The European Union approves new measures in order to refine the working of the pharmacovigilance system

Directive 2012/26/EU and Regulation (EU) number 1027/2012, both of 25 of October, which modify Directive 2001/83/EC and Regulation (EC) number 726/2004

Background

It is well known that in the year 2010 the European Union authorities approved an important package of measures in order to improve the efficiency and coordination of the European pharmacovigilance system.

The aim was to rationalize the procedures for the detection and evaluation of adverse effects, to avoid duplication and unnecessary procedures, to improve communication through new technologies, and to open the system to the citizen by permitting him to directly report adverse effects.

These measures should have been implemented in our internal legislation not later than July 2012. The process, however, suffers a considerable delay in our country due to the need to change a great number of internal regulations, including the law on guarantees and rational use, and the statutory regulations that develop such law as regards authorization and registration, and pharmacovigilance.

However, and without wishing to set a precedent, this delay can for once offer an advantage, as this situation will give us time to implement the new European provisions on pharmacovigilance that were approved last month in the new projects still under procedure.

Why these new changes?

Logically, the first question that comes to our minds when faced with this new package is why a second reform of the system has been considered necessary so soon? And why were these measures not thought of when the first changes were introduced in 2010?

The reason is that the European legislator seeks to provide answers to a number of unfortunate events-especially the so-called case *Mediator*– which have recently revealed some dysfunctions that still subsist in the current European pharmacovigilance system.

Mediator, whose main active ingredient is benfluorex, is a medicinal product which was marketed in the European Union during more than thirty years. In the year 1999 the first questions were raised regarding its safety. However, the medicinal product continued to be available in some member States –as is the case of France– well into the year 2009.

Some sources deem that this medicinal product may have caused, only in this last country, several hundreds of deaths and a significantly higher number of hospitalizations due to heart-valve damage. And, in spite of being a product for the treatment of diabetes, its prescription as an appetite suppressant had become increasingly common.

This fact explains the concern of the European Union authorities in the face of the poor coordination shown by the authorities of the member States in this case as well as in other cases, and why it has been considered necessary to refine the working of the system.

More coordination in the decisions

With this aim in mind, the new package introduces a mechanism which automatically triggers a joint and urgent evaluation for certain safety problems which require a coordinated response at European Union level.

In this way, the urgent European Union procedure shall be automatically triggered when the need to suspend, revoke or to not renew the authorization of a medicinal product is foreseen, or when it is necessary to prohibit its supply.

On the other hand, the urgent procedure may also be requested by the Commission or the member States, as they may now, when it is deemed necessary to urgently restrict the indications of a medicinal product, to reduce the recommended doses or to introduce a new contraindication in the product's Summary of Product Characteristics.

Moreover, it is clarified that the Commission and the member States may suspend the marketing of the medicinal product, as a precautionary measure in any phase of the procedure, until the moment when a final decision is taken.

More information obligations for the pharmaceutical companies

Starting from October 2013, date on which the member States must have implemented the provisions of the new Directive in their internal legal orders, if a pharmaceutical company decides to suspend the marketing of one of its products, to withdraw it from the market, to cancel its marketing authorization, or to not renew such authorization, it must inform the authorities about the specific reasons why it took this decision. So far this information was only required under European Union law in those cases in which the supply was temporarily interrupted or when certain batches were recalled from the market.

In particular, the pharmaceutical company must clarify whether it took this decision for safety reasons, and not for commercial reasons, so that the authorities are provided with early and accurate information which will allow them to act in a swift and coordinated way.

This notification, on the other hand, shall also have to be made when the decision is adopted in a third country which does not form part of the European Union.

More obligations for the wholesalers

The wholesale distribution is also affected. From October 2013, in their operations of export and import the wholesalers shall have to make sure that they deal with organizations which have been duly authorized in their respective countries to intervene in the chain of distribution of medicinal products.

Languages of the labeling

Finally, the new Directive also clarifies that the labeling of medicinal products may be drafted in one or several of the official languages of the member States. It will be the member State who will have to establish in its internal regulations which official language or languages of the country shall be used in such labeling.