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Green light to the amendment of the Law on Guarantees and rational use of medicinal products and medical devices

Agreement of the Council of Ministers on the draft law introduced by the Minister of Health, Social Services and Equality

In its meeting of Friday 19 of October the Council of Ministers agreed to give green light to the draft law through which a series of amendments will be made to the current Law 29/2006 on guarantees and rational use of medicinal products and medical devices.

Without meaning to be exhaustive, and without prejudice to the changes that might be introduced in the draft during its parliamentary proceedings, we will refer here to some of the main amendments that are proposed.

Pharmacovigilance

The law will be adapted to the new European regulations on pharmacovigilance. With the aim to improve the efficiency of the system, the obligations of the industry regarding information and collaboration with the authorities will be reinforced, and public participation will be promoted by allowing patients to notify directly the adverse effects.

Likewise, a list of medicinal products that will have to be subject to a special monitoring by the authorities and by healthcare professionals is expected to be prepared.

Fight against counterfeiting

The preventive measures against the introduction of counterfeit medicinal products in the supply chain will be reinforced. Therefore, there will be an increased control of all agents participating in the supply chain, including an increase of inspections to third country manufacturers of active ingredients, the approval of new good distribution practices, and an increased control on warehouses located at customs and free zones which will be obliged to have an authorization as a wholesale warehouse.

Medical devices and cosmetics

A series of provisions that until now were applicable to medicinal products only are extended to medical devices and cosmetics. For instance, the healthcare administrations are given the authority to limit or prohibit door-to-door selling and any type of indirect selling of prescription medical devices to the public, on account of justified reasons.

Likewise, the regime of infringements and sanctions foreseen until now only for medicinal products is extended to medical devices and cosmetics, although the imposition of a sanction in a maximum degree with regard to these products will be allowed only when the offender has caused a severe and direct risk or damage to public health.

Infringements and sanctions

Some new infringements such as the manufacture, marketing, mediation and distribution of counterfeit medicinal products are introduced, and some of the existing infringements are redefined in the benefit of greater legal certainty.