The new rules for pharmacovigilance of medicinal products for human use are already applicable

Royal Decree 577/2013 regulating pharmacovigilance of medicinal products for human use (Official Journal No 179, of 27 July 2013)

Royal Decree 577/2013, which regulates the pharmacovigilance of medicinal products for human use, was published last July in the Official Journal.

The objective of this regulation, which replaces Royal Decree 1344/2007, is to adapt the Spanish System of Pharmacovigilance to the new rules introduced by the European Union. With this new Royal Decree our country finally ends the implementation of the new European Union guidelines on this subject, that was initiated with the previous reform of Law 29/2006 on Guarantees and rational use of medicinal products and medical devices.

Among other matters, the new regulation deals with the update of the instruments for cooperation between national and European authorities, makes the system more transparent, and submits the agents who participate in it to stricter obligations with the objective to reinforce the safety when using these products. Due to their interest, we will briefly summarize below the most important novelties.

More transparency and more citizen participation

The new Royal Decree widens the definition of "adverse reaction" to any response to a medicinal product which is harmful and was not searched for including therefore the responses produced as a result of a use made outside the authorized conditions, abuses, or medication errors.

With the aim to increase the transparency and the confidence of citizens and professionals in the system, the Spanish Agency for Medicinal Products and Medical Devices will begin to advertise the measures that need to be adopted in this field. Moreover, the information shall be accompanied with the reasons that made it necessary for the agency to intervene.

On the other hand, citizens will be able to notify directly the authorities about suspected adverse reactions to medicinal products that they believe they have suffered. The website of the Spanish Agency for Medicinal Products and Medical Devices has been enabled to make such notifications in order to facilitate the citizen cooperation. Such website must be indicated in the directions for use of all medicinal products.

Special monitoring measures

The European Agency of Medicines shall make a list of medicines that must be object of special monitoring. This list will include medicinal products with new active ingredients, biologic and biosimilar medicinal products, as well as those where a potential safety problem is identified and that must be subject to special restrictions regarding their use or subject to the obligation of obtaining additional information regarding their use in current practice. The medicinal products included in this list, that will be available to the public, shall have to incorporate a sign (a black inverted triangle in their SmPC and directions for use, with the aim

that they might be easily identified by healthcare professionals and by citizens, giving priority therefore to the notification of suspicions of adverse reactions related to them.

New obligations for the industry

Apart from having to comply with the guidelines on pharmacovigilance best practices, approved by the European Medicines Agency in cooperation with Member States, a series of obligations meant to identify the potential safety problems that their products may have are imposed to the industry.

In this respect, in order to obtain the marketing authorization of new medicinal products, it will be necessary to submit an adequate risk management plan. Pharmaceutical companies must periodically evaluate the impact and results obtained through these measures. They may also be required to carry out post-authorization studies with their medicinal products with the aim to generate new information about their safety and efficacy in regular clinical practice.

However, not everything is new obligations. Current procedures are also simplified and telematic submission of periodic safety reports to be filed by marketing authorization holders is as contemplated in the law.

Post-authorization studies

The favorable ruling of a Research Ethics Committee will still be necessary for the performance of these studies, but such ruling will be unique and will have to be recognized by all the Autonomous Communities.

A mutual recognition system of the authorizations issued by the Autonomous Communities will also be enabled. In this same line of simplification, a unique point for the telematic processing of the applications will be established and common criteria will be set.

With regard to the obligations of sponsors, they must inform about the effective date of commencement of the study, issue annual monitoring reports when it is thus established, and submit the final report within the period of twelve months since the termination of the study. Moreover, they will only be allowed to remunerate the healthcare professionals who take part in the study with a compensation for the time invested and the expenses incurred.

Cooperation between authorities

Finally, and with the aim of avoiding lack of coordination such as those that occurred in the famous case Mediator® , a European committee for Pharmacovigilance Risks Assessment is created, an urgent procedure for risks assessment is set at European level, and the subsequent process of decision-making by the Member States is harmonized, warranting that the measures adopted are implemented in a homogeneous and simultaneous way throughout the European Union.

Moreover, the European Commission shall be in charge of auditing every two years the functioning of the pharmacovigilance system of the Member States, with the aim of verifying that they meet the quality standards established by the European Commission. In our case such audit will not only include the actions carried out by the Spanish Agency for Medicinal Products and Medical Devices, but also those performed by the different Autonomous Communities.