Biological medicinal products must be identified by their trademark in medical prescriptions

Royal Decree 81/2014, of 7 February, modifies Royal Decree 1718/2010, of 17 December, on medical prescription and dispensation orders

Background

Royal Decree 81/2014, of 7 of February, which establishes the rules to ensure cross-border healthcare assistance, and which modifies Royal Decree 1718/2010, of 17 of December, on medical prescription and dispensation orders came into force on 8 of February.

The amendment of Royal Decree 1718/2010 is the result of incorporating Directive 2011/24/EU to our internal legal system as well as implementing Directive 2012/52/EU of the Commission, of 20 of December of 2012, which establishes measures to facilitate the recognition of the medical prescriptions issued in other Members States. Due to its interest, we will comment the main novelties introduced in RD 1718/2010 on medical prescription and dispensation orders.

Use of trademark in medical prescriptions

New elements that must appear in the medical prescription are introduced. On the one hand, the name of the medicinal product must be included in the case of a biological medicinal product or if the prescriber considers it necessary from a medical point of view. In this case, the use of the commercial name or the trademark of the medicinal product shall have to be briefly justified in the prescription.

On the other hand, there must appear the direct contact details of the prescribing healthcare professional (email, telephone or fax, both with the international country code), the professional address, including the city, the name of Spain, and his professional qualification.

Dispensing of prescriptions issued in other Member States

A new article 15 bis is introduced, through which the prescriptions of medicinal products and medical devices approved by the AEMPS or by the EMEA issued in another EU Member State might be dispensed in Spain under the provisions of Law 29/2006.

For such purpose, the medical prescription must include: (i) the identification details of the patient, (ii) the date when the prescription was issued, (iii) the identification details of the prescribing healthcare professional, and (iv) the identification details of the medicinal product or medical device, that is, the common name, the trademark if it is a biological product or if the prescriber physician finds it necessary (in this case, the trademark, pharmaceutical form, quantity, doses and dosage will also have to be briefly justified in the prescription).

In case there are doubts regarding the validity of the prescription, the pharmacist can refuse to dispense the product prescribed in another Member State, unless the legitimacy of the prescription can be confirmed.