Client Alert

January 2022

New draft act on clinical trials of human use medicinal products

Poland

In brief

On the beginning of May we sent a newsletter regarding the draft act on clinical trials of medicinal for human use that implements the Regulation 536/2014 of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC ("**Regulation**").

On 17 January the new version has been published in a public domain ("**Draft**").

General comments

First of all, the Draft is still on an early stage of the legislation process, thus it will not come in force by 31 January 2022, when the Regulation comes in force. The Draft assumes to come in force within 30 days as of the date of its publication.

The most important changes introduced in the current version of the draft regard:

- the timelines for ethical review - this section has been completely modified as compared to the initial version;
- creation of the Clinical Trials Compensation Fund at the disposal of Patients Ombudsman in place of Clinical Trial Participant Protection Fund at the disposal of the President of Medical Research Agency, along with reduction in the maximum amounts of compensation benefits for bodily injury, health disorder or death;
- introduction of the "compassionate use" procedure into the Polish legal system.

1. Ethical review of the clinical trial

In the new version of the Project it is clearly indicated that the ethical evaluation is a part of the decision of the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products ("**President of the Office**") resulting from art. 8, 14, 19 and 20 of the Regulation and is prepared in Polish and English on forms prepared by the European Commission for the purposes of the Regulation. According to the justification to the Project the proposed regulations are designed to provide committees with greater participation in the process of issuing permits, e.g., to start clinical trials.

Validation of applications submitted in accordance with the provisions of Chapter II and Chapter III of the Regulation is conducted by the President of the Office, according to the rules set out in the Regulation.

Assessment report - Aspects covered by Part I (Article 6 of the Regulation)

In the case of a clinical trial addressed to:

- Poland, involving a single Member State, the ethical review shall be submitted to the President of the Office within no more than 35 days from the date of validation.
- to a number of countries and Poland is not the reporting country, the ethical review is submitted to the President of the Office within no more than 21 days from the validation date.
- to a number of countries and Poland is not the reporting country, the ethical review shall be submitted to the President of the Office within no more than 30 days from the date of validation.

In case of questions from the committee preparing the ethical review, these are promptly forwarded to the sponsor. The sponsor shall provide additional information within a specified period not exceeding **12 days** from the date of receipt of the request. The final ethics review shall be submitted to the President of the Office within **12 days** of the submission of additional information by the sponsor.

Assessment report - Aspects covered by Part II (Article 7 of the Regulation)

The ethical opinion is produced within a maximum of **35 days**.

If there are questions from the ethics committee, the President of the Office shall forward them immediately to the sponsor. The sponsor shall provide the additional information requested within a maximum of **12 days** of receipt of the request. The final ethical review shall be forwarded to the President of the Office within **12 days** from the date of submission of the additional information by the sponsor.

Extension of the trial to an additional Member State concerned (Article 14 of the Regulation)

Within the scope of activities under Article 14 of the Regulation, the ethical review is prepared within no more than **40 days** from the date of receipt of the application.

Assessment of a substantial amendment to an aspect covered by Part I of the assessment report (Article 18 of the Regulation)

In case of a clinical trial addressed to:

- Poland, covering one Member State, the ethical review is submitted to the President of the Office within no more than **30 days** from the validation date.
- to a number of countries and Poland is the reporting country, the ethical review shall be submitted to the President of the Office within no more than **15 days** from the validation date.
- to a number of countries and Poland is not the reporting country, the ethical evaluation shall be forwarded to the President of the Office within a period no longer than **25 days** from the date of validation.

In case of questions from the committee preparing the ethical review, these are promptly forwarded to the sponsor. The sponsor shall provide additional information within a specified period not exceeding 12 days from the date of receipt of the request. The final ethics review shall be submitted to the President of the Office within **12 days** of the submission of additional information by the sponsor.

Validation, assessment and decision on substantial amendment in the aspect covered by Part II of the assessment report (Article 20 of the Regulation)

Within the scope of activities under Article 20 of the Regulation, the President of the Office is responsible for preparation of the report. The State concerned shall, within **38 days** from the date of submission of the application dossier, prepare a report on Part II of the dossier.

The ethical review is submitted to the President of the Office within **30 days** from the date of validation.

If there are questions from the committee preparing the ethical review, the President of the Office shall forward them immediately to the sponsor. The sponsor shall provide the additional information requested within a period set by the Member State concerned and not exceeding **12 days** from the date of receipt of the request. The final ethical evaluation shall be forwarded to the President of the Office within **12 days** from the date of submission of the additional information by the sponsor.

Ethical reviews will be carried out by opinion panels consisting of at least 5 persons selected by the SBC Chairman or given bioethics committee chairman. Ethical reviews will be accepted by way of resolution adopted by a **3/4 majority vote** in an open ballot.

Provisions regulating appeals have been introduced. In accordance with the proposed changes, the provisions of the Code of Administrative Procedure will not apply to a resolution of the ethics committee and a negative ethical opinion on a clinical trial cannot be appealed. However, in the event that a negative ethical review is the basis for an appeal regarding the decision of the President of the Office, the President of the Office, **within 3 working days** of receipt of the appeal, will request the Supreme Bioethics Committee (SBC) to make a new assessment. The Chairman of the SBC will then appoint a bioethics committee to make an assessment (different from the one that made the first assessment).

2. Sponsor's obligations

The scope of the Sponsor's statutorily defined responsibilities has been reduced from the original version of the Draft and currently includes:

- to carry out the obligations in accordance with the Regulation;
- to obtain written consent from the principal investigator and the investigator to access the source documentation.

In terms of processing of data obtained in connection with the clinical trial, it was clarified that the obligation to provide access to the IT data storage system and change the data in such a way that it is possible to verify the data changes retrospectively should be understood as meaning that clinical trial documentation must allow trace back the course of the trial and all related events and decisions. The sponsor will be obliged to allow only those persons to process personal data authorized in writing by the data controller, who will be obliged to commit in writing to keep them confidential.

3. Liability for damages arising in connection with the clinical trial

No major changes.

4. Clinical Trials Compensation Fund

New version of the Project assumes the creation of the Clinical Trials Compensation Fund ("**Fund**"), managed by the Patient Ombudsman (PO) (instead of Fund for the Protection of Clinical Trial Participants administered by the Medical Research Agency). The Fund shall be established for compensating bodily injury or disorder or death resulting from participation in a clinical trial.

The fee will be charged on each application for approval of a clinical trial, but will have to be paid prior to the start of the trial, however, it will have to be paid prior to the start of the trial and not, as originally proposed, on the date of application. In cases strictly specified in the Project, the fee will be refundable (e.g., in the case where consent for conducting a clinical trial has not been granted). The new version of the Project specifies, that the amount of payment to the Fund will be determined by the regulation of the Minister of Health, after consultation with the PO, taking into account the necessity to ensure its liquidity (this was lacking in the previous version of the Draft). As of today, no executive acts have been published, which means that the possible amount of contribution is still unknown.

Procedure for payment of benefits from the Fund

In the event of personal injury or disorder of health as a result of participation in a clinical trial such a participant will be entitled to a compensation benefit.

If the subject dies, compensation will be payable to the spouse not separated from the subject, the first-degree relative, the person in an adoption relationship, or the person cohabiting with the subject. Compensation will not be payable if the bodily injury or health disorder, or death of a clinical trial participant results from the natural course of the disease. In contrast to the previous version of the Project, the opinion on the occurrence of bodily injury, health disorder or death of a trial subject will be issued by a team appointed by the PO. After obtaining the opinion of the panel, the PO will issue, within 3 months after receiving a complete application, an administrative decision on granting the compensation benefit and setting its amount or refusing to grant it. The benefit will be reduced by the amount of compensation and redress obtained from the person responsible for the damage under civil liability insurance. The applicant (clinical trial participant), as a party to the proceedings will be able to appeal from the decision of the PO to the appeal commission.

The new version of the draft assumes **a reduction of the originally proposed maximum amount of compensation benefits**. Currently, the maximum amount of benefits for:

- bodily injury or disorder of health will range **from PLN 2,000 (~EUR 440) to PLN 200,000 (~EUR 44.000)**, and
- death will range from **PLN 20,000 (~EUR 4.400) to PLN 100,000 (~EUR 22.000)**

The detailed scope and conditions for determining the amount of compensation due to bodily injury or health disorder or death of a clinical trial participant will be determined by the Minister of Health. The Minister of Health will be guided by the need for transparency in determining the amount of the benefit and ensuring that the interests of applicants are protected.

5. Fees

Proposed fees has not been changed since the last version - applications for clinical trial authorization will be subject to fees ranging from PLN 6.000 (~EUR 1.330) for non-commercial clinical trials to PLN 30.000 for phase I-III commercial clinical trials where Poland is a reporting Member State.

6. Financing of clinical trial-related healthcare services

No major changes.

7. Clinical trial inspection

No major changes.

8. Penal liability

Section regarding penal liability has been slightly expanded and the maximum penalty of imprisonment has been reduced from three to two years.

9. Compassionate Use

One of the most important changes included in the new version of the Project is the introduction of the "compassionate use" procedure to the Polish legal system.

General information

Pursuant to proposed changes to the provisions of the Pharmaceutical Law, the President of the Office will be entitled to issue an approval for the use of a medicinal product (within a program of individual use of a medicinal product), for which:

- a clinical trial is being conducted,
- the clinical trial has been completed, or
- an application for marketing authorization has been submitted,

for a defined group of patients suffering from:

- a chronic disease or
- serious debilitating or
- life-threatening,

who cannot be effectively treated with a medicinal product authorized for marketing in the territory of Poland, where such patient:

- participated in a clinical trial of that medicinal product and
- received a therapeutic benefit.

Application

Consent for the use of the medicinal product referred to above is to be granted upon application of:

- the marketing authorization holder (MAH), in the case of a medicinal product for which a marketing authorisation has been applied for in accordance with Article 6 of Regulation 726/2004, or
- the sponsor, for a medicinal product for which a clinical trial is ongoing or has ended,
- the treating physician after consultation with the consultant in the medical field concerned and the MAH and the sponsor.

Essential elements of the application:

- a commitment by the MAH or sponsor to ensure that the medicinal product covered by the application is available for the patients for whom the medicinal product is to be used until the time specified in the consent or until therapy with the medicinal product is completed in patients enrolled in the individual use program;
- an undertaking by the MAH or sponsor to provide the medicinal product covered by the application and the devices used for its administration free of charge to patients included in the individual use program;
- determination of the method of financing the individual use program and declarations which of the specified costs of implementing the program will be covered by the MAH and the sponsor;
- the consent of the medicinal entity to implement the individual use program if the administration of the medicinal product under the individual use program will require its administration at the medicinal entity, under the condition precedent of the consent;
- a detailed description of the individual use program for which consent is to be granted (the draft list of information that is required is 17 points long).

Consent procedure:

- Approval will provide the basis for importing from abroad the requested medicinal product in the quantity necessary for the individual use program. The MAH or sponsor will provide the medicinal products covered by the application and the devices used for their administration free of charge to the patients included in the personalised use programme.
- Upon receipt of an application, the President of the Office will be able to request the EMA to issue an opinion referred to in Article 83(4) of Regulation 726/2004 where such opinion is not contained in the specific description of the individual use programme.
- The President of the Office, before issuing an approval, will be able to consult a consultant in a given medical field on the use of the medicinal product applied for in a given group of patients.
- The President of the Office will consider the application for approval within a maximum of **30 days** (with an option to extend it by an **additional 30 days** if an opinion is sought from the EMA or a consultant).
- Consent, modification and denial of consent will be issued by **administrative decision within 21 days from the date of submission of a complete application**.
- Health care services under the individual application program that are guaranteed benefits will be financed according to the rules specified for non-commercial clinical trials.
- In certain cases the President of the Office will be able to refuse to issue the consent or to withdraw it.
- The consent will be issued for a specified period, not longer than the entry into force of the decision introducing the medicinal product on the market. It will also expire on the date of completion of therapy with the medicinal product in patients enrolled in the individual use program, which will be determined by the President of the Office by way of an administrative decision that will be immediately enforceable..

Obligations of MAH

- The Draft envisages the following obligations of MAH:
- monitor the safety of the medicinal product by actively collecting data on product safety and providing the President of the Office with reports on individual adverse reactions to the medicinal product and including in the periodic reports appropriate for the medicinal product information on all circumstances and events that affect the assessment of product safety and the safety and validity of the implementation of consent;
- inform the President of the Office of changes to the dossier;
- provide the medicinal product in accordance with the conditions included in the documentation justifying the decision (in the case of medicinal products requiring administration in a medical entity, the medicinal product will be able to be labelled in English);
- enter into an agreement with a medicinal entity if the administration of the medicinal product under the individual use program will require its administration in a medicinal entity;
- continue the individual use program until such time as withdrawal or expiration of consent is determined;

- immediately inform the President of the Office of the completion of therapy with the medicinal product to which the consent relates;
- provide, free of charge, to patients enrolled in the individual use program the medicinal products covered by the application and the devices used for their administration.
- Obtaining the approval will not exempt the MAH and the sponsor from criminal or civil liability arising from the use of the medicinal product under the individual use program.
- Each package of the medicinal product covered by the consent should have attached to it a clear information intended for the patient that the medicinal product is being made available on the basis of this consent, information on the principles and safety of use of the medicinal product covered by this program and, if it is not an authorized medicinal product, also information to this effect.

Contact Us

Paweł Hincz
Partner
pawel.hincz@bakermckenzie.com

Juliusz Krzyżanowski
Senior Associate
juliusz.krzyzanowski@bakermckenzie.com