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Substitution and selection of medicinal products in hospital pharmacies

The Spanish Medicines Agency modifies its website in connection with "non-substitutable medicinal products" stating that Order of 28 September 2008 does not apply to hospital pharmacies

The Agency's criteria

Recently, the Spanish Medicines Agency (AEMPS) has updated its website including two surprising statements on its website in connection with the "non-substitutable medicinal products". The first statement says that the Order of 28 September 2008, establishing medicinal products that cannot be substituted by the pharmacist "is applicable to the dispensing of medicinal products made by the pharmacist in the street pharmacy". The second statement says that "the policy of using medicinal products in hospitals is set by interdisciplinary boards promoting the Rational Use of Medicinal Products in accordance with the Law and good practice, including therapeutic exchange".

This means, loud and clear, that someone in the AEMPS has decided to put a quick and definitive end to the controversy as to whether the legal provisions prohibiting substitution of certain medicinal products applies or not to the hospital pharmacies. The reading of these two statements could lead us to think that the AEMPS now considers (contrary to what it had previously stated) that in hospitals it would be lawful and legitimate for a doctor to prescribe a specific biological product to a patient; and that the pharmacist could decide to substitute the prescribed product for another one. One does not have to be a doctor to conclude that this would be aberrant.

It was not necessary, and it was done wrong

Surely, the idea of the AEMPS is different. For the AEMPS, this probably means that the prohibition of substitution of certain medicinal products, or other conditioning factors (such as the prescription and pharmacovigilance of biologics by brand) should not prevent hospitals, through their interdisciplinary boards, from setting on the criteria of selection of products that, as a general rule, will be prescribed and dispensed in hospitals to patients who start a medical treatment. In this regard -and as long as freedom of prescription is respected- there will be room for consensus; but substituting certain products without further authorization from the prescriber and even from the patient would be totally unacceptable.

On the other hand, it was not necessary for the AEMPS to make such statements in the terms it did. The Judgment of the High Court of Madrid, of 24 September 2015, already pointed in this direction and added that the fact that two medicines are not substitutable does not prevent them from being subject to a public tender procedure in accordance with the public procurement regulations. Recently, the Supreme Court has clarified that tendering lots should not include medicinal products which are not interchangeable.

This is, without doubt, a complex area where it is especially important to assure legal certainty. For this, the proliferation of texts (newsletters, instructions, guides, letters and now websites, etc.) pretending to regulate issues as if they had any legal value should be avoided. Lawmakers must be precise and try not to leave regulations unfinished.

It is very worrying that someone thinks that something like this can be done because a note in the website of the AEMPS says so. Patients and legal certainty are once again harmed.