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Clinical trials and the new law on medicines

At the end of 2011, a new law on medicine and medical devices came into force. The previous legislation dated back to 1998, so it was high time for new provisions. Clinical trials, which are predominantly supported by foreign investors in Slovakia, are also affected.

Legal Framework
On December 1, 2011, Act No. 362/2011 Coll. on Medicine and Medical Devices, along with changes and amendments to other acts (the "Act on Medicines"), became effective.

The purpose of the new legislation is to regulate the treatment of medicines and medical devices in a more coherent way and to reflect the harmonization of these issues with EU legislation. An important objective was to ensure the highest level protection for human health.

Clinical trials
Legal definition
The Act on Medicines sets forth a new definition of the clinical trial: A clinical trial is any research on human beings, determining or confirming clinical, pharmacological or other pharmacodynamic effects, the purpose of which is to demonstrate any desirable or undesirable effect and to demonstrate absorption, distribution, metabolism and excretion of one or more tested human products or tested human medicines to determine their safety and efficacy. A clinical trial also determines the bioavailability and bioequivalence of the tested human products or medicines.

Informed consent
The parliament has also specified the obligatory content for the informed consent form, which a test subject must sign to participate in a clinical trial. The informed consent must contain the basic information about the clinical trial, both the possible benefits and possible risks or handicaps of the clinical trial, advice on other treatment options, guarantee of confidentiality, information regarding the rights of a test subject, and information about of withdrawing from the clinical trial including the manner and consequences for withdrawal.

Pursuant to the new provisions on the protection of test subjects, the interest of the test subjects shall always prevail over the interests of science and society. "Recruitment" of test subjects has been substituted with the "selection" of test subjects.

Application for authorization of the clinical trial
There is an additional requirement that shall accompany the application for authorization of the clinical trial. Under the new legislation, the applicant is now obliged to provide such application with a notarized copy of the license to operate as a health care provider acting as a trial site and a statement from the ethics committee.

Upon new correctional measures, the clinical trial may be suspended, prohibited or canceled. Such action may be taken if the requirements for the clinical trial are not fulfilled or if doubts regarding the safety or scientific justification of the study are raised.

Obligations of the sponsor
Submitting of the relevant documentation - The Act on Medicines further stipulates a new obligation for the sponsor to submit to a copy of the clinical trial authorization to a subject's health insurance company as well as a list of subjects insured in that particular company. This list must be submitted before the start of the clinical trial.

Reporting obligations of serious adverse events/reactions - The sponsor must report a serious adverse event and a suspected serious adverse reaction to the subject's health insurance company.

Covering costs connected with the treatment - Besides the obligation of the sponsor to cover all costs regarding the clinical trial and the insurance of the sponsor and investigator, the sponsor is now also obliged to cover all costs connected with the treatment of the subject's disease caused by the clinical trial.

Obligations of the investigator
Reporting obligations of unexpected serious adverse reaction - The investigator must report unexpected serious adverse reaction to the subject's health insurance company.

Non-intervention clinical trials - Non-intervention clinical trials are governed in a new way. Specifically, the general definition has been extended and now includes a responsible person called the "guarantor". Non-intervention clinical trials shall only be approved by the health insurance companies if the medical product has been registered for less than two years.

New list of administrative torts
There are several new administrative torts and misdemeanors associated with clinical trials. If guidelines are not followed, fines may be imposed.

The State Institute for Drug Control
The State Institute for Drug Control (SIDC) should publish specific information concerning clinical trials on its website, including the investigator's name, the trial site, the medical product on trial, the date of commencement and termination of the clinical trial, and the financial valuation of payments to the investigator.

Conclusion
Despite various new reporting and disbursing obligations under the Act on Medicines, Slovakia is still an attractive country for carrying out clinical trials, especially because of its technical equipment and experienced personnel. There are several websites showing the capacities of actively selecting clinical trials in Slovakia[1]. The website of the SIDC contains information regarding the database of interventional and non-interventional clinical trials in Slovakia, as well as in the EU[2].

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[1] http://www.centerwatch.com/clinical-trials/listings/location/international/Slovakia/
[2] http://www.sukl.sk/sk/klinicke-skusanie-liekov/databaza-klinickeho-skusania?page_id=2788