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The "new" law on guarantees and rational use of medicinal products and medical devices

The Government approves the consolidated text of the law on Medicinal Products and Medical Devices

Background

In accordance with article 82 of the Spanish Constitution and by virtue of the delegation that was granted under Law 10/2013, the Government has approved the consolidated text of Law 29/2006 on Guarantees and Rational Use of Medicinal Products and Medical Devices.

This "new" law aims to consolidate in one text the various provisions of Law 29/2006, which have been subject to various amendments; and at the same time, it clarifies and harmonizes some of the provisions in the Law.

In our CAPSULAS No. 159 of March 2015, we provided some ideas on the draft consolidated text that the Ministry of Health was discussing at the time. In this newsletter, we shall discuss the most relevant aspects of the text that has finally been approved.

Definition of active substance and reference price system

In the project that the Government presented in March, it was suggested that for the purposes of the Law, in particular in relation with the reference price system, the definition of active principle would be linked to the level 5 ATC of the anatomical-therapeutical-chemical classification. This proposal, that we criticized at that time, has not been finally included in the text.

We cannot exclude that this idea comes up again in the new Royal Decree on prices of medicines, but this would be a mistake. In connection with this matter, we think that it is important to recall the view of the WHO, which states the following on its website: "basing detailed reimbursement, therapeutic group reference pricing and other specific pricing decisions on the ATC and DDD assignments is a misuse of the system".

In the same way that the WHO strongly opposes to the fact that companies use the ATC system for promotional or commercial purposes, it is also clearly against administrative decisions regarding the reference price system being based on the ATC system.

Generic medicinal products (EFG) and non -replaceable medicinal products

The draft from March contemplated adding, to article 14 of the Law, that the identification of certain medicinal products with the acronym EFG would be without prejudice of the abilities of the Ministry to exclude them as replaceable products. It is fortunate that this wording was not included in the final text. The law continues stating that medicinal products can be identified as EFG (i. e. as generics) on the basis of the determination made by the Spanish Medicines Agency regarding its interchangeability.

Free prices

The draft presented in March contemplated adding to the Law that, for the purposes provided in the Law, medicinal products that are not publicly funded would be covered by the free prices regime. At the time, we criticized this be-

cause in our legislation a "regime of free prices" does not really exist. Free prices are the general rule and this may only be restricted through a law. This is clearly indicated in Law 7/1996. Therefore, we think that it makes sense to state that the prices of the products reimbursed are subject to a special price regime rather than saying that products which are not reimbursed are subject to a free price regime.

Price modifications

In our last CAPSULAS we mentioned it would be good to clarify in article 97 that the modification of prices of medicinal products must be made in a reasoned way and according to objective criteria. The reference to motivation and transparency, as required by Directive 89/101, is already included in section 5 of article 94 on the initial price fixing, and we thought this was a good time to clarify that this also applies to the modification of prices. Although this has not been included in the Law, Directive 89/101 still obliges Member States to use objective criteria in all price review processes.

Substitution of medicinal products

Once again, a good occasion has been lost to clarify that the prohibition of substitution of medicines which are classified as non-replaceable, without having the prior approval of the prescribing doctor, applies to both pharmacy offices and hospital pharmacies.

In our opinion, guaranteeing that substitution shall not take place in these cases, both in pharmacy offices and in hospitals, is an issue related to the protection of the public health, and it should be carefully considered.

Homogenous groups and biosimilars

The opportunity has also been lost to correct the provision that says that when prescription is written using the name of active ingredient the pharmacist must dispense the product with the lowest price within its homogenous group and if all prices are equal, the generic or biosimilar product. Biosimilar drugs cannot be substituted when dispensed and therefore they should not be included in any homogenous group. A recent Judgment of the Supreme Court of 19 June 2015 ratifies this idea.

Which discounts are forbidden?

The Law continues to classify as a very serious infringement to offer bonuses, gifts, awards, contests, discounts or similar initiatives as ways to promote or sell to the public the products regulated in the Law. The consolidated text has not clarified that this should only apply in respect of discounts or other commercial practices that are prohibited by the Law itself.

This clarification would be convenient because the scope of application of the Law is very wide and includes cosmetic products and also non-reimbursed products. Given that all of these products are covered by the Law, it would make sense to clarify that the infringements will apply only to situations where the Law prohibits any such practices.