



The Court of Justice confirms that pharmacies cannot distribute medicinal products without an authorisation to operate as a wholesaler

Judgment of the Court of Justice of 28 of June of 2012, Case C-7/11, Fabio Caronna

Background

Several Italian pharmacists were reported to their home courts for wholesale distributing medicinal products without possessing the authorisation required under Italian law. Most of the proceedings were discontinued on the ground that a pharmacist already authorised to retail medicinal products was exempt from the obligation to obtain the authorisation required for the wholesale distribution. However, in the case of Mr. Caronna the opinion of the competent Italian authority was sought, which put forward that, according to the Italian regulations, the Italian pharmacists do have to obtain a special authorisation for the wholesale of medicinal products. Taking into account that at this point the Italian law reproduces what is laid down in Directive 2001/83/EC, the Italian court decided to stay the proceedings and to refer several questions to the European Court of Justice for a preliminary ruling.

Wholesale distribution

The Italian Court asks the Court of Justice whether the referred Directive is to be interpreted as meaning that the requirement to obtain an authorisation for the wholesale distribution of medicinal products is likewise applicable to a pharmacist who, as a natural person, is also authorised under Italian law to operate as a wholesaler in medicinal products. The Court of Justice responds affirmatively to such question, since it considers that pharmacists are included in the wider class of persons authorised to supply medicinal products to the public and, if they are permitted under

domestic law to engage in activities as wholesale distributors in medicinal products, then they are required to obtain the authorisation for the wholesale distribution of medicinal products in accordance with such Directive. Moreover, to allow pharmacists to engage in wholesale activities without this special authorisation would confer on them an unjustified competitive advantage with vis-à-vis other persons authorised to supply medicinal products to the public, who are indeed required to apply for such authorisation.

Compliance with requirements

The Court of Justice confirms that a pharmacist who is authorised, under domestic law, to operate as wholesaler in medicinal products, must also satisfy all the requirements imposed on holders of authorisation for the wholesale distribution of medicinal products according to the Directive, and it is not sufficient for the pharmacist to fulfill the conditions laid down by domestic law for the retail of medicinal products.

In Spain the applicable rules establish clearly that a pharmacy can neither engage in activities as wholesale distributors of medicinal products to other pharmacies or to wholesalers, nor make shipments of medicinal products outside the national territory. The current wording of Law 29/2006 defines this conduct as a very serious infringement.