



The Supreme Court rejects the arguments of the distribution sector on the “right to be supplied”

Judgment of 15 December 2015 in the appeal of FEDIFAR against Royal Decree 782/2013 on the distribution of medicinal products for human use

Background

In 2013, the Spanish Federation of Wholesalers (FEDIFAR) appealed against Royal Decree 782/2013, requesting its annulment as it was subject of an “unlawful regulatory omission”.

According to FEDIFAR, the Law on Guarantees and Rational Use of Medicinal Products and Medical Devices recognises wholesalers' unconditional right to be supplied by the manufacturers of medicinal products. FEDIFAR claimed that it was essential to further implement such unconditional right by regulating the duty of pharmaceutical companies to supply wholesalers. FEDIFAR believed that without this implementation, wholesalers would be unable to fulfil their supply duties and the availability of all medicinal products at pharmacies would be compromised.

“Regulatory omission” as a cause for annulment

The Supreme Court judgment reminds the plaintiff that an unlawful regulatory omission is only considered as such if the Government ignores an express and unambiguous order from the legislator to regulate a given matter, or if the omission of these specific regulation generates an unlawful legal situation.

The Supreme Court does not believe that this is the case concerning the matter in hand. Notably, the Supreme Court highlights that the law's mention of the Government's duty to

safeguard supply to wholesalers does not make a regulatory development mandatory, given that there are other instruments safeguard said objectives. In other words, the Supreme Court believes that the plaintiff's claim of an “unlawful regulatory omission” represents a mere disagreement on the part of FEDIFAR concerning the contents of the Royal Decree, given that the Government rejected to include in the law what FEDIFAR requested.

Scope of the so-called “right to be supplied”

In addition, the Supreme Court reminds the plaintiff that the Law on Guarantees and Rational Use of Medicinal Products and Medical Devices, has established a distribution system whose basic principles were already implicitly laid out in the previous regulations. This system is based on the freedom of manufacturers to organise the distribution of their products in a manner which is compatible with their duty to secure supply to national pharmacies in a sufficient way.

According to the Supreme Court, this duty to sufficiently secure supply, should not be confused neither with the duty to organise distribution in a given way nor with the distribution sector's interest of preserving its economic activity.