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New controversy regarding the application of the provisions of Royal Decree-Law 16/2012

Position paper from the AEMPS with respect to the guarantees of generic medicinal products

Background

The letter addressed to the Spanish Agency for Medicinal Products and Medical Devices (AEMPS) by the president of the Official Association of Pharmacists of Orense (COFO), in which the latter expresses his doubts on the guarantees offered by some generic medicinal products that the pharmacies must dispense in application of the controversial Royal Decree-Law 16/2012, is still annoying the health organization in charge of the assessment of the quality, safety and efficacy of the medicinal products that are marketed in our country. In its letter COFO complained about the fact that Royal Decree-Law imposes the obligation to replace medicines prescribed by physicians with certain generic medicinal products manufactured abroad and which have been causing problems of supply shortage. Moreover, it complained about the impossibility to contact some of the marketing authorisation holders of the products, and about the fact that they were not granted access to the bioequivalence studies, and to the quality information of these products, in order to verify if they meet all legally enforceable guarantees.

Position of the AEMPS

The AEMPS has had to respond to this information reminding that any medicinal product which is intended to be placed on the Spanish market, regardless of whether it is a generic or innovative medicinal product, must pass an evaluation procedure on its quality, safety and efficacy, as well as on the information of its labelling and consumer leaflet. The AEMPS puts special emphasis on the fact that every marketed generic product, regardless of its origin, has had to provide evidence of its bioequivalence through appropriate bioavailability studies, and that its manufacturer has had to demonstrate that it complies with the European standards on Good Manufacturing Practices.

The lack of finesse of the regulation does not justify inappropriate demands

We are the first to admit the lack of finesse of some provisions of this as well as previous Royal Decree-Laws. Among other flaws, the implications of orienting the system towards saving at all cost, without taking into account the real capacity of supply of some products don't seem to have been thought about hard enough.

However, these mistakes don't justify the spreading of unfounded alarms, that question the work of the evaluating authority. And neither do they justify that organizations such as COFO, whose prestige and contributions in other fields is beyond doubt, try to claim competences that do not correspond to them, such as evaluating the quality, safety and efficacy of the medicinal products. Our legislation reserves this task exclusively to the AEMPS, as it is the technical-scientific organization ideally qualified for it. The fact that some Autonomous Communities wish to make a parallel evaluation, a practice that COFO seems to want to join now, not only lacks all legal coverage but is also inappropriate.