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ROYAL DECREE REGULATING THE SALE AT A DISTANCE TO THE PUBLIC, THROUGH WEBSITES, OF MEDICINAL PRODUCTS

INTRODUCTION

Directive 2011/62/EU, of 8 June 2011 (the "**Directive**"), amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products, regulates at EU level, among other matters, the basic requirements to be incorporated by Member States into their national laws for establishing an adequate system for controlling and monitoring procedures for the sale of non-prescription medicinal products to the public through websites.

In turn, although article 2.5 of Law 29/2006, of July 26, 2006, on the Safeguards for and the Rational Use of Medicinal Products and Medical Devices (the "**LGURMPS**") established that the sale of medicinal products by telematic procedures was limited to non-prescription medicinal products, Law 29/2006 left the rules on this type of sale to be fleshed out by implementing regulations.

Royal Decree 870/2013, of November 8, 2013, regulating the sale at a distance to the public, through websites, of non-prescription medicinal products for human use (the "**RD**") was published in the Official State Gazette on November 9, 2013.

The RD entered into force the day after its publication in the Official State Gazette (i.e., on November 10, 2013) and establishes the requirements to be met by websites selling medicinal products legally in Spain, in order to ensure they are sold with the due safeguards and incorporate the provisions established at European Union level in the Directive.

In the following sections, we take a look at the most important changes ushered in with the publication of the RD.

1. Subject matter and scope of application

In line with article 2.5 LGURMPS, article 1 RD establishes that its provisions will apply to non-prescription medicinal products for human use. The following fall outside the scope of the RD: (i) prescription medicinal products, (ii) medicinal preparations, and (iii) medicinal products for veterinary use. It should be noted that the express exclusion of medical devices contained in the draft RD has been removed.

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The RD also bans the sale of medicinal products by means of information society services other than those provided for in the RD.

2. Requirements to start up the activity of online sale

The RD respects the general principle that medicinal products must be dispensed or sold by legally authorized pharmacies open to the public and with the involvement of a pharmacist. The lawmakers therefore continue with the idea of preserving 'pharmaceutical care', as such concept has come to be accepted in Spain: "*Pharmaceutical care is the active participation of the pharmacist in assisting the patient in the dispensation and monitoring of a pharmacotherapeutic treatment, thereby cooperating with the doctor and other healthcare professionals in order to achieve outcomes that improve the patient's quality of life*" (the definition given by the General Council of Official Pharmacists Associations and contained in the Consensus on Pharmaceutical Care published by the Ministry of Health and Consumer Affairs in 2002 and promoted by the Directorate General of Pharmacy and Medical Devices).

Accordingly, only legally authorized pharmacies can sell non-prescription medicinal products at a distance through a website. To be able to start up a distance-selling business, pharmacies must give at least 15 days' notice to the competent health authorities in the autonomous community of the following information: (i) details of the pharmacist owning the pharmacy, (ii) the proposed start date for the activity of online sale, (iii) the website address, and (iv) information on the procedure to be followed for shipping the medicinal products sold. At least 15 days' notice must also be given if there is any change in this information.

Websites must meet the requirements established in article 8 RD and contain at least the following information, which must be readily and directly accessible at no charge:

a) Links to the websites of the competent health authority charged with its supervision, and of the Spanish Medicines and Medical Devices Agency (AEMPS) and the AEMPS Online Medicinal Product Information Center (CIMA).

b) The identifying, administrative and contact details of the owner and of the pharmacy itself.

c) A common logo, which will be in keeping with the provisions to be determined by the specific EU legislation.

d) The prices of the medicinal products and the estimated time for their delivery.

3. Communication and control by the AEMPS and the competent authorities

The Directive establishes the need for the Member States to put in place communication and control systems to facilitate the identification of websites that comply with the implementing legislation of each country and imposes an obligation on each Member State to set up a website containing relevant information including a list of the persons/pharmacies legally offering medicinal products through websites.

In this connection, the RD provides that the AEMPS will set up a website containing the information required by the Directive for such purposes: (i) a link to a current list of pharmacies selling medicinal products to the public through websites, prepared by the competent authorities of each autonomous community, (ii) information on the applicable national legislation, including information on any differences between that legislation and the laws of other Member States, (iii) information on the risks related to medicinal products dispensed illegally to the public by means of information society services, (iv) a link to the website set up by the European Medicines Agency in relation to the online sale of medicinal products, and (v) information on the purpose of the EU common logo.

The EU common logo is a control instrument envisaged in the Directive and provided for in the RD. The common logo is pending implementation and approval by the European Commission and seeks to identify securely and reliably the websites that comply with the legislation in force in each Member State in relation to the sale at a distance, through websites, to the public of medicinal products. The common logo will also make it easier to identify websites that are not compliant with the applicable legislation and, therefore, may be endangering the health of patients or selling illegal medicinal products in poor condition.

Also, for the purposes of exercising greater control, the AEMPS may impose, by means of a reasoned decision, quantitative or qualitative restrictions on the sale at a distance of medicinal products that call for such restrictions, due to their special characteristics, and their potential for misuse. The AEMPS must post on its website lists of the medicinal products on which it has decided to impose such restrictions.

4. Specific dispensing requirements

The requirements imposed by the RD in order to be able to actually dispense medicinal products at a distance most notably include the following:

- The website must have in place a specific questionnaire where patients must fill in their personal details and address, in order to enable pharmacists to perform their tasks of pharmacovigilance. The information, coupled with data on the medicinal product sold, the quantity and the shipping date, must be kept by pharmacists for a period of at least two years. Orders not containing these details will not be valid.

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- The medicinal products sold must be supplied in all cases from the pharmacy and with the involvement of the pharmacist.

- The medicinal products can be transported by pharmacists or by third parties. In the latter case, there must be a contract stipulating the duties of each party and the pharmacist must inform the carrier of the characteristics and particular conditions for the proper shipment and transportation of the medicinal product in questions.

- Only returns of medicinal products mistakenly dispensed or damaged en route can be accepted. In such case, the pharmacist must destroy the returned products.

- If the medicinal products are to be sold outside Spain to a buyer situated in another Member State, the sale must fulfill the requirements imposed by the RD and other applicable legislation in Spain, as well as the legislation applicable in the Member State of destination.

Lastly, it is to be expected that all the authorities involved (European Commission, the AEMPS, the competent authorities of the autonomous communities, etc.) will be implementing and putting in place as soon as possible the mechanisms provided for in the RD to thereby avoid any type of impediment to the application of the RD in practice and the actual start-up of sales at a distance, through websites, to the public of non-prescription medicinal products.

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