



## The Supreme Court recalls that manipulating medicines in hospitals is a dangerous activity

*Judgments of the Supreme Court, of 17 October 2014, regarding Order 14/2010 of the Health Department of the Region of Valencia*

### Background

In 2010, the Health Department of the Region of Valencia published Order 14/2010, regulating the procedure to authorize and manage the so-called "pharmaceutical units for dose adaptation". The Pharmaceutical Boards of Valencia and Alicante filed a Court appeal against the order, because they understood that it breached the provisions of Law 29/2006 regarding manufacturing and dispatch of medicines. They also thought that the order breached the rules on competence regarding health matters.

These appeals were dismissed by the Administrative Court in Valencia, because the Court understood that the Order did not affect the safety of medicines, and it also understood that it did not invade the competences of the central Government. The plaintiffs decided to bring the matter to the Supreme Court

### Revocation of the Order

The Supreme Court, after examining the question, concluded that the regional authorities in Valencia had invaded the competences of the central Government. It also added that the Order breached the provisions of Law 29/2006 under which the Spanish Medicines Agency must be the one granting approval for all activities involving fractioning, labeling and presentation of medicines.

In connection with the competence issue, the Court recalls that article 146.1.16 of the Spanish

Constitution grants the Central Government the exclusive competence in connection with legislation on pharmaceutical products. According to the jurisprudence, the activities on manufacturing and marketing of these products are included within this legislation. This exclusive competence comprises both the approval of laws and regulations.

In connection with the breach of Law 29/2006, the Court understands that any activity involving the manipulation, fractioning and adaptation of a medicinal product are manufacturing operations, which may only be carried out by those who have obtained an authorization to manufacture granted by the Spanish Medicines Agency, due to the intrinsic danger of manipulating medicines.

At present, the situation is a bit different because through Royal Decree-Law 16/2012, the central Government authorized regional authorities to grant approvals to hospital pharmacy services so they could carry out these operations in order to improve the efficiency of the public system. However, this judgment is still important, because it recalls that the framework designed by the central Government and the good practices guides that have been approved when implementing it must be respected, in particular because of the risks of all of these operations.