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Paying participants in medical research. An ethico-legal analysis of Article 23b(1) of the Polish Act on the Professions of Physician and Dentist[1]

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Summary

This article provides a thorough ethico-legal analysis of Article 23b(1) of the Polish Act on the Professions of Physician and Dentist (APPD). The analyzed provision regulates the permissibility of paying participants in medical experiments in the form of reimbursement of incurred expenses as well as in the form of "incentives and financial rewards". First, we define the scope of Article 23b(1) of the APPD within the context of the legal concept of a medical experiment. Then, we discuss the regulatory gaps and interpretive issues posed by Article 23b(1). We highlight significant discrepancies between the Polish regulations on payment for participation in medical experiments and relevant EU provisions on payment for participation in clinical trials. We also compare Article 23b(1) with the guidelines on research payment endorsed by important international ethical and legal standards for human medical research. Ultimately, we conclude that the analyzed provision of the APPD requires revision to

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better protect participants of medical experiments, as well as to provide researchers and research ethics committees with clearer, more coherent, and better-justified payment guidance.

Key words: medical experiment, clinical trials, cost compensation, incentives and financial rewards for research participants

1. Introduction

The general legal requirements for conducting medical research in Poland are set out in Chapter 4 of the Act on the Professions of Physician and Dentist (further referred to as APPD)[2] titled "Medical Experiments". The chapter was recently amended by the Act of July 16, 2020, which entered into force on January 1, 2021[3]. This revision has already been extensively commented on in the literature[4], so there is no need to repeat both the (few) laudatory and (dominant) critical voices against it. However, one amendment requires further scrutiny, as it has not yet been analyzed

[2] *Journal of Laws* 2024, item 1287, 1897, with amendments [in PL].

[3] Act of July 16, 2020 Amending the Act on the Professions of Physician and Dentist and Certain Other Acts, *Journal of Laws* 2020, item 1291 [in PL].

[4] E.g., M. Gąsior, *Medical experiments in the light of the amendment of the Act on the Profession of a Physician and a Dentist*, „Wiadomości Lekarskie" 2021, vol. 74, no. 8, pp. 1988–1994; P. Konieczniak, *Eksperyment medyczny – sytuacja prawa po nowelizacji ustawy lekarskiej*, „Przegląd Prawa Medycznego" 2021, vol. 3, no. 1-2, pp. 79–120; R. Kubiak, *Nowe uwarunkowania prawne przeprowadzania eksperymentów medycznych*, „Przegląd Sądowy" 2021, no. 1, pp. 5-26; M. Serwach, *Nowe zasady przeprowadzania eksperymentów medycznych na ludziach*, „Medycyna Praktyczna" 2021, no. 708, pp. 132–139; A. Gałęska-Śliwka, *Eksperymenty medyczne po nowelizacji ustawy o zawodach lekarza i lekarza dentysty – wybrane zagadnienia*, „Prawo i Prokuratura" 2022, no. 10, pp. 55–77; K. Sakowski, Art. 21-29a [in:] *Ustawa o zawodach lekarza i lekarza dentysty. Komentarz*, 3rd Edition, ed. E. Zielińska, Warszawa 2022, pp. 709–767; I. Wrzesińska-Wal, D. Hajdukiewicz, A. Augustynowicz, L. Janiszewska, E. Sarnacka, M. Waszkiewicz, *New regulations on current medical problems*, „Wiedza Medyczna" 2022, vol. 4, no. 1, pp. 16–20; A. Gałęska-Śliwka, *Eksperyment medyczny w nowej rzeczywistości prawnej*, „Medycyna Ogólna i Nauki o Zdrowiu" 2023, vol. 29, no. 3, pp. 176–186; R. Kubiak, *Odpowiedzialność karna za przestępstwa związane z nielegalnym przeprowadzeniem eksperymentu medycznego*, „Diametros" 2023, vol. 20, no. 78, pp. 37–71; See also *Report on Public Consultations and Comments on the Draft Act on the Professions of Physician and Dentist and Certain Other Acts (UD27), Concerning Medical Experiments* [in:] Draft Act Amending the Act on the Professions of Physician and Dentist and Certain Other Acts, Parliamentary Print No. 172 of January 16, 2020, Regulatory Impact Assessment, Annex 2, pp. 291–321[in PL], https://orka.sejm.gov.pl/Druki9ka.nsf/0/D7FDC1A357FE57C4C12584F6003ABEF4/%24File/172.pdf [Accessed 12.02.2025]

in detail, namely the introduction of Article 23b, which concerns broadly understood payments[5] to participants in medical experiments (Article 23b(1)), the protection of the vulnerable position of some participants (Article 23b(2)) and – after the amendment of 2023[6] – the inadmissibility of expecting fees from those willing to participate in medical experiments (Article 23b(3)).

This article focuses only on paragraph 1 Article 23b, which reads: "In medical experiments, with the exception of experiments involving participants of legal age who can give legally valid consent, and healthy participants, no incentives or financial rewards can be offered, except for reimbursement of expenses incurred". We will argue that this provision is so poorly drafted that it is susceptible to divergent – and often unacceptable – interpretations. More importantly, it is partially inconsistent with the prevailing ethical and legal international framework for payments in medical research involving humans, including the common EU rules for paying participants of clinical trials; and that it should, therefore, be revised. Revising the provision is essential to ensure the fairness and accountability of payments offered to participants in medical research in Poland, as well as to promote trust in research[7]. These factors are vital for indi-

[5] The research ethics literature, relevant ethical standards, and legal regulations use a variety of terms when referring to financial and non-financial offers made to research participants either to (1) cover, „reimburse," „recompense," or „compensate" for broadly understood costs (expenses, losses, injuries) incurred by individuals as a result of their participation in research, or to (2) „reward," „gratify," „compensate," or „remunerate" them for their service as research participants (i.e., for their time, effort, burdens, or even risks assumed). See J. Różyńska, *Research participants should be rewarded rather than 'compensated for time and burdens'*, „The American Journal of Bioethics" 2021, vol. 21, no. 3, pp. 53–55; J. Różyńska, *The ethical anatomy of payment for research participants*, „Medicine, Health Care and Philosophy" 2022, vol. 25, no. 3, pp. 450–452. In this paper, the term „payment" is used as an umbrella term for both categories of payments, regardless of whether they are offered in money or in kind. The term „reimbursement" is used as a name for the first category of payments, i.e., payments that do not provide a net benefit (gain, profit) to the participant, but only cover the costs incurred. For the sake of clarity, the second category of payments is referred to mainly by the terms used in the relevant Polish and EU legislation, which is the subject of future analysis (i.e. „incentives and financial rewards"). Occasionally, the term „remuneration" is used in reference to this second type of payment.

[6] Article 81(2) of the Act of March 9, 2023 on Clinical Trials of Medicinal Products for Human Use, *Journal of Laws* 2023, item 605, with amendments [in PL].

[7] A. Kerasidou, *Trust me, I'm a researcher!: the role of trust in biomedical research,* „Medicine, Health Care and Philosophy" 2017, vol. 20, no. 1, pp. 43–50; D.B. Resnik, *The ethics of research with human subjects: Protecting people, advancing science, promoting trust*, 2nd Ed. Springer 2024.

viduals' willingness to participate in research, which is key to timely and successful recruitment and, consequently, to advancing medical progress. In short, eliminating ambiguities, gaps, and unjustified prohibitions from Article 23b(1) is crucial for all parties involved in the research enterprise, especially potential and actual participants, sponsors, investigators, and research ethics committees.

Finally, we will argue that the proper interpretation of Article 23b(1) requires considering the duty of researchers and research ethics committees to protect participants from undue influence (undue inducement) and unfair exploitation. These are two critical concerns in the context of appropriate payment to research participants[8]. However, due to their complexity and the limited space available, this paper does not address these issues in detail. We have written a separate article dedicated to these problems, which will be published in an upcoming issue of this journal[9]. To understand when research payments are unduly inducing or exploitative, we recommend that readers also read the second paper.

2. Scope of Article 23b(1) of the APPD

In order to fully understand and assess the normative content of Article 23b(1) of the APPD, it is necessary to explain the scope of the term „medical experiment" used in the APPD.

[8] See, e.g., M. Wilkinson, A. Moore, *Inducement in research*, „Bioethics" 1997, vol. 11, no. 5, pp. 373–389; D.B. Resnik, *Exploitation in biomedical research*, „Theoretical Medicine and Bioethics" 2003, vol. 24, no. 3, pp. 233–259; A. Wertheimer, *Exploitation in clinical research* [in:] *The Oxford textbook on the ethics of clinical research*, eds. J.E. Emanuel, C. Grady, R.A. Crouch, R.K. Lie, F. G. Miller, D. Wendler, Oxford University Press, New York 2008, pp. 201–210; N. Dickert, C. Grady, *Incentives for research participants* [in:] *The Oxford textbook on the ethics of clinical research*…, pp. 386–392; D. B. Resnik, *Bioethical issues in providing financial incentives to research participants*, „Medicolegal and Bioethics" 2015, no. 5, pp. 35–41; E.A. Largent, H. Fernandez Lynch, *Paying research participants: regulatory uncertainty, conceptual confusion, and a path forward*, „Yale Journal of Health Policy, Law, and Ethics" 2017, vol. 17, no. 1, pp. 61-112.

[9] J. Różyńska, E. Kaczmarek, *Protecting research participants against undue influence and exploitation. An ethico-legal analysis of Article 23b(2) of the Polish Act on the Professions of Physician and Dentist*, „Przegląd Prawa Medycznego" 2025, no 4., *forthcoming*.

2.1. Therapeutic and scientific experiments

The APPD does not contain a legal definition of the term „medical experiment". It divides all medical experiments into two categories, the so-called „therapeutic experiments" and „scientific experiments" (Article 21(1)), and provides a description of, and sets additional requirements for each of these categories. „A therapeutic experiment is the introduction of new or only partially tested diagnostic, therapeutic or prophylactic methods in order to obtain a direct benefit for the health of a sick person. It may be carried out when the methods used so far are not effective or their effectiveness is insufficient" (Article 21(2), sentences 1-2). In contrast, „a research experiment is primarily intended to increase medical knowledge" (Article 21(3), sentence 1). It may involve both sick and healthy individuals (Article 21(3), sentences 2), except for fetuses ("a conceived child"), incapacitated persons, soldiers and other persons in a hierarchical dependency that limits the freedom to consent, persons deprived of liberty or subject to detention (Article 23a(1)), and any person who is legally competent but factually incapable of making decisions (Article 25(7) *a contrario*). A scientific experiment is permitted only if there are no risks involved, or if the risks are minimal and are not disproportionate to the benefits („possible positive results") of the experiment. (Article 21(3), sentences 3).

The division of medical experiments into therapeutic and scientific has been criticized in Polish legal literature for years[10]. Critics note that the di-

[10] E.g., M. Safjan, *Prawo i medycyna. Ochrona praw jednostki a dylematy współczesnej medycyny*, Warszawa 1998, pp. 172–174; B. Iwańska, *Warunki prawne dopuszczalności prowadzenia eksperymentów medycznych*, „Państwo i Prawo" 2000, no. 2, pp. 73–74; P. Konieczniak, *Eksperyment naukowy i techniczny a porządek prawny*, Warszawa 2014, pp. 88–92; Różyńska J., *Eksperyment leczniczy - dwa w jednym?,* „Prawo i Medycyna" 2016, vol. 18, no. 4, pp. 5–30; P. Konieczniak, *Eksperyment medyczny* [in:] *System prawa medycznego* (editor-in-chief E. Zielińska). Vol. II. *Regulacja prawna czynności medycznych* [part II], eds. M. Boratyńska, P. Konieczniak, Warszawa 2019, pp. 98-91; L. Bosek, M. Gałązka, *Eksperyment medyczny* [in:] *System prawa* medycznego (eds. in chief M. Safjan, L. Bosek). Vol II: *Szczególne* świadczenia *zdrowotne*, eds. L. Bosek, A. Wnukiewicz-Kozłowska, Warszawa 2018, pp. 52–61; M. Gałązka, *Prawnokarne granice nowatorskiej interwencji medycznej*, Lublin 2019, pp. 540–550. See also critical comments of the Supreme Council of Physicians and the Appellate Bioethics Committee in: *Report on Public Consultations and Comments* …, pp. 291–292, 299–300.

stinction is based on the criterion of the researcher's dominant intention, which, due to its subjective nature, cannot be clearly and objectively verified. Moreover, it blurs the fundamental distinction between (i) research practice, which is aimed at the development of generalizable knowledge for the benefit of science and society and is governed by the principles of research ethics, and (ii) medical (therapeutic) practice, which is aimed to serve the best interests of individual patients and is governed by clinical ethics principles[11]. It is also argued that the phrase „therapeutic experiment" is ambiguous and misleading, and may evoke „therapeutic misconception"[12]. Additionally, it is unclear what it means that the methods to be applied experimentally are „new or only partially tested." It is also unclear when existing methods are ineffective or insufficiently effective. And whose opinion on this matter should prevail: the scientific community, the physician, or the patient[13]? Furthermore, it has been demonstrated that the term „therapeutic experiment" is employed in Polish legal and medical literature to denote two distinct practices with different objectives and ethical commitments[14]: (i) medical research with therapeutic

[11] It is worth noting that similar charges were leveled 25 years ago against one of the most important international documents setting ethical standards for medical research involving human participants, i.e., the World Medical Association's Declaration of Helsinki, which from its inception in 1964 until its 1996 version distinguished "between clinical research in which the aim is essentially therapeutic for a patient, and the clinical research, the essential object of which is purely scientific and without therapeutic value to the person subjected to the research". In response to strong criticism from the international research community and ethicists, the WMA abandoned the distinction in 2000. Unfortunately, the Polish legislator has not yet followed the WMA's steps. See: J. Różyńska, *Regulacja ryzyka i potencjalnych korzyści badania biomedycznego z udziałem człowieka w standardach międzynarodowych*, „Prawo i Medycyna" 2016, vol. 18, no. 2, pp. 59–65. All previous archived versions of the Declaration are available at: https://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/ [Accessed 12.02.2025]

[12] J. Różyńska, *Eksperyment leczniczy*…, pp. 17–18. See e.g., P. S. Appelbaum, L. H.Roth, C. Lidz, *The therapeutic misconception: informed consent in psychiatric research*, „International Journal of Law Psychiatry" 1982, vol. 5, no. 3-4, pp. 319–329; P. S. Appelbaum, L. H. Roth, C. W. Lidz, P. Benson, W. Winslade, *False hopes and best data: Consent to research and the therapeutic misconception*, „The Hastings Center Report" 1987, vol. 17, no. 2, pp. 20–24.

[13] Ibidem, pp. 20–27.

[14] Ibidem, pp. 7-13. Cf. W. Wanatowska, *Eksperyment lekarski* „Studia Prawno-Ekonomiczne" 1974, vol. 12, no. 5, pp. 74–75; A. Wnukiewicz-Kozłowska, *Eksperyment medyczny na organizmie ludzkim w prawie międzynarodowym i europejskim*, Warszawa 2004, pp. 34–37; P. Konieczniak, *Eksperyment naukowy i techniczny* …pp. 89–90.

potential – a planned, systematic, protocol-based investigation designed to produce generalizable knowledge aimed at understanding the causes, development, and effects of diseases or health conditions and/or at improving the safety, effectiveness, efficiency, accessibility, and quality of preventive, diagnostic, and therapeutic interventions that has the potential to provide direct therapeutic benefit to participants[15]; and (ii) experimental therapy – a treatment of last resort, designed and performed *ad hoc* for a specific patient or small group of patients, without the intention of providing reliable, generalizable scientific evidence, involving methods whose safety and efficacy have not been fully validated scientifically[16].

Finally, it has been argued that this duality of the meaning of „therapeutic experiment" is problematic in view of two general legal requirements established by the APPD for all medical experiments, i.e., the requirement to obtain a positive opinion from a research ethics committee („komisja bioetyczna", Article 29) and the obligation, introduced in 2021, to take out civil liability insurance for the benefit of the participants and any person who may be directly affected by the results of the experiment (Article 23c). Research ethics committees are not suited to review a „therapeutic experiment", understood as an experimental therapy for an individual patient in need, for a number of reasons[17]. First, they are difficult to access. They are located mainly in large cities at medical or health sciences universities, regional chambers of physicians and densities, and research institutes (Article 29(4)), not in health care facilities. They do not operate on a daily basis, but typically meet once a month. Second, the process of obtaining an opinion from the research ethics committees is bureaucratic, formalistic and time-consuming, and the committee has up to 3 months to review the submitted project (Article 29(14)). And that

[15] See World Medical Association, *WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Participants,* Helsinki, Finland, October 2024, para. 7, https://www.wma.net/policies-post/wma-declaration-of-helsinki/ [Accessed 12.02.2025]

[16] See also ibidem, para. 37 (Unproven interventions in clinical practice); J. Borysowski, A. Górski, A. Wnukiewicz-Kozłowska, *Terapia eksperymentalna* [in:] *System prawa medycznego* (eds. in chief M. Safjan, L. Bosek). Vol II: *Szczególne* świadczenia *zdrowotne*, eds. L. Bosek, A. Wnukiewicz-Kozłowska, Warszawa 2018, pp. 85–126.

[17] J. Różyńska, *Eksperyment leczniczy*…, pp. 28–29.

may be too long to wait for a very sick patient who desperately needs an experimental treatment. Third, the committee members are selected from among professionals (mostly physicians) „with high moral authority, high professional qualifications and significant experience in matters relating to medical experiments" (Article 29(4)). Thus, they are composed of experts in medical research, research ethics and law, but not necessarily experts in a specific medical field relevant to the patient's condition and the specific ethical and clinical challenges posed by the use of innovative or not fully tested therapeutic interventions.

Also, the new requirement for civil liability insurance may have serious negative consequences for the availability of experimental therapies in Poland. This requirement definitely strengthens the protection of research participants and is more than needed. It is essential that participants do not bear the costs of potential health damage resulting from their participation in research. However, it is difficult to justify applying the same requirement to large-scale medical experiments and clinical trials and to individual cases of experimental therapy[18]. It has already been noted in the literature that therapeutic experiments „are not research studies and therefore will not be financed (including insurance) from the research grants or subsidies. Hospitals in financial difficulties may refuse to conduct therapeutic experiments due to lack of funds to cover the cost of insurance"[19].

To summarize the above analysis, Article 23b(1) of the APPD uses the concept of „medical experiment" which applies to both „scientific experiments" and „therapeutic experiments", including experimental therapies aimed at improving the health of an individual patient through the use of new or only partially tested diagnostic, therapeutic or prophylactic

[18] The minimum guarantee amount for an event and for all events whose consequences are covered by the insurance is set at 50.000 euros for therapeutic experiments and 100.000 euros for research experiments. Regulation of the Minister of Finance, Funds and Regional Policy of December 23, 2020 on Compulsory Liability Insurance of the Entity Conducting a Medical Experiment, *Journal of Laws* 2020, item. 2412 [in PL].

[19] I. Wrzesińska-Wal, D. Hajdukiewicz, A. Augustynowicz, L. Janiszewska, E. Sarnacka, M. Waszkiewicz, *New regulations on current medical problems*…, p. 17.

methods. However, the analysis of the scope of application of Article 23b(1) does not end with this conclusion. There are two reasons for this, which are discussed below.

2.2. Experiments on human biological material

The 2021 revision of the APPD added paragraph 4 to Article 21 stating that research on biological material, including genetic material, taken from a person for scientific purposes shall also be treated as a medical experiment and, as such, shall meet all legal requirements for the latter. This laconic provision is not elaborated on in any other part of the Act. Needless to say, it provides a grossly insufficient and inadequate regulation of medical research on human biological material. Unfortunately, further analysis of this issue goes beyond the scope of this paper and must be left for another occasion[20].

However, of interest to this inquiry is that Article 23b(1) of the APPD also applies to research on human biological material. Its applicability is limited, though, because „the collection, processing, storage and distribution of biological material for scientific purposes" are expressly excluded from the definition of „medical experiment" (Article 29a(2))[21]. This exclusion encompasses procedures that most typically involve incentives or financial rewards, namely the recruitment of living donors and the consent-based procurement of their biological material for a specific project or broadly defined future research.

[20] See T. Pietrzykowski, M. Gąsior, *Badanie ludzkiego materiału biologicznego w* świetle *ustawy o zawodach lekarza*, „Przegląd Prawa Medycznego" 2022, vol. 10, no. 1, pp. 63–82; P. Konieczniak, *Eksperyment medyczny – sytuacja prawa po nowelizacji ustawy lekarskiej*…, pp. 81-98. See also critical comments of the Polish Coalition for Personalized Medicine, the Conference of Deans of Natural Science Faculties of Polish Universities, the University of Łódź, the Polish Association for Good Clinical Practice GCPpl, and the Medical University in Wroclaw in: *Report on Public Consultations and Comments* …, pp. 294–298, 306–308, 310–314, 318–319, respectively.

[21] Sakowski rightly notes, but does not elaborate on, that this exclusion is contrary to Article 21(4) of the APPD. Undoubtedly, the collection and processing of human biological material for research purposes are essential steps in any research project involving such material. K. Sakowski, *Art. 29a*, [in:] *Ustawa o zawodach lekarza*…, p. 766.

2.3. Medical experiments and clinical trials

Finally, the regulatory relationship between the terms „medical experiment" and „clinical trial" needs to be clarified[22]. Article 29a(1) of the APPD stipulates that the provisions of Chapter 4 ("Medical Experiments") are without prejudice to the provisions of other legal acts which provide for different rules and procedures for the conduct of clinical trials or genetic testing. Article 29b of the APPD further states that "a medical experiment that is also a clinical trial" within the meaning of Article 2(2)(2) of Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on Clinical Trials on Medicinal Products for Human Use, and repealing Directive 2001/20/EC[23] (further referred to as the Clinical Trials Regulation or CTR) is subject to the provisions of the 2023 Act on Clinical Trials on Medicinal Products for Human Use[24] (hereafter referred to as ACT). The ACT ensures full application of Clinical Trials Regulation in the Polish legal system. However, it must be emphasized that CTR, by the very nature of this type of EU legislation, is binding in its entirety and directly applicable in EU member states without the need for national implementing legislation, unless it leaves states with a margin of discretion to regulate certain specific matters.

Thus, although clinical trials of medicinal product are still treated by Polish law as a type of medical experiment, the provisions of the CTR

[22] See, e.g., K. Miłowska, P. Zięcik, *Art. 37a* [in:] *Prawo farmaceutyczne. Komentarz,* ed. W.L. Olszewski, Warszawa 2016, pp. 340-341; L. Bosek, M. Gałązka, *Eksperyment medyczny* [in:] *System prawa medycznego*…, pp. 58–60; P. Konieczniak, *Eksperyment medyczny* [in:] *System prawa medycznego*..., pp. 77–89; (All written with q direct reference to the „old" Polish regulations on clinical trials implementing the repealed EU Directive 2001/20/EC.)

[23] *Official Journal of the European Union* L 158 of May 27, 2014, pp. 1–76, with amendments, https://eur-lex.europa.eu/eli/reg/2014/536/2022-12-05. Article 2(2)(2) of the CTR reads: „'Clinical trial' means a clinical study which fulfils any of the following conditions: (a) the assignment of the subject to a particular therapeutic strategy is decided in advance and does not fall within normal clinical practice of the Member State concerned; (b) the decision to prescribe the investigational medicinal products is taken together with the decision to include the subject in the clinical study; or (c) diagnostic or monitoring procedures in addition to normal clinical practice are applied to the subjects".

[24] Act of March 9, 2023 on Clinical Trials on Medicinal Products for Human Use, *Journal of Laws* 2023 item 605, with amendments [in PL].

and the ACT regulate the conduct of clinical trials in Poland. This also applies to the rules governing the provision of „incentives and financial inducements" to participants of such trials, which are directly governed by Articles 28(h), 31(1)(d), 32(1)(d), and 33(d) of the CTR, and will be analyzed in more detail below. The ACT contains only one provision on this matter, namely Article 77(2), which imposes a penalty of a fine, restriction of liberty or imprisonment for up to two years for the use of incentives or financial rewards in violation of the above-mentioned provisions of the CTR.

Finally, the provisions of Chapter 4 of the APPD (including Article 23b(1)) do not apply to clinical investigations of medical devices (with the exception of Article 29, which pertains to the organization and functioning of research ethics committees). Clinical investigations of medical devices are directly regulated by the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC[25] and the Polish Act on Medical Devices[26]. Articles 64(1)(d), 65(d), and 66(c) of Regulation 2017/745 establish rules for providing „incentives and financial inducements" to participants in clinical investigations of medical devices. These rules are identical to those in the CTR on clinical trials. For the sake of brevity, and where relevant, we will only refer to payments for clinical trial participants. However, whenever the latter is discussed, it also applies to payments for participants of clinical investigations.

[25] *Official Journal of the European Union* L 117 of May 5, 2017, pp. 1–175, with amendments. In the Polish version of the Regulation, „clinical investigation" on a medical device is translated as „badanie kliniczne", and the latter term is also traditionally used as the Polish translation of „clinical trial". Thus, in Polish legal terminology, the term ‚badanie kliniczne' (without additional specifications) may refer to clinical trials of medicinal products or clinical investigations of medical devices.

[26] Act of April 7, 2022 on Medical Devices, *Journal of Laws* 2024, item 1620 [in PL]. Article 31(1) of the Act stipulates that only Article 29 of the APPD applies to clinical investigation of medical devices, but with modification set forth in this Act.

3. An ethico-legal analysis of Article 23b(1) of the APPD

Having explained the scope of Article 23b(1) of the APPD, we can now analyze the rules set out in the article concerning the provision of incentives or financial rewards to participants in medical experiments, and the legal and ethical problems they pose.

3.1. Problems with the interpretation of and gaps in Article 23b(1) of the APPD

As noted above, Article 23b(1) of the APPD states that: „In medical experiments, with the exception of experiments involving participants of legal age who can give legally valid consent, and healthy participants, no incentives or financial rewards[27] can be offered, except for reimbursement of expenses incurred". A quick look at the provision is enough to see that it raises a multitude of questions.

Article 23b(1) allows the reimbursement of expenses in all medical experiments, while establishing a general prohibition on offering incentives and financial rewards, with only a few exceptions[28]. Many Polish commentators support this negative approach toward research remuneration[29], despite the fact that it finds no support in international and

[27] The Polish version of Article 23b(1) uses the expression "zachęty i gratyfikacje finansowe", which follows the language used in the Polish version of EU Directive 2001/20/EC (Articles 4(d) and 5(d)) and the CTR (Articles 31(1)(d), 32(1)(d) and 33(d)). However, this is not a faithful translation of the English version of the EU legislation, which uses the pleonastic expression „incentives and financial inducements".

[28] It is noteworthy that Article 23b is often presented under the heading ‚Prohibition of offering incentives and financial rewards to participants in medical experiments...' in both legal literature (e.g., M. Gąsior, *Medical experiment*..., p. 1991) and the most popular Polish online legal databases and information services, as if the law did not permit any exceptions to this prohibition. See: LEX System Informacji Prawnej, https://sip.lex.pl/akty-prawne/dzu-dziennik-ustaw/zawody-lekarza-i-lekarza-dentysty-16798282/art-23-b; LexLege.pl, https://lexlege.pl/ustawa-o-zawodach-lekarza-i-lekarza-dentysty/rozdzial-4-eksperyment-medyczny/5723/#ustawa-o-zawodach-lekarza-i-lekarza-dentysty/art-23b/ [Accessed 12.02.2025].

[29] P. Konieczniak, *Eksperyment medyczny – sytuacja prawa po nowelizacji ustawy lekarskiej…,* pp. 109–110; R. Kubiak, *Nowe uwarunkowania prawne*…, p. 13; K. Sakowski, *Art. 23b* [in:] *Ustawa o zawodach lekarza*…, p. 736; I. Wrzesińska-Wal, D. Hajdukiewicz, A. Augustynowicz, L. Janiszewska, E. Sarnacka, M. Waszkie-

European standards for human medical research, nor in research ethics scholarship. This topic will be discussed in more detail in the following sections of the paper. First, however, three other issues regarding the interpretation of Article 23b(1) must be addressed. All of these problems stem from the provision's poor drafting. Though it is only one sentence, it contains two „exception" clauses, a compound conjunction, and ambiguous syntax and wording.

The first problem is determining who can be reimbursed for research-related expenses. While Article 23b(1) allows offering reimbursement in „all medical experiments", it does not specify whose expenses can be reimbursed or to whom the reimbursement can be paid. Consider the legal representatives of a minor participant. They are not participants in a medical experiment[30], but they are engaged in the experiment by providing proxy consent and assisting the participant in following the experimental regimen. They are also usually responsible for paying travel and other direct and indirect costs associated with participation, both for the child and themselves. However, Article 23b(1) does not settle whether the legal representatives of a minor participant may be offered reimbursement for their own expenses incurred as a result of the child's participation in the study. The same question arises in relation to the legal representatives of incapacitated persons taking part in medical experiments, as well as to anyone else supporting research participants, such as caregivers or family members of participants with physical disabilities.

The second problem concerns the scope of participants of medical experiments to whom it is permissible to offer incentives and financial rewards. Article 23b(1) introduces an exception to its general prohibition

wicz, *New regulations on current medical problems*…, p. 16; R. Kubiak, *Odpowiedzialność karna* …, p. 53, and literature referenced in footnote 37. Interestingly, during the governmental legislative process the Appellate Bioethics Committee proposed to completely prohibit any incentives and financial rewards for participation in medical experiments. The National Council of Physicians and the Polish Association for Good Clinical Practice (GCPpl) disagreed and argued in favor of offering incentives and financial rewards to all competent adult participants (both healthy and unhealthy), but only in scientific experiments. In: *Report on Public Consultations and Comments* …, p. 301, 392, 315, respectively.

[30] Article 21(5) of the APPD states that a participant in a medical experiment is the person "on whom the medical experiment is directly conducted".

on research remuneration in two phrases, each containing the word „participants" and linked by a conjunction („and"). The first phrase is „participants of legal age who can give legally valid consent," and the second is „healthy participants". Should these phrases be treated as referring to two independent categories of research participants or as describing a single category?

The first interpretation would lead to the following conclusion: it is permissible to offer incentives and financial rewards to (i) all adults capable of giving informed consent, both healthy and unhealthy, and (ii) other healthy participants, including healthy minors and incapacitated persons. This would be consistent with the growing international ethical-legal consensus on the permissibility of rewarding unhealthy adults for their participation in research, including research with therapeutic potential (see next two sections). However, it would contradict the prevailing view in research ethics that minors and other persons unable to give consent should not be rewarded for their participation in research because they may be vulnerable to exploitation for financial gain by their representatives or guardians.

The second interpretation would lead to the conclusion that the exception set forth in Article 23b(1) applies only to persons who jointly meet the following criteria: they are of legal age (adults), they are capable of giving consent, and they are healthy. This interpretation does not permit paying individuals who are incapable of providing informed consent. However, it unfairly eliminates the possibility of rewarding competent adult participants with medical conditions. Nevertheless, this interpretation seems to reflect the intention of the proponents of Article 23b(1), who stated during the legislative process that the restriction on offering remuneration „relates only to remuneration for participation in therapeutic experiments"[31] (wrongly assuming that unhealthy individuals do not participate in scientific experiments).

[31] See the drafters' response to the comments of the National Council of Physicians, in: *Report on Public Consultations and Comments*…, p. 292.

The prohibition on rewarding unhealthy research participants has its regulatory roots in Article 37e of the Pharmaceutical Law[32], which was repealed by the ACT[33]. Article 37e of the Pharmaceutical Law was introduced in 2004[34] as an implementation of Directive 2001/20/EC into the Polish legal system[35]. It regulated payments to clinical trial participants, but more strictly than the Directive, which prohibited "incentives or financial inducements" only in trials involving minors (Article 4d) and "incapacitated adults not able to give informed legal consent" (Article 5d). The 2004 version of Article 37e of the Pharmaceutical Law read: "In clinical trials, with the exception of clinical trials conducted on adult and healthy participants of clinical trial, no financial incentives or financial rewards may be offered, except for reimbursement of costs incurred". In 2011 the provision was amended to stipulate the following: "In clinical trials, with the exception of clinical trials involving adult, able to give consent, and healthy participants of clinical trial, no financial incentives or financial rewards may be offered, except for reimbursement of costs incurred"[36]. The 2011 version of Article 37e of the Pharmaceutical Law was in effect until mid-2023, when the provision was repealed. This means that it governed payments in clinical trials in Poland at the time that Article 23b(1) of the APPD was being drafted, debated and adopted. Although some scholars criticized the payment rules endorsed by

[32] Act of September 1, 2011 on the Pharmaceutical Law, *Journal of Laws* 2024, item 686, with amendments [in PL].

[33] Article 82(10) of the ACT.

[34] Article 1(27) of the Act of April 20, 2004 amending the Pharmaceutical Law, the Act on the Professions of Physician and Dentist, the Act – Introductory Provisions of the Pharmaceutical Law, the Act on Medical Devices and the Act on the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, *Journal of Laws* 2004 no. 92, item 882 [in PL].

[35] Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Relating to the Implementation of Good Clinical Practice in the Conduct of Clinical Trials on Medicinal Products for Human Use, *Official Journal of the European Union* L 121 of May 1, 2001, pp. 34–44, with amendments, https://eur-lex.europa.eu/eli/dir/2001/20/2022-01-01 [Accessed 12.02.2025]

[36] Article 11(24) of the Act of March 18, 2011 on the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, *Journal of Laws* 2011 no. 82, item 451 [in PL].

Article 37e of the Pharmaceutical Law[37], these rules were nevertheless repeated in Article 23b(1) of the APPD, albeit in a less clear manner.

The third problem with interpreting Article 23b(1) of the APPD concerns the terms „reimbursement of expenses incurred" and „incentives or financial rewards". The provision does not define any of these, leaving their interpretation to the discretion of investigators and research ethics committees. While it seems uncontroversial that necessary expenses directly related to participation (e.g., travel, lodging, meals) are eligible for reimbursement, it remains unclear whether other indirect and less necessary expenses are covered (e.g., the cost of hiring a babysitter for a child left at home for the duration of the experiment), and whether it is permissible to reimburse participants (or their legal representative) for loss of earnings. Many questions also remain open due to the lack of clarity around the meaning of „incentives" and „financial rewards". Does „incentive" refer to non-financial rewards only? If so, does it also include small gifts offered to participants as a token of appreciation? Does „financial reward" encompass all financial offers, regardless of size or value? Or is it more about remuneration that is commensurate with the participant's contribution of time, effort, and burdens?

All of these ambiguities and gaps blur the line between prohibited and permitted reimbursements, incentives and financial rewards, and leave investigators and research ethics committees in doubt about what payments can be made. Is it permissible to compensate the minor's parents for loss of income due to the child's participation in a medical experiment? Is it permissible to offer an underage participant a T-shirt, movie ticket, or a voucher code for an online bookstore? Is it permissible to encourage a competent patient to provide a sample of biological material for scien-

[37] For critical voices, see: W. Masełbas, *Art. 37e* [in:] *Prawo farmaceutyczne. Komentarz*, 2 Edition, ed. M. Kondrat, Warszawa 2016, p. 507; M. Świerczyński, *Problem wynagradzania uczestników* [in:] *Prawo farmaceutyczne*, 3rd Edition, eds. M. Krekora, M. Świerczyński, K. Traple, Warszawa 2000, p. 320. For supporting voices, see: L. Bosek, M. Gałązka, *Eksperyment medyczny* [in:] *System prawa medycznego* …, p. 82; K. Miłowska, P. Zięcik, *Art. 37e* [in:] *Prawo farmaceutyczne*..., pp. 358–359; L. Ogiegło, *Art. 37e*, [in:] *Prawo farmaceutyczne. Komentarz*. 3rd Edition, ed. L. Ogiegło, Warszawa 2018, pp. 394–395; A. Wnukiewicz-Kozłowska, *Badania kliniczne dorosłych*, 5.2. [in:] *System prawa medycznego* (eds. in chief M. Safjan, L. Bosek). Vol. IV. *Prawo farmaceutyczne*, ed. J. Haberko, Warszawa 2019, p. 199, f. 17.

tific experiment by offering a free diagnostic blood test unrelated to the study's purpose? Is it permissible to reward a healthy volunteer based on the level of risk involved in the experiment?

The lack of legal clarity on these and similar issues can expose sponsors and researchers to the risk of criminal liability. According to Article 58(5) of the APPD, anyone who conducts a medical experiment in violation of the conditions set forth in Article 23a or Article 23b shall be punished by a fine, restriction of liberty or imprisonment for up to 2 years. In addition, these legal ambiguities may lead to significant differences in the payment schemes that research ethics committees consider acceptable, even for identical or very similar projects. This in turn can undermine confidence in their work. It can also lead to the unjustified transfer of research costs to participants, which can result in their exploitation.

3.2. Different standards of payment for participation in medical experiments and clinical trials

In addition to the above issues, Article 23b(1) of the APPD creates inconsistencies in the Polish regulatory framework for payments in medical research. This is because its prohibitive approach to paying participants in medical experiments conflicts with the CTR rules on paying participants in clinical trials, particularly unhealthy volunteers. And there is no valid reason for clinical trials and other medical experiments to be subject to different rules regarding permissible payment schemes. Both clinical trials and medical experiments may impose minimal or substantial burdens and risks on participants. They may or may not have the potential to provide participants with direct therapeutic benefits. They may have a low or high probability of achieving the intended outcome. All of these factors depend on the objectives and design of a particular project. However, if two research projects are similar in all relevant respects, it is unjustifiable to pay their participants differently just because one is labelled a "clinical trial" and the other is not.

As previously explained, Article 23b(1) of the APPD does not apply to clinical trials. The provision of reimbursements, as well as "incentives and financial inducements", to trial participants is governed directly by the Clinical Trials Regulation (CTR). The CTR clearly states that one of the conditions for conducting clinical trials is that „no undue influence, including that of a financial nature, is exerted on subjects to participate in the clinical trial" (Article 28(1)(h))[38]. But it does not prohibit – as a general rule – paying participants for their contribution to the development of new, safer and more effective medical products. Rather, it identifies three categories of potential participants who are particularly vulnerable to undue influence and exploitation, and who, for the sake of their protection, should not be offered any payment except reimbursement. These categories are: incapacitated individuals (Article 31), minors (Article 32), and pregnant or breastfeeding women (Article 33). The CTR stipulates that, in the case of trials involving representatives of these groups, no „incentives or financial inducements" should be given to participants or to their legally designated representatives, when applicable, except for „compensation for expenses and loss of earnings directly related to the participation in the clinical trial" (Articles 31(1)(d), 32(1) and 33(d), respectively)[39].

These payment rules have been further explained by the Clinical Trials Coordination and Advisory Group (CTAG), an expert group established

[38] Please note that there is a slight difference between the Polish and English versions of Article 28(1)(h) of the CTR. The Polish version reads: „na uczestników nie jest wywierany niepożądany wpływ, w tym wpływ o charakterze finansowym, w celu skłonienia ich do udziału w badaniu klinicznym" (literally: „no undue influence, including *influence of a financial nature*, will be exerted on subjects to participate in the clinical trial"). This could be interpreted to mean that any influence of a financial nature constitutes undue influence and is prohibited as such. However, such an interpretation is inconsistent with the rest of the CTR, which clearly allows financial remuneration of clinical trial participants, with an exception for three categories of participants. The National Center for Bioethics at the Medical Research Agency of Poland recently explained this in their statement *Compensation for trial participants: an analysis of current legal regulations regarding the compensation of participants in clinical trials*, May 7, 2025, https://kcb.abm.gov.pl/kcb/kompendium-krajowego-centrum-b/3118,Platnosci-dla-uczestnikow-badania-klinicznego-ang-compensation-for-trail-partici.html [Accessed 12.08.2025]

[39] Identical prohibitions can be found in Regulation 2017/745 on medical devices, specifically in Articles 64(1)(d), 65(d) and 66(c), which relate to incapacitated participants, minors and pregnant or breastfeeding women, respectively.

to assist the European Commission and member states in the effective and efficient implementation of the CTR. The CTAG has endorsed a template entitled "Compensation for Trial Participants", which sponsors are recommended to submit as part of an application dossier[40]. The template clarifies that „a small token of appreciation is not considered an incentive, but needs to be explicitly evaluated and approved by the ethics committee". Thus, such tokens of gratitude may be offered to all participants of clinical trials, including minors[41] and incapacitated adults. It also emphasizes that the legal representative of the trial participant may be offered reimbursement for expenses (travel, accommodation, and meal costs) and loss of earnings. Furthermore, reimbursements, as well as monetary and non-monetary payments, may be offered to other persons „supporting a subject to participate" (partners, caregivers, etc.). The template also suggest that other forms of payment may be permissible if approved by the research ethics committee, as it provides space for "other" types of "compensation" to be specified. In general, the template requires sponsors to describe and justify any payment offered, including its form, amount, calculation method, or value, and mode of provision. However, it also requires an explanation if no reimbursement or reward is offered, thereby suggesting that at least some reimbursement should be the default option.

In summary, there are important differences between the payment rules adopted by the CTR and Article 23b(1) of the APPD. The most significant ones are illustrated in the table.

[40] European Commission, Clinical Trials Coordination and Advisory Group, *Compensation for trial participants*, version 5, June 2023, https://health.ec.europa.eu/document/download/f982c9a5-a841-4199-b4fd-0d4049e64e5d_en?filename=payment_compensation_template_en.docx [Accessed 12.02.2025]

[41] See also, European Commission, Expert Group on Clinical Trials for the Implementation of Regulation (EU) No 536/2014 on Clinical Trials on Medicinal Products for Human Use, *Ethical considerations for clinical trials on medicinal products conducted with minors. Recommendations of the Expert Group on Clinical Trials for the Implementation of Regulation (EU) No 536/2014 on Clinical Trials on Medicinal Products for Human Use*, 2017, sec. 21, https://health.ec.europa.eu/document/download/d721d6cb-687a-477f-b40f-8c7922e9ec9a_en [Accessed 12.02.2025]

	MEDICAL EXPERIMENTS	**CLINICAL TRIALS**
Legal basis	Article 23b(1) of the APPD	Articles 31(1)(d), 32(1)(d) and 33(d) of the CTR
Payments to participants by category		
Reimbursement of expenses incurred	Permissible (? unclear whether also to LR and SP)*	Permissible (also to LR and SP)
Reimbursement of loss of earnings	**?**	**Permissible** (also to LR and SP)
Small tokens of appreciation	**?**	**Permissible** (also to LR and SP)
General rule regarding incentives and financial rewards	**Prohibited**	**Permissible** (also to SP)
Exceptions to the general rule regarding incentives and financial rewards	Permissible to: "participants who are of legal age and able to give legally valid consent, and healthy participants"	Prohibited to: (1) incapacitated adults; (2) minors; (3) pregnant and breastfeeding women, and (4) their legal representatives, when applicable
"Incentives and financial rewards" by participant category**		
Competent*** and healthy adults	Permissible	Permissible
Competent and unhealthy adults	**Prohibited**	**Permissible**
Incapacitated adult****	Prohibited	Prohibited
Minors	Prohibited	Prohibited
Pregnant and breastfeeding women	Permissible when competent, adult and healthy; otherwise prohibited.	Prohibited

** LR – legal representative; SP – supporting person.*

*** In accordance with the second interpretation of the exception clause presented above.*

**** Individuals who are legally competent to consent and have the capacity to make decisions about participation.*

***** In accordance with Article 2(2)(19) of the CTR, which states that "'incapacitated subject' means a subject who is, for reasons other than the age of legal competence to give informed consent, incapable of giving informed consent according to the law of the Member State concerned".*

It is worth noting that attempts were made to include in the ACT more stringent provisions on incentives and financial rewards in clinical trials than those provided by the CTR. Examining these historical debates sheds more light on the prohibitive attitude of Polish regulators toward payments to research participants.

The governmental draft of the ACT was prepared by the Ministry of Health and submitted for intergovernmental and public consultation in 2021[42]. Article 3(1) of the draft ACT stipulated that no incentives, financial rewards or promises of health improvement may be used in clinical trials, except for reimbursement for expenses incurred. Exceptions to this general prohibition were made in Article 3(2), which stated that "financial rewards may be offered to adult, healthy and sick participants in a phase I clinical trial or a bioequivalence or bioavailability study". For violation of these rules, Article 77(2) of the governmental draft ACT provided a criminal penalty of a fine, restriction of liberty or imprisonment for up to three years. The drafters of the act claimed[43] that it was consistent with Recital 31 of the CTR, which states that "in order to certify that informed consent is given freely, the investigator should take into account all relevant circumstances which might influence the decision of a potential subject to participate in a clinical trial, in particular whether the potential subject belongs to an economically or socially disadvantaged group or is in a situation of institutional or hierarchical dependency that could inappropriately influence her or his decision to participate". However, the drafters overlooked two crucial facts. First, they failed to recognize that the proposed Articles 3(1) and 3(2) conflict with the relevant provisions of the CTR. Second, they ignored the fact that the CTR does not grant Member States the discretion to regulate "incentives and financial inducements" for clinical trial participants differently.

[42] Draft Act on Clinical Trials on Medicinal Products for Human Use (UC63), April 19, 2021 [in PL], https://legislacja.rcl.gov.pl/docs//2/12346302/12784804/12784805/dokument501321.pdf [Accessed 12.02.2025]

[43] Ibidem, p. 51 (The explanatory statement).

As shown above, the CTR does not limit the possibility of offering rewards only to participants in phase I trials and bioequivalence or bioavailability studies, nor does it impose a ban on promises of health improvement (which can reasonably be expected in phase IV trials). It allows offering "incentives and financial inducements" to all competent adult participants (both healthy and unhealthy) in all types and phases of clinical trials, with the exception of pregnant and breastfeeding women[44]. Such inducements are permissible as long as they do not constitute undue influence, particularly with regard to participants who are economically, socially, or institutionally vulnerable (Recital 31, Article 28(h)). Both the sponsor/investigator and the research ethics committee are responsible for ensuring that offers of payment do not compromise a participant's ability to give fully voluntary and informed consent to a clinical trial.

Interestingly, only two government bodies – the Ministry of European Union Affairs[45] and the Government Legislative Center[46] – and a few professional organizations[47] that participated in the intergovernmental and public consultations on the draft ACT noticed the unacceptable discrepancies between proposed Article 3(1) and (2) of the draft ACT and the CTR. These critical voices successfully prompted the Ministry of Health to remove the controversial provisions from the draft law before

[44] There is a lively debate in the literature about whether there should be any *a priori* restrictions on pregnant and breastfeeding women participating in medical research, or on paying them for this. See F. Baylis, A. Ballantyne, eds., *Clinical research involving pregnant women*, Springer 2017.

[45] Ministry of European Union Affairs, *Opinion of June 10, 2021 on the* Draft Act *on Clinical Trials on Medicinal Products for Human Use* (UC63) [in PL], pp. 1-2, https://legislacja.rcl.gov.pl/docs//2/12346302/12784804/12784807/dokument539818.docx; Idem, *Opinion of January 26, 2022 on the* Draft Act *on Clinical Trials on Medicinal Products for Human Use* (UC63) [in PL], p. 1-2, https://legislacja.rcl.gov.pl/docs//2/12346302/12784826/12784828/dokument540737.pdf [Accessed 12.02.2025].

[46] Government Legislative Center, *Opinion* of June 1, 2021 on the Draft Act *on Clinical Trials on Medicinal Products for Human Use* (UC63) [in PL], pp. 2-3, https://legislacja.rcl.gov.pl/docs//2/12346302/12784804/12784807/dokument539820.pdf [Accessed 12.02.2025].

[47] Employers' Union of Innovative Pharmaceutical Companies INFARMA**,** Polish Association of Employers of Companies Conducting Clinical Trials on Contract POLCRO, Polish Association for Good Clinical Practice GCPpl, *Joint opinion of May 28, 2021 on the* D*raft Act* on Clinical Trials on Medicinal Products for Human Use (UC63) [in PL]*,* https://legislacja.rcl.gov.pl/docs//2/12346302/12784810/12784813/dokument539846.docx [Accessed 12.02.2025].

submitting it to the Polish Parliament[48]. Consequently, the enacted ACT rightly does not establish substantive rules regarding incentives and financial rewards for clinical trial participants. Instead, it only sets out Article 77(2), which prescribes penalties for violations of Articles 31(1)(d), 32(1)(d) and 33(1)(d) of the CTR.

3.3. Conflict with international and European standards for paying unhealthy volunteers in medical research

Article 23b(1) of the APPD does not only conflict with EU regulatory framework for clinical trials, but also with the majority of international ethical standards and European regulations governing human medical research, including research payment. No prominent global or regional standard adopts such a prohibitive approach to research payments. None of them preclude offering remuneration to consenting adults in an unhealthy condition.

The World Medical Association's Declaration of Helsinki[49] contains only indirect guidance regarding payment for research participation. However, it does not prohibit reimbursing or remunerating research participants, nor does it a priori exclude the possibility of paying any group of participants. It only requires that information about „incentives to participants" be given to the potential research participant in the process of obtaining his or her informed consent (para. 26) and be clearly stated in the study protocol (para. 22), leaving the assessment of the acceptability of incentives to the discretion of the research ethics committee. Thus, in principle, the Declaration allows for paying both healthy and unhealthy individuals for participating in research. However, it reminds that "some individuals, groups, and communities are in a situation of more vulnerability as research participants due to factors that may be fixed or contextual and dynamic, and thus are at greater risk of being wronged or

[48] Draft Act on Clinical Trials on Medicinal Products for Human Use, Parliamentary Print no. 2843 of November 29, 2022, https://orka.sejm.gov.pl/Druki9ka.nsf/0/5D58C3895C6FC899C125890C004EEF90/%24File/2843.pdf [Accessed 12.02.2025].

[49] World Medical Association, *WMA Declaration of Helsinki* …

incurring harm" (para. 19); and that some may give consent to participate under duress or because of a dependent relationship with the researcher or physician involved in recruiting for the study (para. 27). Researchers and research ethics committees should take all these factors into account when designing and evaluating research projects, including incentives for participants. Medical research should not perpetuate or exacerbate existing inequalities and disparities (para. 6, part 2; para. 19-20).

The International Ethical Guidelines for Health-related Research Involving Humans[50], adopted by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization, go even further in their acceptance for research payments. Guideline 13 of the Guidelines ("Reimbursement and compensation for research participants") reads[51]: "Research participants should be reasonably reimbursed for costs directly incurred during the research, such as travel costs, and compensated reasonably for their inconvenience and time spent. Compensation can be monetary or non-monetary. The latter might include free health services unrelated to the research, medical insurance, educational materials, or other benefits" (part 1). Thus, the CIOMS Guidelines stipulate that reimbursing and remunerating research participants (both healthy volunteers and unhealthy volunteers) is not only ethically permissible, but also ethically recommended and even ethically obligatory. This is consistent with the view of many research ethicists, who argue that there is a moral obligation to pay research participants, stemming from either the requirement of justice[52] or the principle of social beneficence[53]. Like the WMA Declaration of Helsinki, Guideline 13 of the CIOMS Guidelines emphasizes that "compensation must not be so

[50] Council for International Organizations of Medical Sciences, *International Ethical Guidelines for Health-Related Research Involving Humans*, Geneva, Switzerland 2016, https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf [Accessed 12.02.2025].

[51] Ibidem, p. 53.

[52] L. Gelinas, E. A. Largent, I. G. Cohen, S. Kornetsky, B. E. Bierer, H. Fernandez Lynch, *A framework for ethical payment to research participants*, „New England Journal of Medicine" 2018, vol. 378, no. 8, pp. 766–771.

[53] J. Różyńska, *The ethical anatomy of payment*…, pp. 452-454; T.F. Ackerman, *An ethical framework for the practice of paying research subjects*, „IRB: Ethics & Human Research" 1989, vol. 11, no. 4, pp. 1–4.

large as to induce potential participants to consent to participate in the research against their better judgment ('undue inducement')" and states that "a local research ethics committee must approve reimbursement and compensation for research participants" (Guideline 13, part 2).

The CIOMS recommendations regarding the payment of research participants are further elaborated upon in the Commentary on Guideline 13[54]. Although some of the views expressed in the Commentary are still the subject of debate in research ethics and practice[55], one of them is certainly worth supporting and incorporating into Polish law. The Commentary notes that "the obligation to reasonably reimburse and compensate participants arises even when study enrolment offers participants potential individual benefits (for example, an investigational drug). This is because the vast majority of clinical research studies involve research procedures that have no potential individual benefits for participants but are performed for research purposes, such as additional blood draws, extra hospital visits and overnight stays. Moreover, it cannot be known before the research that investigational interventions will benefit participants. Indeed, some research interventions may cause more harm than good"[56].

These are compelling arguments for offering remuneration to all competent research participants, whether they are healthy or unhealthy, and whether the research has therapeutic potential or not. However, they are not the only ones. Just like healthy volunteers, patients (i.e. unhealthy individuals) can also volunteer for research that has no potential for direct therapeutic benefit. This could be research aimed solely at understanding

[54] Council for International Organizations of Medical Sciences, *International Ethical Guidelines …,* pp. 53-54.

[55] On alternative models for paying research participants see N. Dickert, C. Grady, *What's the price of a research subject? Approaches to payment for research participation,* „New England Journal of Medicine" 1999, vol. 341, pp. 198–203; N. Dickert, C. Grady, *Incentives for research participants*…pp. 386-388; On a "wage--model", e.g., J. A. Anderson, C. Weijer, *The research subject as wage earner*, „Theoretical Medicine and Bioethics" 2002, vol. 23, no. 4, pp. 359–376; T. Phillips, *A living wage for research subjects*, „The Journal of Law, Medicine & Ethics" 2011, vol. 39, no. 2, pp. 243–253; H. Fernandez Lynch, *Human research subjects as human research workers*, „Yale Journal of Health Policy, Law, and Ethics" 2014, vol. 4, no. 1, pp. 122–193.

[56] Council for International Organizations of Medical Sciences, *International Ethical Guidelines …,* p. 53.

the cause of a particular disease, or bioequivalence or bioavailability studies of drugs that do not target the participant's background medical condition[57]. There is also considerable debate in the literature regarding the classification of phase I oncological trials involving patients as studies of therapeutic potential, with many scientists arguing against this[58]. These examples clearly demonstrate that patients' decisions to participate in research are not always motivated by the desire to address their own medical needs. They also provide further arguments for rejecting the claim that the prospect of obtaining direct therapeutic benefits from research is always sufficient compensation for unhealthy participants, and that they should therefore not be rewarded for their participation, either financially or otherwise. Of course, when such benefits are reasonably expected, researchers and research ethics committees can consider them when designing and reviewing the appropriateness of the payment offered. However, this should be done on a case-by-case basis. The same applies to studies involving healthy individuals. Although they typically do not stand to gain direct therapeutic benefits from the research, in some cases their participation has the potential to provide them with a health benefit (albeit not a direct or immediate one), so they may also be motivated by the hope of advancing their own medical interests. This is best illustrated by public health emergency vaccine trials, particularly phase III-IV trials[59].

[57] See comment of the Polish Association for Good Clinical Practice GCPpl in: *Report on Public Consultations and Comments*…, pp. 315.

[58] J. Kimmelman, *Is participation in cancer phase I trials really therapeutic?*, „Journal of Clinical Oncology" 2017, vol. 35, no. 2, pp.135–138. J.J. Adashek, P.M. LoRusso, D.S. Hong, R. Kurzrock, *Phase I trials as valid therapeutic options for patients with cancer*, „Nature Reviews. Clinical Oncology" 2019, vol. 16, no. 12, pp. 773–778; J. Halpern, D. Paolo, A. Huang, *Informed consent for early-phase clinical trials: therapeutic misestimation, unrealistic optimism and appreciation*, „Journal of Medical Ethics" 2019, vol. 45, no. 6, pp. 384–387; M. Bittlinger, S. Bicer, J. Peppercorn, J. Kimmelman, *Ethical considerations for phase I trials in oncology*, „Journal of Clinical Oncology" 2022, vol. 40, no. 30, pp. 3474–3488.

[59] A. Dean , F. Rose, K. Jones, A. Scantlebury, J. Adamson, P. Knapp, *Why do people take part in vaccine trials? A mixed methods narrative synthesis*, „Patient Education and Counseling" 2023, vol. 114, 10786. A protocol of the Pfizer study on BNT162 RNA-based COVID-19 vaccines in healthy volunteers explicitly stated that: "Taking into account the measures taken to minimize risk to participants participating in this study, the potential risks identified in association with BNT162 RNA-based COVID-19 vaccine are justified by the anticipated benefits that may be afforded to healthy participants", i.e., the receipt of an efficacious COVID-19 vaccine during a global pandemic and access to COVID-19 diagnostic

In conclusion, both healthy and unhealthy individuals who participate in medical research are exposed to risks that are not offset by any prospect of direct therapeutic benefit. This is because all studies involve risky procedures that are performed solely for scientific purposes. Additionally, in some research, such therapeutic benefits are not even expected due to the study objectives and methods. Both healthy and unhealthy people may participate in medical research for altruistic reasons, personal reasons (not necessarily health-related), or a combination of the two. Therefore, there is no valid justification for excluding all competent unhealthy participants a priori from receiving remuneration for their research contributions. The Council of Europe also takes a rather permissive approach to the reimbursement and remuneration of research participants, including those taking part in research with the potential for direct therapeutic benefit. The Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research[60] addresses research payments in Article 12 („Undue influence"), which states that "the ethics committee must be satisfied that no undue influence, including that of a financial nature, will be exerted on persons to participate in research. In this respect, particular attention must be given to vulnerable or dependent persons". This laconic provision is further elaborated in the Explanatory Report to the Protocol[61]. While the Report focuses extensively on the need to protect the most vulnerable from any form of undue influence, it clearly emphasizes that "payments made to research participants are not prohibited by the Protocol but are subject to the scrutiny of the ethics committee"[62]. And it explains that: „If any compensation to

testing. Pfizer, Protocol C4591001 - A Phase 1/2/3, placebo-controlled, randomized, observer-blind, dose-finding study to evaluate the safety, tolerability, immunogenicity, and efficacy of SARS-COV-2 RNA vaccine candidates against COVID-19 in healthy individuals (ver. 2022), p. 71, https://cdn.clinicaltrials.gov/large-docs/28/NCT04368728/Prot_000.pdf [Accessed 12.02.2025].

[60] Council of Europe, *Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research*, CETS 195, Strasbourg, France 2005, https://rm.coe.int/168008371a [Accessed 12.08.2025].

[61] Council of Europe, *Explanatory Report to the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research*, CETS 195, Strasbourg, France 2005, https://rm.coe.int/16800d3810 [Accessed 12.02.2025].

[62] Ibidem, sec. 62.

the research participants, and where appropriate their representatives, is provided, it would not be considered undue influence if it is appropriate to the burden and inconvenience. However, compensation should not be provided at a level that might encourage participants to take risks that they would not otherwise find acceptable. This should be evaluated by the ethics committee. Reimbursement for any expenses or financial loss shall not be regarded as undue influence. While it is permissible to compensate research participants for expenses or lost time, it is not permissible to pay them to accept a higher level of risk than would otherwise be the case"[63]. These clarifications leave no doubt that compensating research participants for their time and inconveniences is not considered per se to violate the prohibition of financial gain from the human body and its parts as set forth in Article 21 of the Council of Europe Convention on Human Rights and Biomedicine[64] (as has been suggested by some Polish scholars[65]), nor is it always considered to constitute an undue influence (undue inducement). Rather, the opposite is true. Rewarding research participants is consistent with respect for human dignity and is ethically and legally acceptable, provided that it meets (at least) the requirements of the Convention and the Additional Protocol concerning Biomedical Research.

The above brief review of international and European standards for the payment of research participants clearly shows that there is general acceptance of offering financial and non-financial remuneration to competent adult research participants, regardless of their health status. There is also a broad consensus that such payments must never be used to unduly induce participation or "perpetuate or exacerbate existing inequalities and disparities"[66]. Surprisingly, despite the very protective (even paternalistic) position of the APPD, the concerns about undue influence

[63] Ibidem, sec. 64.

[64] Council of Europe, *Convention for the Protection of Human Rights and Dignity of the Human Beings with regard to the Application of Biology and Medicine. Convention on Human Rights and Biomedicine*, ETS 164, Oviedo, Spain 1997, https://rm.coe.int/168007cf98 [Accessed 12.02.2025].

[65] L. Bosek, M. Gałązka, *Eksperyment medyczny* [in:] *System prawa medycznego*…, p. 82.

[66] World Medical Association, *WMA Declaration of Helsinki*…., paras. 6, 19-20.

(undue inducement) and unfair exploitation are not clearly expressed in Article 23b(1) of the Act. However, as we argue at length in an article to be published in the next issue of this journal[67], the general duty to protect against such inappropriate payment offers stems from Article 31b(2), which states that „it is forbidden to conduct a medical experiment by taking advantage of a forced situation of a person participating in such an experiment".

4. Conclusions

This comprehensive analysis of the legal and ethical aspects of Article 23b(1) of the APPD leads to three key conclusions. First, Article 23b(1) of the APPD should be revised to remove ambiguities and inconsistencies with EU legislation on payments in clinical trials and clinical investigations, at the very least. There is no ethical justification for different payment rules for medical experiments and clinical trials/investigations. In particular, there is no justification for excluding unhealthy individuals or those participating in therapeutic experiments from research incentives and financial rewards a priori. Second, the appropriateness of a payment scheme proposed by researchers should be assessed by research ethics committees on a case-by-case basis. However, committees should be provided with more detailed legal and/or ethical standards regarding research payments, including reimbursement and remuneration.

This would enhance the quality, transparency, accountability, and reliability of research ethics oversight. Third, research ethics committees should pay particular attention to methods and modes of participant recruitment, including offers of payment for participation, in order to minimize the risk of undue influence (undue inducement), and prevent unfair exploitation. In an upcoming paper, we will argue that Article 23b(2) of the APPD should be interpreted as establishing a general obligation to protect vulnerable individuals against (also) these risks and abuses[68].

[67] J. Różyńska, E. Kaczmarek, *Protecting research participants against undue influence and exploitation*…

[68] Ibidem.

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S t r e s z c z e n i e

Wynagradzanie uczestników badań medycznych. Analiza etyczno-prawna art. 23b ust. 1 ustawy o zawodzie lekarza i lekarza dentysty

Artykuł zawiera kompleksową analizę etyczno-prawną art. 23b ust. 1 ustawy o zawodach lekarza i lekarza dentysty (u.z.l.). Analizowany przepis reguluje dopuszczalność wynagradzania uczestników eksperymentów medycznych w formie rekompensaty poniesionych kosztów oraz w formie „zachęt i gratyfikacji finansowych". W pierwszej kolejności wyjaśniamy zakres stosowania art. 23b ust. 1 u.z.l. w świetle ustawowego pojęcia eksperymentu medycznego. Następnie omawiamy luki regulacyjne i problemy interpretacyjne, jakie rodzi przepis art. 23b ust. 1 u.z.l. Wskazujemy na istotne rozbieżności między zasadami wynagradzania uczestników eksperymentów medycznych a przepisami regulującymi wynagradzanie uczestników badań klinicznych obowiązującymi w całej UE. Porównujemy także treść art. 23b ust. 1 u.z.l z wytycznymi dotyczącymi wynagradzania uczestników badań medycznych zawartymi w najważniejszych międzynarodowych standardach etycznych i prawnych dotyczących badań z udziałem człowieka. Przeprowadzane analizy prowadzą do wniosku, że przepis art. 23b ust. 1 u.z.l. wymaga zmiany, aby lepiej chronić uczestników eksperymentów medycznych i dostarczyć badaczom i komisjom bioetycznym jasnych, spójnych i etycznie uzasadnionych wytycznych dotyczących płacenia uczestnikom.

Słowa kluczowe: eksperyment medyczny, badania kliniczne, rekompensata kosztów, zachęty i gratyfikacje finansowe dla uczestników badań