The Ministry releases the draft for the new regulation on trials with medicinal products and medical devices

Draft Royal Decree which regulates clinical trials with medicinal products, ethics committees on investigation with medicinal products and the registry of clinical trials

Last May the Ministry of Health, Social Services and Equality released a new draft Royal Decree, through which very important changes will be introduced in the current regulation of clinical trials with medicinal products and medical devices in our country.

Through these changes the Ministry aims at anticipating the new European regulation on this matter which is foreseen to be issued in 2014, and which seeks to facilitate research in the territory of the European Union. Due to its interest, we will briefly summarize some of the most relevant novelties.

Simplification of procedures

The main objective of the draft is to simplify the procedure for obtaining the authorization necessary to implement a clinical trial in Spain. With this aim, it is foreseen to improve the coordination between the Spanish Agency for Medicinal Products and Medical Devices (AEMPS) and the new Evaluation Committees for Research with medicinal products –that will progressively replace the current Clinical Research Ethics Committees– in order to avoid duplicities in the process of evaluation of the trial.

Likewise, the long expected "single ruling" shall be finally implemented. The principle of mutual recognition, deeply ingrained in European pharmaceutical law, has finally arrived to the rulings with regard to clinical trials. In this way, the ruling issued by the Evaluation Committees for Research with medicinal products chosen by the sponsor shall have to be accepted by the rest of the committees involved in the trial. Other measures along the same line are the introduction of the figure of the "low risk clinical trial", for which there will be less burdensome requirements, the introduction of a single point of contact between the sponsor and the authorities, or the generalization of the use of electronic media in the communications between the two.

More transparency

More and better information on clinical trials carried out in our country will be put at the disposal of the public, through the creation of a state registry of clinical trials. Such registry, which will be managed by the AEMPS, shall allow for more transparency and will provide interested patients with the possibility to participate in the trials that will be started.

A single contract model

The plan to implement a single contract model to be used in all public hospitals that depend on the National Health System should also be emphasized.

It is moreover foreseen that the signing of such contract between the centre and the sponsor should take place in a period of 60 days. However, and since there are no implications involved in case that such term is exceeded, we will have to wait for the approval of the draft to see how effective this mandate is.