



Pharmacies may not engage in the wholesale of medicinal products

Royal Decree 782/2013, of 11 October, on the distribution of medicinal products for human use (Official Journal No 251/2013)

Background

On September 2011, the Health Authorities of Cantabria fined a pharmacy upon detecting that such pharmacy had sold medicinal products to a wholesaler on several occasions. The Cantabrian Health Authorities understood that the pharmacy committed a serious administrative infringement by carrying out these sales and, consequently, decided to impose a fine of 30.000 Euros.

The owner of the pharmacy, not agreeing with such decision, brought the matter before the Administrative Court of Santander. After analysing the facts, the Court decided to cancel the fine imposed, considering that such sales could not be regarded as an administrative infringement at the time they were performed. In August 2011, which was after the facts in this case occurred, Law 29/2006, of 26 of July, on Guarantees and Rational Use of Medicinal Products and Medical Devices was modified so as to expressly include the fact that the distribution of medicinal products by pharmacies to other pharmacies or to wholesalers constitutes an infringement of Law. And even though the previous version of the Law already established that the distribution of medicinal products by unauthorized entities was a serious infringement, the Court understood that these sales could not be considered "distribution" given that the pharmacy only provided small quantities of medicinal products to the wholesaler.

Position of the Superior Court of Justice

The government of Cantabria decided to appeal against the aforementioned decision before the Cantabrian Superior Court of Justice. On 27 September 2013 the Superior Court did not hesitate to fully revoke the decision of the Administrative Court of Santander and re-establish the sanction.

Quoting a case-law of 2009, which was adopted in a very similar case that occurred in Andalusia, the Cantabrian Superior Court of Justice reminded that pharmacies are only authorized to sell medicinal products at retail level and that the distribution or wholesale can only be carried out by duly authorized wholesalers or, as the case may be, by the holder of the marketing authorization himself.

The Superior Court of Justice of Cantabria concluded that the decision adopted by the Health Authorities of Cantabria was correct and that the sanction was appropriate. According to such Superior Court of Justice, the sales made by the pharmacy could not be considered as a mere dispensing of medicinal products –an activity that is certainly covered by the authorization of the pharmacy– as there is no evidence that the medical prescriptions necessary to carry out such dispensation were requested, and also because the sales of medicinal products involved important quantities.