Review paper

Out-of-court models of compensating medical injuries in Poland

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Abstract

The Polish legal system has limited experience in developing out-of-court models of compensating medical injuries. This situation began to change gradually in the second decade of the 21st century with the introduction of the so-called regional commissions for medical events in Polish law. The new solutions allowed people to claim compensation and redress for so-called medical events without the need to go to court. These legal changes, along with rapid economic and social development and a new approach to the role of the state, led to the introduction in Polish law of the so-called compensation funds, including the Vaccination Compensation Fund, the Clinical Trials Compensation Fund, and the Medical Event Compensation Fund. Each fund was created under different circumstances and serves a distinct purpose, and Poland has not yet established a single, unified model for compensating medical injury. The purpose of this article is to examine how these funds operate.

Introduction

Under Polish law, the conditions for the provider's liability for damage include the following: the occurrence of a harmful event, the occurrence of damage, and an adequate, clear cause-and-effect relationship between the harmful event and the damage [1]. Proving fault, damage, and a causal relationship is a challenging task that requires both medical and legal expertise [2]. In this context, an increasing number of Western countries have adopted insurance-based and no-fault compensation schemes for injuries resulting from medical errors and other adverse medical events. In 2011, the Polish legislature attempted to introduce a medical injury compensation system inspired by Nordic no-fault models, referred to as No Fault Patient Insurance. It was introduced by the amendment of 28 April 2011 to the Act of 6 November 2008 on Patients' Rights and the Patients' Rights Ombudsman. Under this system, the injured party (either the patient or, in the event of the patient's death, their legal successors) could apply to the medical event adjudication commissions in each region to determine if a so-called medical incident had occurred. The idea was that the applicant would receive compensation for both pecuniary and non-pecuniary damage within just a few months. The amounts were to be limited, similar to the approach in Western systems.

It seemed that the model introduced through the commission would effectively counterbalance court proceedings and that the goals pursued by the legislature would be achieved [3–6]. Over time, however, it has become clear that the timeframes set by the legislature [7], the procedural rules for applications [8], the lack of co-participation provisions [9], the subject limitations [10], and the challenges in developing an insurance offer for hospitals [11], as well as the regional commission's lack of authority to verify the amount of compensation proposed by the insurer or hospital operator [12], will undermine the effectiveness of the commission model. These issues have prevented the system from significantly relieving the burden of medical cases on the courts and have not led to a simpler or faster process for compensation claims [13, 14]. The identified shortcomings led to a significant amendment of the Patients' Rights Act and the Patients' Rights Ombudsman. As a result, according to Article 8 of the Law of 16 June 2023, which amends the Patients' Rights Act and the Patients' Rights Ombudsman, as well as certain other laws (Journal of Laws, item 1675), the regional commissions that were responsible for deciding on medical events were abolished starting 1 July 2024. The decision to abolish the regional medical event decision-making commissions is directly connected to the establishment of the Medical Incident Compensation Fund, which is discussed later in this paper.

Vaccination compensation fund

Recent experiences, especially the COVID-19 pandemic, have shown that limited access to vaccinations

presents real risk to life and health, particularly during a pandemic. At the same time, growing distrust in vaccines, including concerns about their safety, is or could become a significant barrier to the successful implementation of vaccination programmes [15]. The Vaccination Compensation Fund was created by the Law of 17 December 2021, amending the Law on the Prevention and Control of Infections and Infectious Diseases in Humans and Certain Other Laws (Journal of Laws 2022, item 64). One factor intended by the creators to address public concern was the debate over the mode of compensating injuries caused by vaccines. Initially, the Vaccination Compensation Fund applied solely to COVID-19 vaccinations. However, starting 1 January 2023, the Fund expanded to cover all mandatory and other epidemic-control vaccinations administered after this date. If, as a result of preventive vaccination, as referred to in regulations issued under Article 3, paragraph 4, item 2, Article 17, paragraph 10, or Article 46, paragraph 4, item 7 of the Act of 5 December 2008 on the prevention and control of infections and infectious diseases in humans (Journal of Laws 2024, item 924), the individual who received the vaccination experiences, within 5 years from the date of administration of the vaccine(s), adverse reactions listed in the Summary of Product Characteristics, and as a result required hospitalisation for at least 14 days or experienced anaphylactic shock necessitating observation in a hospital emergency department or admissions unit or hospitalisation for less than 14 days, then the individual is entitled to a compensation benefit from the Vaccination Compensation Fund. The Fund is a state-designated fund established to compensate individuals who have experienced harm. It is administered by the Patients' Rights Ombudsman, who oversees the compensation process. The application for compensation must be submitted to the Patients' Rights Ombudsman within 1 year from the last day of observation or hospitalisation and no later than 5 years from the date of vaccination. If the Summary of Product Characteristics is updated to include a new adverse reaction not previously listed therein for a vaccine or vaccines administered, an application for compensation for this newly listed adverse reaction can be submitted within 1 year of the update, but no later than 5 years from the date of the preventive vaccination. Proceedings for granting compensation benefits will not begin, and those already underway will be discontinued, if in connection with the vaccination, the State Treasury has already provided compensation or for pecuniary and non-pecuniary damage to the applicant through a final court ruling in a civil case related to adverse reactions following the administered vaccine(s), or if such a civil case is still currently underway. Any compensation benefit awarded will be credited against any compensation or for pecuniary or non-pecuniary damage granted in civil proceedings related to the occurrence of adverse reactions to the administered vaccine or administered vaccines. The procedure for granting compensation benefits is managed by the Patients' Rights Ombudsman. The key assessment of the application is carried out by the team in charge of granting benefits from the Vaccination Compensation Fund. The team's opinion, as a rule, should be issued within 1 month from the date of receiving a complete application for compensation benefits, which requires the review of three team members. On the other hand, the administrative decision regarding the approval and amount of the compensation benefit, or the denial of the benefit, should be issued by the Patients' Rights Ombudsman within 2 months from the date of receipt of a complete application for compensation benefits. The decision may be appealed to an administrative court. In December 2023, the Patients' Rights Ombudsman reported that, to date, payments had been made to more than 220 individuals, totalling nearly 5 million PLN [16].

Clinical trials compensation fund

The work on the Clinical Trials Compensation Fund was triggered by the adoption of Regulation No. 536/2014 by the European Parliament and Council, which focuses on clinical trials on medicinal products for human use and replaces Directive 2001/20/EC. According to Article 76 of the Regulation, Member States must have systems in place to compensate individuals for damage suffered due to participation in a clinical trial conducted on their territory. These systems may include insurance, guarantees, or similar arrangements that match the nature and scale of the risk involved. The sponsor and researcher of the trial are required to use the system in the form specified by the Member State in which the trial is conducted. The creators of the Regulation decided that the details regarding civil liability and compensation for damage should be handled by each country's national laws. Under Polish law, the needed clarification was provided by the adoption of the Act of 9 March 2023 on clinical trials on medicinal products for human use. Currently, there are two ways to handle compensation for harm caused during a clinical trial. First, the sponsor and investigator can be held legally responsible for any harm they cause to a participant through their actions or neglect. Running the trial does not remove them from their civil liability to compensate for any damage resulting from it. We are referring here to liability governed by the provisions of the Polish Civil Code (Article 415 et seq.) and enforced through judicial proceedings.

The sponsor and researcher for the conduct of clinical trials are required to have mandatory civil liability insurance that covers damage caused in connection with the conduct of a clinical trial. Detailed

solutions regarding the conditions of civil liability for the researcher and sponsor do not constitute a significant legislative innovation and are beyond the scope of this study [17]. Second, similarly to the Vaccination Compensation Fund, the legislature decided to introduce another compensation fund into Polish law. Once again, it is the responsibility of the Patients' Rights Ombudsman, who is responsible for investigating damage resulting from a clinical trial. The revenues of the Clinical Trials Compensation Fund come from payments made by sponsors when applying for research permits, fees for compensation benefit applications, donations, bequests, and other sources of income. The amount of payments made by sponsors depends on the planned number of participants in the clinical trial who will take the tested medicine or be in the control group. The payment in euros is as follows: up to 20 people – 2000 euros, from 21 to 50 people – 4000 euros, from 51 to 100 people – 8000 euros, more than 100 people – 10,000 euros. The individuals who can file an application are the injured participant of the clinical trial and, if they have died, their spouse (if not separated), a first-degree relative, an adopted relative, or a person living with the participant. Such a concept of indirectly affected persons is admittedly narrower than the one used in Polish civil law, but it seems acceptable, given the simplified nature of the compensation process. The amount of the compensation benefit has been determined somewhat differently from that of the Vaccination Compensation Fund, ranging from 2000 to 200,000 PLN for bodily injury or health issues, and from 20,000 to 100,000 PLN in the event of the participant's death (for each indirectly affected person). The Ministry of Health, after consulting the opinion of the Patients' Rights Ombudsman, has outlined the detailed procedure on how to determine compensation amounts in the 18 October 2023 Regulation on compensation for injuries suffered while participating in a clinical trial (Journal of Laws, item 2343). Proceedings for compensation benefits will not be initiated, and any ongoing proceedings will be discontinued if a final court decision has already been made regarding compensation or reparation for the same incident, or if there are ongoing civil proceedings for compensation or redress. The applicant is required to inform the Patients' Rights Ombudsman if, during the compensation proceedings, they receive compensation for pecuniary or non-pecuniary damage from the person responsible for the damage, including from civil liability insurance, specifying the amount received. If compensation for pecuniary or non-pecuniary damage is obtained from the person responsible for the damage, including through civil liability insurance, the compensation benefit will be reduced by the amount of such compensation. Most importantly, the model in question also requires that any benefit received must be returned. This happens if compensation or pecuniary or non-pecuniary damage is obtained from the person responsible for the damage, including through civil liability insurance after receiving the compensation benefit. In this case, the amount must be returned to the Fund within 14 days from when the compensation is received, up to the amount that was obtained. If the reimbursement is not made, the amount will be determined by the Patients' Rights Ombudsman through a decision. The amount owed will be recovered according to the rules for enforcement in administrative proceedings. To apply for the compensation benefit, the applicant must submit a request to the Patients' Rights Ombudsman. The applicant has 1 year from the date they became aware of the injury, health issue, or death of the clinical trial participant to submit the application. However, this period cannot exceed 3 years from the date on which the event resulting in the injury or health disorder or the death of the clinical trial participant occurred. The Patients' Rights Ombudsman has a team dedicated to issuing benefits from the Clinical Trials Compensation Fund. Their task is to provide opinions on whether a clinical trial participant's injury, health disorder, or death was caused by their participation in a clinical trial. They also assess the nature of the health consequences and the extent of discomfort caused by the injury or health issue, including the impact of treatment, damage to health, or decline of quality of life. Within 3 months of receiving the team's opinion, the Patients' Rights Ombudsman shall issue an administrative decision on whether to grant the compensation benefit and determine its amount, or to deny the benefit. The applicant may appeal the decision of the Patients' Rights Ombudsman to the Appeals Committee for Benefits of the Clinical Trials Compensation Fund and to the administrative court.

Medical Event Compensation Fund

The negative assessment of the regional commissions responsible for settling medical events, combined with the relatively successful implementation of successive compensation funds, led the Polish legislator to introduce new regulations regarding the settlement of damage that occurs in hospitals during routine diagnostic and therapeutic procedures [18]. These regulations took effect on 6 September 2023 and are detailed in Chapter 13b, titled "Compensation for Damage Resulting from Medical Events" of the Patients' Rights Act and the Patients' Rights Ombudsman [19].

The new regulations apply to medical events that occur while providing or as a result of providing or failing to provide health care services financed by public funds, according to the terms of the Act of 27 August 2004 on publicly funded health care services in a hospital. The compensation benefit is paid to the patient

and in the event of the patient's death, to a first-degree relative, a non-separated spouse, an adoptive family member, or a person living with the patient. The compensation benefit itself is paid from the Medical Events Compensation Fund. The amount of the compensation benefit depends on the type of medical event and the seriousness of the health effects, including the difficulty of treatment, the damage to health, and the impact on the quality of life. The article presents the initial statutory amounts without taking into account subsequent indexation. In the case of an infection with a biological pathogen, the amount of the compensation benefit awarded in case of a single event for a single applicant ranges from 2000 to 200,000 PLN. In the case of bodily injury or health disorder the compensation ranges from 2000 to 200,000 PLN, and in the event of the patient's death, compensation ranges from 20,000 to 100,000 PLN. In the process of determining the amount of the compensation benefit, the following factors are taken into account: infection with a biological pathogen – the nature of the health consequences and the degree of discomfort caused by the infection, including the inconvenience of treatment, damage to health, and decline in the quality of life; bodily injury or health disorder – the nature of the health consequences and the degree of discomfort caused by the medical incident, including treatment difficulties, damage to health, and decline in the quality of life; and the death of the patient – factors such as being married at the time of the patient's death, family relationship, adoption status, cohabitation, and the age of the person referred to in Article 67r, Section 2 of the Patients' Rights Act and the Patients' Rights Ombudsman, as well as the age of the deceased patient. According to the Ministry of Health's decree of 10 June 2024, regarding how to determine compensation amounts for cases of infection with a biological pathogen, bodily injury, health disorder, or patient death (Journal of Laws, item 883), the compensation amount is calculated by summing amounts based on the type and severity of health effects, including damage to health, treatment difficulties, and decline of quality of life. For example, the total loss of an upper limb above the elbow is valued at 55,000 PLN, the total loss of an arm at 40,000 PLN, creation of a urinary stoma at 15,000 PLN, and the patient's isolation for more than 10 days at 2000 PLN. The compensation amounts related to the decline in quality of life are, for example, 40,000 PLN for the inability to live independently, 25,000 PLN for a significant reduction in sexual function, and 12,000 PLN for a major reduction in the ability to fulfil social or family roles. The said regulation also sets different compensation benefit amounts for the death of a patient based on the applicant's relationship to the deceased as well as their ages. For instance, if the applicant is the patient's biological or adopted child under 18 years old, they are entitled to an amount of 100,000 PLN if the deceased was under 25 years old. If the deceased was 25–42 years old, the compensation is 90,000 PLN; if 46–65 years old, it is 80,000 PLN; and if over 65 years old, it is 70,000 PLN. To apply for the compensation benefit, the applicant must submit a request to the Patients' Rights Ombudsman. The person entitled to submit it is the patient, or in the case of the patient's death, a first-degree relative, a non-separated spouse, a person in an adoption relationship, or a person living with the patient. Submitting an application requires a 300 PLN fee, which will be refunded if the compensation benefit is approved. The application must contain, among other things, a justification and facts that support the application. Compensation benefit proceedings will not be initiated, and any ongoing proceedings will be discontinued if, in relation to the medical incident, the following circumstances form the grounds for the application: a claim for compensation, a compensatory annuity, or compensation for non-pecuniary damage has already been legally adjudicated; civil proceedings concerning compensation, a compensatory annuity, or compensation for non-pecuniary damage are pending; the applicant has received a compensation, a compensatory annuity, or compensation for non-pecuniary damage from the person responsible for the damage, including under civil liability insurance; or the court has imposed an obligation to redress the damage, compensate for the harm suffered, or make a related monetary payment. The Patients' Rights Ombudsman has a team responsible for granting benefits from the Medical Events Compensation Fund. This team is responsible for issuing opinions on the occurrence of medical incidents and their consequences. The Team must issue its opinion within 2 months from the date of receiving the application. Decisions are made by up to 3 members of the team. The importance of Article 67x(4) of the Patients' Rights Act cannot be underestimated, as it mandates that the team consist of at least 20 members appointed by the Patients' Rights Ombudsman, with a minimum of 15 practising in the medical profession field. The practical implementation of this requirement, particularly in forming a sufficiently large and experienced team, is crucial for the effectiveness of the entire procedure. Any shortcomings here could impact the timeliness of both the team's opinion and the Patients' Rights Ombudsman decision. Comparing the new solutions with the legal framework under which the regional commissions for assessing medical events operated, it is important to note the absence of a counterpart to the revoked Article 67i(7) of the Patients' Rights Act, which allowed the commission to consult a physician in a specific field of medicine from the list referred to in Article 32(2) of the Patients' Rights Act and the Patients' Rights Ombudsman, or a regional consultant in a relevant field of medicine, pharmacy, or another area related to healthcare, if de-

termining circumstances significant to the ruling required specialised knowledge. The decision should be issued within 3 months from the date of receipt of a complete and properly paid application. Within 30 days of the date, the decision granting the compensation benefit and determining its amount becomes final, the applicant must submit to the Patients' Rights Ombudsman a statement of acceptance or waiver of the compensation benefit. Submitting a statement accepting the compensation benefit means that the applicant is giving up any further claims for compensation, pension, or money related to the medical incident for damage that occurred up to the date the application was submitted. On the other hand, submitting a statement of waiver for the compensation benefit or failing to submit any statement means the applicant gives up the compensation benefit. The benefit will be paid within 14 days after the statement of acceptance is submitted. According to the adopted regulation, the Patients' Rights Ombudsman must inform the entity providing medical services, related to the application, about the payment of compensation benefits. The entity is then required to analyse the root causes of the medical incident and develop and implement recommendations to improve the quality and safety of healthcare services, aiming to prevent the recurrence of such an event, unless such an analysis has already been conducted. It seems that if the entity ignores this obligation and fails to take action to eliminate the factors responsible for the medical incident within the hospital structure, it could be seen as a practice that puts a group of potential patients at risk of experiencing a similar medical incident again. Therefore, it can be argued that this practice violates the collective rights of patients as outlined in Article 59 of the Patients' Rights Act and the Patients' Rights Ombudsman. The applicant has the right to appeal the decision made by the Patients' Rights Ombudsman to the Appeals Committee for Benefits from the Medical Event Compensation Fund. The appeal is subject to a fee of 200 PLN. If the decision is overturned as a result of the appeal, the fee will be refunded. The Committee makes decisions during a closed session, based on a majority vote. In the event of an equally divided vote, the chairman's vote will be decisive. A member of the Commission may not abstain from voting.

Conclusions

Out-of-court models of compensating medical injuries in Poland are still in their early stages. Following the unsuccessful experience with the regional commissions for medical incidents, the legislator took significant steps to reform the existing system, greatly expanding its scope. Of particular note is the major shift in the Polish state's approach to this issue. It should be noted that over the years, we have moved away from a model where the state's primary role was to settle disputes between the injured party and the liable entity. Currently, increasingly often, the State Treasury shares responsibility for financing compensation benefits paid to its citizens. The aforementioned financial foundation is supplemented by funds from non-public sources (such as contributions from clinical trial sponsors, vaccine suppliers, applicants, etc.). However, it seems that the benefits paid from these compensation funds do not fully reflect the extent of the damage suffered by patients and their families. Further practice in the operation of compensation funds will reveal whether the new models of compensation for medical injuries will significantly alleviate the burden on the judicial system and provide effective assistance to victims.

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Conflict of interest

The authors declare no conflict of interest.

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