The re-evaluation of medicines by the regions conflicts with the current legislation

Judgment of the Administrative Court of Castilla y Leon of 21 July 2014

Background

In recent times, it is frequent that committees and evaluation groups formed within the regional administrations in Spain or in scientific societies reassess the efficacy of medicines which have been accepted for reimbursement within the National Health System. Frequently, the conclusions of these pseudo-evaluations are used to give instructions on prescription. Sometimes, doctors who continue prescribing without taking them into account are penalized in their income or salary.

In this context, a ruling given in 2013 by the Court of Valladolid sustained our appeal, declaring that the re-evaluation of clinical evidence of a medicine carried out by the authorities in Castilla y Leon and its later listing as a drug having no or little therapeutic efficacy was a material act which had to be declared null in its entirety.

Adopting decisions through "fait accompli" is also a reason for nullity

The regional authorities filed an appeal against the judgment of the Court of First Instance, claiming that they had not acted illegally. In its filing, the regional authorities of Castilla y Leon claimed that their evaluation of the clinical evidence on the product, and their conclusion that the product had no or little therapeutic efficacy, was an internal decision that they could adopt, exercising their competence within the area of rational use of medicines and of education of their healthcare professionals. Because of this, the authorities claimed that they did not need to adopt a formal administrative act, nor carry out any specific procedure. They also claimed that they did not need to give the reasons for their decision.

The Administrative Court of Castilla y Leon did not accept the appeal, and confirmed the ruling of the lower Court. In this judgment, the Court recalls that a "voie de fait" exists both when the Administration lacks any competence to adopt the conduct ("manque de droit") and also when it acts without following any procedure and without adopting an administrative ruling ("manque de procedure").

Under this idea, the Court concludes that the publication and circulation of the list of medicines that the authorities considered having little or no therapeutic value cannot be considered as an administrative act capable of providing legal foundation for this conduct. Especially, this happens when no administrative procedure has been followed at all for the purposes of adopting this decision, and when the motives and grounds for the decision are totally unknown.

This ruling opens the path for contesting this type of actions by some authorities who try to impose their own criteria by acting on their own motion without following any special procedure and lacking competence to take these decisions.