The new regulatory framework for the distribution of medicinal product was finally approved

Royal Decree 782/2013, of 11 October, on distribution of medicinal product for human use (Official Journal No 251/2013)

This new provision, which replaces Royal Decree 2259/1994, seeks to adapt the activity to the new times, regulating the concepts that have emerged in the market, and reinforcing the obligations of the operators regarding pharmacovigilance and fight against the counterfeit of medicinal products.

Requirements for the practice of this activity

The new regulatory framework will apply not only to the traditional wholesaler warehouse, but also to bonded warehouses, to warehouses set forth in the contract, and to brokers or intermediaries who do not get to have physical contact with the medicine. Except for the brokers -who will only have to notify the AEMPS– they must all have a previous authorization and a certificate of compliance with the good distribution practices. Moreover, the warehouses set forth in the contract must be included in the authorization of the pharmaceutical company or distributor using its services. On the other hand, such authorizations can be revoked if activity does not take place over a period of one year.

New obligations

These operators, as well as the pharmaceutical companies that directly distribute their medicinal products, shall be subject to the same obligations as the wholesalers, although there are certain exceptions. They will have to comply with the Good Distribution Practices of the European Union, make sure that the deals are made only with entities that are authorized to intervene in the distribution chain, and dispose of a minimum stock in order to guarantee an adequate supply. The obligations regarding the manufacture, importation and distribution of active ingredients and excipients are also strengthened.

The new provision has not established the "right to supply" that the distribution sector demanded, although pharmaceutical companies and distributors are imposed the obligation to cover national needs as a matter of priority. The AEMPS will be able to restrict exportations in cases of shortage of supply that creates therapeutic deficiency or that affects non replaceable medicinal products. On the other hand, the distributors of medicinal products for human use are recognized the right to distribute also veterinary medicinal products and other characteristic products from the channel.

Direct sale of medicinal products

Finally, pharmacy offices are authorized to sell to doctors the medicinal products that they require for their professional activity. This practice was common and tolerated by the authorities but, however, it had no legal standing until now. This direct sale to the doctors will also be carried out in the future by pharmaceutical companies, although it will be restricted to certain medicinal products that the AEMPS shall identify.