

Legal Alert

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Act of March 9, 2023 on clinical trials of medicinal products for human use

On March 21, 2023, the long-awaited act on clinical trials of medicinal products for human use was signed by the President of the Republic of Poland.

The adoption of the Act resulted from the need to ensure the application 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 in the Polish legal order.

The act also aims to increase the competitiveness of Poland as a place to conduct clinical trials:

- ✓ issues related to the conduct of proceedings regarding clinical trials (including the issuance of authorisations to conduct clinical trials, as well as their suspension or withdrawal), including the powers of the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products in this respect;
- ✓ functioning of the Chief Bioethics Committee operating at the Medical Research Agency, including the procedure for its appointment, composition and tasks;

- ✓ rules for the ethical evaluation of clinical trials, which will be prepared by the Chief Bioethics Committee or a designated bioethics committee;
- ✓ obligations of the sponsor, principal investigator and investigator, including civil liability resulting from the conducted clinical trial, as well as the rules of operation and financing of the Clinical Trials Compensation Fund;
- ✓ rules for financing healthcare services related to a clinical trial;
- ✓ an indication of the entities authorised to inspect clinical trials, including the procedure for conducting it;
- ✓ the amount of fees for submitting applications for a permit, e.g. to conduct commercial and non-commercial clinical trials.

The Act will enter into force 14 days after the announcement, although with some exceptions (e.g. the provisions on the Chief Bioethics Committee will come into force on the day following the announcement).

The text of the law can be read at the link: [Link](#)



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