Reports of Cases

JUDGMENT OF THE COURT (Second Chamber)

28 June 2012*

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

In Case C-7/11,

REFERENCE for a preliminary ruling under Article 267 TFEU from the Tribunale di Palermo (Italy), made by decision of 1 December 2010, received at the Court on 5 January 2011, in the criminal proceedings against

Fabio Caronna,

THE COURT (Second Chamber),

composed of J.N. Cunha Rodrigues, President of the Chamber, U. Lõhmus (Rapporteur), A. Rosas, A. Ó Caoimh and A. Arabadjiev, Judges,

Advocate General: P. Cruz Villalón,

Registrar: A. Calot Escobar,

having regard to the written procedure,

after considering the observations submitted on behalf of:

— Mr Caronna, by M. Tuzzolino, avvocato,

— the Estonian Government, by M. Linntam, acting as Agent,

— the Greek Government, by F. Dedousi and I. Pouli, acting as Agents,

— the Spanish Government, by J.M. Rodríguez Cárcamo, acting as Agent,

— the Hungarian Government, by M.Z. Fehér and K. Szíjjártó, acting as Agents,

— the Polish Government, by M. Szpunar, acting as Agent,

— the Portuguese Government, by L. Inez Fernandes, acting as Agent,

— the European Commission, by M. Šimerdová and C. Zadra, acting as Agents,

having decided, after hearing the Advocate General, to proceed to judgment without an Opinion,

* Language of the case: Italian.

gives the following

Judgment

1 This reference for a preliminary ruling concerns the interpretation of Articles 76 to 84 of 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), as amended by Commission Directive 2009/120/EC of 14 September 2009 (OJ 2009 L 242, p. 3) ('the Directive').

2 The reference was made in criminal proceedings against Mr Caronna, a pharmacist, concerning the wholesale of medicinal products in which he was engaged without obtaining the authorisation required under Italian law.

Legal context

European Union law

3 Recitals 2 to 5 and 35 and 36 of the Directive are worded as follows:

'(2) The essential aim of any rules governing the production, distribution and use of medicinal products must be to safeguard public health.

(3) However, this objective must be attained by means which will not hinder the development of the pharmaceutical industry or trade in medicinal products within the [European Union].

(4) Trade in medicinal products within the [European Union] is hindered by disparities between certain national provisions, in particular between provisions relating to medicinal products … and such disparities directly affect the functioning of the internal market.

(5) Such hindrances must accordingly be removed; whereas this entails approximation of the relevant provisions.

...

(35) It is necessary to exercise control over the entire chain of distribution of medicinal products, from their manufacture or import into the [European Union] through to supply to the public, so as to guarantee that such products are stored, transported and handled in suitable conditions. The requirements which must be adopted for this purpose will considerably facilitate the withdrawal of defective products from the market and allow more effective efforts against counterfeit products.

(36) Any person involved in the wholesale distribution of medicinal products should be in possession of a special authorisation. Pharmacists and persons authorised to supply medicinal products to the public, and who confine themselves to this activity, should be exempt from obtaining this authorisation. It is however necessary, in order to control the complete chain of distribution of medicinal products, that pharmacists and persons authorised to supply medicinal products to the public keep records showing transactions in products received.'

4 Wholesale distribution of medicinal products is defined in Article 1(17) of the Directive as '[a]ll activities consisting of procuring, holding, supplying or exporting medicinal products, apart from supplying medicinal products to the public. Such activities are carried out with manufacturers or their depositories, importers, other wholesale distributors or with pharmacists and persons authorised or entitled to supply medicinal products to the public in the Member State concerned'.

5 Title IV of the Directive, entitled 'Manufacture and importation', contains Article 40(1) and (2), which provide as follows:

'1. Member States shall take all appropriate measures to ensure that the manufacture of the medicinal products within their territory is subject to the holding of an authorisation. This manufacturing authorisation shall be required notwithstanding that the medicinal products manufactured are intended for export.

2. The authorisation referred to in paragraph 1 shall be required for both total and partial manufacture, and for the various processes of dividing up, packaging or presentation.

However, such authorisation shall not be required for preparation, dividing up, changes in packaging or presentation where these processes are carried out, solely for retail supply, by pharmacists in dispensing pharmacies or by persons legally authorised in the Member States to carry out such processes.'

6 The rules governing the wholesale distribution of medicinal products are set out in Title VII of the Directive, which comprises Articles 76 to 85.

7 Article 76 of the Directive provides that all medicinal products for wholesale distribution are to be covered by a marketing authorisation.

8 Article 77(1) to (3) of the Directive provide as follows:

'1. Member States shall take all appropriate measures to ensure that the wholesale distribution of medicinal products is subject to the possession of an authorisation to engage in activity as a wholesaler in medicinal products, stating the place for which it is valid.

2. Where persons authorised or entitled to supply medicinal products to the public may also, under national law, engage in wholesale business, such persons shall be subject to the authorisation provided for in paragraph 1.

3. Possession of a manufacturing authorisation shall include authorisation to distribute by wholesale the medicinal products covered by that authorisation. Possession of an authorisation to engage in activity as a wholesaler in medicinal products shall not give dispensation from the obligation to possess a manufacturing authorisation and to comply with the conditions set out in that respect, even where the manufacturing or import business is secondary.'

9 Article 78 of the Directive lays down a period of 90 days within which an application for a distribution authorisation is to be examined by the competent authority of the Member State concerned.

10 Article 79 of the Directive is worded as follows:

'In order to obtain the distribution authorisation, applicants must fulfil the following minimum requirements:

(a) they must have suitable and adequate premises, installations and equipment, so as to ensure proper conservation and distribution of the medicinal products;

(b) they must have staff, and in particular, a qualified person designated as responsible, meeting the conditions provided for by the legislation of the Member State concerned;

(c) they must undertake to fulfil the obligations incumbent on them under the terms of Article 80.'

11 Article 80(b) and (c) of the Directive provide as follows:

‘Holders of the distribution authorisation must fulfil the following minimum requirements:

…

(b) they must obtain their supplies of medicinal products only from persons who are themselves in possession of the distribution authorisation or who are exempt from obtaining such authorisation under the terms of Article 77(3);

(c) they must supply medicinal products only to persons who are themselves in possession of the distribution authorisation or who are authorised or entitled to supply medicinal products to the public in the Member State concerned.’

12 The first paragraph of Article 81 of the Directive is worded as follows:

‘With regard to the supply of medicinal products to pharmacists and persons authorised or entitled to supply medicinal products to the public, Member States shall not impose upon the holder of a distribution authorisation which has been granted by another Member State, any obligation, in particular public service obligations, more stringent than those they impose on persons whom they have themselves authorised to engage in equivalent activities.’

13 The first paragraph of Article 82 of the Directive sets out the information which must be included in the documentation enclosed with all supplies of medicinal products by the authorised wholesaler to any person authorised or entitled to supply medicinal products to the public. The second paragraph of Article 82 is worded as follows:

‘Member States shall take all appropriate measures to ensure that persons authorised or entitled to supply medicinal products to the public are able to provide information that makes it possible to trace the distribution path of every medicinal product.’

14 Article 83 of the Directive authorises Member States to adopt more stringent requirements in respect of the wholesale distribution of narcotic or psychotropic substances and certain types of medicinal product.

15 In accordance with Article 84 of the Directive, the European Commission is to publish guidelines on good distribution practice.

Italian law

16 The Directive was transposed into Italian law by Legislative Decree No 219 of 24 April 2006 (GURI No 142 of 21 June 2006) (‘Decree 219/2006’).

17 According to the Tribunale di Palermo, the original version of Article 100(2) of Decree 219/2006 did not permit pharmacists to engage in activity as wholesale distributors in medicinal products, stating that this was incompatible with the sale of medicinal products to the public in pharmacies.

18 Decree Law No 223 of 4 July 2006 (GURI No 153 of 4 July 2006), converted into law by Law No 248 of 4 August 2006 (GURI No 186 of 11 August 2006), known as the ‘Bersani Decree’, repealed Article 100(2) of Decree 219/2006.

19 Following amendments introduced by Legislative Decree No 274 of 29 December 2007 (GURI No 38 of 14 February 2008) and Legislative Decree No 135 of 25 September 2009 (GURI No 223 of

25 September 2009), converted into law by Law No 166 of 20 November 2009 (GURI No 274 of 24 November 2009), Article 100 of Decree 219/2006 is worded as follows:

'1. The wholesale distribution of medicinal products shall be subject to possession of an authorisation granted by the region or the autonomous province or by the other competent authorities designated by the legislation of the regions or autonomous provinces.

1a. Pharmacists and companies of pharmacists, being in possession of a licence to operate a pharmacy within the meaning of Article 7 of Law No 362 of 8 November 1991, as well as companies operating municipal pharmacies may engage in activity as wholesale distributors in medicinal products, subject to the provisions laid down under this title. Companies which engage in activity as wholesale distributors in medicinal products may similarly sell medicinal products to the public by operating municipal pharmacies.

1b. It is prohibited for manufacturers and wholesale distributors to impose on retailers, without due justification, conditions that are different from those previously included in standard contract terms.

…'

20 Article 101 of Decree 219/2006 sets out the conditions for obtaining authorisation for the wholesale distribution of medicinal products.

21 Article 147 of Decree 219/2006, entitled 'Criminal penalties', provides in paragraph 4 thereof as follows:

'The proprietor or legal representative of the undertaking which initiates the activity of wholesale distribution of medicinal products without obtaining the authorisation required under Article 100, or who continues to pursue such activity notwithstanding the fact that the authorisation has been withdrawn or suspended, shall be liable to punishment in the form of imprisonment for a term of six months to one year and a fine of between EUR 10 000 and EUR 100 000. Those penalties shall also apply to any person who pursues the authorised activity without having the person designated as responsible referred to in Article 101.'

The dispute in the main proceedings and the questions referred for a preliminary ruling

22 Following investigations carried out by the Carabinieri, certain pharmacists, including Mr Caronna, were reported to the judicial authorities for engaging in activity as wholesale distributors in medicinal products without possessing the authorisation required under Italian law.

23 The public prosecutor's office of the Tribunale di Palermo initiated criminal proceedings against each pharmacist in respect of whom a complaint had been made. Some of those proceedings were discontinued at the instigation of the prosecuting authorities on the ground that a pharmacist already authorised to retail medicinal products was exempt from the obligation to obtain the authorisation required under the material national and European Union rules applicable.

24 In the criminal proceedings against Mr Caronna, the prosecuting authorities also requested that the case be discontinued. However, the Tribunale di Palermo decided to order further investigations in order to ascertain the position of the competent administrative authorities. The administrative authorities replied that a pharmacist already authorised to retail medicinal products was required to obtain special authorisation also for the purpose of the wholesale of such products. The prosecuting authorities nevertheless reiterated their request that the case be discontinued, on the ground that such special authorisation was not required under European Union law.

25 The Tribunale di Palermo considers that, in so far as the defendant's criminal liability hinges on the requirement to hold a form of authorisation which he has not sought, it is necessary for it to be apprised of the correct interpretation of Article 77 of the Directive, which is reproduced in the national legislation. That court also asks whether it is justified to subject a pharmacist to the formal and substantive requirements relating to the authorisation in question when those requirements are, essentially, already prescribed under national law for the retail of medicinal products.

26 In those circumstances, the Tribunale di Palermo decided to stay the proceedings and to refer the following questions to the Court for a preliminary ruling:

'(1) Is Article 77(2) [of the Directive] to be construed as meaning that pharmacists are included among the class of persons who must obtain authorisation for the wholesale distribution of medicinal products, or was it the [European Union] legislature's intention, instead, to exempt pharmacists from the requirement to apply for such authorisation, as would appear to be suggested by recital 36 in the preamble to the Directive?

(2) In more general terms, what is the correct interpretation to be given to the rules governing authorisation to distribute medicinal products laid down by Articles 76 to 84 of the [Directive], with particular reference to the requirements to be met in order for a pharmacist (that is, a natural person, not a company) who, by virtue of that status, is already authorised to retail medicinal products under national law, also to be able to distribute such products by wholesale?'

Consideration of the questions referred

Question 1

27 By its first question, the referring court asks, in essence, whether Article 77(2) of the Directive, in the light of recital 36 in the preamble thereto, is to 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 national law to operate as a wholesaler in medicinal products.

28 Article 77(1) of the Directive imposes on the Member States a general obligation to make the wholesale distribution of medicinal products subject to the possession of a special authorisation. The same obligation is referred to in the first sentence of recital 36 in the preamble to the Directive, which states that '[a]ny person involved in the wholesale distribution of medicinal products should be in possession of a special authorisation'.

29 Article 77(2) of the Directive provides that that obligation also applies to persons authorised or entitled to supply medicinal products to the public if they may also engage in wholesale business.

30 Mr Caronna is of the view that the Directive draws a distinction between pharmacists and persons authorised to supply medicinal products to the public. In his view, under Article 77(2) of the Directive, the requirement to obtain an authorisation applies to persons authorised or entitled to supply medicinal products to the public. It follows that pharmacists are not subject to that requirement, since they are not expressly referred to in that provision and do not form part of the wider class of 'persons authorised or entitled to supply medicinal products to the public' within the meaning of the provision.

31 That argument cannot be accepted.

32 As the Hungarian and Portuguese Governments and the Commission rightly point out, the Directive does not use the terms 'pharmacists' and 'persons authorised or entitled to supply medicinal products to the public' consistently. While Article 1(17) and the first paragraph of Article 81 of the Directive use both those terms, Articles 77(2), 80(c) and 82 of the Directive refer only to the latter term.

33 If pharmacists were excluded from the class of persons authorised or entitled to supply medicinal products to the public, wholesale distributors of medicinal products would not be able, under Article 80(c) of the Directive, to supply medicinal products to them because pharmacists are not referred to in that provision. However, Articles 1(17) and 81 of the Directive expressly refer to pharmacists and to persons authorised or entitled to supply medicinal products to the public as persons to whom medicinal products are supplied by wholesale distribution.

34 The only exemption from the requirement to obtain such authorisation is provided for in Article 77(3) of the Directive for holders of a manufacturing authorisation. It should be noted in that connection that the rules on the manufacture of medicinal products were harmonised under Title IV of the Directive.

35 In particular, while, under Article 40(1) of the Directive, the manufacture of medicinal products is subject in general to the requirement to obtain an authorisation, the second subparagraph of Article 40(2) of the Directive provides that the manufacturing authorisation is not required for preparation, dividing up, changes in packaging or presentation 'where these processes are carried out, solely for retail supply, by pharmacists in dispensing pharmacies or by persons legally authorised in the Member States to carry out such processes'. It follows that, where such manufacturing processes are not carried out for the purpose of the retail supply of medicinal products, pharmacists are not exempt from the requirement to hold a manufacturing authorisation, which also covers the authorisation for the wholesale distribution of medicinal products.

36 Moreover, to allow pharmacists to engage in activity as wholesale distributors in medicinal products without special authorisation would confer on them an unjustified competitive advantage vis-à-vis other persons authorised or entitled to supply medicinal products to the public, who are required, under Article 77(2) of the Directive, to apply for such authorisation.

37 The Court therefore finds that pharmacists are included in the wider class of persons authorised or entitled to supply medicinal products to the public within the meaning of Article 77(2) of the Directive and are required, if they are permitted under domestic law to engage in activity as wholesale distributors in medicinal products, to obtain the authorisation prescribed under Article 77(1).

38 That interpretation cannot be invalidated by recital 36 in the preamble to the Directive, the second sentence of which states that '[p]harmacists and persons authorised to supply medicinal products to the public, and who confine themselves to this activity, should be exempt from obtaining this authorisation'.

39 It is apparent from that wording that only pharmacists and persons authorised to supply medicinal products to the public 'who confine themselves to this activity' — that is, who do not engage in activity as wholesale distributors in medicinal products — are exempt from the requirement to obtain a special authorisation. There is therefore no contradiction between recital 36 and Article 77(2) of the Directive, as claimed by the referring court.

40 In any event, the preamble to a European Union act has no binding legal force and cannot be relied on either as a ground for derogating from the actual provisions of the act in question or for interpreting them in a manner clearly contrary to their wording (Case C-308/97 *Manfredi* [1998] ECR I-7685, paragraph 30; Case C-136/04 *Deutsche Milch-Kontor* [2005] ECR I-10095, paragraph 32; and Case C-134/08 *Tyson Parketthandel* [2009] ECR I-2875, paragraph 16).

41 It follows from the foregoing that the answer to Question 1 is that Article 77(2) of the Directive 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.

Question 2

42 By its second question, the Tribunale di Palermo asks, in essence, whether pharmacists who are also authorised under domestic law to operate as wholesalers 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 76 to 84 of the Directive or whether it is sufficient for them to fulfil the conditions laid down by domestic law for the retail of medicinal products.

43 As a preliminary point, it should be noted that the conditions applicable to the supply of medicinal products to the public are not harmonised under European Union law as it currently stands. Accordingly, Member States may impose conditions for supplying medicinal products to the public within the limits laid down in the FEU Treaty (see recital 21 in the preamble to Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products (OJ 2011 L 174, p. 74)). Consequently, the regime applicable to persons entrusted with the retail supply of medicinal products varies from one Member State to another (Case C-531/06 *Commission* v *Italy* [2009] ECR I-4103, paragraph 38).

44 On the other hand, the minimum requirements to be satisfied by applicants for and holders of authorisation for the wholesale distribution of medicinal products are harmonised by the Directive, in particular in Article 79 to 82 of the Directive. Question 2 must therefore be considered in the light of those provisions.

45 Thus, Article 79 of the Directive provides that the granting of authorisation to operate as a wholesaler in medicinal products is contingent on the existence of suitable premises, installations and equipment and qualified staff, so as to ensure proper conservation and distribution of the medicinal products.

46 Checks are carried out during the period in which that authorisation is held to ensure that the conditions for the granting thereof are satisfied. There are further requirements, set out in Articles 80 to 82 of the Directive, which the holder of the authorisation must comply with, including those relating to the documentation of transactions, the supply of medicinal products and compliance with the principles and guidelines relating to good distribution practice.

47 Given that the retail of medicinal products has different characteristics from the wholesale distribution of such products, it cannot be presumed from the simple fact that pharmacists satisfy the conditions governing retail supply in their respective Member States that they also satisfy the conditions laid down by harmonised rules at European Union level for wholesale distribution.

48 Accordingly, in order to ensure that the Directive's objectives are achieved, in particular those relating to the protection of public health, the removal of barriers to trade in medicinal products within the European Union and the need to exercise control over the entire chain of distribution of medicinal products, referred to in recitals 2 to 5 and 35 in the preamble to the Directive, the minimum requirements for the wholesale distribution of medicinal products must be fulfilled in a uniform and effective manner by all persons who engage in that activity in all Member States.

49 That conclusion 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.

50 Consequently, the answer to Question 2 is that 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 the Directive.

The obligation to interpret national law in conformity with European Union law in criminal matters

51 It should be noted, as correctly pointed out by the Commission, that even though national courts are required to interpret domestic law, so far as possible, in light of the wording and purpose of a Directive in order to achieve the result sought by the Directive and, accordingly, to comply with the third paragraph of Article 288 TFEU, that obligation to interpret national law in conformity with European Union law is subject to certain limits in criminal matters.

52 As the Court has held, the principle of interpreting national law in conformity with European Union law is limited by general principles of law which form part of the European Union legal system, in particular, the principles of legal certainty and non-retroactivity. Thus, a directive cannot, of itself and independently of a national law adopted by a Member State for its implementation, have the effect of determining or aggravating the liability in criminal law of persons who act in contravention of the provisions of that directive (see, inter alia, Case C-60/02 *X* [2004] ECR I-651, paragraph 61 and the case-law cited).

53 In the present case, it is apparent from the order for reference that the criminal liability of Mr Caronna derives from the offence set out in and governed by Article 147(4) of Decree 219/2006, read in conjunction with Article 100(1) and (1a) of that decree, even though the former provision does not expressly refer to pharmacists, notwithstanding the removal of the prohibition on pharmacists engaging in activity as wholesale distributors in medicinal products.

54 However, it is not for the Court to interpret domestic law, that being exclusively a matter for the national court.

55 If the referring court were to reach the conclusion that national law, in the version applicable at the material time in the main proceedings, did not require pharmacists to obtain special authorisation for the wholesale distribution of medicinal products and contained no express provision under which pharmacists were 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, would prohibit the imposition of criminal penalties for such conduct, even if the national rule were contrary to European Union law (see, by analogy, *X*, paragraph 63).

56 Accordingly, the interpretation of the Directive, as is apparent from paragraphs 41 and 50 above, 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.

Costs

57 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Second Chamber) hereby rules:

1. **Article 77(2) of 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, as amended by Commission Directive 2009/120/EC of 14 September 2009, 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.**

2. **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 the Directive.**

3. **That interpretation 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.**

[Signatures]