Reports of Cases

OPINION OF ADVOCATE GENERAL
BOT
delivered on 12 June 2014[1]

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

Criminal proceedings
v
D. (C-358/13),
G. (C-181/14)

(Requests for a preliminary ruling from the Bundesgerichtshof (Germany))

(Medicinal products for human use — Directive 2001/83/EC — Scope — Interpretation of the concept of 'medicinal product by function' — Scope of the criterion relating to the capacity to modify physiological functions — Product based on herbs and synthetic cannabinoids marketed solely for recreational purposes — Absence of medical or therapeutic benefits — Included)

1. Can a combination of substances based on herbs and synthetic cannabinoids designed to induce a state of intoxication in human beings comparable to that resulting from the consumption of cannabis fall within the definition of 'medicinal product' within the meaning of Article 1(2)(b) of Directive 2001/83/EC?[2]

2. In other words, can the definition of 'medicinal product' in that provision cover a substance or a combination of substances which, while it is capable of modifying human physiological functions, is not designed to prevent or cure disease, where it is administered to human beings solely for recreational purposes?

3. These are, in essence, the questions referred to the Court by the Bundesgerichtshof (Federal Court of Justice, Germany).

4. Those questions form part of two sets of criminal proceedings instigated by the Generalbundesanwalt beim Bundesgerichtshof (Procurator General attached to the Bundesgerichtshof, 'the Generalbundesanwalt') against two individuals, Mr D. and Mr G., who, between 2010 and 2012, marketed herb mixtures to which various synthetic cannabinoids were added which were designed to mimic the effects of cannabis when smoked.

1 — Original language: French.

2 — Directive 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').

5. At the time of the facts in the main proceedings, it was not possible under German legislation relating to combating narcotic drugs to impose criminal law sanctions in respect of the marketing of these new psychoactive substances. In the absence of express legislative provision, the national courts therefore applied the legislation on medicinal products, taking the view that the sale of a product such as that in question fell within the definition of placing an unsafe medicinal product on the market and, on that basis, constituted an offence.

6. Pursuant to that legislation, the Landgericht Lüneburg (Regional Court, Lüneburg, Germany) — in Case C-358/13 — sentenced Mr D. to one year and nine months imprisonment which was suspended, on the basis that he had marketed mixtures of herbs and synthetic cannabinoids in the form of air fresheners and deodorants in his shop, 'G. Alles rund um Hanf'. Under the same legislation, the Landgericht Itzehoe (Regional Court, Itzehoe, Germany) — in Case C-181/14 — sentenced Mr G. to four and a half years imprisonment and fined him EUR 200 000 for having sold those products through his online shop, initially alone and, subsequently, with another person.

7. It is in the context of the appeals on a point of law lodged by Mr D. and Mr G. that the Bundesgerichtshof has raised the question of how these mixtures of herbs and synthetic cannabinoids are to be classified under EU law. As the Bundesgerichtshof points out in its orders for reference, these individuals can be found to be criminally liable only in so far as the measure or preparation in question may be classified as a 'medicinal product' within the meaning of Article 1(2)(b) of Directive 2001/83.

8. According to that provision, the term 'medicinal product' must be regarded as covering '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'.[3]

9. In the main proceedings, it is not disputed that the consumption of synthetic cannabinoids contained in these mixtures of herbs triggers a modification of physiological functions in human beings by exerting a pharmacological action, particularly through their nerve receptors.

10. The Bundesgerichtshof therefore asks whether, notwithstanding the risks which the combination of substances in question poses to human health, the capacity of that combination to modify physiological functions is sufficient for it to be classified as a 'medicinal product' within the meaning of Article 1(2)(b) of Directive 2001/83, or whether it is also necessary for the administration of that combination to be of therapeutic benefit for human beings.

11. As the Bundesgerichtshof entertains doubts as to the correct interpretation of Article 1(2)(b) of Directive 2001/83, it has decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

'(1) 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?

(2) 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 … [D]irective [2001/83]?'

3 — Emphasis added.

12. In their observations, the Generalbundesanwalt and the German, Czech, Estonian, Italian, Finnish and Norwegian Governments submit that the definition of 'medicinal product' in Article 1(2)(b) of Directive 2001/83 covers all substances or combinations of substances capable of modifying human physiological functions, including where such substances or combinations of substances are not of any therapeutic benefit. Consequently, they consider that substances or combinations of substances which are consumed solely for their intoxication-inducing psychoactive effects and which are, on any view, harmful to health, may fall within that definition.

13. The Hungarian and United Kingdom Governments disagree with that interpretation, arguing that a product which is consumed solely for its psychoactive effects and not for any therapeutic purpose must be excluded from the definition of medicinal product. Similarly, the European Commission considers that the criterion relating to the capacity to modify physiological functions laid down in Article 1(2)(b) of Directive 2001/83 is not, in itself, decisive for the purpose of classifying a product as 'medicinal'. In this respect, it submits that 'medicinal products by function' covered by that provision must perform an action which goes beyond triggering a chemical or biological process in the human body, a process which must be evaluated in the light of the medical or therapeutic purpose of the product concerned.

14. In this Opinion, I shall explain the reasons for my view that the definition of 'medicinal product' in Article 1(2)(b) of Directive 2001/83 is not intended to cover combinations of substances such as those in question, the consumption of which admittedly leads to a modification of human physiological functions but the administration of which, purely for recreational purposes, is not intended either to prevent or cure disease.

I – **Legal framework**

A – *EU law*

15. Under Article 1(2) of Directive 2001/83, the definition of 'medicinal product' covers:

'…

(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.'

B – *German legislation*

16. The term 'medicinal product' is defined in Article 2(1) of the Law relating to trade in medicinal products (Gesetz über den Verkehr mit Arzneimitteln (Arzneimittelgesetz)). [4]

4 — According to the information provided by the referring court in Case C-358/13, the applicable version of this law is that of 17 July 2009 (BGBl. 2009 I, p. 1990, 'the AMG').

17. Article 2(2) of the AMG defines medicinal products as substances or preparations consisting of substances:

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

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

(b) making a medical diagnosis.'

18. Article 5 of the AMG prohibits the placing on the market or the use in or on human beings of unsafe medicinal products. Unsafe medicinal products are 'medicinal products in respect of which there are, given the current state of scientific knowledge, reasonable grounds for considering that, should they be used in accordance with their intended purpose, they will produce harmful effects which go beyond what is regarded as acceptable given the current state of medical knowledge'.

19. Article 95(1)(1) of the AMG provides that any person who, in breach of Article 5(1) of that law, places a medicinal product on the market or uses it in or on human beings is to be punished by a term of imprisonment of up to three years or a fine.

II – **Analysis**

A – *Context*

20. Before examining the questions referred, it is necessary to consider the context in which they arose.

21. Synthetic cannabinoids fall under the category of 'new psychoactive substances'. According to Article 3 of Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk assessment and control of new psychoactive substances,[5] a new psychoactive substance is a new narcotic drug or a new psychotropic drug which is not subject to control under the United Nations Single Convention on Narcotic Drugs, concluded in New York on 30 March 1961,[6] or the United Nations Convention on Psychotropic Substances, concluded in Vienna on 21 February 1971,[7] but which may nevertheless pose a threat to public health comparable to the drugs covered by those conventions.[8] Cannabis is among the substances and products referred to in those conventions.

22. New psychoactive substances, which are often synthetic, are designed to mimic the effects of the drugs controlled under those conventions. Their molecular structures are similar to those of the substances they copy without being exactly the same, which enables them — at least in the short term — to circumvent narcotics legislation.

23. Synthetic cannabinoids are thus designed to simulate the effects of delta-9-tetrahydrocannabinol, which is the active ingredient of cannabis, while enhancing those effects. In common with that molecule, synthetic cannabinoids have an effect on cannabinoid receptors, thereby affecting the human central nervous system. These cannabinoids were initially synthesised in the course of medical research and have been the subject of pharmacological studies, especially in the context of pain

5 — OJ 2005 L 127, p. 32.

6 — Convention as amended by the 1972 Protocol (*United Nations Treaty Series*, vol. 976, p. 120, No 14152).

7 — *United Nations Treaty Series*, vol. 1019, p. 175, No 14956.

8 — The European Union is a party to 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, p. 95, No 27627).

management. However, it proved difficult to isolate the therapeutic properties of synthetic cannabinoids on account of their side effects — deemed to be too many — and, in particular, their psychoactive effects. As the referring court has observed in Case C-358/13, the series of pre-experimental studies were therefore discontinued at the first pharmacological stage. In the same way as cannabis, the consumption of synthetic cannabinoids poses risks to human health, in so far as it affects individuals' vital functions, such as concentration and attention, aggravates mental health problems such as anxiety and depression, and induces psychiatric manifestations such as hallucinations and paranoia, as well as posing a potential risk of abuse and dependence. As the Generalbundesanwalt pointed out at the hearing, these psychoactive effects could even induce suicidal impulses. The above risks are obviously increased by the fact that the substances in question are added in varying and indeterminate quantities to herbal mixtures sold without proper labelling and instructions for use.

24. Decision 2005/387 did not enable Member States to adopt effective monitoring and control measures with regard to these substances.[9] As the Commission pointed out in its Report on the assessment of the functioning of that decision,[10] such substances are difficult to identify and regulate because of their diversity and the speed with which they are developed to replace those that are controlled.[11] The procedure based on information exchange and risk assessment is a lengthy one, while the dangers posed by these substances and the speed with which they appear on the market require swift action to be taken by Member States. Furthermore, this procedure does not enable action to be taken against groups of chemical substances, while psychoactive substances are developed — as has been seen — through minor changes to their chemical composition.

25. Consequently, the Member States have adopted different approaches and have had recourse to different legislative measures to control and regulate the manufacture, sale and possession of these substances, whose medical value has neither been determined nor recognised. Thus, as the Commission again points out in the same report, some Member States have relied on legislation for combating narcotic drugs. Others have had recourse to the principles established in the context of food safety or to the rules on consumer protection or those relating to dangerous substances and products.[12] Lastly, some Member States, such as the Federal Republic of Germany, have applied legislation on the marketing of medicinal products.

26. At the time of the facts in the main proceedings, it was not possible under German legislation on narcotic drugs to impose criminal law sanctions in respect of the marketing of mixtures of herbs and synthetic cannabinoids. In the absence of express legislative provision, the national courts therefore punished such conduct by having recourse to the AMG, taking the view that the sale of products such as those in question entailed, for the purpose of that legislation, the placing on the market of unsafe medicinal products within the meaning of Article 5(1) of the AMG and, on that basis, infringed Article 95(1)(1) of the AMG.

27. The cases under consideration therefore raise the question whether that legislation is the appropriate vehicle for combating the emergence and the placing on the market of these new psychoactive substances.

9 — See, as regards the deficiencies of the current system and its reform, the Communication from the Commission to the European Parliament and the Council entitled 'Towards a stronger European response to drugs' (COM(2011) 689 final) and the Council conclusions on new psychoactive substances of 13 and 14 December 2011 (available on the website of the Council of the European Union at the following address: http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/jha/126879.pdf).

10 — Report from the Commission on the assessment of the functioning of Council Decision 2005/387/JHA on the information exchange, risk assessment and control of new psychoactive substances (COM (2011) 430 final).

11 — Page 3.

12 — Page 4.

B – *Interpretation*

28. By its questions, the Bundesgerichtshof essentially asks the Court whether a preparation such as that at issue in the main proceedings, comprising a mixture of herbs and synthetic cannabinoids, can be classified as a 'medicinal product' within the meaning of Article 1(2)(b) of Directive 2001/83, simply because when it is administered to human beings, it modifies physiological functions, even though it is not designed to prevent or cure disease.

29. In the present cases, it is not disputed that the synthetic cannabinoids contained in such herb mixtures trigger a substantial modification of human physiological functions by exerting a pharmacological action on the human body, particularly through its nerve receptors. However, unlike the narcotic drugs used for medical and scientific purposes, the objective of this combination of substances is not to prevent or cure disease, since it is consumed solely for recreational purposes, the consumer seeking the psychic effects associated with the consumption of cannabis, particularly intoxication. The approach which must be adopted in this regard must therefore be credible and realistic, since the context is serious. The point is not to prevent the medical use of narcotic drugs, since such use, as we know, is essential to alleviate pain, but rather to restrict the placing on the market of psychoactive substances administered to human beings without any medical or therapeutic application, in spite of the risks associated with their consumption.

30. It is apparent from Article 1(2)(b) of Directive 2001/83 that a substance or combination of substances falls within the definition of medicinal product by function if it is capable of restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action on the human body, and if that capability must have been scientifically established. [13]

31. According to settled case-law, in order to determine whether a product falls within that definition, the national authorities must decide on a case-by-case basis. They must take account of all the characteristics of the product, in particular its composition, its pharmacological, immunological or metabolic properties, in so far as they can be established in the present state of scientific knowledge, the manner in which the product is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail. [14] It must be pointed out that the existence or otherwise of a risk to human health posed by the substance or combination of substances in question is not the only determining factor for the purpose of its classification as a 'medicinal product by function'. [15]

32. It is on the basis of the pharmacological, immunological or metabolic properties of the product concerned that the competent national authorities must ascertain, in the light of the potential capacities of the product, whether it may, for the purpose of Article 1(2)(b) of Directive 2001/83, be used in or administered to human beings with a view to restoring, correcting or modifying physiological functions. [16]

33. In the cases in the main proceedings, most of the governments which submitted observations consider that, in view of the wording of Article 1(2)(b) of Directive 2001/83 and the Court's case-law, the existence of a therapeutic benefit deriving from the product concerned is not a factor to be taken into account for the purpose of determining whether that product falls within the definition of 'medicinal product by function', for the purpose of Directive 2001/83. The Generalbundesanwalt and the Finnish Government consider, inter alia, that by referring to the '[modification] of physiological

13 — See *Chemische Fabrik Kreussler*, C 308/11, EU:C:2012:548, paragraph 30 and the case law cited.

14 — See, in that regard, *Laboratoires Lyocentre*, C-109/12, EU:C:2013:626, paragraph 42 and the case-law cited.

15 — See, in that regard, *BIOS Naturprodukte*, C-27/08, EU:C:2009:278, paragraph 26 and the case-law cited.

16 — See *Laboratoires Lyocentre*, EU:C:2013:626, paragraph 43 and the case-law cited.

functions' in Article 1(2)(b) of Directive 2001/83, the EU legislature chose to use a neutral word, unlike the words 'restoring' and 'correcting', which precede it. Accordingly, the question whether the effects of the substance or combination of substances in question on human physiological functions are beneficial or harmful to health is irrelevant.

34. I do not agree. The existence of a medical or therapeutic benefit deriving from the substance or combination of substances administered to human beings is, in my view, inherent in the definition of 'medicinal product' in Article 1(2)(b) of Directive 2001/83 and transcends all the criteria established for that purpose by the legislature and Courts of the European Union.

35. It is true, I note, that the existence of a medical or therapeutic benefit deriving from the product concerned is not apparent from the expression 'modifying physiological functions', unlike the expressions which precede it, in which, in particular, the words 'restoring' and 'correcting' allude to such a benefit.

36. However, the Court has repeatedly held that, when 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. [17]

37. In the first place, it appears to me that subparagraphs (a) and (b) of Article 1(2) of Directive 2001/83 must be read in conjunction with each other. Whilst (a) defines the concept of 'medicinal product by presentation' and (b) defines the concept of 'medicinal product by function', the fact remains that both are designed to define the boundaries of a single category of product intended to be marketed to the public. It is clear from the wording of Article 1(2)(a) of Directive 2001/83 that a substance or combination of substances can fall within the definition of medicinal product 'by presentation' only if it has 'properties for treating or preventing disease in human beings'. [18] That wording very clearly refers to a medical or therapeutic benefit deriving from the medicinal product.

38. In the second place, I do not think that the criterion relating to the capacity to modify physiological functions referred to in Article 1(2)(b) of Directive 2001/83 can be interpreted in isolation, independently of its context and the medical application for which the substance or combination of substances is intended.

39. In my opinion, that criterion must be construed in the light of the two other criteria which precede it and which throw particularly clear light on it, namely the criteria relating to the capacity to restore and to correct human physiological functions. By using the verbs 'restore' and 'correct', the EU legislature is obviously referring to an improvement in or restoration of human physiological functions, which again suggests the existence of a medical or therapeutic benefit. The criterion relating to the capacity to modify physiological functions must also be interpreted in the light of the criterion which immediately follows it, namely that relating to the capacity to 'mak[e] a medical diagnosis', which, once again, obviously suggests a therapeutic application and objective.

40. It is also necessary to take account of the Court's settled case-law concerning the scope of that criterion.

17 — *Brain Products*, C-219/11, EU:C:2012:742, paragraph 13 and the case-law cited.

18 — The Court's interpretation of the concept of 'medicinal product by presentation' is a broad one, in order to 'protect consumers from products which do not have the effectiveness which they are entitled to expect' (see, in that regard, *Hecht-Pharma*, C-140/07, EU:C:2009:5, paragraph 25 and the case-law cited).

41. The Court has repeatedly held that the criterion relating to the capacity to restore, correct or modify human physiological functions can be met only in so far as the administration of the product in question, having regard to its composition and if used as intended, has an appreciable physiological effect on the human body. [19]

42. Here, the Court tends to distinguish substances or combinations of substances which are capable of being classified as 'medicinal product' from foodstuffs which, if consumed, may also have physiological effects. [20] Thus, wine — when consumed in significant quantities — leads to a modification of human physiological functions by way of a metabolic action, as do salt, sugar and many other foodstuffs.

43. The Court considers that these physiological effects must go far beyond the 'benefits' to health in general which may arise from the consumption of foodstuffs, since the administration of the product in question must 'have the function of treating or preventing disease'. [21] The wording used by the Court — which I have reproduced verbatim — clearly shows that, quite apart from the modification of physiological functions referred to in Article 1(2)(b) of Directive 2001/83, the administration of the product in question must lead to a modification of the way in which the human body functions so as to prevent or cure an illness or a disease.

44. In the third place, I consider that the above interpretation is the correct one, in the light of the purpose of Directive 2001/83.

45. In my view, it would be absolutely contrary to the aims of that instrument to introduce into an economic and commercial network — currently under close supervision by health agencies — substances or combinations of substances posing risks to human health comparable to those posed by drugs and which are administered or used without any medical or scientific application.

46. The principles established by the EU legislature concerning the legislation applicable to medicinal products are based on the protection of human health and on the free movement of goods within the European Union. [22]

47. By laying down rules regarding marketing authorisation, manufacturing, importation, labelling, classification, distribution or advertising of medicinal products, the EU legislature seeks to ensure that the substance or combination of substances concerned contributes — in accordance with Article 168 TFEU and Article 35 of the Charter of Fundamental Rights of the European Union — to a high level of human health protection and, in particular, the prevention of illnesses and obviating sources of danger to the physical and mental health of all persons. These rules, especially those governing the classification of a product as a 'medicinal product', must, in due course, make it possible to place on the market and allow to move freely within in the European Union a safe and effective product, whose composition has been analysed, whose indications, contra-indications, risks and adverse effects have been assessed, and whose dosage, pharmaceutical form and method of administration have been identified. Such rules should not be applied to a combination of substances such as that at issue, whose exclusion from the market is in fact sought. This is because the objective of the national authorities is to prohibit the marketing and free movement of substances recognised as having no medical or therapeutic benefit whatsoever and posing dangers to individuals which are comparable to those posed by the drugs covered by the abovementioned international conventions.

19 — *Hecht-Pharma*, EU:C:2009:5, paragraphs 41 and 42 and the case-law cited, and *Chemische Fabrik Kreussler*, EU:C:2012:548, paragraph 35.

20 — *Commission* v *Germany*, C-319/05, EU:C:2007:678, paragraph 63.

21 — Ibidem (paragraph 64).

22 — See recitals 3 and 4 of Directive 2001/83 and *Hecht-Pharma*, EU:C:2009:5, paragraph 27.

48. Furthermore, it should not be overlooked that substances such as those in question are marketed and consumed solely for recreational purposes, the consumer seeking the psychic effects associated with the consumption of drugs. The marketing of new psychoactive substances purely for recreational purposes clearly falls outside the legal economic sphere of the internal market. In *Josemans*,[23] the Court clearly stated that 'narcotic drugs which are not distributed through channels which are strictly controlled by the competent authorities to be used for medical and scientific purposes are, because of their very nature, subject to a prohibition on importation and offering for sale in all the Member States'.[24] While, according to settled case-law, narcotic drugs which have a medical or scientific application therefore clearly come under the rules of the internal market,[25] narcotic drugs imported illegally or intended for illicit purposes do not. The latter are not like other goods and are not subject to the rules intended to apply to the internal market where the marketing of such goods is unlawful.

49. In those circumstances, I am therefore satisfied that the principles established by the EU legislature in Directive 2001/83 are not applicable to the placing on the market of a combination of substances such as that in question in the main proceedings, the administration of such substances to human beings solely for recreational purposes not being of any medical or therapeutic benefit to them.

50. I share the concern regarding the need to ensure that conduct which poses a danger to European Union citizens does not fall outside criminal law sanctions and I understand why, when confronted with a legal void, the Federal Republic of Germany was therefore tempted to apply its legislation on medicinal products in order to control and punish more effectively the placing on the market of these new psychoactive substances. I also understand that the reason for that approach was the need to protect public health from the dangers posed to the general population by synthetic cannabinoids. However, a satisfactory outcome will not be achieved by applying the rules on medicinal products. The intention to penalise this type of conduct cannot justify a broad interpretation, or even a distortion, of the definition of 'medicinal product' in Article 1(2)(b) of Directive 2001/83. The present cases involve 'twisting' that definition so that it covers substances consumed without any medical or scientific application, irrespective of their harmful effects on to human health and whether they are lawful. The legislation applicable to medicinal products, which guarantees a high level of protection for human health in the European Union, is obviously not the appropriate vehicle. Indeed, I would be surprised if, by applying the line of reasoning put forward by most of the Governments in these cases, a wine produced from banned chemical derivatives could be subject to action under Directive 2001/83.

51. Consequently, in my opinion only repressive measures based on the control of narcotic drugs will enable, through the objectives of public safety, public policy and public health pursued by such measures, a response to be given with the requisite speed to the appearance on the market of substances whose effects are similar to those of narcotic drugs on account of, inter alia, their derived chemical composition and acute toxicity.

52. On this view, I can only encourage the adoption — at EU level — of clear legislation.

53. In this connection, it must be noted that in its proposal for a regulation of the European Parliament and of the Council on new psychoactive substances,[26] the Commission gave an undertaking that such substances would, in the future, be caught by the criminal law provisions applicable to controlled substances and would therefore be subject in due course to a 'permanent

23 — C-137/09, EU:C:2010:774.

24 — Paragraph 41 and the case-law cited. Also see paragraphs 36 and 38 and the case-law cited.

25 — See, inter alia, *Evans Medical and Macfarlan Smith*, C-324/93, EU:C:1995:84.

26 — COM(2013) 619 final, 'the proposal for a regulation on psychoactive substances'. Article 2 of that proposal defines a 'new psychoactive substance' as 'a natural or synthetic substance that, when consumed by a human, has the capacity to produce central nervous system stimulation or depression, resulting in hallucinations, alterations in motor function, thinking, behaviour, perception, awareness or mood, which is intended for human consumption or is likely to be consumed by humans even if not intended for them with the purpose of inducing one or more of the effects mentioned above, which is neither controlled under the 1961 United Nations Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, nor the 1971 United Nations Convention on Psychotropic Substances'.

market restriction'.[27] To that end, the Commission decided to accompany the proposal for a regulation on psychoactive substances, which seeks to reform the procedure set out in Decision 2005/387, with a proposal for a directive amending Framework Decision 2004/757/JHA.[28] If that proposal for a directive is adopted, the Member States will have to take all necessary measures and, in particular, adopt the criminal law sanctions necessary to render unlawful the production, manufacture, extraction, offering for sale, transport, importation and exportation of all new psychoactive substances, which will then be subject to a 'permanent market restriction'.

54. Although the proposal for a regulation on new psychoactive substances seems to meet the objective of combating the distribution of these substances on the market, I have some reservations regarding the precision of some of the expressions used in the proposal and its legal basis.

55. Thus, I do not think that the objective and the practical effect of an intention to ban those products from the market are precisely rendered by the expression imposing a 'market restriction' on them, when only a prohibition is capable of achieving the desired goal.

56. Furthermore, the distribution of psychoactive substances is organised in the manner of a veritable trade, the cross-border nature of which is evidenced by the number of governments that have submitted written observations in these cases and also participated in the hearing. All of them were in favour of banning the use and marketing of these products. That is why, in the interests of clarity, I think it would be more appropriate and more consistent for the forthcoming legislation to be adopted on the basis of Article 83(1) and (2) TFEU, which would avoid the use of expressions which clearly belong to the vocabulary of the internal market in a field which clearly falls within the area of freedom, security and justice. Coordination between the Member States to combat this phenomenon would *ipso facto* be made possible, without giving rise to one of those — sometimes abstract — disputes over the applicable legal base.

57. In the light of all the foregoing considerations, I therefore consider that the definition of 'medicinal product' in Article 1(2)(b) of Directive 2001/83 must be interpreted as meaning that it does not cover substances or combinations of substances, such as preparations based on herbs and synthetic cannabinoids, which are capable of modifying human physiological functions but whose administration, purely for recreational purposes, is not intended to prevent or cure disease.

III – **Conclusion**

58. In the light of the foregoing considerations, I propose that the Court should reply as follows to the questions submitted for a preliminary ruling by the Bundesgerichtshof: The term 'medicinal product' in 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 meaning that it does not cover substances or combinations of substances, such as preparations based on herbs and synthetic cannabinoids, which are capable of modifying human physiological functions but whose administration, purely for recreational purposes, is not intended to prevent or cure disease.

27 — See Article 13 of the proposal.

28 — Proposal for a directive of the European Parliament and of the Council amending Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking, as regards the definition of drug (COM(2013) 618 final).