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The novelties introduced in Law 29/2006 on Guarantees and Rational Use of Medicinal Products and Medical Devices come into force

Law 10/2013 which incorporates Directives 2010/84/EU and 2011/62/EU, and modifies Law 29/2006 (Official Journal No 177, 25 July 2013)

Introduction

After its parliamentary procedure was finished, on 25 July Law 10/2013, which amends Law 29/2006 on Guarantees and rational use of medicinal products and medical devices, was published in the Official Journal. The provisions of Law 10/2013 came into force immediately, the next day after its publication.

The initial objective of the project, as is widely known, was to incorporate into our national law the European directives on pharmacovigilance and on the fight against the trade of counterfeit medicinal products. This process, by the way, was completed with the publication, only two days later, of the new Royal Decree 577/2013 on pharmacovigilance. The interest raised by the novelties in this field, however, has ended up being secondary in front of other amendments that were also introduced in Law 29/2006, and that captured much more public attention due to their immediate importance for the pharmaceutical sector.

In practical terms, these other changes in Law 29/2006 are extremely important, both for the sector as well as for the patients. The increase in the number of measures taken by certain Autonomous Regions in recent times, in their efforts to reduce expenditure at all cost, were beginning to put at serious risk the unity of the Spanish pharmaceutical market and the equity in the access to treatments.

Due to this situation the central government has forced the law to state very clearly the limits that must be respected by the regions in the exercise of their powers as regards the rational use of medicinal products and medical devices.

Although these ideas were already very present in the basic legislation and in the constitutional case-law, the law now reserves exclusively to the State the authority to adopt any type of measure that might affect the price of reimbursed medicinal products and medical devices, or the right of the patients to have full access to these benefits of the system. All of this without prejudice, of course, to the participation of the regions in the different committees of the Ministry of Health, Social Services and Equality or to measures taken by the Interterritorial Council of the National Health System.

It is no exaggeration to say that these changes imply a true turning point in the way in which pharmaceutical coverage has been managed in recent times, providing a basis, this time it appears to be certain, for the long promised stable and predictable legal framework for the sector.

In addition to this, Law 10/2013 introduces very important novelties in other matters. We will briefly refer to all of this in this newsletter.

Financing and pricing

The new Article 88 of Law 29/2006 emphasizes the exclusive competence of the State as regards financing and pricing of medicines. Measures taken by the regions must not generate inequalities for the users of the system, who shall have access to all reimbursed medicinal products and medical devices. The resolutions on pricing and reimbursement and regulations of the State will have to be executed in all regions once they enter into force. Therefore the doors should be closed to measures such as the Andalusian tenders or the Galician catalogue, which in practice implied restricting the products to which patients of such regions had access.

Moreover, the regions will not be able to adopt measures that have the effect of modifying the ex-factory price set by the State for medicinal products and medical devices, without prejudice to measures adopted at state level that require the application of discounts in all the national territory.

The Government, in view of the doubts raised by the scope of such a broad prohibition, has cleared out that it will not affect discounts for prompt payment or volume of purchase to pharmacies, as well as discounts to hospitals that were already permitted by law. In this same line, the opportunity was taken to clarify the fact that the deductions foreseen in the recent Royal Decrees-Law will not be applicable within centralized purchasing procedures, as long as the amount of the corresponding deduction is at least evened by the discount offered in the tender.

Finally, but not less important, Additional Provision three of Law 10/2013 includes a new mandate, restricting acts intended to establish the medical positioning of any product as well as its comparison with other options. This, under the new law, may only be made by the Spanish Agency for Medicinal Products and Medical Devices (AEMPS). This provision should impede the regions to declare alleged therapeutic equivalencies and should also be putting an end to pseudo-evaluations that, in a more or less explicit way, have been made by some of them.

Homogeneous groups and substitution

Substitution rules are also clarified. Substitution will be possible only if the price of the prescribed medicinal product is superior to the one of the product having the “minor price” in the homogeneous group. Other prices that may be offered to pharmacies shall not be considered.

On the other hand, although the discrimination in favor of the generics is still maintained in the event that the price is the same, the new law will permit original medicinal products to include the acronym EFG (Generic Pharmaceutical Equivalent) subject to approval by the AEMPS it. This opens a path to terminate this discrimination. The language of the law, however, is somewhat unclear, because “Generic” and “Generic Pharmaceutical Equivalent” do not mean the same; and because the law still says that if the prices are equal, the pharmacist must dispatch a "Generic".

The clarification introduced in Article 86 of the law is likewise important, or maybe even more. It reminds that in the case of biological medicinal products the special rules regarding interchangeability must be respected. Such rules prohibit the substitution of this type of medicinal products even if there are biosimilar products.

Finally, and with the aim to avoid extraordinary price reductions, if a company offers a given price which becomes the lowest in the group but can then not meet the demand of the

market, such company shall be liable of a very serious infringement under the law and may face heavy sanctions.

Pharmacovigilance and fight against fraud

Provision is made for the creation of a registry of manufacturers, importers and distributors of active ingredients, as well as another registry in which intermediaries who participate in the marketing of medicinal products must be inscribed, even if they do not handle physically any product.

Nevertheless, the marketing authorisation holder will still be responsible for making sure that active ingredients and excipients used in his products have been manufactured, stored and transported according to the current demands of quality and good practices of distribution.

The obligations of traceability of medicinal products are also extended to pharmacies, and pharmacies are prohibited to remarket the units that are returned to them, since there are no guarantees that they have been adequately stored.

With regard to pharmacovigilance, contrary to what might be expected, the novelties in the law are very few.

Most of the measures that are necessary to implement the new European directive have been introduced through the new recently published Royal Decree on pharmacovigilance. The law simply introduces the idea that failure to comply with the conditions that have been imposed on the marketing authorisation holder in the field of pharmacovigilance could be a sufficient reason to put on hold -or even to revoke– the marketing authorization of the product.

Distribution

With regard to the distribution, it is important to note that the new law will not permit pharmacists to own new cooperatives or wholesale distribution companies. However, pharmacists may continue to form part of already existing cooperatives, as long as the cooperative has more than 20 members -or the companies have more than 100 shareholders– and as long as their shares are held only by these healthcare professionals.

Moreover, it is also clarified that wholesale distributors can act in a legitimate way for pharmaceutical companies as a contracted wholesaler. This is something perfectly logical, on the other hand, because the rules governing these activities are meant to address issues that can have an impact on health, and not to prevent legitimate commercial practices.

Advertising of medicinal products and medical devices

There are also novelties in the field of advertising and promotion.

A very important measure has been the suppression of the need for prior administrative approval for advertising of over-the-counter medicinal products. These products may now be promoted without the need for a prior authorization, without prejudice, it is clear, to the fact that any advertising is subject to review by the authorities and to sanctions if it does not comply with the rules. This is a recognition, well deserved in our opinion, of the rigor with which FARMAINDUSTRIA and ANEFP (Personal Healthcare Association), with the help of the Advertising Jury of AUTOCONTROL, have been supervising compliance by the industry.

As regards medical devices, however, a great deal of discussion was generated as a consequence of the reform. In line with the changes introduced for medicinal products, Law 10/2013 has also suppressed the provision of the General Health Law that permitted to make advertising of medical devices to the public subject to a prior administrative authorization.

The AEMPS has rushed to point out that this suppression was due to an involuntary error that will be soon corrected. This is surprising, since it makes no sense that advertising of medical devices be subject to a stricter regime than the one for medicinal products.

We will finally highlight two issues.

On the one hand, it is clarified that the rules on advertising of medical devices shall have to be also respected by clinics that use these products when promoting the services or techniques that they offer. The purpose of this measure is to avoid that the advertising of the services of the clinic is used to indirectly promote medical devices that cannot be object of advertising addressed to the general public.

In the second place, the legal conditions under which these products may be sold outside pharmacy offices is also clarified. Door-to-door selling, which is prohibited in the case of the medicinal products, can also be limited or prohibited in the case of medical devices if it is advisable on account of healthcare or safety reasons. With regard to telematic or mail sale, it will remain being prohibited in the case of prescription only medicinal products and of prescription only medical devices.

Other measures as regards administrative steps and procedures

Finally, we cannot fail to mention other changes of the law which despite affecting only procedures are still equally interesting. In this line, and with the aim to conclude with the plethora of rules that existed at the time, the regime of infringements and sanctions applicable to medicinal products, medical devices, cosmetics, and products of personal care is revised in Law 29/2006. Moreover, new infringements are included, such as the already commented shortage of medicinal products that are offered as having the lowest price of any homogeneous group.

With regard to fees, their amounts are updated, the period granted to the pharmaceutical company for the submission of an application once the corresponding fee was paid is reduced to 10 days, and the refund regime is clarified.

Certain administrative procedures that were an unnecessary burden are also simplified and replaced them with a simple affidavit. This is the case, for instance, importation or manufacturing of cosmetics and personal care products in Spain. A self-compliance declaration shall suffice instead of an authorisation. This is good news for the sector, although this step forward in the path of bureaucratic simplification has been clouded by the extension of the list of procedures in which petitions will not benefit from the regime of positive administrative silence. Among such procedures we should highlight the requests demanding that a medicinal product may be declared galenic innovation, any major variations in the administrative authorization of pharmaceutical companies, the authorization of medicinal products through the decentralized procedure, or the authorization and renewal of authorizations for parallel importation of medicinal products.