Reports of Cases

ORDER OF THE COURT (Eighth Chamber)

2 March 2017 *

(Reference for a preliminary ruling — Article 99 of the Rules of Procedure of the Court of Justice — Drug precursors — Regulation (EC) No 273/2004 — Article 2(a) — Definition of 'scheduled substance' — Exclusion of medicinal products — Directive 2001/83/EC — Article 1(2) — Definition of 'medicinal product' — Medicinal product containing ephedrine or pseudoephedrine — Regulation (EC) No 111/2005 — Article 2(a) — Definition of 'scheduled substance' — Annex — Inclusion of medicinal products containing ephedrine or pseudoephedrine — No effect on the scope of Regulation (EC) No 273/2004)

In Case C-497/16,

REQUEST for a preliminary ruling under Article 267 TFEU from the Nejvyšší soud (Supreme Court, Czech Republic), made by decision of 25 August 2016, received at the Court on 16 September 2016, in the criminal proceedings against

Juraj Sokáč,

THE COURT (Eighth Chamber),

composed of M. Vilaras, President of the Chamber, M. Safjan and D. Šváby (Rapporteur), Judges,

Advocate General: M. Szpunar,

Registrar: A. Calot Escobar,

having decided, after hearing the Advocate General, to give a decision by reasoned order, in accordance with Article 99 of the Rules of Procedure of the Court of Justice,

makes the following

Order

1 The present request for a preliminary ruling concerns 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), as 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; 'Regulation No 273/2004').

2 The request has been made in criminal proceedings brought against Mr Juraj Sokáč for drug-related crimes and offences.

* * Language of the case: Czech.

Legal context

EU law

Directive 2001/83

3 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 (OJ 2001 L 311, p. 67), as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 (OJ 2004 L 136, p. 34; 'Directive 2001/83') provides:

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

2. Medicinal product:
   (a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or
   (b) Any 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.'

Regulation No 273/2004

4 Article 1 of Regulation No 273/2004 states:

'This Regulation establishes harmonised measures for the intra-Union control and monitoring of certain substances frequently used for the illicit manufacture of narcotic drugs or psychotropic substances with a view to preventing the diversion of such substances.'

5 Article 2(a) of that regulation defines 'scheduled substance' as 'any substance listed in Annex I that can be used for the illicit manufacture of narcotic drugs or psychotropic substances, including mixtures and natural products containing such substances but excluding mixtures and natural products which contain scheduled substances and which are compounded in such a way that the scheduled substances cannot be easily used or extracted by readily applicable or economically viable means, medicinal products as defined in point 2 of Article 1 of Directive [2001/83] and veterinary medicinal products as defined in point 2 of Article 1 of Directive 2001/82/EC of the European Parliament and of the Council [of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ 2001 L 311, p. 1)].

6 That definition was laid down in the amendment to Regulation No 273/2004 by Regulation No 1258/2013, which entered into force on 30 December 2013. Recital 4 of the latter regulation states:

'This Regulation clarifies the definition of a scheduled substance: in this regard, the term "pharmaceutical preparation", which stems from the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances adopted in Vienna on 19 December 1988, is deleted as it is already covered by the relevant terminology of Union legal acts, namely "medicinal products". Moreover, the term "other preparations" is deleted as it duplicates the term "mixtures" already used in that definition.'

7 Since its original version, Annex I to Regulation No 273/2004 has contained an exhaustive list of 'scheduled substances', within the meaning of Article 2(a) of that regulation, which includes, under Category 1, ephedrine and pseudoephedrine.

Regulation No 111/2005

8 The first paragraph of Article 1 of Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Union and third countries in drug precursors (OJ 2005 L 22, p. 1), as amended by Regulation (EU) No 1259/2013 of the European Parliament and of the Council of 20 November 2013 (OJ 2013 L 330, p. 30; 'Regulation No 111/2005') provides:

'This Regulation lays down rules for the monitoring of trade between the Union and third countries in certain substances frequently used for the illicit manufacture of narcotic drugs and psychotropic substances … for the purpose of preventing the diversion of such substances. It applies to imports, exports and intermediary activities.'

9 Article 2(a) of that regulation defines 'scheduled substance' as 'any substance listed in the Annex that can be used for the illicit manufacture of narcotic drugs or psychotropic substances, including mixtures and natural products containing such substances, but excluding mixtures and natural products which contain scheduled substances and which are compounded in such a way that the scheduled substances cannot be easily used or extracted by readily applicable or economically viable means, medicinal products as defined in point 2 of Article 1 of Directive [2001/83], and veterinary medicinal products as defined in point 2 of Article 1 of Directive [2001/82], except medicinal products and veterinary medicinal products listed in the Annex'.

10 Since its original version, the Annex to Regulation No 111/2005 has contained an exhaustive list of 'scheduled substances', within the meaning of Article 2(a) of that regulation, which includes, under Category 1, ephedrine and pseudoephedrine.

11 Recitals 2, 3 and 7 of Regulation No 1259/2013 state:

'(2) Trade in medicinal products is not controlled in the existing Union control system for drug precursors, since they are currently excluded from the definition of scheduled substances.

(3) The Commission report pointed out that medicinal products containing ephedrine and pseudoephedrine were diverted into the illicit drug manufacture outside the Union, as a substitute for internationally controlled ephedrine and pseudoephedrine. The Commission therefore recommended strengthening the control of international trade in medicinal products containing ephedrine or pseudoephedrine exported from or transiting through the customs territory of the Union in order to prevent their diversion for the illicit manufacture of narcotic drugs or psychotropic substances.

…

(7) Medicinal products and veterinary medicinal products … containing ephedrine or pseudoephedrine should be controlled without impeding their legitimate trade. To that end, a new category (Category 4) should be added to the Annex to Regulation (EC) No 111/2005 listing medicinal products containing certain scheduled substances.'

12 Since the entry into force of Regulation No 1259/2013, the Annex to Regulation No 111/2005 includes a new category of scheduled substances, namely Category 4, which covers 'medicinal products and veterinary medicinal products containing ephedrine or its salts' and 'medicinal products and veterinary medicinal products containing pseudo-ephedrine or its salts'.

Czech law

13 Paragraph 283(1) of the Criminal Code reads:

‘Any person who produces, imports, exports, transports, offers, provides, sells or otherwise supplies to another person or receives on behalf of another person, any narcotic drug or psychotropic substance, preparations containing narcotic drugs or psychotropic substances, precursors or poison, without authorisation, shall be subject to a custodial sentence of from one to five years or a fine.’

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

14 By judgment of 20 August 2015, the Obvodní soud pro Prahu 7 (Prague District Court 7, Czech Republic) found Mr Sokáč guilty, first, of the offence of obstruction of the implementation of a decision of the national authorities and obstruction of a removal order, and, secondly, of criminal offenses on the basis that he had unlawfully manufactured and otherwise engaged in transactions relating to narcotic drugs, psychotropic substances and poisons under the Czech Criminal Code. He was sentenced to a total of two years’ imprisonment and four years’ exclusion from the Czech Republic. As a security measure, 120 tablets of the medicinal product Nurofen Stopgrip, which he had in his possession, were also seized.

15 Following a linguistic analysis of the definition of ‘scheduled substance’, within the meaning of Article 2(a) of Regulation No 273/2004, the Obvodní soud pro Prahu 7 (Prague District Court 7) came to the conclusion that ‘medicinal products’, within the meaning of Directive 2001/83, which contain a ‘scheduled substance’, within the meaning of that provision, constitute drug precursors. In that regard, that court relied on Regulation No 111/2015, which expressly includes in its scope medicinal products containing ephedrine or pseudoephedrine. Accordingly, it concluded that the term ‘scheduled substance’, within the meaning of Regulation No 273/2004, should also be interpreted as covering, inter alia, medicinal products containing ephedrine and pseudoephedrine, notwithstanding the fact that the Annex to that regulation, which lists scheduled substances, does not expressly mention those medicinal products as such.

16 By judgment of 15 October 2015, the Městský soud v Praze (Prague City Court, Czech Republic) varied the judgment of the Obvodní soud pro Prahu 7 (Prague District Court 7), first, in so far as that decision relates to Mr Sokáč being found guilty of unlawfully manufacturing and otherwise engaging in transactions relating to narcotic drugs, psychotropic substances and poisons, and, secondly, in relation to the whole of the operative part concerning the sentence and the security measure imposed. Nevertheless, the Městský soud v Praze (Prague City Court) imposed the same sanctions on Mr Sokáč, on the basis of the same provisions of the Criminal Code, as those applied by the Obvodní soud pro Prahu 7 (Prague District Court 7).

17 Mr Sokáč brought an appeal on a point of law before the referring court, the Nejvyšší soud (Supreme Court, Czech Republic), against the judgment of the Městský soud v Praze (Prague City Court). In support of that appeal, he maintains, inter alia, that the product which was the object of the security measure, the medicinal product Nurofen Stopgrip, which contains pseudoephedrine, is not a drug precursor within the meaning of Regulation No 273/2004 and is excluded from the scope of that regulation. Accordingly, Mr Sokáč claims that the Městský soud v Praze (Prague City Court) erred in finding him guilty, on the basis of that regulation, of possessing a drug precursor.

18 In that context, the referring court observes, first, that the scope of Regulation No 111/2005 is different from that of Regulation No 273/2004 and, secondly, that, even though Regulation No 111/2005 provides for an exception relating to medicinal products containing ephedrine and pseudoephedrine, that exception does not appear in Regulation No 273/2004.

19 Furthermore, the referring court observes that it is not clear from the different language versions, in German, English, Polish and Slovak, of Article 2(a) of Regulation No 273/2004, whether medicinal products containing such a substance may be classified as 'drug precursors', within the meaning of that regulation.

20 In those circumstances, the Nejvyšší soud (Supreme Court) decided to stay the proceedings and to refer the following question to the Court for a preliminary ruling:

'Can "medicinal products", as defined in Directive [2001/83], which contain "scheduled substances", within the meaning of [Regulation No 273/2004], be regarded as excluded, on the basis of Article 2(a) of that regulation, from the scope of the regulation, in accordance with the judgment of the Court of Justice of the European Union of 5 February 2015, *M. and Others* [C-627/13 and C-2/14, EU:C:2015:59], even after amendment of that provision by Regulation No 1258/2013 and in view of the fact that Article 2(a) of [Regulation No 111/2005] brings medicinal products containing ephedrine and pseudoephedrine within the scope of Regulation No 111/2005?'

Consideration of the question referred

21 By its question, the referring court asks, essentially, whether 'medicinal products', within the meaning of Article 1(2) of Directive 2001/83, containing 'scheduled substances', within the meaning of Article 2(a) of Regulation No 273/2004, such as ephedrine and pseudoephedrine, remain excluded from the scope of that regulation following the entry into force of Regulations Nos 1258/2013 and 1259/2013.

22 Under Article 99 of its Rules of Procedure, where a question referred to the Court for a preliminary ruling is identical to a question on which the Court has already ruled, where the reply to such a question may be clearly deduced from existing case-law, or where the answer to the question referred for a preliminary ruling admits of no reasonable doubt, the Court may at any time, on a proposal from the Judge-Rapporteur and after hearing the Advocate General, decide to rule by reasoned order.

23 It is appropriate to apply that provision in the present case.

24 The Court has previously been called upon to clarify the scope of the term 'scheduled substance' within the meaning of the original versions of Regulations Nos 273/2004 and 111/2005. The Court concluded that the definition of that term was identical in both of those regulations and held that 'medicinal products', within the meaning of Article 1(2) of Directive 2001/83, containing a substance included in Annex I to Regulation No 273/2004, were excluded from the definition of 'scheduled substance' within the meaning of Article 2(a) of both Regulation No 273/2004 and Regulation No 111/2005 (see, to that effect, judgment of 5 February 2015, *M. and Others*, C-627/13 and C-2/14, EU:C:2015:59, paragraphs 63 and 67).

25 The definition of the term 'scheduled substances' in Article 2(a) of Regulation No 273/2004 and Article 2(a) of Regulation No 111/2005 derives from the amendments made to those provisions by, respectively, Regulation No 1258/2013 and Regulation No 1259/2013.

26 In essence, the following modifications have been made. First, it has been specified that 'scheduled substances' are substances which can be used for the illicit manufacture of narcotic drugs or psychotropic substances. Secondly, that definition now also excludes 'veterinary medicinal products', within the meaning of Directive 2001/82. Thirdly, 'pharmaceutical preparations' and 'other preparations', inter alia, have been removed from the scope of the definition since they are already covered by 'medicinal products' or are duplicates of the term 'mixtures' already used in the definition. Fourthly, the Union legislature has changed the order in which the various products excluded from the definition of 'scheduled substances' are presented.

27 Nevertheless, with specific regard to Regulation No 111/2005, even though, following the amendment made to that regulation by Regulation No 1259/2013, Article 2(a) of Regulation No 111/2005 excludes, as did Regulation No 273/2004, 'veterinary medicinal products as defined in point 2 of Article 1 of Directive [2001/82]', it nevertheless includes an exception as regards 'medicinal products and veterinary medicinal products listed in the Annex'. A new category, namely Category 4, has also been added to the list of scheduled substances set out in the Annex to Regulation No 111/2005, which includes 'medicinal products and veterinary medicinal products containing ephedrine or its salts' and 'medicinal products and veterinary medicinal products containing pseudo-ephedrine or its salts'.

28 It follows from the foregoing considerations that, as regards the definition of 'scheduled substance' in Article 2(a) of Regulation No 273/2004, the original version of which already expressly excluded 'medicinal products as defined in Directive [2001/83]', the amendment made to that provision by Regulation No 1258/2013 was merely intended to clarify that term, as is clear from recital 4 of that regulation, and did not, in any way, affect the exclusion of 'medicinal products' from the scope of that definition.

29 It is therefore undoubtedly clear from the wording of Article 2(a) of Regulation No 273/2004 that 'medicinal products', within the meaning of Directive 2001/83, cannot, per se, be regarded as 'scheduled substances', as defined in that provision, as the Court previously held in its judgment of 5 February 2015, *M. and Others* (C-627/13 and C-2/14, EU:C:2015:59), in relation to the original version of Regulation No 273/2004.

30 That finding cannot be called into question by the fact that Regulation No 1259/2013 added medicinal products containing ephedrine and pseudoephedrine to the definition of 'scheduled substance', in Article 2(a) of Regulation No 111/2005.

31 In that regard, it should be borne in mind that, as the Nejvyšší soud (Supreme Court) rightly noted, the respective fields of application of Regulations Nos 273/2004 and 111/2005 are different.

32 Although it is true that the objective of both those regulations is to combat the diversion of substances commonly used in the illicit manufacture of narcotic drugs and psychotropic substances, it is clear from Article 1 of Regulation No 273/2004 that that regulation establishes harmonised measures across Member States for the control and monitoring of such substances, whereas Article 1 of Regulation No 111/2005 lays down rules for monitoring trade in those substances between the Union and third countries.

33 It is clear from recitals 2, 3 and 7 of Regulation No 1259/2013 that before the entry into force of that regulation, medicinal products were excluded from the definition of 'scheduled substance', within the meaning of Regulation No 111/2005, and, therefore, were not subject to the system for controlling international trade established by Regulation No 111/2005. The intention of the Union legislature was, through the amendments made to Regulation No 111/2005 by Regulation No 1259/2013, to strengthen the control of trade in medicinal products containing ephedrine or pseudoephedrine exported from or transiting through the customs territory of the Union, without impeding legitimate trade in those products, in order to prevent their diversion for the illicit manufacture of narcotic drugs or psychotropic substances, given that medicinal products containing those two substances are being diverted for the purpose of illicit drug manufacture outside the Union (see, to that effect, judgment of 5 February 2015, *M. and Others*, C-627/13 and C-2/14, EU:C:2015:59, paragraphs 64 and 65).

34 Accordingly, the amendment of Regulation No 111/2005 by Regulation No 1259/2013 cannot influence the interpretation of Article 2(a) of Regulation No 273/2004, according to which all 'medicinal products', within the meaning of Directive 2001/83, including those containing ephedrine and pseudoephedrine, are excluded from the definition of 'scheduled substance', in Article 2(a) of Regulation No 273/2004.

35 In those circumstances, the answer to the question referred is that 'medicinal products', within the meaning of Article 1(2) of Directive 2001/83, containing 'scheduled substances', within the meaning of Article 2(a) of Regulation No 273/2004, such as ephedrine and pseudoephedrine, remain excluded from the scope of that regulation following the entry into force of Regulations Nos 1258/2013 and 1259/2013.

Costs

36 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.

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

'Medicinal products', within the meaning of 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 Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004, which contain 'scheduled substances', within the meaning 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, as amended by Regulation (EU) No 1258/2013 of the European Parliament and of the Council of 20 November 2013, such as ephedrine and pseudoephedrine, remain excluded from the scope of Regulation No 273/2004 following the entry into force of Regulation No 1258/2013 and Regulation (EU) No 1259/2013 of the European Parliament and of the Council of 20 November 2013 amending Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Union and third countries in drug precursors.

[Signatures]