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ANALYSIS OF LEGISLTION OF UKRAINE IN THE FIELD OF MEDICINES AND RESEARCH

For a long time, Ukraine did not have clearly defined legal framework for regulation of relations in the sphere of drug circulation. Only in 1996, the Law of Ukraine on Medicinal Products came into effect and set the requirements for legitimacy of clinical trials of drugs and authorization procedures.

In particular, clinical trials are allowed with a written consent of the patient (volunteer) to participate in clinical trials or a written consent of his legal representative to conduct clinical trials involving a minor or an incapacitated patient. The patient or his legal representative shall obtain all information about the nature and possible consequences of the trials, characteristics of the tested pharmaceutical drug, its expected efficiency and risk level.

The leader of clinical trials must stop such trial or its particular stages in the event of a threat to the health or life of the patient as the result of such trials, as well as after the request of the patient or his legal representative was received. In 2004, Ukraine adopted the National Program on harmonization of the legislation of Ukraine with the EU legislation. According to this program, clinical trials in the Ukraine shall be regulated by the legislation harmonized with the EU requirements and must comply with applicable directives of the European Parliament and the EU Council, such as the Directive 2001/20/EC of the European Parliament and of the Council, the Declaration of Helsinki, the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, the UN Convention on the Rights of the Child, the Guidelines issued by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and legally adapted in the EU (CPMP/ICH/135/95 (E6), CPMP/ICH/137/95 (E3), CPMP/ ICH/291/95 (E8).

The process of Ukraine's integration into the international system of clinical trials was initiated in 1996, and already in 2003-2006, there was a rapid increase in the number of clinical trials as well as research centers. In the recent years, the field of clinical trials in the Ukraine moved from the phase of active formation to the phase of swift growth.

There have been concerns that the Ukraine is an attractive region for clinical trials because it belongs to the group of countries with average income level and such concerns are supported by the opinion of legal counsels, who study the responsibility of health professionals or crimes against human life and health. According to law enforcement bodies of Ukraine, medical institutions do not make evaluation of their own expenses during clinical trials. A significant amount of funds is received by researchers, specifically doctors registered as private entrepreneurs, rather than medical institutions.

Out-payments are determined by customer companies sponsoring the research, thus, creating conditions for prejudicing medical institutions. In addition, life and health insurance agreements are usually not concluded with patients. Customer companies conclude only insurance agreements of third-party property liability, while the Ukrainian legislation provides for the conclusion of life and health insurance agreements with patients.

According to acting legislation of Ukraine, a mandatory part of clinical trials is their compliance with the legislation regulating relationships in this area, monitoring the observance of human rights, safety conditions, ethical and moral standards, and confidentiality of participants in such trials. As to liability for violation of these rules, the legislation of Ukraine contains provisions for criminal liability for the breach of legal procedures for circulation and clinical trials of medicines, namely improper performance of duties with regard to children's life safety and healthcare (Article 137 of the Criminal Code of Ukraine (CC)), improper performance of duties by a member of medical or pharmaceutical institution (Article 140 of the CC), violation of rights of a patient (Article 141 of the CC), illegal experimentation on a human being (Article 142 of the CC) and illegal disclosure of confidential medical information (Article 145 of the CC).

Recently, the Criminal Code has been substantially amended with regard to provisions concerning liability for offenses related to counterfeiting, pre-clinical study, clinical trials and state registration of medicines. This step is related to the ratification of the Council of Europe Convention on the Counterfeiting of Medical Products and Similar Crimes involving Threats to Public Health by the Verkhovna Rada of Ukraine. The provisions of this Convention define the responsibility of the state-party to criminalize a number of acts that threaten public health.

If talking about the liability of medical and pharmaceutical workers, the existing criminal law (Articles 139-142 of the Criminal Code of Ukraine) already establishes criminal responsibility.