New insurance obligations, rules for the participation of minors and penalty regulations – overview of the most important changes in respect of running medical experiments

As of 1 January 2021, changes in the regulations regarding medical experiments, introduced in amendments to the Medical Profession Act, will come into force. As a reminder, we would like to point out, that a clinical trial of a medicinal product is considered to be a medical experiment with a medicinal product performed on people.

The amendments in question will not affect any medical experiments with respect to which a bioethics committee has already issued or will issue an opinion before 1 January 2021. Therefore, the changes discussed in more detail further will not apply to any proceedings for the submission of an opinion on a proposed medical experiment which is initiated and not completed before the above date.

At the same time, we would like to underline, that ongoing legislative works continue with respect to the Act on Clinical Trials which are aimed at establishing an independent legal framework to conduct clinical trials of medical products in Poland. This Act is intended to adapt Polish regulations to the requirements of Regulation No. 536/2014. The draft is currently being prepared by the Council of Ministers and should be published shortly in order to undertake public consultations.

Entities conducting medical experiments must conclude an additional insurance contract for participants

Currently, under the Pharmaceutical Law, the Sponsor and the Investigator are obliged to conclude a civil liability insurance agreement for any damages caused in connection with the conduct of a clinical trial, i.e. for the acts or omissions of the Sponsor/Investigator which result in the personal injury, disease or death of the clinical trial's participant. Therefore, the scope of insurance includes the liability of the Sponsor and the Investigator. The trial participant is not insured themselves. The trial participant must prove the Sponsor's/Investigator's fault in order to obtain compensation, which in practice may prove difficult.

From 1 January 2021, an entity conducting a medical experiment will be obliged to conclude a civil liability insurance contract in favour of the participant and also for any person who can be directly affected by the results of the experiment. The catalogue of entities required to conclude an insurance contract is not clear. On the one hand, the literal wording of the Act suggests that the Investigator themselves is subject to this duty, as they conduct the medical experiment, but a draft of the implementing regulation suggests that it is the site at which the experiment is conducted. Note that the list of entities subject to this duty as stated in the draft regulation includes: research institutes, medical universities and healthcare institutions associated with a medical university.

At first, it appeared that such insurance should cover the participant as well as their family. The amended act was drafted in such a manner as to suggest that the insurance contract should be concluded for the benefit of both the participant and persons who are directly affected by the experiment (the latter term also appears in the context of granting consent to conduct the study, which suggests that it refers to a family member).

Details regarding the scope of compulsory insurance, the date on which the obligation to purchase such insurance arises and the minimum guarantee amount are regulated further in the draft implementing regulation dated 13 November 2020, which has since been widely

criticized by the medical community. The obligation to insure civil liability arises no later than the day on which an application for an opinion on the medical experiment is submitted (however, this will be probably changed by stating that the obligation arises no later than the day preceding the day of the beginning of the medical experiment). The minimum guarantee amount for one event and all events is EUR 50,000 in the case of therapeutic experiments, and EUR 100,000 for research experiments.

As an aside, please note that the amended act allows for the insurance contract to be abandoned in exceptional cases and due to a direct threat to the participant's life.

Additionally, it is worth bearing in mind that conducting a medical experiment without concluding a compulsory insurance contract as described above is subject to criminal sanctions - in such cases, the law provides for a fine of between PLN 1,000 and 50,000.

Who may grant permission to participate in a research experiment

The age limit from which a minor may give their consent to participate in an experiment has been lowered. Thus: i) if the participant is under 13 years of age, consent to their participation in the experiment is given by their legal representative; and, ii) if the participant is above 13 years of age, the consent of both the participant and their legal representative is required (in case of a disagreement between these parties, the matter will be settled by a court).

In the case of partially incapacitated persons, who are not under parental authority, consent shall be given by their curator or legal guardian (in case of a disagreement between these parties, the matter will be settled by a court).

If a person's legal representative refuses to give consent for their participation in an experiment, such consent may be given by a court. The entity conducting the experiment may also apply to a court to grant consent for a person to participate in an experiment.

When is consent not required?

The possibility of conducting a therapeutic experiment without the prior consent of the participant or their legal representative has now been regulated. Thus, it is now possible to conduct a therapeutic experiment in the event that: i) the participant is incapable of giving consent, ii) there is an urgent case, iii) it is not possible to experiment on persons who are not in an urgent situation, iv) the participant has not previously objected, and vi) the participant or their statutory representative receives all relevant information.

It should be noted that the above conditions are cumulative and must be fulfilled together.

Penalty regulations for the performance of a medical experiment

Criminal sanctions have been introduced for the conduct of a medical experiment: i) without the required consent of the participant or the court's authorization to participate in the study (subject to a penalty of imprisonment of up to 3 years), ii) in violation of the rights of the patient/participant, such as where an experiment is conducted on a person deprived of liberty (subject to a penalty of a fine, a penalty of restriction of liberty, or a penalty of imprisonment of up to 2 years), iii) without obtaining the positive opinion of the bioethics committee or against its conditions; or iv) without concluding a civil liability agreement in favour of the participant (both cases iii) and iv) are subject to a penalty of a fine of between PLN 1,000 and PLN 50,000). Regardless of the above, the grounds for criminal liability in respect of clinical trials are also regulated in Art. 126a of the Pharmaceutical Law, which partially overlaps with those noted above.

Participation of a minor in a research experiment

An additional condition was introduced concerning the participation of minors in research experiments.

To date, minors could take part in research experiments: i) if the expected benefits were directly relevant to the minor's health, and ii) an experiment of comparable effectiveness could not be a performed with the participation of an adult. The Act added the condition that the experiment must significantly expand medical knowledge.

Additional right of participants

The use of a placebo is limited only to those situations where there are no other methods with proven efficacy or where the withdrawal/suspension of methods with proven efficacy does not represent an unacceptable risk or burden to the experiment's participant.

Participation in a medical experiment must not delay or deprive the subject of medically necessary preventive, diagnostic, or therapeutic procedures.

The new regulations also prohibit medical experiments using the forced position of the participant in such an experiment.

It is worth highlighting that the provisions of the Pharmaceutical Law regulating the conduct of clinical trials of medicinal products, together with, the regulation on Good Clinical Practice, are the applicable lex specialist, and will thus have priority over the Medical Profession Act.

In case of any questions, please contact our lawyers from the Intellectual Property team and the Insurance Law team:

Agnieszka Wiercińska-Krużewska
advocate, partner
>
Intellectual Property
agnieszka.wiercinska@wkb.p

dr hab. Jakub Pokrzywniak
attorney-at-law, partner

>
Insurance
jakub.pokrzywniak@wkb.pl>

Aleksandra Bączykowska
advocate

>
Intellectual property
Aleksandra.baczykowska@wkb.pl

Legal basis:

- > Act of 16 July 2020 amending the Medical Profession Act and other acts
- > Pharmaceutical Law of 6 September 2001
- > Draft Regulation of the Minister of Finance, Funds and Regional Policy on compulsory third party liability insurance for the entity carrying out a medical experiment.