Statement of the President of 19 March 2020 on clinical trials conducted in pandemic conditions

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PREZES
Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych

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COMMUNICATION

OF THE PRESIDENT OF THE OFFICE OF REGISTRATION OF MEDICINAL PRODUCTS, MEDICAL PRODUCTS AND BIOCIDAL PRODUCTS
of 19 March 2020.

on clinical trials in pandemic conditions

in connection with activities carried out in the territory of the Republic of Poland in the field of protection against SARS-CoV-2 virus infections affecting clinical trials, the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products provides the following information and recommendations to researchers, sponsors and other persons / entities involved in conducting clinical trials.

In the light of the dynamically changing situation in all activities related to conducting clinical trials in the territory of the Republic of Poland , the safety of patients in the broadly understood context of both continuation of therapy and the current epidemiological situation should be taken as an absolute priority .

It is recommended that the activities related to the supervision of clinical trials (monitoring, audit) take into account the current epidemiological situation and the fact that the staff of medical hospitals are involved in activities related to SARS-CoV-2 virus infection.

It is recommended that changes resulting from the need to adapt to the epidemiological situation be treated as immediate security measures in accordance with Article 37y of the Pharmaceutical Law of September 6, 2001: *"1. In the event of any event that could affect the safety of clinical trial subjects, the sponsor or investigator shall withdraw from conducting the clinical trial in accordance with the applicable clinical trial protocol. In this case, the sponsor and investigator must take appropriate measures to ensure the safety of clinical trial participants. 2. The sponsor shall immediately inform the President of the Office and the bioethics commission which has issued an opinion on the clinical trial about the situation and the security measures applied. "*. Given the current situation, it is permissible to send the above information by e-mail to urpl@urpl.gov.pl (mailto:urpl@urpl.gov.pl) . The information on immediate safety measures should include a detailed risk assessment resulting from the introduced changes.

It is recommended that changes resulting from the need to adapt to the epidemiological situation be treated as immediate security measures in accordance with Article 51 of the Act of 20 May 2010 on medical devices: *"1. In the event of an event that could affect the safety of study participants, the sponsor or clinical investigator shall take measures to ensure safety of study participants,*

and suspend or withdraw from conducting a clinical trial. 2. (...) information on the event referred to in para. 1, the sponsor immediately, but no later than within 7 days of receiving information about the event, and in the event of an event indicating an immediate risk of death, serious injury or serious illness, when immediate remedial action should be taken, within 2 days of receiving the information about the event, he shall forward to the President of the Office and to the bioethics commission, which gave opinions on the clinical trial, and to the competent authorities of the Member States in the territories of which the clinical trial is conducted. This information may be provided by the sponsor in English and transmitted electronically without the need for a qualified electronic signature. ". It is recommended that the above information be forwarded to the President of the Office by e-mail to incydenty@urpl.gov.pl (mailto:incydenty@urpl.gov.pl) .

In view of the above, it is recommended to consider the appropriateness of submitting, in the present situation, new applications for the commencement of a clinical trial of the medicinal product and applications for the authorization of a clinical trial for a medical device.

It is advised that the inspection activities of clinical trials are suspended until the end of April 2020, and the decision to resume the inspection process will be taken depending on the epidemiological situation. It is recommended to document deviations from the protocol in accordance with the procedures of the study.

President of the Office for Registration of
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