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Speaking of the controversial positioning of the Spanish Medicines Agency on the substitution of medicinal products in hospitals

European positioning regarding the substitution of biosimilar medicinal products

Background

The recent modification introduced by the Spanish Medicines Agency on its website about "non-substitutable medicinal products" has been a much debated and very controversial issue in Spain.

Contrary to its traditional positioning, the Spanish Medicines Agency now states on its website that the Order of September 2008, defining those medicinal products which cannot be substituted by the pharmacist without the approval of the prescriber, is only applicable to retail pharmacies and not to hospital pharmacies.

European consensus

In our opinion, we should not lose sight of what's really important: any debate on this issue should have as main purpose the protection of the rights and interests of the patients. This objective is often forgotten due to economic and budgetary emergency situations arising from time to time.

To such effect, we must highlight the consensus reached by the European Medicines Agency, the European Commission and other main European stakeholders - such as the European Patients Forum, the European Federation of Crohn's & Ulcerative Colitis Associations, the Standing Committee of European Doctors, the European Federation of Pharmaceutical Industries and Associations (EFPIA), the European Association for Bioindustries (EuropaBio) and Medicines for Europe - which was put together in an informative document on biosimilar medicinal products aimed at patients in Europe.

This document seeks to clear any possible doubts that patients may have on biosimilar medicinal products. In this regard, it begins by reminding the reader that biosimilars are not simply "cheap copies" of the reference medicines, but that they are products manufactured using state-of-the-art methods, following strict quality requirements to which the same high standards on safety and efficacy as the reference medicinal products are applied.

The European document also states that biosimilar medicines are not the same as generic medicines, because unlike non-biological medicines, biological medicines cannot be exactly copied.

The document emphasizes that while in some Member States there is a growing practice to switch from a biological medicine to a biosimilar medicine, any decision in this regard should be taken by the doctor in consultation with the patient.

Such principle is also included in the Spanish legal system, specifically in Law 41/2002, regulating the autonomy of patients. Consequently, any decision in connection with the substitution of medicines made by Spanish authorities without considering this principle would be clearly unsatisfactory and incomplete.