WKB lawyers

CLINICAL TRIALS IN POLAND

LEGAL ALERT

AUGUST 2023

WKB lawyers

FOUR MONTHS SINCE THE ACT ON CLINICAL TRIALS CAME INTO FORCE IN POLAND – PRACTICAL REFLECTIONS

As of 14 August 2023, four months have passed since the Act on Clinical Trials of Medicinal Products for Human Use (the "Act") came into force. The Act supplements EU Regulation 536/2014 on Clinical Trials, which also applies to Poland. The EU harmonization of clinical trials is being viewed as an opportunity to increase the number of clinical trials taking place in EU Member States, including Poland.

Clinical trials are playing an increasingly important role both in the EU and globally. This view is also reflected by the steps being taken to revise the Good Clinical Trials Practice document ICH GCP E6 R3. These revisions are predominantly being made in light of technological developments and challenges (e.g., widespread digitisation, e-Consent, availability of large data sets, but also the introduction, especially in times of pandemic, of techniques and tools for remote monitoring of trial conduct and data quality).

Below, we present the practical implications of the most important changes to the Polish Act for entities involved in conducting clinical trials in Poland.

LEGAL CHANGES INTRODUCED BY THE ACT AND THEIR APPLICATION IN POLAND

1) Poland is part of the CTIS system

- As a reminder, sponsors no longer submit applications in the traditional way to the Polish authority (“URPL”).
- According to EU Regulation 536/2014 on Clinical Trials, applications related to starting a clinical trial in any of the EU Member States, including Poland, are submitted through the European system via the Clinical Trial Information System (CTIS).
- From 1 January 2023, using CTIS is mandatory in Poland.

2) Fees related to receiving authorization to conduct a clinical trial in Poland

- The Act sets the fees related to the authorization of a clinical trial. The value of the fee is dependent on what phase of the clinical trial the applicant is currently on, and the country acting as the reporting Member State.
- Currently, these fees are higher than before. The fees range from PLN 6000 to PLN 30,000 (approximately from € 1300 to € 6700) depending on which commercial phase (I-III) the clinical trial is at and where Poland is acting as the reporting Member State. Previously, the application fee was a flat fee of PLN 5,000 (approximately €1100).

3) A new solution for compensating those injured as a result of a clinical trial

- The rules regarding the liability of the investigator and sponsor for damage caused in a clinical trial (based on fault liability) remain unchanged.
- It is still possible to obtain compensation for damage incurred in connection with the participation in a clinical trial by pursuing a claim (on a fault basis) against a sponsor/PI and insurer, via an out-of-court or civil court claim.

- With the view that civil court proceedings are long-lasting and difficult, a new solution, the Clinical Trials Compensation Fund, was established.
- The Fund will make it easier for clinical trial participants to obtain compensation. Compensation between PLN 2,000 and PLN 200,000 (approx. € 444 to € 44,000) could be granted within 3 months for proceedings which are on a no-fault basis, held by the Patient Ombudsman, and when requested by the participant.
- We are still waiting for an additional regulation that would set out details regarding the level of compensation available to the patient dependent on the category of injury.
- The compensation benefit shall not be provided where injury or death of a clinical trial participant is due to the natural course of the participant's disease.
- Contributions to the Fund are made by the sponsor and range from € 2,000 to € 10,000 depending on the number of trial participants. This is in addition to the fee due for permission to start a clinical trial.
- It is not possible to be compensated twice for the same event. If the injured participant has received compensation from the sponsor/insurer/investigator, the compensation received from the Fund will be reduced by the amount of the acquired compensation e.g., in the court proceedings.
- For the purposes of the procedure, a sponsor, investigator, or clinical site may be required to provide information, explanations, and documents that are in their possession for the review of compensation claims. If this obligation is not fulfilled, the Patient Ombudsman may impose a fine of up to PLN 50,000 (approximately € 11,210) on the sponsor and/or investigator.

4) Principles and procedures for the bioethical assessment of clinical trials

- The Act introduced a new institution in Poland related to clinical trials, the Supreme Bioethics Committee (Naczelna Komisja Bioetyczna "NKB") standing over bioethics committees included in the official list of bioethics committees. The NKB and bioethics committees are responsible for the ethical assessment of a clinical trial taking place in Poland.
- The sponsor is no longer able to select the bioethics committee which will conduct the assessment (as it was before). NKB will now decide whether the request for a clinical trial is assessed by NKB or by one of the bioethics committees.
- When appointing a bioethics committee, NKB takes into account: 1) the experience of the bioethics committee in the ethical assessment of clinical trials in the field of medicine and the study population specific to the clinical trial for which the assessment is to be made; and 2) the ability to prepare in a timely manner and ethical assessment of a clinical trial.
- Additionally, the selected bioethics committee must now follow strict deadlines and rules when assessing clinical trial requests. Previously, there was more flexibility in this respect which resulted in delays.

5) Scientific advice from the President of URPL

- From 1 July 2023, the President of URPL can issue scientific advice to potential MAHs registering medicinal products in Poland. This advice is based on the model used by

the European Medicines Agency (EMA). Scientific advice is an important tool offered to help potential MAHs generate evidence on a medicine's benefits and risks.

- Scientific advice from the President of URPL:
  - may relate to the conduct of tests and studies necessary to demonstrate the quality, safety, or efficacy of medicinal products within the scope of ongoing or planned studies (safety, quality, technical issues); and
  - a potential MAH must use the template of the application for scientific advice (provided by the implementing regulation);
  - is issued at the request of the interested party, and is subject to a fee ranging from PLN 13 200 to PLN 52 800 - approximately € 3000 to € 11 200 - (the fee depends on the scope of the advice); and
  - shall be issued within 90 days of the applicant being informed that the application is complete; and
  - is not binding in administrative proceedings before the President of URPL;
  - the provision of scientific advice might be refused if: the advice concerns the application of the provisions of general applicable law regulating the issue of marketing authorization of medicinal products, it is related to guideline interpretation, the application for this scientific advice was also submitted to the EMA, the scientific advice concerns ongoing proceedings on marketing authorization, or a representative of the Republic of Poland acts as a rapporteur in the process of marketing authorization of a medicinal product in the ongoing centralized procedure.

If any questions or doubts arise as a result of the above discussion, our team remains at your disposal and is ready to support you in any legal matters.

AUTHORS

ALEKSANDRA BĄCZYKOWSKA
COUNSEL
ALEKSANDRA.BACZYKOWSKA@WKB.PL

JOLANTA PIETRKIEWICZ-KNECHT
SENIOR ASSOCIATE
JOLANTA.PIETRKIEWICZ-KNECHT@WKB.PL

MONIKA RADZIKOWSKA-PIECHOTA
ASSOCIATE
MONIKA.RADZIKOWSKA-PIECHOTA@WKB.PL