Article 109 of the Family and Guardianship Code, if the child's well-being is at risk, the guardianship court will issue appropriate orders and, in particular, may oblige the parents and the minor to take specific actions.

However, it is difficult to agree with M. Boratyńska's opinion that "The provision has a very broad structure and is independent of the procedure for suspending or removing parental authority. It provides the guardianship court with the power to act quickly, avoiding lengthy proceedings. The court may initiate a case *ex officio* (Article 570 of the Code of Civil Procedure) based on a notification from any person. Therefore, there are no obstacles to appointing a guardian just to take the child for compulsory vaccinations" [Boratyńska 2013, 74]. This argument is supported by the fact that although Article 109 of the Family and Guardianship Code does not refer directly to the concept of "violation of the child's best interests", there is no doubt that in this respect, the guardianship court is obliged to take actions aimed primarily at protecting the interests of the youngest person. The court's action will consist not only in preventing further negative effects of a given situation, but also in limiting the irregularities that have already occurred [Długoszewska 2012, 30]. Therefore, it is unclear whether appointing a guardian is justified only for the purpose of taking the child for compulsory vaccinations, or whether the purpose of appointing the guardian should be of primary concern.

If a responsible person who is a legal representative [Fiutak 2017, 155-69], a legal guardian, or an actual guardian evades the fulfillment of a statutory obligation [Staniszewska 2018, 197-201], they may be subject to indirect coercion [Augustynowicz and Czerw 2013, 35-51]. The position presented by E. Zielińska, that "the concept of *compulsory treatment* should be understood as the obligation to undergo treatment, and failure to comply with it is sanctioned by the use of a measure of direct coercion and should be distinguished from the ordinary obligation to undergo medical activities, e.g. compulsory vaccination, which does not involve the use of direct coercion, but only the imposition of financial sanctions" [Zielińska 2001, 371], seems to be appropriate. And although direct coercion consisting in immobilization, holding or forced administration of a drug does not directly apply to vaccinations, it can only be used in two cases. The first case applies when the person evading the obligation [Danecka 2018, 91] is a suspected person or has been diagnosed with a particularly dangerous or highly infectious disease that poses a threat to the health or life of other people. This solution should be assessed as appropriate due to the obligatory nature of direct coercion in the context of combating infectious diseases, including Covid-19.

However, indirect coercion may be applied by a family doctor and involves submitting quarterly reports on vaccinations to the state district sanitary inspector. The second section of this form contains information on the list of people who evade the obligation to vaccinate their children. From a legal point of view, there may be doubts as to whether such a solution does not constitute a violation of medical confidentiality, and whether it is sufficient to regulate this issue by law. By analogy, these legal solutions can also be applied to vaccinations against Covid-19, and it should be clearly stated that only the lack of health contraindications to their implementation should justify the refusal to vaccinate.

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