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

The Ministry presents a Draft Royal Legislative Decree which should be approved by the Government before the 25 of July

Background

In accordance with Article 82 of the Spanish Constitution, a Royal Legislative Decree is a rule that the Government can approve in order to consolidate into a single text certain rules, which have already been approved. Furthermore, the Government can take this opportunity to regulate, clarify and harmonise the rules that are to be consolidated; provided that this power has been previously delegated by the Spanish General Courts.

By virtue of the delegation that was granted under Law 10/2013, the Ministry of Health is currently working on the revised text of Law 29/2006 on Guarantees and Rational Use of Medicinal Products and Medical Devices.

In this special edition of CAPSULAS, we provide some ideas on the consolidated draft text that the Ministry of Health has published.

Definitions

The draft provides for the definitions of article 8 of Law 29/2006 to be transferred to article 2 of the Consolidated Text. Once they have been transferred, we suggest they be sorted in alphabetical order, this way it will be easier to find them. This is typically done with contracts and readers appreciate it.

Definition of the active substance and the reference price system

Currently, the Law contains a definition of "active substance". According to article 8 active substance means, "any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis.

Article 99 of the draft Royal Decree points out that the reference price system must include all financed presentations of medicinal products with the same active substance. The Ministry now intends to include in article 99 that "for the purposes provided in this Law, active substance means level ATC 5 of the anatomical therapeutic chemical classification".

If this amendment is approved, the Law will contain two definitions for the active substance one provided in article 8 and another one in article 99, which is not coherent.

Furthermore, if this modification is included in article 99, the Ministry would directly contravene the view expressed by the World Health Organization (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 basing the decisions regarding the reference price system on the ATC system.

Generic medicinal products (EFG) and non replaceable medicinal products

The draft Royal Decree also suggests to add to Article 14 of the Law that identifying certain medicinal products with the acronym EFG is without prejudice of the abilities of the Ministry to exclude them as replaceable medicinal products.

We believe it would be more accurate to say that the medicinal products considered as non-replaceable under article 90 of the Law cannot be identified with the acronym EFG. We believe that it is necessary to clarify that in order for a non-replaceable medicinal product not to be identified as EGF there is no need for an additional decision of the Ministry; and if the medicinal products bear the acronym EFG due to their interchangeability, it is reasonable to clarify that non-replaceable medicinal products cannot use this acronym.

Brands and non-replaceable medicinal products

In our opinion, this might be a good opportunity to clarify Article 83, which says that medicinal products considered as non-replaceable can be prescribed by brand, to point out that in these cases prescription by brand is compulsory.

In particular, this would be the case of biological medicinal products in accordance with Royal Decree 81/2014, which amended Royal Decree 1718/2010 when implementing Directive 2011/24/EU.

In this context, it is important to remember that Royal Decree 577/2013 requires that adverse reactions of biological medicinal products are reported by identifying the brand and the batch number of the product administered.

Substitution of medicinal products

In recent years some organizations have also pointed out that the decision of the Ministry concerning which medicinal products are not replaceable, based on the current article 86 of the Law, applies only to retail pharmacies (as it is included in Chapter IV of Title VII, "On the rational use of medicinal products in retail pharmacies" and do not apply to hospital pharmacies.

This confusion justifies the need to clarify and harmonize this matter, therefore it would be useful to add a paragraph to article 4 (Guarantees for the Protection of Public Health) pointing out that it is forbidden to substitute non-replaceable medicines without having an authorization of the prescribing doctor.

Article 5 is the appropriate framework, because the substitution of non-replaceable medicinal products deserves to be considered as one of the guarantees for the protection of public health provided for in this article.

Homogenous groups and biosimilars

As is generally known, the Law points out that presentations of financed medicinal products that might be interchanged when dispensed will be included in each homogenous group; and the prescription of non-replaceable medicinal products should be done by brand and not by active substance.

However, Article 88 of the Law continues saying that when the prescription is made by active substance, the pharmacist will dispense the medicinal product having the lowest price of its homogenous group and, in the event of having the same price, the corresponding generic or the biosimilar medicinal product.

It would be reasonable that, when Law 29/2006 is regularized, clarified and harmonized, the reference to the "corresponding biosimilar medicinal product" is removed from this article. Alternatively, deletion of section 4 from article 88 can be considered since article 88 regulates the prescription (not the dispensing), and that this issue is covered in section 5 of article 90.

Free prices

The draft submitted intends to add, in article 95.4 of the Law, that for the purposes provided in the law, medicinal products that are not publicly funded shall be deemed as covered by the free pricing regime.

In our opinion, it would be advisable not to add this text because there is no "free pricing regime" in our legal system. Freedom to set prices is the general rule, and it can be limited only by law. This is clearly indicated in Article 13 of Law 7/1996 which establishes that: "selling prices of items will be freely determined and offered on a general basis in accordance with the defense of free and fair competition legislation, with the exceptions established in special laws".

Therefore it, makes sense to say that prices of financed medicinal products are subject to a special regime of set prices, instead of saying that non financed medicinal products are covered by free pricing regime.

Notified Prices

The draft intends to add a provision saying that for the purposes provided in the Law, the Interministerial Price Commission for Medicines will be able to admit notified prices from hospitals but not from retail pharmacies.

We believe that it would be incorrect to add this provision. The Interministerial Price Commission for Medicines does not have the power to admit notified prices. According to Royal Decree 200/2012 this Commission can only establish the maximum industrial price of medicinal products publicly financed. It has no sense to confer to this Commission the authority "to admit" notified prices. The revised text of the Law can neither create new procedures nor give competences that did not exist.

Price modification

When harmonizing the text of the Law it would be good to clarify in article 97 that modifications of the prices of medicinal products must be made in a reasoned way and according to objective criteria. The reference to the motivation and compliance with objective criteria required by Directive 89/105/EEC, is already included in section 5 of article 95 on the initial price-setting and it is convenient to clarify that this also applies to prices' changes.

Which discounts are forbidden

Currently, the Law classifies as a very serious infringement to offer bonuses, free gifts, awards, contests, discounts or similar initiatives as ways to promote or sell to the general public the products regulated by this law.

This clarification is fully justified because the scope of the law enforcement is very wide, including medicinal products and medical devices with set prices, other non financed products, and even cosmetics. Being all these products regulated by law, it makes sense to clarify that the infringement is limited to the cases where forbidden discounts or other benefits are offered and it does not apply, for instance, to discounts offered by pharmacies on non-financed medicinal products or medical devices, or those offered on cosmetics.

Professional incompatibilities

In the new article 3 on the guarantees of supply, the term "wholesale warehouses" has been replaced by "distributing entities", which is correct because it harmonizes the terminology used in the Law with the one in Royal Decree 782/2013 on the distribution of medicines.

However, when rewriting the article on incompatibilities, it is stated that the professional practice of the pharmacy is incompatible with holding direct interests in "institutions that intervene in the distribution and/or commercial circulation".

The problem that was triggered by the diversion of medicines in recent times, compels us to be very rigorous in relation with this matter, but the rigor is not incompatible with the legal certainty. The Ministry should not create any new cases of incompatibility when consolidating the rules. Therefore, the reference to "institutions that intervene in the distribution and/or commercial circulation" is unfortunate and should be avoided.

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