



The administration must respect the rules of procedure even in urgent cases

The Judgment of the National High Court of 25 July 2012 annuls a decision of the AEMPS that ordered the cessation of the manufacture of certain medicinal products

Background

In July 2009, during an inspection, the inspectors of the Spanish Agency for Medicinal Products and Medical Devices (AEMPS for its acronym in Spanish) ordered a company to immediately cease the manufacture of certain homeopathic medicinal products. The inspection report stated that the order was based on the serious nature of the irregularities detected, since the company did not have the corresponding authorization.

It is widely known that the manufacture and marketing of medicinal products without having a prior administrative authorization constitutes a breach of the Law for which administrative and even criminal liabilities can be claimed. Well, although the administrative procedure may seem justified, it was annulled by the courts because the company concerned brought a contentious-administrative appeal on the ground that its right to an objective procedure had been violated.

The importance of the process

In administrative law, the procedure constitutes the guarantee for the citizens and companies that public authorities who exercise police functions shall act in accordance with the basic principles of the rule of law.

In the case at issue, Central Court number 3 understood that the order given by the inspectors for the immediate cessation of the

manufacture was an injunction, adopted outside of the established procedure, which had to be annulled.

The Court cannot avoid to mention that probably the AEMPS did well as regards the substance of the matter, and in this sense it highlights that the administration's intention was more than reasonable. Nevertheless, the judgment points out that this decision has to follow a specific procedure, even if it is a summary one. In the framework of this procedure, the administration could achieve the pursued effect by pronouncing a final resolution or adopting a preventive measure; reason for which the judgment criticizes the way the inspectors acted, which ultimately obliged the court to annul an act more than reasonable in terms of its content.

The State attorney filed an appeal before the National High Court, forgetting maybe that there was little or nothing to be done to fix the situation. In its judgment, the National High Court reminds once again that the administration has the power to adopt preventive measures as long as they are properly motivated and they respect the company's right to submit arguments in this regard; and that the procedure demands that inspections must be ended with the issuance of a report and possibly with a follow-up report. The law does not provide that an inspector may order an immediate cessation. Therefore, the performance of the AEMPS was considered null and void.