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News regarding prescriptions in Spain and in Europe: more guarantees for the patient, especially in the case of biological medicinal products

During the year 2013 Royal Decree 1718/2010, of 17 of December and Directive 2012/52/EU of the Commission shall come into force

Private prescriptions

Royal Decree 1718/2010, of 17 of December, regarding medical prescriptions and dispensation orders requires that starting from 21 of January of 2013 private prescriptions, both in paper as well as in electronic form, must have a homogeneous content and format in the entire territory of Spain.

The regulation details the data that will have to be included in the prescription and it points out that if the prescription is issued on paper, each one of them shall include only one medicinal product and one sku of such product. In same cases, however, more skus may be included (in the case of single dose presentations, up to 6 skus are allowed per prescription). On the contrary, one single electronic prescription may include one or more medicinal products and medical devices.

Another novelty of the new regulation is that private prescriptions must be made of materials that prevent or make their forgery difficult, and they will include safety measures that guarantee their authenticity, through mechanisms similar to bar codes.

Prescriptions issued in other States

Meanwhile, Directive 2012/52/UE obliges Members State to adopt various measures to facilitate the recognition of prescriptions issued in any Member State.

For such purpose, the Directive imposes on the States the obligation to recognize prescriptions that are issued in any country of the EU if they contain the elements established in its Annex, on the idea that what is important is to facilitate a correct identification of the product and to verify its authenticity.

What draws attention is that the medicinal product must be identified by its common name, which helps avoiding errors in the case of products that are marketed under different brand names. However, the Directive points out that the brand name must always be used in the case of biological medicinal products with the aim to ensure they are unequivocally identified given their special features.

The Directive also indicates that the brand name may be used to identify other medicinal products when the prescribing health professional considers it necessary from the medical point of view; but in this case the prescription must shortly state the reasons that justify the use of the brand name.

In the case of medical devices, the contact details of the prescriber must appear so that, if necessary, the dispensing health professional might ask him or her about such product and identify it correctly.