Reports of Cases

JUDGMENT OF THE COURT (Fourth Chamber)

10 July 2014*

(Medicinal products for human use — Directive 2001/83/EC — Scope — Interpretation of the concept of 'medicinal product' — Scope of the criterion based on the capacity to modify physiological functions — Herb and cannabinoid-based products — Not included)

In Joined Cases C-358/13 and C-181/14,

REQUESTS for a preliminary ruling under Article 267 TFEU from the Bundesgerichtshof (Germany), made by decisions of 28 May 2013 and 8 April 2014, received at the Court on 27 June 2013 and 14 April 2014, respectively, in the criminal proceedings against

Markus D. (C-358/13)

and

G. (C-181/14),

THE COURT (Fourth Chamber),

composed of L. Bay Larsen, President of the Chamber, M. Safjan, J. Malenovský (Rapporteur), A. Prechal and K. Jürimäe, Judges,

Advocate General: Y. Bot,

Registrar: K. Malacek, Administrator,

having regard to the order of the President of the Court in relation to G. (Case C-181/14, EU:C:2014:740) that Case C-181/14 is to be determined pursuant to the expedited procedure provided for in Article 23a of the Statute of the Court of Justice of the European Union and Article 105(1) of the Rules of Procedure of the Court of Justice,

having regard to the written procedure and further to the hearing on 14 May 2014,

after considering the observations submitted on behalf of:

— Mr D., by B. Engel, Rechtsanwalt,

— the Generalbundesanwalt beim Bundesgerichtshof, by H. Range, S. Ritzert, and S. Heine, acting as Agents,

— the German Government, by T. Henze and B. Beutler, acting as Agents,

* Language of the case: German.

— the Czech Government, by M. Smolek, S. Šindelková and D. Hadroušek, acting as Agents,

— the Estonian Government, by K. Kraavi-Käerdi and N. Grünberg, acting as Agents,

— the Italian Government, by G. Palmieri, acting as Agent, and M. Russo, avvocato dello Stato,

— the Hungarian Government, by M. Fehér, acting as Agent,

— the Finnish Government, by S. Hartikainen, acting as Agent,

— the United Kingdom Government, by S. Brighouse and S. Lee, acting as Agents,

— the Norwegian Government, by B. Gabrielsen and K. Winther, acting as Agents, and M. Schei, advokat,

— the European Commission, by B.-R. Killmann, M. Šimerdová and A. Sipos, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 12 June 2014,

gives the following

Judgment

1 These requests for a preliminary ruling concern the interpretation of the term 'medicinal product' within the meaning of Article 1(2)(b) 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').

2 The requests have been made in criminal proceedings instigated against Mr D. and Mr G., respectively, in which they have been charged with selling herb mixtures containing, inter alia, synthetic cannabinoids, which, at the material time, did not fall under the German law on narcotic drugs (Betäubungsmittelgesetz) ('the BtMG').

Legal context

EU law

Directive 2001/83

3 Recital 7 in the preamble to Directive 2001/83 is worded as follows:

'The concepts of harmfulness and therapeutic efficacy can be examined only in relation to one another and have only a relative significance, depending on the progress of scientific knowledge and the use for which the medicinal product is intended. The particulars and documents which must accompany an application for marketing authorisation for a medicinal product must demonstrate that potential risks are outweighed by the therapeutic efficacy of the product.'

4 Article 1(2) of Directive 2001/83 states that, for the purpose of the directive, the following definition is to apply:

'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'.

5 Article 4(4) of Directive 2001/83 provides as follows:

'This Directive shall not affect the application of national legislation prohibiting or restricting the sale, supply or use of medicinal products as contraceptives or abortifacients. The Member States shall communicate the national legislation concerned to the Commission.'

Directive 2004/27

6 Recital 3 in the preamble to Directive 2004/27 states as follows:

'It is … necessary to align the national laws, regulations and administrative provisions which contain differences with regard to the basic principles in order to promote the operation of the internal market while realising a high level of human health protection.'

German law

7 The Gesetz über den Verkehr mit Arzneimitteln (Law relating to trade in medicinal products) transposes Directive 2001/83 into German law. According to the information provided by the referring court, the version of that law applicable to the disputes in the main proceedings is that deriving from Article 1 of the Gesetz zur Änderung arzneimittelrechtlicher und anderer Vorschriften (Law amending the legislation governing medicinal products and other provisions) of 17 July 2009 (BGB1. 2009 I, p. 1990) ('the AMG'). Article 2 of the AMG provides as follows:

'(1) Medicinal products are substances or preparations consisting of substances:

1. which are intended for use in or on the human or animal body and are intended as remedies with properties for the treating, alleviating or preventing of human or animal diseases or pathological complaints, or

2 which may be used in or on or administered to human beings or animals with a view to either

(a) restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or

(b) making a medical diagnosis.'

…'

8 Article 4(17) of the AMG reads as follows:

‘The placing on the market is defined as possession for the purposes of sale or other form of transfer, display for the purposes of sale, offering for sale and transfer to other persons.’

9 In accordance with Article 5(1) of the AMG:

‘It is prohibited to place on the market or use in or on the human body unsafe medicinal products.’

10 Article 95 of the AMG is worded as follows:

‘(1) Any person shall be punished by imprisonment of a maximum term of three years or a fine where such person:

1. in breach of Article 5(1), places a medicinal product on the market or uses it in or on the human body.

…’

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

Case C-358/13

11 Mr D. sold in his shop, bearing the sign ‘G. — Alles rund um Hanf’ (G. — All about hemp), among other things, small bags containing herbs to which synthetic cannabinoids had been added. The bags contained neither fixed quantities of any active substance nor any indications as to the active substance or dosage guidance. In general, they carried a statement that they were air fresheners and that the contents were not fit for human consumption.

12 It is apparent from the file available to the Court that Mr D. was aware of the fact that his customers used the mixtures sold in those bags as a substitute for marijuana.

13 The consumption of the synthetic cannabinoids in question generally induces a state of intoxication which may range from intense excitement to hallucinations. It may also cause nausea, intense vomiting, heart-racing, disorientation, delusions and even cardiac arrest.

14 The synthetic cannabinoids in question were tested by the pharmaceutical industry in pre-experimental studies. The series of tests were discontinued at the first experimental/pharmacological stage since the desired health effects of those substances could not be achieved and considerable side effects were foreseeable due to their psychoactive effects.

15 At the material time, synthetic cannabinoids did not fall within the BtMG. They were, however, classed as unsafe medicinal products within the meaning of the AMG on account of their harmful effects on health.

16 Mr D. was sentenced by the Landgericht Lüneburg (Regional Court, Lüneburg) to one year and nine months imprisonment, the sentence being suspended. That court took the view that, by selling the herb mixtures at issue in the main proceedings, Mr D. had placed on the market unsafe medicinal products within the meaning of Articles 5(1) and 4(17) of the AMG and thus infringed Article 95(1) of that law.

17 Mr D brought an appeal on a point of law before the Bundesgerichtshof. He challenges in particular the Landgericht Lüneburg's evaluation of the evidence and the claim that he was aware of the unsafe effects of synthetic cannabinoids.

18 The referring court considers that the resolution of the case pending before it depends on whether the products sold by Mr D. may be classified as 'medicinal products' within the meaning of Article 1(2) of Directive 2001/83, which was transposed into German law by Article 2(1) of the AMG.

Case C-181/14

19 Between May 2010 and May 2011, Mr G. ordered and sold, initially alone via his online trading outlet and, from October 2012 to November 2012, following the closure of that outlet, with another person, small bags of herbs similar to those described in connection with Case C-358/13, which also contained synthetic cannabinoids.

20 Since, at the material time, the BtMG did not contain any express provisions concerning those substances, the national courts applied the legislation relating to medicinal products, in so far as those substances were classed as unsafe medicinal products within the meaning of the AMG on account of their harmful effects on health.

21 Accordingly, the Landgericht Itzehoe (Regional Court, Itzehoe) convicted Mr G. on 87 counts of intentionally marketing unsafe medicinal products, sentenced him to four years and six months imprisonment and fined him EUR 200 000.

22 Mr G. brought an appeal on a point of law before the Bundesgerichtshof.

23 That court considers that the resolution of the case before it depends on whether the products sold by Mr G. may be classified as 'medicinal products' within the meaning of Article 1(2) of Directive 2001/83, which was transposed into German law by Article 2(1) of the AMG.

24 The Bundesgerichtshof decided to stay the proceedings and to refer to the Court, in each of these cases, the following question for a preliminary ruling:

'Is Article 1(2)(b) of Directive 2001/83 to be interpreted as meaning that substances or combinations of substances within the meaning of that provision which merely modify — that is, do not restore or correct — human physiological functions are to be regarded as medicinal products only if they are of therapeutic benefit or at any rate bring about a modification of physiological functions along positive lines? Consequently, do substances or combinations of substances which are consumed solely for their — intoxication-inducing — psychoactive effects, and in the process also have an effect which at least poses a risk to health, fall under the definition of 'medicinal product' contained in the directive?'

Procedure before the Court

25 By decision of the Court of 6 May 2014, Cases C-358/13 and C-181/14 were joined for the purposes of the oral procedure and judgment.

Consideration of the question referred

26 By the question referred, the national court is asking, in essence, whether the term medicinal product in Article 1(2)(b) of Directive 2001/83 must be interpreted as not covering substances, such as those at issue in the main proceedings, which produce effects that merely modify physiological functions and which do not bring about any improvement in those functions, are consumed solely in order to induce a state of intoxication and are, as such, harmful to human health.

27 Article 1(2) of Directive 2001/83 gives two different definitions of the term medicinal product. Accordingly, first, Article 1(2)(a) of the directive provides that 'any substance or combination of substances presented as having properties for treating or preventing disease in human beings' is a medicinal product. Second, according to Article 1(2)(b) of Directive 2001/83, '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' constitutes a medicinal product.

28 It is settled case-law that a product is a medicinal product if it falls within either of those two definitions (the judgment in *HLH Warenvertrieb and Orthica*, C-211/03, C-299/03 and C-316/03 to C-318/03, EU:C:2005:370, paragraph 49).

29 While those two provisions of Directive 2001/83 are separated by the word 'or', they cannot be regarded as unconnected with each other (see, to that effect, the judgment in *Upjohn*, C-112/89, EU:C:1991:147, paragraph 18) and must, therefore, as observed by the Advocate General at point 37 of his Opinion, be read conjunctively. That presupposes that the various elements of those provisions cannot be read in such a way as to render one element in conflict with another.

30 The question referred by the national court concerns more specifically the definition given in Article 1(2)(b) of Directive 2001/83, in particular the words 'modify the physiological functions' used in that provision.

31 Admittedly, according to its ordinary meaning in everyday language, the word 'modify' is neutral in terms of whether the effects produced are beneficial or harmful.

32 However, it is settled case-law that in interpreting a provision of EU law, it is necessary to consider not only its wording but also the context in which it occurs and the objectives pursued by the rules of which it is part (see, inter alia, the judgments in *Merck*, Case 292/82, EU:C:1983:335, paragraph 12, and in *Brain Products*, C-219/11, EU:C:2012:742, paragraph 13).

33 According to recital 3 in the preamble to Directive 2004/27, in aligning national laws, it is necessary to attain a high level of human health protection. Accordingly, the whole of Directive 2001/83, and in particular Article 1(2) thereof, must be read bearing that objective in mind. That provision is not merely neutral with regard to action taken in connection with human health and implies that a beneficial effect should be secured for human health.

34 In that regard, it should be noted that the definition in Article 1(2)(a) of Directive 2001/83 refers to 'properties for treating or preventing disease in human beings', words which unambiguously allude to the existence of a beneficial effect for human health.

35 Article 1(2)(b) of that directive also uses terms which imply the existence of such a beneficial effect, since, at the end of that provision, it refers to a 'medical diagnosis', the purpose of such a diagnosis being to identify any disease or illness so that it may be treated in good time.

36 The expressions ‘restore’ and ‘correct’ physiological functions in the definition of a medicinal product in Article 1(2)(b) of Directive 2001/83 do not evade such an interpretation either. Those expressions must be understood as reflecting the legislature’s intention to highlight the beneficial effects which the substances concerned are meant to have on the functioning of the human organism and, as a consequence — be it immediately or over a period of time — on human health, even in the absence of disease (see, with regard to the latter point, the judgment in *Upjohn*, EU:C:1991:147, paragraph 19).

37 In order to ensure, in accordance with paragraph 29 above, consistency in the overall interpretation that must be given to the two definition of medicinal product in Article 1(2) of Directive 2001/83 and to avoid an interpretation of their various elements that may be contradictory, any reading of the word ‘modify’, which comes after the words ‘restore’ and ‘correct’ in the same phrase, must be in line with the teleological considerations set out in the preceding paragraph. The word ‘modify’ must, therefore, be interpreted as encompassing substances which are capable of having a beneficial effect on the functioning of the human organism and, as a consequence, on human health.

38 It follows from the foregoing considerations that the term ‘medicinal product’ in Article 1(2)(b) of Directive 2001/83 must be interpreted as not covering substances whose effects merely modify physiological functions and which are not such as to entail immediate or long-term beneficial effects for human health.

39 That conclusion is not affected by the argument that, in essence, that interpretation is at odds with the intention of the legislature, which designated as medicinal products in Article 4(4) of Directive 2001/83 ‘contraceptives or abortifacients’, even though such products modify physiological functions without being such as to entail a beneficial effect for human health.

40 Indeed, it should be noted, first, that ‘contraceptives or abortifacients’ are subject to a special regime under Directive 2001/83, since the Member States are authorised by Article 4(4) thereof to apply to those products their own restrictive rules.

41 Accordingly, the position of such products under Directive 2001/83 is not in any way comparable to that of medicinal products falling within the general scheme established by that directive.

42 Second, it should be recalled that, according to established case-law, for the purpose of determining whether a product falls within the definition of a medicinal product for the purposes of Directive 2001/83, the national authorities, acting under the supervision of the courts, must decide on a case-by-case basis, taking account of all the characteristics of the product, in particular its composition, its pharmacological, immunological or metabolic properties, to the extent to which they can be established in the present state of scientific knowledge, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail (the judgments in *Upjohn*, EU:C:1997:147, paragraph 23, *and BIO Naturprodukte*, C-27/08, EU:C:2009:278, paragraph 18).

43 It should be noted that, in Article 4(4) of Directive 2001/83, the legislature designated as medicinal products, not specific products but, in a general manner, a whole category of products.

44 Such a designation on the part of the legislature must not be confused with the classification, on a case-by-case basis, of a specific product carried out by the national authorities in accordance with Article 1(2) of Directive 2001/83 and the requirements set out in paragraph 42 above.

45 In the light of the foregoing, there can be no justification for taking into account, when determining the meaning of the elements of the general definitions of the term ‘medicinal product’ in Article 1(2) of Directive 2001/83 — in particular the expression ‘modify’ — certain characteristics particular to a category of products enjoying special status under the directive, such as the category referred to in Article 4(4) thereof.

46 Moreover, it is apparent from the second part of the question referred that the substances at issue in the main proceedings are consumed not for therapeutic but purely for recreational purposes and that they are, as such, harmful to human health.

47 Given the objective referred to in paragraph 33 above, the need for a consistent interpretation of the term medicinal product referred to in paragraph 29 above and the need to weigh any harmful effects a product under examination may have against its therapeutic effects, referred to in recital 7 in the preamble to Directive 2001/83, such substances cannot be classified as 'medicinal products'.

48 Lastly, the fact that, as is apparent from the order for reference, a conclusion such as that reached by the Court in the preceding paragraph will mean that the marketing of the substances at issue in the main proceedings is not subject to any criminal law sanctions cannot call that conclusion into question

49 It is sufficient in that regard to note the objective of imposing criminal law sanctions in respect of the introduction on the market of harmful substances such as those at issue in the main proceedings cannot have any effect of the definition of the term medicinal product given in Directive 2001/83 or on any classification of such substances as medicinal products on the basis of that definition.

50 It follows from all the foregoing considerations that the answer to the question referred is that Article 1(2)(b) of Directive 2001/83 must be interpreted as not covering substances, such as those at issue in the main proceedings, which produce effects that merely modify physiological functions but which are not such as to have any beneficial effects, either immediately or in the long term, on human health, are consumed solely to induce a state of intoxication and are, as such, harmful to human health.

Costs

51 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 (Fourth Chamber) hereby rules:

Article 1(2)(b) 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, must be interpreted as not covering substances, such as those at issue in the main proceedings, which produce effects that merely modify physiological functions but which are not such as to have any beneficial effects, either immediately or in the long term, on human health, are consumed solely to induce a state of intoxication and are, as such, harmful to human health.

[Signatures]