Reports of Cases

JUDGMENT OF THE COURT (Fifth Chamber)

5 February 2015 *

(Request for a preliminary ruling — Drug precursors — Monitoring of trade between the Member States — Regulation (EC) No 273/2004 — Monitoring of trade between the European Union and third countries — Regulation (EC) No 111/2005 — Trade in medicinal products containing ephedrine or pseudoephedrine — Definition of 'scheduled substance' — Composition — Exclusion of all medicinal products or only those containing scheduled substances and the composition of which does allow those substances to be readily extracted — Directive 2001/83/EC — Definition of 'medicinal product')

In Joined Cases C-627/13 and C-2/14,

REQUESTS for a preliminary ruling under Article 267 TFEU from the Bundesgerichtshof (Germany), made by decisions of 22 October and 5 December 2013, received at the Court on 2 December 2013 and 3 January 2014 respectively, in criminal proceedings against

Miguel M. (C-627/13),

and

Thi Bich Ngoc Nguyen,

Nadine Schönherr (C-2/14),

THE COURT (Fifth Chamber),

composed of T. von Danwitz, President of the Chamber, C. Vajda, A. Rosas, E. Juhász and D. Šváby (Rapporteur), Judges,

Advocate General: M. Szpunar,

Registrar: A. Calot Escobar,

having regard to the written procedure,

after considering the observations submitted on behalf of:

— the Generalbundesanwalt beim Bundesgerichtshof, by H. Range, acting as Agent,

— the Spanish Government, by L. Banciella Rodríguez-Miñón, acting as Agent,

— the Portuguese Government, by L. Inez Fernandes and A.P. Antunes, acting as Agents,

— the European Commission, by T. Maxian Rusche and K. Talabér-Ritz, acting as Agents,

* Language of the case: German.

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

gives the following

Judgment

1 These requests for a preliminary ruling concern the interpretation of Article 2(a) of Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors (OJ 2004 L 47, p. 1) and of Article 2(a) of Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors (OJ 2005 L 22, p. 1).

2 The requests have been made in appeal proceedings on a point of law brought against judgments delivered by German criminal courts which found Mr M. and Ms Nguyen and Ms Schönherr guilty of having participated, as a perpetrator or accomplice, in the illicit trade of a 'basic substance' intended for use in the illegal manufacture of narcotic drugs.

Legal context

International law

3 Headed 'Substances frequently used in the illicit manufacture of narcotic drugs or psychotropic substances', Article 12 of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, concluded in Vienna on 20 December 1988 (*United Nations Treaty Series*, vol. 1582, No 1-27627) and approved by Council Decision 90/611/EEC of 22 October 1990 (OJ 1990 L 326, p. 56) ('the 1988 United Nations Convention'), provides in paragraph (1) that '[t]he Parties shall take the measures they deem appropriate to prevent diversion of substances in Table I and Table II used for the purpose of illicit manufacture of narcotic drugs or psychotropic substances, and shall co-operate with one another to this end'.

4 Article 12(14) of that convention states:

'The provisions of this article shall not apply to pharmaceutical preparations, nor to other preparations containing substances in Table I or Table II that are compounded in such a way that such substances cannot be easily used or recovered by readily applicable means.'

5 Ephedrine and pseudoephedrine are among the substances listed in Table I of the 1988 United Nations Convention.

European Union law

Directive 2001/83

6 As evidenced by recitals 2 and 3 in the preamble to 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 Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 (OJ 2006 L 378, p. 1) ('Directive 2001/83'), its essential aim is to safeguard public health by means which will not hinder the development of the pharmaceutical industry or trade in medicinal products within the European Union.

7 Recitals 6, 29, 32 and 35 in the preamble to that directive are worded as follows:

‘(6) In order to reduce the disparities which remain, rules should be laid down on the control of medicinal products and the duties incumbent upon the Member States’ competent authorities should be specified with a view to ensuring compliance with legal requirements.

...

(29) The conditions governing the supply of medicinal products to the public should be harmonised.

...

(32) It is therefore appropriate, as an initial step, to harmonise the basic principles applicable to the classification for the supply of medicinal products in the Community or in the Member State concerned, while taking as a starting point the principles already established on this subject by the Council of Europe as well as the work of harmonisation completed within the framework of the United Nations, concerning narcotic and psychotropic substances.

...

(35) It is necessary to exercise control over the entire chain of distribution of medicinal products, from their manufacture or import into the Community 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.’

8 Article 1(2) of that directive provides:

‘For the purposes of this Directive, the following terms shall bear the following meanings:

(2) Medicinal product:

(a) [a]ny substance or combination of substances presented as having properties for treating or preventing disease in human beings; or

(b) [a]ny substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.’

9 Article 2(2) of that directive, which comes under Title II thereof, entitled ‘Scope’, provides:

‘In cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a “medicinal product” and within the definition of a product covered by other Community legislation the provisions of this Directive shall apply.’

10 Article 6(1) of that directive is worded as follows:

‘No medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State in accordance with this Directive or an authorisation has been granted in accordance with Regulation (EC) No 726/2004 [of the European Parliament and of the Council of 31 March 2004 laying down Community

procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ 2004 L 126, p. 1)], read in conjunction with Regulation … No 1901/2006 …'

11 Under Title IV of Directive 2001/83, headed 'Manufacture and importation', Articles 40 to 53 of that directive provide that Member States are to take all appropriate measures to ensure that the manufacture of the medicinal products within their territory is subject to the holding of an authorisation, which authorisation is to be required even when the medicinal products manufactured are intended for export, and lay down the criteria and detailed rules for granting that authorisation.

12 Article 71(1) of that directive provides:

'Medicinal products shall be subject to medical prescription where they:

...

— are frequently and to a very wide extent used incorrectly, and as a result are likely to present a direct or indirect danger to human health, …

...'

13 Articles 77 to 81 of that same directive provide that 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, and lay down the criteria and detailed rules for granting that authorisation.

14 Under Article 80(b) and (c) of Directive 2001/83:

'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;

…'

Regulations Nos 273/2004 and 111/2005

15 In order to avoid the misuse of the substances frequently used for the illicit manufacture of narcotic drugs or psychotropic substances and to comply with the requirements laid down in Article 12 of the 1988 United Nations Convention, the EU legislature adopted internal and external monitoring and control measures, defined by Regulations Nos 273/2004 and 111/2005 respectively.

– Regulation No 273/2004

16 Recital 13 in the preamble to Regulation No 273/2004 reads:

‘A significant number of other substances, many of them traded legally in large quantities, have been identified as precursors to the illicit manufacture of synthetic drugs and psychotropic substances. To subject these substances to the same strict controls as those listed in Annex I would present an unnecessary obstacle to trade involving licences to operate and documentation of transactions. Therefore, a more flexible mechanism at Community level should be established whereby the competent authorities in the Member States are notified of such transactions.’

17 Article 2 of that regulation provides inter alia:

‘For the purposes of this Regulation:

(a) “scheduled substance” means any substance listed in Annex I, including mixtures and natural products containing such substances. This excludes medicinal products as defined by [Directive 2001/83], pharmaceutical preparations, mixtures, natural products and other preparations containing scheduled substances that are compounded in such a way that they cannot be easily used or extracted by readily applicable or economically viable means’.

18 Article 3(2) and (3) of that regulation provides:

‘2. Operators shall be required to obtain a licence from the competent authorities before they may possess or place on the market scheduled substances of category 1 of Annex I. …

3. Any operator holding a licence referred to in paragraph 2 shall supply scheduled substances of category 1 of Annex I only to natural or legal persons who hold such a licence and have signed a customer declaration as provided for in Article 4(1).’

19 Annex I to that same regulation contains the complete list of ‘scheduled substances’ within the meaning of Article 2(a) thereof, including, in Category 1, ephedrine and pseudoephedrine.

– Regulation No 111/2005

20 The definition of ‘scheduled substance’ in Article 2(a) of Regulation No 111/2005 is, in essence, identical to the one in Article 2(a) of Regulation No 273/2004.

21 Article 6(1) of that regulation states that ‘[o]perators established in the Community, other than customs agents and transporters when acting solely in that capacity, engaged in import, export or intermediary activities involving scheduled substances listed in Category 1 of the Annex, shall hold a licence. …’

22 The Annex to Regulation No 111/200, referred to in Article 2(a) of that regulation is also, in essence, identical to Regulation No 273/2004.

Regulations Nos 1258/2013 and 1259/2013

23 The definition of ‘scheduled substance’ in Articles 2(a) of Regulations Nos 273/2004 and 111/2005 was amended by Regulation (EU) No 1258/2013 of the European Parliament and of the Council of 20 November 2013 (OJ 2013 L 330, p. 21) and Regulation (EU) No 1259/2013 of the European

Parliament and of the Council of 20 November 2013 (OJ 2013 L 330, p. 30). However, as those regulations entered into force only on 30 December 2013, they are not applicable to the disputes in the main proceedings.

German law

24 Paragraph 1(1) of the Law on the monitoring of the trafficking in precursors which may be misused for the illicit manufacture of narcotics (Gesetz zur Überwachung des Verkehrs mit Grundstoffen, die für die unerlaubte Herstellung von Betäubungsmitteln missbraucht werden können) ('the GÜG') defines 'basic substance' as a 'scheduled substance' within the meaning of Article 2(a) of Regulation No 273/2004, read in conjunction with Annex I thereof and of Article 2(a) of Regulation No 111/2005, read in conjunction with the annex thereto.

25 Article 3 of the GÜG provides that 'it is prohibited to hold, manufacture, put on the market or, without putting it on the market, to import or export, put into transit or transport under this Law, sell, transfer a basic substance intended to be used for the illicit manufacture of narcotics or to offer in any way the possibility to another party of actually possessing, acquiring or obtaining such a substance in any manner whatsoever.'

26 Paragraph 19 of the GÜG states:

'(1) Any person who:

1. contrary to Paragraph 3, possesses, manufactures or puts into trade or, without putting it into trade, imports or exports, circulates or transports within the meaning of the present law, sells or transfers a basic substance or makes it possible in any manner for another party effectively to dispose thereof, acquires or obtains such a substance in any manner whatsoever,

shall be subject to a prison sentence of a maximum of five years and a fine.

...'

Procedure before the Court

27 By decision of the President of the Court of 20 January 2014, Cases C-627/13 and C-2/14 were joined for the purposes of the written and oral procedure and the judgment.

28 In Case C-2/14 *Nguyen and Schönherr*, the referring court, in its request for a preliminary ruling, requested the application of the provision of Article 105 of the Rules of Procedure of the Court on the expedited procedure.

29 As there was no urgency, that request was rejected by order of the President of the Court in *Nguyen and Schönherr* (C-2/14, EU:C:2014:1999).

30 The President of the Court of Justice decided on 8 January and 20 January 2014 respectively that Cases C-627/13 and C-2/14 were to be given priority pursuant to Article 53(3) of the Rules of Procedure.

The actions in the main proceedings and the question referred for a preliminary ruling

Case C-627/13

31 Through Mr M., between 15 June 2007 and 6 October 2008 a company based in Brussels (Belgium) shipped to Belize and Mexico ephedrine tablets legally produced and intended for use as medicinal products. However, already before those shipments were undertaken, Mr M. was aware that the tablets, which contained a 4.179 kilograms of ephedrine hydrochloride, were to be used for the production of methamphetamine.

32 By judgment of 23 January 2013, the Landgericht Krefeld (Regional Court, Krefeld), on the basis of Paragraph 19(1)(1) of the GÜG, read in conjunction with Paragraph 1(1) and (3) of that law, sentenced Mr M. to a total of three years and three months' imprisonment for trade in 'basic substances' intended for use in the illicit manufacture of narcotic drugs and decided to divest the offender of the assets which he had obtained as a result of the offence.

33 In the appeal proceedings on a point of law brought by Mr M. against that judgment, the Bundesgerichtshof (Federal Supreme Court) observes that the criminal nature of the facts turns on whether or not the medicinal products in question, about which it is common ground that they contain a substance listed in Category 1 of the relevant annexes to Regulations Nos 273/2004 and 111/2005, come within the scope of those regulations.

34 In that regard, the Bundesgerichtshof observes that 'basic substance' within the meaning of Paragraph 1(1) of the GÜG is defined by reference to the definition of 'scheduled substance' in Article 2(a) of Regulations Nos 273/2004 and 111/2005 and that the formulation of the latter provision is not unequivocal.

35 A grammatical reading of the German version of that provision could tend to indicate instead that the medicinal products are excluded from the scope of those regulations only where they are compounded in such a way that the scheduled substances cannot be easily used or extracted by readily applicable or economically viable means, as it has previously been interpreted by certain German courts. None of the other language versions provides any decisive guidance.

36 Conversely, the historical and teleological interpretation of the regulations could, rather, support the view that medicinal products are always excluded as such from the definition of 'scheduled substances', which is apparent from both the 1988 United Nations Convention which Regulations Nos 273/2004 and 111/2005 serve to implement, and the directives which preceded those regulations. This is also true of the European Commission's interpretation in certain non-binding documents as well as draft amendments to Regulations Nos 273/2004 and 111/2005.

37 In those circumstances, the Bundesgerichtshof has decided to stay proceedings and to refer the following question to the Court for a preliminary ruling:

'Are medicinal products, as defined in Directive 2001/83, which contain scheduled substances listed in Regulations Nos 273/2004 2 and 111/2005 always excluded from the scope of those regulations in accordance with Article 2(a) of both those regulations, or only where the medicinal products are compounded in such a way that the scheduled substances cannot be easily used or extracted by readily applicable or economically viable means?'

Case C-2/14

38 Between August 2010 and March 2011, Ms Nguyen acquired on eight occasions, directly or indirectly in Germany and in Hungary, large quantities of medicinal products to be used in the production of the narcotic methamphetamine. Those medicinal products, which were then sent to the Czech Republic, contained a quantity of 29.5 kilograms of pseudoephedrine, from which it was possible to produce 6.5 kilograms of methamphetamine. Ms Schönherr participated, fully aware of the circumstances described, in the transport of some of those medicinal products from Germany to the Czech Republic.

39 By judgment of 13 February 2013, the Landgericht München II (Regional Court, Munich II), on the basis of Paragraph 19(1)(1) and Paragraph 19(3) of the GÜG, sentenced Ms Nguyen to a period of imprisonment of 6 years and 6 months for illicit dealing in a 'basic substance' intended for use in the illicit manufacture of narcotic drugs, whilst Ms Schönherr was sentenced to a period of imprisonment of 10 months on the basis of Paragraph 19(1)(1) and Paragraph 19(3) of the GÜG and Paragraph 27 of the German Criminal Code (Strafgesetzbuch), together with a suspended sentence for being an accessory to the illicit dealing in a basic substance intended for use in the illicit manufacture of narcotic drugs.

40 Ms Nguyen and Ms Schönherr both brought appeals on a point of law ('Revision') before the referring court. Ms Nguyen argued inter alia that the medicinal products in question could not be categorised as a 'basic substance' within the meaning of Paragraph 19(1)(1) and Paragraph 19(3) of the GÜG.

41 On the same grounds as stated in its order of 22 October 2013, the Bundesgerichtshof decided to stay the proceedings and to make a reference to the Court of Justice for a preliminary ruling on a question which is, in essence, identical to the question referred in Case C-627/13.

The question referred for a preliminary ruling

42 By its question on the two sets of main proceedings, the referring court asks, in essence, whether Articles 2(a) of Regulations Nos 273/2004 and 111/2005 respectively must be interpreted as meaning that a medicinal product, as defined in Article 1(2) of Directive 2001/83, containing a substance referred to in Annex I to Regulation No 273/2004 and in the annex to Regulation No 111/2005 and able easily to be used or extracted by readily applicable or economically viable means, must be categorised as a 'scheduled substance', or that a 'medicinal product' cannot, as such, be categorised as a 'scheduled substance'.

43 As a preliminary point, it is appropriate to bear in mind that the notion of 'scheduled substance' is defined in Articles 2(a) of Regulations Nos 273/2004 and 111/2005 as any substance listed in the relevant annexes to those regulations, including mixtures and natural products containing such substances, but excluding medicinal products as defined by Directive 2001/83, pharmaceutical preparations, mixtures, natural products and other preparations containing scheduled substances that are compounded in such a way that such substances cannot be easily used or extracted by readily applicable or economically viable means.'

44 It is apparent from that definition that the notion of 'scheduled substance', to which the GÜG refers, does not, as the referring court notes, enable it to be determined whether the exclusion of 'medicinal products' within the meaning of Directive 2001/83 from that definition is subject to the fact that the substances listed in the relevant annexes to Regulations Nos 273/2004 and 111/2005 and contained in those 'medicinal products' cannot easily be used or extracted by readily applicable or economically viable means.

45 A comparison of the different language versions of those provisions shows that certain versions, in particular the German, Greek, English, Dutch, Slovak and Swedish language versions, may permit, on a grammatical analysis thereof, the view to be taken that the 'medicinal products' within the meaning of Directive 2001/83 are not excluded from the notion of 'scheduled substance' unless they are compounded in such a way that the substances listed in the relevant annexes to Regulations Nos 273/2004 and 111/2005 which they contain cannot easily be used or extracted by readily applicable or economically viable means.

46 However, other language versions, such as the French, Italian and Portuguese versions, cannot lead to such an interpretation and exclude, per se, 'medicinal products' within the meaning of Article 1(2) of Directive 2001/83 from the definition of 'scheduled substance' within the meaning of Articles 2(a) of Regulations Nos 273/2004 and 111/2005 respectively, since the final part of the sentence of the latter definition, namely 'containing scheduled substances that are compounded in such a way that they cannot be easily used or extracted by readily applicable or economically viable means', cannot, by virtue of an interpretation based on a grammatical analysis, refer, in particular, to the medicinal products.

47 Moreover, Article 12(14) of the 1988 United Nations Convention, of which Regulations Nos 273/2004 and 111/2005 constitute the implementation into the EU legal order, cannot confirm either interpretation.

48 In such circumstances, it is settled case-law that the wording used in one language version of a provision of EU law cannot serve as the sole basis for the interpretation of that provision, or be made to override the other language versions in that regard. Provisions of EU law must be interpreted and applied uniformly in the light of the versions existing in all EU languages (judgment in *Ivansson and Others*, C-307/13, EU:C:2014:2058, paragraph 40 and the case-law cited).

49 Where there is divergence between the various language versions of an EU legislative text, the provision in question must be interpreted by reference to its context and the objectives pursued by the rules of which it is part (see, to that effect, judgment in *Kirin Amgen*, C-66/09, EU:C:2010:484, paragraph 41 and the case-law cited).

50 The express reference made by the EU legislature in Articles 2(a) of Regulations Nos 273/2004 and 111/2005 respectively to the notion of 'medicinal product' as defined by Directive 2001/83 is significant in that regard in the interpretation of those provisions.

51 Accordingly, it is necessary to take into consideration the fact that that notion constitutes, in comparison to the other notions used in that provision, namely 'pharmaceutical preparations', 'mixtures', 'natural products' and 'other preparations', the only notion which is precisely defined in another EU legislative text, in this case Directive 2001/83, the purpose of which is to regulate the production, distribution and use of the medicinal products which it covers.

52 At the same time, it is necessary to state that, by Regulations Nos 273/2004 and 111/2005, the EU legislature gives a detailed definition of the scheme applicable to drug precursors.

53 In those circumstances and while taking due account of the objectives of Regulations Nos 273/2004 and 111/2005, adopted with a view to combating effectively the misuse of substances commonly used in the illicit manufacture of narcotic drugs or psychotropic substances by putting into place a monitoring system for the trade in those substances together with effective, proportionate and dissuasive penalties, it is not possible to interpret the notion of 'scheduled substance' without consideration of the legal system applicable to medicinal products, as defined by Directive 2001/83, including the objectives and the scope thereof.

54 In that respect, as regards the legal system applicable to medicinal products within the internal market, it must be noted that Article 6(1) of Directive 2001/83 provides, in particular, that no medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that State in accordance with that directive or unless an authorisation has been issued in accordance with the centralised procedure provided for in Regulation No 726/2004 for medicinal products referred to in the annex to that regulation (judgment in *Commission* v *Poland*, C-185/10, EU:C:2012:181, paragraph 26).

55 That prior authorisation system is, moreover, supplemented by a full system of rules applicable to the manufacture, import and wholesale distribution of medicinal products, the exercise of those activities being, as is clear, in particular, from Articles 40 and 77 of Directive 2001/83, subject to the holding of an authorisation, like the approval required to hold and put on the market scheduled substances, by application of Article 3(2) of Regulation No 273/2004.

56 As regards the wholesale distribution of medicinal products, Article 80(b) and (c) of Directive 2001/83 requires, in particular, that the holder of the authorisation 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, and also 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. Such a system is comparable to that established by Article 3(3) of Regulation No 273/2004.

57 Moreover, and concerning more specifically medicinal products containing a substance referred to in Annex I to Regulation No 273/2004 and able easily to be used or extracted by readily applicable or economically viable means and as rightly pointed out by the Generalbundesanwalt beim Bundesgerichtshof, the Portuguese Government and the Commission, the second indent of Article 71(1) of Directive 2001/83 provides that medicinal products must be subject to medical prescription when they are frequently and to a very wide extent used incorrectly, and as a result are likely to present a direct or indirect danger to human health, thus enabling stricter controls on such medicinal products.

58 Thus, the authorisation and control systems put into place by the EU legislature, applicable to scheduled substances and medicinal products pursuant to Regulation No 273/2004 and Directive 2001/83 are in essence similar.

59 It is not apparent from any part of Regulation No 273/2004, in the version applicable to the facts material to the main proceedings, that it seeks to make medicinal products containing a substance referred to in Annex I thereto and able easily to be used or extracted by readily applicable or economically viable means subject to an additional authorisation and control system other than that applicable to medicinal products under Directive 2001/83.

60 That finding is corroborated by recital 13 in the preamble to Regulation No 273/2004, from which it follows that it is appropriate to limit the unnecessary obstacles to trade involving substances traded legally in large quantities, but nevertheless identified as precursors to the illicit manufacture of synthetic drugs and psychotropic substances.

61 With regard to Regulation No 111/2005, it must indeed be noted that it provides a set of precise rules which do not correspond to any in Directive 2001/83 on medicinal products. In particular, Section 5 of Chapter II of that regulation defines a specific authorisation and control system for exports of scheduled substances.

62 Having said that, it cannot be deduced from that fact alone that the EU legislature intended to make medicinal products containing a substance referred to in Annex I thereto and able easily to be used or extracted by readily applicable or economically viable means subject not only to Directive 2001/83 but also to this regulation.

63 A systematic analysis of the drug precursors system also leads to that conclusion. It is clear from Articles 2(a) of Regulations Nos 273/2004 and 111/2005 respectively that the definition of 'scheduled substance' is identical, thus excluding medicinal products which are not subject to Regulation No 273/2004 within the internal market from being subject to Regulation No 111/2005 as regards their export to third countries.

64 Thus, furthermore, it is clear from recitals 2, 3 and 7 in the preamble to Regulation No 1259/2013, amending Regulation No 111/2005, firstly, that the EU legislature considers that the trade in medicinal products, before the entry into force of that regulation, was not controlled as part of the EU drug precursors control system, medicinal products being, under the regime of the preceding legislation, excluded from the definition of 'scheduled substance'.

65 Secondly, it is also for that reason that the EU legislature decided, in the context of Regulation No 1259/2013, to make only medicinal products containing two scheduled substances, in this case ephedrine and pseudoephedrine and their salts, subject to the control system for trade in drug precursors between the EU and third countries.

66 In consequence, a product which, such as those at issue in the main proceedings, corresponds to the definition of 'medicinal product' within the meaning of Directive 2001/83, cannot be categorised as a 'scheduled substance' within the meaning of Articles 2(a) of Regulations Nos 273/2004 and 111/2005 respectively.

67 Having regard to the foregoing considerations, the answer to the question referred is that Articles 2(a) of Regulations Nos 273/2004 and 111/2005 respectively must be interpreted as meaning that a medicinal product, as defined in Article 1(2) of Directive 2001/83, cannot be categorised as a 'scheduled substance' as such, even if it contains a substance referred to in Annex I to Regulation No 273/2004 and in the annex to Regulation No 111/2005 and can easily be used or extracted by readily applicable or economically viable means.

Costs

68 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 (Fifth Chamber) hereby rules:

Articles 2(a) of Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors and of Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors respectively must be interpreted as meaning that a medicinal product as defined in Article 1(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 Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006, cannot be categorised as a 'scheduled substance' as such, even if it contains a substance referred to in Annex I to Regulation No 273/2004 and in the annex to Regulation No 111/2005 and can easily be used or extracted by readily applicable or economically viable means.

[Signatures]