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The Ministry of Health seeks to ban hospitals from buying medicinal products that have received an express resolution of no reimbursement

The General Directorate publishes a "Report" about the rules applicable to medicinal products that have been expressly denied reimbursement

Background

One of the hot topics in Spanish pharmaceutical law is knowing how to act from the moment when a product is authorized by the EU until a resolution of its inclusion (or not inclusion) in the pharmaceutical provision is adopted.

Spanish law provides that before marketing a medicinal product in Spain it is compulsory to "have offered" the same to the National Health System (NHS). Until now, the Spanish Ministry of Health (MoH) has interpreted such rule in the sense that "having offered" shall mean "having finalized the corresponding price and reimbursement process".

In view of the foregoing, before the completion of such proceeding, authorized medicinal products are only available under the special rules contained in Chapter IV of Royal Decree 1015/2009.

Upon conclusion of the price and reimbursement process, at least until now, all stakeholders of the sector have understood that if the General Directorate ruled against the inclusion of the product in the pharmaceutical provision of the NHS, hospitals may still acquire and use such product if the commission responsible for treatment protocols of their Autonomous Community so approves. This possibility is specifically foreseen in Royal Decree 178/2010 on prescriptions and dispensing orders.

The Report is null and void

In this context, the MoH has published a Report "on the public reimbursement of medicines where an express resolution of non-inclusion in the pharmaceutical provision of the NHS has been adopted". According to this document, the Autonomous Regions and the hospitals may not reimburse with public funds (that is, they may not acquire) medicinal products which have received an express resolution denying reimbursement.

Royal Decree 1047/2018 on the structure and powers of the MoH does not include any provision authorizing the Directorate General to issue such a Report, one that creates a new category of medicinal products (those expressly not included in the pharmaceutical provision of the NHS); that categorically imposes restrictions on the actions of the Autonomous Regions and the hospitals; and which complicates patients' access to medicinal products. Because of this, our view is that this Report has no legal basis and it is null and void.

Attorneys must always have in mind what Von Kirchmann said: only three words of the legislature can destroy whole libraries. We must definitively accept such words when they come from an authorized legislature acting in the sphere of its competence. This is not happening in this case.