



Press and Information

Court of Justice of the European Union
PRESS RELEASE No 91/12
Luxembourg, 28 June 2012

Judgment in Case C-7/11
Criminal proceedings against Fabio Caronna

A pharmacist who is also authorised under national law to operate as a wholesaler in medicinal products must obtain authorisation for wholesale distribution under EU law

On the other hand, that interpretation of EU law cannot, in 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 without such authorisation

The Directive on the Community code relating to medicinal products for human use¹ governs, *inter alia*, the wholesale distribution of such products. Under the Directive, Member States are required to ensure that wholesale distribution of medicinal products is subject to possession of an authorisation to engage in such activity, even where persons entitled to supply medicinal products to the public are also authorised under national law to engage in wholesale business.

Italian legislation authorises pharmacists and companies of pharmacists in possession of a licence to operate a pharmacy to operate as wholesale distributors of medicinal products, subject to certain conditions. Under that legislation, the wholesale distribution of medicinal products is subject to the requirement to hold an authorisation granted by the region or the autonomous province. Any person in breach of the national legislation is liable to punishment in the form of imprisonment for a term of six months to one year and a fine of between €10 000 and €100 000.

Certain pharmacists in Italy were reported for engaging in activity as wholesale distributors in medicinal products without authorisation. In criminal proceedings brought against Mr Caronna, the Tribunale di Palermo (District Court, Palermo) asks the Court of Justice whether the requirement laid down in the directive to obtain authorisation for the wholesale distribution of medicinal products applies to pharmacists who, as natural persons, are already authorised under national law to supply such products to the public. Moreover, the Court is asked whether pharmacists must satisfy all the requirements imposed for wholesale distribution or whether it is sufficient for them to fulfil the conditions laid down by domestic law for retail supply.

The Court points out, first of all, that **the directive² imposes on Member States a general obligation to make the wholesale distribution of medicinal products subject to possession of a special authorisation**, an obligation which also applies to persons authorised or entitled to supply medicinal products to the public if they may also engage in wholesale business.

The Courts finds that pharmacists are part of the wider class of persons authorised or entitled to supply medicinal products to the public and are required, if they are authorised under domestic law to distribute them on a wholesale basis, first to obtain the authorisation required by the directive.

It is apparent from the directive that pharmacists and persons authorised to supply medicinal products to the public who confine themselves to that activity are exempt from the requirement to obtain authorisation for wholesale distribution.

¹ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67)

² Article 77.

It follows that **the requirement under the directive 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.**

Next, the Court points out that, under EU law as it currently stands, the conditions applicable to the supply of medicinal products to the public are not harmonised and, consequently, the regime applicable to the retail supply of medicinal products varies from one Member State to another.

On the other hand, **the minimum requirements to be satisfied for the wholesale distribution of medicinal products are harmonised by the Directive³.** Checks are carried out throughout the whole period in which the authorisation is held to ensure compliance with the conditions imposed.

Since the retail of medicinal products has different characteristics from wholesale distribution, **it cannot be presumed from the simple fact that pharmacists satisfy the conditions laid down by the Member States for retail supply that they also comply with the conditions laid down by harmonised rules at EU level for wholesale distribution.**

Accordingly, in order to ensure that the directive's objectives are satisfied – in particular the protection of public health, the removal of barriers to trade in medicinal products within the EU and the need to control the entire chain of wholesale distribution of medicinal products – the minimum requirements for wholesale distribution must be fulfilled in a uniform manner in all Member States.

However, that conclusion does not mean that a national authority cannot, when authorising pharmacists for the purposes of wholesale distribution of medicinal products, take into account any equivalent conditions laid down by national rules for the purposes of retail distribution of such products.

The Court next addresses the question of Mr Caronna's liability in criminal law. It points out that even though national courts are required to interpret domestic law in light of the purpose of a directive, that obligation is subject to certain limits in criminal matters. Thus, a directive cannot have the effect of determining or aggravating the liability in criminal law of persons who act in contravention of the provisions of the directive.

If the referring court were to reach the conclusion that **national law**, in the version applicable at the material time, **did not require pharmacists to obtain special authorisation for the wholesale distribution of medicinal products and did not provide that pharmacists were subject to criminal liability, the principle that criminal penalties must have a proper legal basis⁴ would prohibit the imposition of criminal penalties for such conduct**, even if the national rule were contrary to EU law.

NOTE: A reference for a preliminary ruling allows the courts and tribunals of the Member States, in disputes which have been brought before them, to refer questions to the Court of Justice about the interpretation of European Union law or the validity of a European Union act. The Court of Justice does not decide the dispute itself. It is for the national court or tribunal to dispose of the case in accordance with the Court's decision, which is similarly binding on other national courts or tribunals before which a similar issue is raised.

Unofficial document for media use, not binding on the Court of Justice.

The [full text](#) of the judgment is published on the CURIA website on the day of delivery.

Press contact: Christopher Fretwell 📞 (+352) 4303 3355

³ These include requirements relating to the existence of suitable premises, installations and equipment, qualified staff to ensure proper conservation and distribution of medicinal products, the documentation of transactions, the supply of medicinal products and compliance with good distribution practice.

⁴ The Charter of Fundamental Rights of the European Union (Article 49(1)).