



Reports of Cases

Case C-7/11 Fabio Caronna

(Reference for a preliminary ruling from the Tribunale di Palermo)

(Medicinal products for human use — Directive 2001/83/EC — Article 77 — Wholesale distribution of medicines — Mandatory special authorisation for pharmacists — Conditions for granting)

Summary of the Judgment

1. *Acts of the institutions — Preamble — Binding legal force — None*
2. *Approximation of laws — Medicinal products for human use — Directive 2001/83 — Wholesale distribution of medicinal products — Requirement to obtain authorisation for distribution — Scope ratione personae — Pharmacists who are also authorised under domestic law to operate as wholesalers in medicinal products — Included*

(European Parliament and Council Directive 2001/83, as amended by Directive 2009/120, Art. 77(2))
3. *Approximation of laws — Medicinal products for human use — Directive 2001/83 — Wholesale distribution of medicinal products — Requirement to obtain authorisation for distribution — Requirements imposed on applicants for and holders of such authorisation — Whether those requirements are applicable to a pharmacist who is also authorised under domestic law to operate as a wholesaler in medicinal products*

(European Parliament and Council Directive 2001/83, as amended by Directive 2009/120, Arts 79 to 82)
4. *Acts of the institutions — Directives — Implementation by Member States — Need to ensure that directives are effective — Obligations of national courts — Obligation to interpret national law in conformity with European Union law — Limits — Principle that criminal penalties must have a proper legal basis*

(Art. 288(3) TFEU; European Parliament and Council Directive 2001/83, as amended by Directive 2009/120)

1. See the text of the judgment.

(see para. 40)

2. Article 77(2) of Directive 2001/83 on the Community code relating to medicinal products for human use, as amended by Directive 2009/120, must be interpreted as meaning that the requirement to obtain authorisation for the wholesale distribution of medicinal products is applicable to a pharmacist who, as a natural person, is also authorised under domestic law to operate as a wholesaler in medicinal products.

Only pharmacists and persons authorised to supply medicinal products to the public who confine themselves to this activity are exempt from the requirement to obtain a special authorisation.

(see paras 39, 41, operative part 1)

3. A pharmacist who is also authorised under domestic law to operate as a wholesaler in medicinal products must satisfy all the requirements imposed on applicants for and holders of authorisation for the wholesale distribution of medicinal products in Articles 79 to 82 of Directive 2001/83 on the Community code relating to medicinal products for human use, as amended by Directive 2009/120.

That requirement does not mean that a competent national authority cannot, when authorising pharmacists for the purposes of wholesale distribution of medicinal products, take into account any equivalent conditions relating to authorisation for the purposes of retail distribution of such products, in application of national rules.

(see paras 49, 50, operative part 2)

4. If the law of a Member State does not require pharmacists to obtain special authorisation for the wholesale distribution of medicinal products and contains no express provision under which pharmacists operating as wholesalers are subject to criminal liability, the principle that criminal penalties must have a proper legal basis, enshrined in Article 49(1) of the Charter of Fundamental Rights of the European Union, prohibits the imposition of criminal penalties for such conduct, even if the national rule is contrary to European Union law.

The interpretation of Directive 2001/83 on the Community code relating to medicinal products for human use, as amended by Directive 2009/120, to the effect that a pharmacist authorised to operate as a wholesaler in medicinal products must obtain authorisation for the wholesale distribution of medicinal products and satisfy all the requirements imposed on applicants for and holders of such authorisation cannot, of itself and independently of a law adopted by a Member State, give rise to or aggravate liability in criminal law on the part of a pharmacist who has engaged in activity as a wholesale distributor in medicinal products without the requisite authorisation.

(see paras 41, 50, 55, 56, operative part 3)