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LEGAL REGULATIONS OF CLINICAL TRIALS IN THE POLISH LEGAL SYSTEM

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Abstract. The article deals with the issue of regulation of clinical trials against the background of the Polish legal system. The starting point is the analysis of the institution of medical experimentation in the context of clinical trials on humans. The paper pays particular attention to the informed and voluntary consent of the participant in a clinical trial, taking into account the current case-law of the Supreme Court. Drafts of future legislative changes concerning clinical trials have been announced recently.

Keywords: medical experiment; research experiment; clinical trials; participant consent; evidence-based medicine

INTRODUCTION

The development of medical science is associated with the creation of new pharmacotherapy regimens. Advances in medical technology allow the use of increasingly effective treatments, personalized therapy, individually tailored to the patient, such as molecularly targeted anticancer treatment, is emerging. Technological advances are giving hope to many patients, effective therapies are being developed for conditions to date considered incurable, but an indispensable prerequisite for bringing a drug product to life is testing it in the experimental phase.

The global pharmaceutical market is developing rapidly, the number of studies related to related to medicinal products in humans is increasing.

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In the laboratories of pharmaceutical companies, technologically new substances are created, which undergo successive phases of research before routine use. The literature presents a view that clinical trials are a recognized method of verifying the efficacy and safety of medicinal products and medical devices coinciding with the paradigm of evidence-based medicine [Wąsik and Koczur 2016, 25].

In addition to the term clinical trial, an essential element of which is the research objective, in literature there is the concept of experimental therapy. Experimental therapy, also called novel treatment, innovative treatment or therapeutic innovation, is based on the premise of providing medical assistance to a specific patient using a new, insufficiently tried therapeutic method [Gałązka 2019, 60-61]. It includes off-label treatment, i.e., off-label use, and the administration of off-label drugs, which are the subject of clinical trials, outside the protocol [Borysowki, Górski, and Wnukiewicz-Kozłowska 2018, 90].

1. THE STATISTICS OF CLINICAL TRIALS IN POLAND

In the medical literature, normative elements are woven into the understanding of the concept of clinical research, hence the understanding of the concept can vary [Gałązka 2019, 55]. It should be listed alongside basic research, which aims to determine the discovery of a disease-modifying substance, and from preclinical research, which aims to study the effect on cells, tissues and animals [ibid., 56]. Clinical research refers to the next stages of testing the therapeutic effect in humans. The first phase of the clinical trial evaluates the pharmacokinetic and pharmacodynamic properties of the investigational product. The second phase, involving a control group, is used to establish therapeutic doses, while the third phase is a form of comparative studies on a larger group of patients. The fourth phase determines the long-term efficacy and safety of the new drug already on the market [ibid., 57-58].

A report published by the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products has published data related to the area of registration of medicinal products in Poland. In 2021, the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products received a total of 17,430 applications, of which 13,200 applications were related to making changes to the authorization and the documentation on which the marketing authorization is based, 838 applications were related to the related to the marketing authorization of a medicinal product

or pharmaceutical raw material. 654 decisions on marketing authorization of a medicinal product or pharmaceutical raw material were issued.[1]

In 2021, there were 685 applications to start a clinical trial, and the number of clinical trials of medicinal products registered in the Central Register of Clinical Trials was 683, the highest number of applications to start a clinical trial in a calendar year in the Office's history. About 47% of the applications were for phase III trials, about 33% for phase II trials, the largest percentage, more than 27% of clinical trials were related to oncology treatment.[2]

2. STATUTORY REGULATION OF MEDICAL EXPERIMENTATION

In the dictionary meaning, an experiment is an attempt to implement a novel idea, also a scientific experiment conducted to study a phenomenon.[3] From the essence of an experiment, it follows that it is a method as yet untested, bearing risks. Therefore, the need arises for the establishment of appropriate regulations both at the national and international level, the purpose of which is to guarantee the safety of research participants in particular, as well as to allow the access to modern discoveries to as many people as possible [Gutowska-Ibbs 2022, 3]. Much of the international research is carried out in parallel in several or more research centers, hence the need for effective strategies to enable the exchange of information [ibid.].

The overarching regulation of medical experimentation is found in Article 39 of the Constitution of the Republic of Poland,[4] which stipulates that no one may be subjected to scientific experimentation, including medical experimentation, without freely given consent. The Constitution does not prohibit medical experiments on human beings, but makes them conditional on the consent of both the person being experimented on and the experimenter, and requires that consent be freely given [Ogiegło 2015, 343]. Informed consent is a principle in medical law for carrying out any medical intervention, but the regulation of constitutional rank applies only to medical experimentation, which emphasizes the importance of the consent of the person participating in the experiment, although the consent of the participant is not the only prerequisite for the legality of medical intervention [Drozdowska 2013, 11-12].

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[1] See Annual report published by the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, https://www.urpl.gov.pl/sites/default/files/pictures/plakat%20URPL_2021.pdf [accessed: 08.03.2023].

[2] Ibid.

[3] See https;//sjp.pwn.pl/sjp/eksperyment;2556243.html [accessed: 08.03.2023].

[4] Constitution of 2 April 1997, Journal of Laws No. 78, item 483 as amended.

The legality of a medical experiment in Poland is conditional on obtaining a positive opinion from an independent bioethics committee and the issuance of a permit by the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products [ibid., 12].

The President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products issues, by way of a decision, an authorization to conduct a clinical trial or a veterinary clinical trial pursuant to Article 4 of the Act of March 18, 2011 on the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products.[5]

The basic legal act regulating medical experimentation in Poland is the Act of December 5, 1996 on the professions of physician and dentist,[6] where in Articles 21-29 there are provisions regulating medical experimentation. In addition, provisions related to the clinical testing of medicinal products are found in the act of September 6, 2001, the Pharmaceutical Law, in the Regulation of the Minister of Health of May 2, 2012 on the manner of conducting clinical trials involving minors. When participating in medical experiments, doctors are also required to comply with the ethical standards contained in the Code of Medical Ethics.[7]

In addition to the regulations contained in generally applicable laws, the guidelines concerning clinical trials can be found in the Principles for the Proper Conduct of Clinical Trials. The Principles for the Proper Conduct of Clinical Trials were created on the basis of the Declaration of Helsinki,[8] which contains rules for conducting experiments on humans, and based on international standards related to the conduct of clinical trials, recognized in the countries of the European Union, Japan and the United States. The guidelines also include recommendations from the World Health Organization. The aim of the standards is to conduct experiments on the basis of respect for the rights of the people involved and the application of special precautionary rules, they also contain precise guidelines for researchers [Kubiak 2002, 82].

The Principles for the Proper Conduct of Clinical Trials are an elaboration of the provisions of the law on the professions of physician and dentist, and contain guidelines for conducting clinical trials. These guidelines should

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[5] Act of 18 March 2011 on the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Journal of Laws No. 82, item 451.

[6] Act of 5 December 1996 on the professions of physician and dentist, Journal of Laws No. 28, item 152.

[7] See the Code of Medical Ethics, https://sip.lex.pl/akty-prawne/akty-korporacyjne/kodeks-etyki-lekarskiej-286454095 [accessed: 09.03.2023].

[8] See the Principles for the Proper Conduct of Clinical Trials were created on the basis of the Declaration of Helsinki, https://nil.org.pl/dzialalnosc/osrodki/osrodek-bioetyki/etyka-w-badaniach-naukowych/1553-deklaracja-helsinska [accessed: 10.03.2023].

be taken into account when conducting clinical trials of medicinal products in Poland, and can also serve as guidelines during clinical experiments to guarantee safety rules. Their use has been recommended by the Minister of Health and posted on the website of the Ministry of Health.[9]

It is worth pointing out at this point that in the field of post-registration studies, concerning new drugs, a similar role to the Good Clinical Practice Principles is fulfilled by the guidelines concerning supervision over the safety of pharmacotherapy, known as Pharmacovigilance guidelines, which are in force in all European Union countries and in Poland have been recommended by the Director of the Institute of Medicine.

The safety of the use of medicinal products in humans, known as Pharmacovigilance, is controlled by the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. The purpose of the control is to verify whether the responsible entity with marketing authorizations for medicinal products monitors safety in the use of medicinal products, as stipulated by Polish law, as well as European Union law.[10] The inspection is carried out by inspectors of the Department of Medicinal Products Inspection and Medical Devices, who, under the authorization of the President of the Office, may inspect the responsible entities with regard to the system of monitoring the safety of use of medicinal products, demand the presentation of relevant documentation and explanations, regarding the operation of the system of monitoring the safety of use of medicinal products.

3. MEDICAL EXPERIMENTS ON THE GROUNDS OF THE LAW ON THE PROFESSION OF PHYSICIAN AND DENTIST

The law on the professions of physician and dentist introduces a division of medical experiments into two categories. The legislator has divided medical experiments into therapeutic experiments and research experiments, creating legal definitions for both procedures. According to Article 21 of the Law on the Profession of Physician and Dentist, a medical experiment conducted on humans may be either a therapeutic experiment or a research experiment. The legislator also includes as a medical experiment the conduct of tests on biological material, including genetic material, taken from a person for scientific purposes, and defines the person on whom the experiment is conducted as "participant".

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[9] See https://www.gov.pl/web/zdrowie/zasady-prawidlowego-prowadzenia-badan-klinicznych [accessed: 10.03.2023].

[10] See https://urpl.gov.pl/pl/urząd/inspekcja-badań-klinicznych-i-phv/kontrola-pharmacovigilance-produktów-leczniczych-stosowanych [accessed: 10.03.2023].

The innovative or experimental nature of medical procedures should be understood broadly, which means that they should include both methods used for the first time, as well as methods already known but insufficiently studied, evaluated or discussed in the medical literature and in clinical practice [Ogiegło 2015, 346]. Such a broad view of the experimental nature of medical procedures makes it possible to include in experimental procedures both clinical trials of medicinal products and the use of medicinal products outside of registration indications.

The legal definition of a therapeutic experiment is contained in Article 21(2) of the Law on the Profession of Physician and Dentist, according to which a therapeutic experiment is the introduction of new or only partially tried diagnostic, therapeutic or prophylactic methods in order to achieve a direct benefit to the health of a patient. It can be carried out if the methods used so far are not effective or if their effectiveness is not sufficient. The participation of pregnant women in a therapeutic experiment requires a particularly careful assessment of the associated risks to the mother and the conceived child.

The literature indicates that the subject limitation regarding the conceived child included in the statutory definition of therapeutic experimentation with the entry into force of the amendment of July 16, 2020 of the Law on the Profession of Physician and Dentist testifies to the rank of the above regulation and indicates that the participation of pregnant women is allowed only as part of a therapeutic experiment [Sakowski 2022, 715].

The statutory definition distinguishes three areas of therapeutic experimentation, these are the scope of diagnostic methods, the scope of therapeutic methods, and the scope of preventive methods, and allows experimentation in each of these areas [Ogiegło 2015, 346].

Conducting a therapeutic experiment depends on the implementation of new or only partially proven methods related to the diagnosis, therapy or prevention of disease entities, but the condition for the use of the opportunity to use a therapeutic experiment is the lack or unsatisfactory effectiveness of available methods. An additional assumption is the experimental method is intended to achieve a direct health benefit of the treated person [ibid.].

The second type of experiment is a research experiment. Paragraph 3 of Article 21 of the Law on the Profession of Physician and Dentist indicates the purpose of the research experiment and the conditions for participation, stating that the research experiment is primarily aimed at expanding medical knowledge. It can be conducted on both an ill and a healthy person. Conducting a research experiment is permissible when participation in it is not associated with risk, or the risk is minimal and not in disproportion to the possible positive results of such an experiment. Thus, the essence

of a research experiment is to advance medical knowledge and search for new solutions, assuming low risk for the participants taking part in the experiment.

The doctrine recognizes that a medical experiment with a medicinal product conducted on humans is also a clinical trial of a medicinal product [ibid., 343].

The law contains specific requirements for the possibility of conducting a research experiment, excluding from participation in them specific categories of people, due to the potential possibility of their exploitation and harm [ibid., 347].

Article 23a of the Law on Medical and Dental Professions contains a catalog of prohibitions related to the related to the research experiment. It is prohibited to conduct a research experiment on: (1) a conceived child; (2) an incapacitated person; (3) a soldier and any other person in a in a hierarchical relationship limiting the freedom of voluntary consent; 4) a person deprived of liberty or subjected to detention. The provision contained in Article 23a(2) of the Law of the Law on the Profession of Physician and Dentist contains conditions for the participation of minors in a research experiment. Participation in a research experiment by a participant who is a minor is permitted when all of the following conditions are met: 1) the expected benefits are of direct relevance to the health of the minor subjected to the research experiment or other minors belonging to the same age group; 2) the research experiment will bring about a significant expansion of medical knowledge; 3) there is no possibility of conducting such an experiment of comparable effectiveness with the participation of an adult.

The statutory ban on the participation of incapacitated persons or children conceived both *in vivo* and *in vitro* in research experiments stems from their inability to recognize their own situation and their inability to make a free decision [Sakowski 2022, 732-33].

Participation of a minor in a research experiment is permitted when three conditions are all met. First, the expected benefits are of direct relevance to the health of the minor subjected to the research experiment or other minors of the same age group, the research experiment will bring about a significant expansion of medical knowledge, and there is no possibility of conducting such an experiment of comparable effectiveness with the participation of an adult. Before giving consent, the participant should receive oral and written information, presented in an understandable manner. The fact of receiving this information should be recorded in the documentation on the experiment.

4. CONSENT TO PARTICIPATE IN A MEDICAL EXPERIMENT

The provision contained in Article 25 of the Law on the Profession of Physician and Dentist concerns consent to participate in a medical experiment, and stipulates that a medical experiment may be conducted with the consent of the participant or a person who may be directly affected by the consequences of the experiment. In a case when the participant is a minor who has not reached the age of thirteen, the consent of their legal representative is needed. When the participant is a minor who has reached the age of thirteen, the consent of the participant and their legal representative is required. In case of disputes, the case is decided by the guardianship court. When the participant is a person who is completely incapacitated, the consent to participate in the in the therapeutic experiment is given by the legal guardian. Consent is required if the totally incapacitated person has sufficient understanding.

Article 25 of the Law on Physician and Dentist Professions was amended by an amendment on July 16, 2020, which took effect on January 1, 2021, the change concerned the possibility of conducting a medical experiment without obtaining the consent of the participant. The above situation could arise in a case of urgency and when there was an immediate threat to life. In the doctrine there was criticism of such a solution, as contradicting Article 39 of the Constitution of the Republic of Poland, prohibiting scientific experiments without freely given consent. In addition, it has been pointed out that due to the increased risk of experimental treatment, the legal requirements cannot be more lenient than those imposed on standard therapy. The current regulation indicates that only a therapeutic experiment can be conducted without the consent of the participant, after cumulative fulfillment of the statutory conditions, and takes into account the suggestions of the doctrine [Sakowski 2022, 752-53].

Paragraph 3 of Article 25 of the Law on the Profession of Physician and Dentist assumes the expression of consent in writing, and if written consent is not possible, oral consent given in the presence of two impartial witnesses with full legal capacity shall be considered equivalent. If the legal representative refuses to consent to the participant's participation in the therapeutic experiment, permission to conduct the experiment may be granted by the guardianship court.

The legislator, in Article 25a of the Law on the Profession of Physician and Dentist, allows situations of conducting a therapeutic experiment without the required consent after the following conditions are all met: 1) the participant is incapable of giving consent to participate in this experiment; 2) there exists a case of urgency and, due to the need for immediate action, it is not possible to obtain consent to participate in the therapeutic

experiment from the participant's legal representative or court authorization within a sufficiently short period of time; 3) an experiment of comparable effectiveness cannot be conducted on persons not in an urgent situation; 4) the participant has not previously objected to participation in such an experiment; 5) the participant in a therapeutic experiment conducted in a situation of urgency and, if applicable, his or her legal representative will be provided with all relevant information regarding participation in the therapeutic experiment or their issuance by the court.

In the doctrine one can find the view that the patient's consent to participate in a medical experiment is a consent of a special nature, it should be based on comprehensive information about the possible consequences of the experiment and the dangerous consequences associated with it. The patient should be informed of all possible consequences of the experiment [Ogiegło 2015, 354-55]. At this point, it is worth emphasizing that according to the position of the doctrine that the patient participating in the experiment cannot waive the right to information, which is possible in the case of routine treatment; and if he refuses to accept the information, he should be excluded from the experiment [Sakowski 2022, 743].

On the other hand, an opinion is presented that the essence of an experiment is the search for something new, which has not yet been studied, and therefore it is not possible to determine the exact risks involved. Therefore, the danger of unknown consequences cannot be completely included in the balance of benefits and disadvantages, and the final outcome of a novel experiment always remains a certain unknown [ibid., 711].

It should be pointed out that the patient's consent must be informed and explained. The patient should be given all the information about the diagnosis, treatment methods, possible effects and risks, about alternative treatments and also about the abandonment of treatment. The extent of the information provided by the doctor depends on the type of medical procedure, on the mental state and sensitivity of the patient, as well as on what an objectively reasonable person in the patient's situation should hear from the doctor in order to be able to make an informed decision [Nesterowicz 2017, 511-12].

The patient's consent to medical treatment has been topic of analysis by the Constitutional Court. In its verdict K 16/10 of November 11, 2011, the Constitutional Court[11] indicated that the institution of consent to perform a medical procedure is a manifestation of the individual's right to decide for themselves and is one of the prerequisites for the legality of treatment activities. The informed and voluntary consent of participants in a clinical

[11] Judgement of the Constitutional Court of 11 November 2011, ref. no. K 16/10, Journal of Laws No. 240, item 1436.

trial was analyzed by the Supreme Court, which, in its judgment of September 21, 2022, I NSNc 75/21,[12] indicated that the lack of legally effective consent expressed by participants in a clinical trial violates human dignity and freedom, a medical experiment conducted in violation of the law will always be an illegal experiment. The main issue of the judgment in question was the resolution of the criteria for awarding compensation to participants in a clinical trial conducted with informed and voluntary consent. The Supreme Court, in the judgment in question, pointed out that the failure to demonstrate disruption of health cannot be a circumstance justifying even a symbolic award of compensation for pain and suffering.

In the literature, there was a gloss on the Supreme Court's judgment of September 21, 2022, I NSNc 75/21, in which B. Kozielewicz-Kutrzepa emphasized the social importance and legal significance of the judgment for the legal protection of participants in clinical trials, and stressed that the judgment in question will be an important point of reference alongside the common law and pharmaceutical law for determining liability for infringement of personal rights of participants in a medical experiment [Kozielewicz-Kutrzepa 2022, 121].

Due to the increased risk for participants in a medical experiment, a special form of consent is provided. Consent to participate in a medical experiment in accordance with Article 25(3)(8) requires written form. The regulation allows oral consent given in the presence of two impartial witnesses with full legal capacity in the event that written consent cannot be given. Such consent shall be considered equivalent to written consent. Consent so given shall be recorded in the documentation of the medical experiment. The law reserves the rigor ad probationem for the written form. This statutory solution is accepted in the literature with regard to medical experiments. The literature presents the view that for research experiments the number of witnesses should be increased to three, with one of the witnesses being a person from the medical staff [Ogiegło 2015, 356].

5. THE PURPOSE OF A THERAPEUTIC EXPERIMENT VS. THE LEGAL DEFINITION OF A CLINICAL TRIAL

The Law on Physician and Dentist Professions indicates the essential purpose of conducting a medical experiment. First of all, the expected therapeutic or cognitive benefit is important, and the expected achievement of this benefit, as well as the purposefulness of the and manner of conducting the experiment should be reasonable in light of the current state

[12] Judgement of the Supreme Court of 21 September 2022, ref. no. I NSNc 75/21, OSNKN 2022, No. 4, item 23.

of knowledge and consistent with the ethics of the medical profession. The legislator also concretizes the conditions that must be met by the person in charge of the medical experiment, indicating in Article 23 of the Law on the Profession of Physician and Dentist that they must be a physician with specialization in a field of medicine that is particularly relevant to the nature or conduct of the experiment, and with appropriately high professional and research qualifications.

In Article 2(2) of the Pharmaceutical Law, the definition of a clinical trial is any study conducted with human subjects to discover or confirm the clinical, pharmacological, including pharmacodynamic, effects of one or more investigational medicinal products, or to identify adverse effects of one or more investigational medicinal products, or to follow the absorption, distribution, metabolism and excretion of one or more investigational medicinal products, with a view to their safety and efficacy.

An investigational medicinal product is, according to Article 2(2c) of the Pharmaceutical Law, a substance or a mixture of substances given a pharmaceutical form of an active substance or a placebo that is being tested or used as a reference product in a clinical trial, including a product already authorized for marketing but used or prepared in a manner different from the authorized form or used for an indication not covered by the authorization, or used to obtain additional information on already authorized forms.

The legal definition of a clinical trial was constructed for the possibility of bringing new drugs to the market, but the definition also implies the possibility of testing drugs after they have already been registered. Therefore, part of clinical trials cannot be of an experimental nature. It is possible to divide clinical trials into two groups, the first will be new data of clinical relevance, in terms of already existing, registered therapies, and the second group is research, where a novel therapy will be used [Drozdowska 2013, 15-16].

The Pharmaceutical Law includes provisions on civil and criminal liability. According to Article 37c of the Pharmaceutical Law, the conduct of a clinical trial does not exempt the sponsor and investigator from criminal or civil liability arising from the from the conduct of the clinical trial. Article 126a contains standards imposing criminal penalties in connection with the improper conduct of clinical trials.

One example is conducting a clinical trial without obtaining the informed consent of the clinical trial participant or his legal representative [Wąsik and Koczur 2016, 186].

At the same time, the lack of consent should be understood as the granting of uninformed consent, which is not preceded by providing

full information about the purpose of the study and the rights and obligations of the participant.

Legislative work is currently underway on a new law of January 13, 2023 on clinical trials of medicinal products for human use.[13] The purpose of introducing new legislation in the area of clinical trials stems from the need to ensure the application of Regulation (EU) No. 536/2014 of the European Parliament and of the Council of April 16, 2014 on clinical trials of medicinal products for human use[14] and repealing Directive 2001/20/EC.

CONCLUSIONS

The experimental phase of a medicinal product is a prerequisite for bringing a new drug to market. Clinical trials are a method to evaluate the efficacy and safety of medicinal products, and are an indispensable part of evidence-based medicine. They constitute a research experiment, which is a form of medical experimentation aimed at improving medical knowledge and seeking new solutions in medicine. The essential legal regulations related to the area of clinical trials are found in the Pharmaceutical Law and the Law on the Profession of Physician and Dentist. Persons conducting clinical trials may incur criminal and civil liability, and the Pharmaceutical Law itself contains criminal law provisions. A new law on clinical trials conducted in humans is currently in the final stages of legislative work.

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