



## Almost ten years debating hospital dispensing

### *Judgement of the Supreme Court of 2 March 2016 on the hospital dispensing of medicinal products for non-hospital treatment*

#### Background

The Judgement in question dates back to a ruling issued by the Andalusian Health System (SAS), at the end of 2010, which provided that certain medicinal products should be dispensed via hospital pharmacy services given the need to exercise specific oversight, supervision and control measures, preventing them from being dispensed at pharmacies.

The Business Confederation of Pharmacies in Andalusia appealed this ruling and both the Supreme Court of Justice of Andalusia and the Supreme Court have supported its arguments.

#### The evolution of hospital dispensing

The debate on hospital dispensing started with the entry into force of Royal Decree 618/2007, which set out the requirements and procedure for establishing restrictions, subject to approval through a visa procedure, concerning the prescription and dispensing conditions of certain medicinal products. The purpose of this regulation was to verify their use, in addition to ensuring the adequacy between the medicinal products prescribed and those reimbursed.

Between 2008 and 2010, some Autonomous Communities released instructions and rulings stating that certain medicinal products could only be dispensed via hospital pharmacy services. A number of these instructions and rulings were annulled by the Supreme Courts of Justice, including the aforementioned ruling.

Subsequently, Royal Decree 618/2007 was amended by Royal Decree-Law 4/2010 in order to grant the Ministry of Health the power to limit the dispensing to non-hospitalised patients, with no need for approval through a visa procedure, to hospital pharmacy services.

Furthermore, on that same year, Royal Decree 1718/2010 was published, which defined, amongst other issues, the hospital dispensing order; the following year, Royal Decree-Law 9/2011, which is the legislation currently in force, came into effect establishing the difference between medicinal products to be administered in hospitals, medicinal products for hospital use and, finally, medicinal products to be dispensed at hospitals. The justification for this third category, which did not exist previously, was entirely economic, being the Ministry of Health the only body able to decide which medicinal products would have to be subject to the hospital dispensing system.

#### The powers of the State

In the context of the discussions on hospital dispensing, as part of the Judgement of 2 of March, the Supreme Court has stressed that the only body empowered to legislate on issues concerning medicinal products is the State and that the powers of the Autonomous Communities are limited to the implementation of such state legislation.