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Update of the Spanish rules in connection with the so-called 'prescription by nurses' of medicines and medical devices

Royal Decree 1302/2018, amending Royal Decree 954/2015 on the indication, use and dispensation authorization of medicinal products and medical devices by nurses

Background

On 24 October 2015, Royal Decree 954/2015, regulating the indication, use and authorization for dispensation of medicinal products and medical devices by nurses, came into force. Three years later, on 24 October 2018, this new Royal Decree 1302/2018 came into force to modify the previous one. The modification was aimed to solve certain difficulties arisen from the application of the 2015 regulations.

Main changes

The main modifications introduced by Royal Decree 1302/2018 are the following:

1) Certification: According to Royal Decree 954/2015, in order for nurses to be able to carry out the activities of indicating, using and authorizing the dispensation of medicinal products and medical devices, it is required that such nurses previously obtain a certification for such purposes. The need of such a certification has not changed. However, the authorities in charge of handling the procedure and granting the certification will now be the local authorities of the relevant Spanish region.

Furthermore, the requirements that nurses must meet to obtain the certification have been eased. According to the old rules, nurses were required to hold a Nursing Degree and to pass a training course. Now, more education certificates are allowed, such as a Nursing Diploma or Technical Healthcare Assistant, and the applicant can choose between passing a training course or proving that he/she has at least one year of professional experience. Also, pursuant to the new regulations, nurses may exceptionally need additional training when the scientific developments and the complexity of certain medicinal products require so. The Protocols and Guidelines referred to in the next section will regulate these exceptional cases.

2) Protocols and Guidelines: Pursuant to the provisions contained in the 2015 regulations, there are certain Protocols and Guidelines on Clinical Practice, which must be drafted by the Pharmacy Committee of the Interterritorial Council of the National Health System (together with physicians' and pharmacists' associations, among others) and approved by the Directorate General of Public Health, Quality and Innovation of the Ministry of Health. The new Royal Decree sets 24 October 2020 as the deadline to approve these Protocols and Guidelines. Until then, regional rules in force on this matter remain applicable.

3) Physicians are less involved: According to the old rules, before certified nurses could indicate, use and authorize the dispensation of medicinal products, it was required that a physician had previously determined the diagnosis, prescription and the protocol or medical guideline to be followed. The new rules eliminate this requirement. From now on, the Protocols and Guidelines on Clinical Practice will be the ones regulating the performance of these activities by nurses. Also, these Protocols and Guidelines will set those specific cases in which a previous approval by a physician is required.