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# New Spanish rules on commercialization, supply and control of medicinal products for human use

***Royal Decree 717/2019 modifying Royal Decree 1345/2007 regulating the authorization procedure, and dispensation conditions for medicinal products for human use***

## Introduction

On 6 December 2019, Royal Decree 717/2019 was published on the Spanish Official Gazette. This Royal Decree modified another one, which regulates the authorization procedure and dispensation conditions for medicinal products for human use. Here are some of the main modifications:

## Ceasing commercialization

Pursuant to article 23a of Directive 2001/83/EC, the marketing authorization holder (MAH) must notify the authorities at least 2 months in advance (other than in exceptional circumstances) if its product ceases to be placed on the market, either temporarily or permanently. The new Royal Decree extends this period from 2 to 6 months. Therefore, MAHs intending to cease commercialization of their products in Spain must notify this circumstance to the Spanish Medicines Agency at least 6 months before ceasing such commercialization.

On the other hand, the Spanish Medicines Agency is now obliged to publish the MAH's intention to cease commercialization of its product. Until now, the Agency could make this publication or not but now it is mandatory to do so.

Despite these modifications, there has been no change in article 28.6 of Royal Decree 1345/2007. According to the provisions contained in this article, the Spanish Medicines Agency is entitled to keep a marketing authorization in force and to require the actual placing on the market of a medicinal product, if it considers that taking the product off the market could create a therapeutic gap arises. In our opinion, these Spanish legal provisions are contrary to EU legislation.

## Supply shortages

Up until now, MAH's obligations in connection with supply shortages were regulated through Instruction 3/2011 of the Spanish Medicines Agency, a document that is clearly inappropriate for regulating these obligations. The new Royal Decree now regulates this matter, establishing that MAHs must notify the Spanish Medicines Agency as soon as any 'abnormal restriction' in the supply of their medicinal products is detected. Furthermore, according to the new Royal Decree, in case the supply shortages have a 'healthcare impact', the MAH in collaboration with the Spanish Medicines Agency must put corrective measures in place. Finally, the MAH must keep the information on the commercialization status of its products updated in the Medicines Registry.

This regulation of supply shortages was previously announced on the 'Plan for Medicines Supply Guarantees 2019-2022' published by the Spanish Medicines Agency.

## SMC and blood derived medicines

The category of the so-called 'special medical control medicines', which were subject to restricted prescription, has been eliminated. As explained in the preamble of the new Royal Decree, the control measures that these products were subject to are now covered by the current pharmacovigilance legislation. As regards the medicinal products derived from blood, the manufacturing of each batch of finished dosage form must be previously authorized by the Spanish Medicines Agency, except when such batch has been certified by the authorities of another Member State. The new Royal Decree includes another exception for those cases when, based on a risk analysis, the Spanish Medicines Agency considers that its authorization is not needed.

## Identification and authentication system

This is the biggest modification introduced by the new Royal Decree, aiming to regulate those aspects which the EU legislation allows Member States to regulate internally. There is a new Chapter IX in Royal Decree entirely dedicated to this matter.

According to EU legislation, Member States are allowed to extend the scope of application of the group of medicines that must bear the safety features based on safety, reimbursement or pharmacovigilance reasons.

Precisely, the new Royal Decree contemplates that the Spanish MoH can issue decisions extending such scope of application based on these reasons. The decisions issued by Spanish MoH in this regard will be published on the websites of both the MoH and the Spanish Medicines Agency.

On the other hand, distributors must verify the authenticity of the unique identifier. The new Royal Decree sets that distributors must make additional verifications when the Spanish Medicines Agency decides so, based on a potential health risk.

Furthermore, the new regulation contemplates other actions to take place in connection with the safety features when medicinal products are sold directly to physicians for their professional use, when they are destined to public health programs or when they are supplied to the sponsor of a clinical trial. In these cases, the safety features will be verified and decommissioned.

As regards suspected falsification or tampering, the new Royal Decree sets that the manufacturer who suspects that a medicinal product might not be authentic or that has been subject to tampering, must notify the Spanish Medicines Agency in order for the latter to take 'appropriate measures'.

Finally, the new Royal Decree creates a specific system called 'Nodo SNSFarma', which is defined as a tool for technological integration and exchange of information with the Spanish medicines database.