European Court of Justice, 20 September 2007, State v Antroposana

TRADEMARK LAW

Community code relating to medicinal products for human use

- **That products coming within the definition of 'medicinal products' in Article 1(2) of Directive 2001/83 which are not mentioned in the Annex to Regulation No 2309/93, now replaced by the Annex to Regulation No 726/2004, must be registered under one of the procedures laid down in the aforementioned directive.**

That conclusion is not called into question by the argument put forward by Antroposana and Others and the German Government to the effect that the harmonisation process in the field of medicinal products for human use is being carried out in stages and is not yet complete. Accordingly, the Member States retain their freedom to lay down or maintain specific authorisation procedures for certain medicinal products, parallel to the procedures applicable under Directive 2001/83, in so far as that directive does not lay down special and adequate procedures for those products.

In support of that argument, Antroposana and Others, and the German Government, refer, first of all, to the 14th recital in the preamble to Directive 2001/83 according to which the directive 'represents an impor-tant step towards achievement of the objective of the free movement of medicinal products' and '[f]urther measures [to] abolish any remaining barriers to the free movement [may] be necessary'. Secondly, they refer to the fact that Directive 2004/24 introduced 'traditional use registration' for certain traditional herbal medicinal products, mentioned in paragraph 14 of this judgment.

However, as the Advocate General remarked in points 61 to 68 of his Opinion, the line of reasoning adopted by Antroposana and Others and the German Government is based on the erroneous premise that complete harmonisation in the field of medicinal prod-ucts for human use is incompatible with the fact that that field is in a state of continuing evolution.

In reality, the fact that Directive 2001/83 lays down a complete system of authorisation procedures for medicinal products in no way means that the Com-munity legislature cannot amend or adapt those procedures or, if necessary, introduce new ones so as better to attain the objectives of removing barriers to intracommunity trade and the protection of public health.

In addition, the circumstance, relied on by Antroposana and Others, that some Member States did not comply with Directive 2001/83, when it was amended in 2004 – in that they introduced or maintained registration or authorisation procedures not provided for in the directive – does not affect the fact that the directive established a complete regulatory framework for registration and market authorisation procedures in respect of medicinal products for human use.

In the light of all of the foregoing considerations, the answer to the first question must be that anthroposophic medicinal products may be marketed only on condition that they have been authorised under one of the procedures referred to in Article 6 of Directive 2001/83.

Source: **curia.europa.eu**

European Court of Justice, 20 September 2007

(P. Jann, R. Schintgen, A. Tizzano, A. Borg Barthet and E. Levits)

JUDGMENT OF THE COURT (First Chamber)

20 September 2007 (*)

(Community code relating to medicinal products for human use – Articles 28 EC and 30 EC – Registration and marketing authorisation – Anthroposophic medicinal products)

In Case C-84/06,

REFERENCE for a preliminary ruling under Article 234 EC, by the Hoge Raad der Nederlanden (Netherlands), made by decision of 27 January 2006, received at the Court on 10 February 2006, in the proceedings

Staat der Nederlanden

v

Antroposana, Patiëntenvereniging voor Antroposofische Gezondheidszorg,

Nederlandse Vereniging van Antroposofische Artsen,

Weleda Nederland NV,

Wala Nederland NV,

THE COURT (First Chamber),

composed of P. Jann, President of Chamber, R. Schintgen, A. Tizzano (Rapporteur), A. Borg Barthet and E. Levits, Judges,

Advocate General: Y. Bot,

Registrar: M. Ferreira, Principal Administrator,

having regard to the written procedure and further to the hearing on 15 March 2007,

after considering the observations submitted on behalf of:

– Antroposana, Patiëntenvereniging voor Antroposofische Gezondheidszorg, Nederlandse Vereniging van Antroposofische Artsen, Weleda Nederland NV and Wala Nederland NV, by S. Evers and J. Sijmons, advocaten,

– the Netherlands Government, by H.G. Sevenster and P. van Ginneken, acting as Agents,

– the German Government, by M. Lumma and C. Schulze-Bahr, acting as Agents,

– the Italian Government, by I.M. Braguglia, acting as Agent, assisted by G. De Bellis, avvocato dello Stato,

– the Commission of the European Communities, by B. Stromsky and M. van Beek, acting as Agents,

after hearing the **Opinion of the Advocate General at the sitting on 24 May 2007**,

gives the following

Judgment

1 This reference for a preliminary ruling concerns the interpretation 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), and of Articles 28 EC and 30 EC.

2 The reference was made in proceedings between the Staat der Nederlanden (Netherlands State) and Antroposana, Patiëntenvereniging voor Antroposofische Gezondheidszorg (Association of Patients for Anthroposophic Health Care), Nederlandse Vereniging van Antroposofische Artsen (Netherlands Association of Anthroposophic Doctors), Weleda Nederland NV and Wala Nederland NV (hereinafter referred to collectively as 'Antroposana and Others') – the two last-mentioned parties being companies which manufacture and market anthroposophic medicinal products – concerning the conditions for the grant of authorisation to place anthroposophic medicinal products on the market.

Legal context

Community rules

3 Directive 2001/83 codified and brought together in a single text the directives on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products for human use, one of which is Council Directive 92/73/EEC of 22 September 1992 widening the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to medicinal products and laying down additional provisions on homeopathic medicinal products (OJ 1992 L 297, p. 8).

4 According to the second, fourth and fifth recitals in the preamble thereto, the purpose of Directive 2001/83 is to 'safeguard public health' and to eliminate hindrances to 'trade in medicinal products within the Community'.

5 The 14th recital in the preamble to the directive reads as follows:

'This Directive represents an important step towards achievement of the objective of the free movement of medicinal products. Further measures [to] abolish any remaining barriers to the free movement of proprietary medicinal products [may] be necessary in the light of experience gained …'

6 The 22nd recital in the preamble to Directive 2001/83 states that:

'The anthroposophic medicinal products described in an official pharmacopoeia and prepared by a homeopathic method are to be treated, as regards registration and marketing authorisation, in the same way as homeopathic medicinal products'.

7 Article 1(2) of Directive 2001/83 defines the expression 'medicinal product' as follows:

'any substance or combination of substances presented for treating or preventing disease in human beings.

any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product'.

8 Article 2 of Directive 2001/83 provides that the provisions of that directive are to apply to 'industrially produced medicinal products for human use intended to be placed on the market in Member States'.

9 Article 6(1) of Directive 2001/83 provides 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 [Council] Regulation (EEC) No 2309/93 [of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (OJ 1993 L 214, p. 1)].'

10 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 136, p. 1), 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), 'Regulation No 726/2004', replaced Regulation No 2309/93 and established inter alia a centralised procedure for authorisation of the placing on the market in the Community of the medicinal products referred to in the annex thereto.

11 Chapter 1 of Title III of Directive 2001/83, entitled 'Marketing Authorisation', lays down a general authorisation procedure for placing medicinal products on the market.

12 That chapter, which was amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ 2004, L 136, p. 34), now lays down – in Article 10a thereof – a simplified procedure under which the applicant is not required to provide the results of scientific tests if he can demonstrate that the active substances of the medicinal product have been in 'well-established medicinal use'.

13 Chapter 2 of Title III of Directive 2001/83, entitled 'Specific provisions applicable to homeopathic medicinal products', establishes a special, simplified procedure for homeopathic medicinal products which satisfy certain criteria.

14 Also in Title III of Directive 2001/83, Chapter 2a, entitled 'Specific provisions applicable to traditional herbal medicinal products' – introduced by Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ 2004 L 136, p. 85) – establishes a simplified authorisation procedure for some of those products.

National rules

15 Under Articles 3 to 5 of the Wet op de Geneesmiddelenvoorziening (Law on Medicinal Products, 'the Law'), the marketing of an unregistered pharmaceutical product is unlawful and may give rise to the application of criminal penalties.

16 The Besluit houdende regelen met betrekking tot de registratie van farmaceutische specialités en farmaceutische preparaten of 8 September 1977 (Decree on the registration of pharmaceutical specialities and pharmaceutical preparations), last amended in 2004, lays down the rules for the registration and authorisation of pharmaceutical products for human use. Specific rules concerning the registration of homeopathic pharmaceutical products were laid down in the Besluit homeopathische farmaceutische producten of 24 December 1991 (Decree on homeopathic pharmaceutical products, 'the Homeopathic Products Decree'), last amended in 2000.

17 Anthroposophic medicinal products, which, prior to the transposition of Directive 92/73, did not need to be pre-registered, were subject to transitional rules exempting them from the pre-registration requirement until 1 July 2002. Since the end of the transitional period, anthroposophic medicinal products prepared by a homeopathic method may be registered under the simplified procedure laid down in the Homeopathic Products Decree. All other anthroposophic medicinal products are subject to the normal registration rules put in place by the Decree of 8 September 1977 on the registration of pharmaceutical specialities and pharmaceutical preparations, as amended.

The main proceedings and the questions referred to the Court

18 It can be seen from the order for reference and from the observations submitted to the Court in these proceedings that, unlike traditional medicine (also called 'allopathic medicine'), which is based essentially on physically observable phenomena, anthroposophic medicine is based on the idea that a human being is composed of four elements: the physical body, the etheric body, the astral body and the 'ego'. Anthroposophic medicinal products are intended to re-establish the balance between the four constituents of a human being; they are prepared by a specific method and may contain different vegetable, mineral, animal or metallic substances.

19 It can also be seen from the order for reference that Antroposana and Others contested, before the Rechtbank te 's-Gravenhage, the applicability to anthroposophic medicinal products of Article 3 of the Law.

20 In particular, Antroposana and Others argued that the Netherlands legislation was unsuitable and disproportionate inasmuch as the requirement that such products be registered in accordance with the forms and procedures laid down in Directive 2001/83 made it impossible in practice to market a great many anthroposophic medicinal products in the Netherlands. It is difficult to prove the therapeutic effectiveness of such medicinal products on the basis of the objective criteria applied to traditional medicinal products. What is more, it is also impossible, in the case of many anthroposophic products, to have them registered under the simplified procedure laid down in the Homeopathic Products Decree, since that procedure is based on the description of the product in an officially recognised pharmacopoeia. Anthroposophic medicinal products are described only partially in official pharmacopoeias.

21 The Netherlands authorities replied that Directive No 2001/83 carried out a complete harmonisation of the procedures for the issue of marketing authorisations for medicinal products. The Member States are therefore required to follow the harmonised registration procedures in the case of all medicinal products and are not free to apply different procedures, not provided for in the Community rules, to specific categories of medicinal product such as anthroposophic medicinal products.

22 In parallel with those substantive proceedings, Antroposana and Others also brought an action against the Netherlands State before the judge hearing applications for interim relief of the Rechtbank te 's-Gravenhage, asking for an order directing the Netherlands State to suspend application of the prohibition contained in Article 3(4) of the Law until judgment had been delivered on the substance of the case or, in the alternative, to 'tolerate' the manufacture and marketing of anthroposophic medicinal products.

23 By decision of 15 April 2003, the judge hearing the application for interim relief granted the alternative form of order sought by Antroposana and Others and ordered the Netherlands State to 'tolerate' the manufacture and marketing of anthroposophic medicinal products, but only in the case of those prescribed by a doctor.

24 The Netherlands State appealed to the Gerechtshof te 's-Gravenhage. Antroposana and Others lodged a cross-appeal before the same court.

25 By judgment of 27 May 2004, the Gerechtshof te 's-Gravenhage quashed the interim order to the extent that it contained a restriction limiting its scope to anthroposophic medicinal products prescribed by a doctor. For the rest, it upheld the judge's decision.

26 The Netherlands State appealed to the Hoge Raad der Nederlanden, which, in considering the appeal, decided to stay the proceedings and to refer the following questions to the Court for a preliminary ruling:

'1. Does Directive 2001/83/EC … oblige Member States to make anthroposophic medicinal products which are not at the same time homeopathic medicinal products subject to the requirements in respect of authorisation as set out in Chapter 1 of Title III of that directive?

2. If the answer to Question 1 is in the negative: is the Netherlands statutory provision which makes those anthroposophic medicinal products subject to the aforementioned requirements in respect of authorisation an exception to the prohibition under Article 28 EC which is authorised by virtue of Article 30 EC?'

The questions referred to the Court

27 In its first question, the national court is essentially asking the Court whether anthroposophic medicinal products may be marketed only on condition that they have been authorised under one of the procedures laid down in Directive 2001/83.

28 The Italian and Netherlands Governments, as well as the Commission of the European Communities, propose that the Court should answer that question in the affirmative. They argue, in particular, that the directive carried out a complete harmonisation of national authorisation and registration procedures for medicinal products for human use, with a view to their being placed on the market in the Member States.

29 On the other side, Antroposana and Others suggest – as does the German Government – that the Court should answer the question in the negative. They contend that the Member States are free to lay down or maintain specific authorisation procedures for the categories of medicinal product for which Directive 2001/83 does not provide special and adequate procedures.

30 In order to answer this question, it should be pointed out that, under the first subparagraph of Article 1(2) of Directive 2001/83, a medicinal product is '[a]ny substance or combination of substances presented for treating or preventing disease in human beings'. According to the second subparagraph of that provision, '[a]ny substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings' is likewise to be considered a medicinal product.

31 The directive thus gives two definitions of medicinal products, one 'by virtue of their presentation' and one 'by virtue of their function'. A product is a medicinal product if it falls within either of those definitions (Case C-60/89 Monteil and Samanni [1991] ECR I-1547, paragraphs 10 and 11). It is also settled case-law that those two definitions are to be broadly construed (see, to that effect, Case 35/85 Tissier [1986] ECR 1207, paragraph 26; Monteil and Samanni, paragraph 23, and **Case C-112/89 Upjohn [1991] ECR I-1703**, paragraph 16).

32 In the present case, it can be seen from the order for reference that the products at issue in the main proceedings are presented as 'medicinal products' prepared on the basis of the principles of anthroposophic medicine.

33 It follows that such products come within the definition of 'medicinal products' laid down in Article 1(2) of Directive 2001/83.

34 It should be noted that the first subparagraph of Article 6(1) of Directive 2001/83 provides that '[n]o 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 (EEC) No 2309/93'.

35 Consequently, it is absolutely clear from the terms of that provision that, as the Court has already pointed out, if medicinal products are to be marketed in the Community, authorisation must first have been obtained, in accordance with the procedures laid down in the directive, for their placing on the market (see, to that effect, **Joined Cases C-211/03, C-299/03 and C-316/03 to C-318/03 HLH Warenvertrieb and Orthica [2005] ECR I-5141**, paragraph 57).

36 Moreover, that interpretation of the provision in question is, as the Advocate General pointed out in points 56 to 60 of his Opinion, in accordance with the objectives which Directive 2001/83 seeks to attain, namely, the elimination of hindrances to trade in medicinal products between the Member States and the protection of public health.

37 It follows from all the foregoing considerations that products coming within the definition of 'medicinal products' in Article 1(2) of Directive 2001/83 which are not mentioned in the Annex to Regulation No 2309/93, now replaced by the Annex to Regulation No 726/2004, must be registered under one of the procedures laid down in the aforementioned directive.

38 That conclusion is not called into question by the argument put forward by Antroposana and Others and the German Government to the effect that the harmonisation process in the field of medicinal products for human use is being carried out in stages and is not yet complete. Accordingly, the Member States retain their freedom to lay down or maintain specific authorisation procedures for certain medicinal products, parallel to the procedures applicable under Directive 2001/83, in so far as that directive does not lay down special and adequate procedures for those products.

39 In support of that argument, Antroposana and Others, and the German Government, refer, first of all, to the 14th recital in the preamble to Directive 2001/83 according to which the directive 'represents an important step towards achievement of the objective of the free movement of medicinal products' and '[f]urther measures [to] abolish any remaining barriers to the free movement [may] be necessary'. Secondly, they refer to the fact that Directive 2004/24 introduced 'traditional use registration' for certain traditional herbal medicinal products, mentioned in paragraph 14 of this judgment.

40 However, as the Advocate General remarked in points 61 to 68 of his Opinion, the line of reasoning adopted by Antroposana and Others and the German Government is based on the erroneous premise that complete harmonisation in the field of medicinal products for human use is incompatible with the fact that that field is in a state of continuing evolution.

41 In reality, the fact that Directive 2001/83 lays down a complete system of authorisation procedures for medicinal products in no way means that the Community legislature cannot amend or adapt those procedures or, if necessary, introduce new ones so as better to attain the objectives of removing barriers to intracommunity trade and the protection of public health.

42 In addition, the circumstance, relied on by Antroposana and Others, that some Member States did not comply with Directive 2001/83, when it was amended

in 2004 – in that they introduced or maintained registration or authorisation procedures not provided for in the directive – does not affect the fact that the directive established a complete regulatory framework for registration and market authorisation procedures in respect of medicinal products for human use.

43 In the light of all of the foregoing considerations, the answer to the first question must be that anthroposophic medicinal products may be marketed only on condition that they have been authorised under one of the procedures referred to in Article 6 of Directive 2001/83.

44 Having regard to the answer to the first question, there is no need to answer the national court's second question.

Costs

45 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 (First Chamber) hereby rules:

Anthroposophic medicinal products may be marketed only on condition that they have been authorised under one of the procedures referred to in Article 6 of Directive 2001/83 of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

OPINION OF ADVOCATE GENERAL BOT

delivered on 24 May 2007 1(1)
Case C-84/06
Staat der Nederlanden
v
Antroposana, Patiëntenvereniging voor Antroposofische Gezondheidszorg,
Nederlandse Vereniging van Antroposofische Artsen,
Weleda Nederland NV,
Wala Nederland NV
(Reference for a preliminary ruling from the Hoge Raad der Nederlanden (Netherlands))
(Community code relating to medicinal products for human use – Anthroposophic medicinal products – Registration and marketing authorisation – Complete harmonisation)

– Introduction

1. In these proceedings for a preliminary ruling the Hoge Raad der Nederlanden (Netherlands) is asking the Court of Justice two questions concerning the interpretation 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, (2) and of Articles 28 EC and 30 EC, with regard to the conditions under Dutch law for authorisation to place anthroposophic medicinal products on the market.

2. That category of medicinal product is used in the context of anthroposophic medicine, which is a branch of medicine founded in the 1920s by the Austrian philosopher and scientist, Rudolf Steiner (1861-1925). (3) Anthroposophic medicinal products are prepared from vegetable, mineral or animal substances.(4)

3. The problem raised by this reference is whether Directive 2001/83 is to be regarded as having carried out a complete harmonisation of the national registration and marketing authorisation procedures relating to medicinal products for human use with a view to their being placed on the market in the Member States or, on the contrary, whether that directive is merely a step on the way to harmonisation which leaves the door open to separate national procedures covering categories of medicinal product for which no provision is made under that directive, such as anthroposophic medicinal products which are neither homeopathic medicinal products nor traditional herbal medicinal products.

4. In this Opinion, I will show that Directive 2001/83 completely harmonised the national procedures for authorisation and registration of the medicinal products for human use which come within its scope ratione materiae. Consequently, I will propose that the Court should reply to the Hoge Raad der Nederlanden that Directive 2001/83 should be interpreted as requiring the Member States to make anthroposophic medicinal products which are covered neither by the simplified registration procedure for homeopathic medicinal products nor by the simplified registration procedure for traditional herbal medicinal products subject to the general authorisation procedure laid down in Chapter 1 of Title III of that directive.

II – Legal framework

A – Community rules

5. Directive 2001/83, which is based on Article 95 EC, codified the earlier directives adopted for the purpose of approximating the provisions laid down by law, regulation or administrative action relating to medicinal products for human use by assembling them into a single text.

6. In the view of the Community legislature, the essential aim of any rules governing the production, distribution or use of medicinal products must be to safeguard public health. However, this objective must be attained by means which will not hinder the development of the pharmaceutical industry or trade in medicinal products within the European Community. (5)

7. Starting from the finding that trade in medicinal products within the Community is hindered by disparities between national provisions relating to medicinal products and that such disparities directly affect the functioning of the internal market, the Community legislature sought to remove such hindrances by approximation of those national provisions (6)

8. Directive 2001/83 therefore represents 'an important step towards achievement of the objective of the free movement of medicinal products'. (7) The Community legislature added, however, that 'further measures [to] abolish any remaining barriers to the free

movement of proprietary medicinal products [may] be necessary in the light of experience gained … in the … Committee for Proprietary Medicinal Products. ’(8)

9. Article 1(2) of Directive 2001/83 defines ‘medicinal product’ as follows:

‘…

(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;’.

10. Unlike a homeopathic medicinal product, which is defined in Article 1(5) of Directive 2001/83, no definition is provided in the directive of an anthroposophic medicinal product. However, reference is made to that type of medicinal product in the 22nd recital in the preamble to the directive, which states that ‘[t]he anthroposophic medicinal products described in an official pharmacopoeia and prepared by a homeopathic method are to be treated, as regards registration and marketing authorisation, in the same way as homeopathic medicinal products’.

11. According to the first subparagraph of Article 6(1) of Directive 2001/83:

‘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 (EEC) No 2309/93. [(9)]’

12. Directive 2001/83 provides for three types of procedure in regard to national marketing authorisations for medicinal products for human use.

13. First of all, Chapter 1 of Title III of that directive contains provisions concerning a general procedure for the issue of marketing authorisations. The applicant for such an authorisation is required to submit the results of pharmaceutical, pre-clinical and clinical tests. (10) However, Article 10a of the directive provides that the applicant is not required to provide the results of pre-clinical tests or clinical trials if he can demonstrate that the active substances of the medicinal product have been in well-established medicinal use within the Community for at least ten years, with recognised efficacy and an acceptable level of safety in terms of the conditions set out in Annex I to the directive. In that event, the test and trial results are to be replaced by an appropriate scientific bibliography.

14. Secondly, Chapter 2 of Title III of Directive 2001/83, entitled ‘Specific provisions applicable to homeopathic medicinal products’, lays down a simplified registration procedure for homeopathic medicines which fulfil the conditions laid down in Article 14(1) of the directive. (11)

15. Thirdly, Chapter 2a of Title III of Directive 2001/83, entitled ‘Specific provisions applicable to traditional herbal medicinal products’ establishes a simplified procedure for traditional herbal medicinal products which fulfil all of the criteria laid down in Article 16a(1) of Directive 2001/83.

B – National rules

16. It is prohibited under Article 3(4) of the Wet op de Geneesmiddelenvoorziening (Law on Medicinal Products, ‘the Law’) to prepare, sell, supply, import or market unregistered pharmaceutical specialities and pharmaceutical preparations or to maintain stocks of such products for purposes of supply. The marketing of an unregistered pharmaceutical product is subject to criminal penalties.

17. The rules for registration are set out in the Royal Decree of 8 September 1977 on the registration of pharmaceutical specialities and pharmaceutical preparations, as amended in 2004. (12) Moreover, specific rules for the registration of homeopathic pharmaceutical products were laid down in the Royal Decree of 24 December 1991, as amended in 2000. (13) Article 1(2) of the Homeopathic Products Decree provides that, for the purposes of its application, a product prepared in accordance with the anthroposophic method is to be regarded as a homeopathic pharmaceutical product if it is prepared in accordance with the method generally used to prepare homeopathic pharmaceutical products.

18. Anthroposophic medicinal products were subject to transitional rules exempting them from the registration requirement until 1 July 2002.

19. Since the end of the transitional period, the Netherlands authorities have applied the prohibition under Article 3(4) of the Law fully to medicinal products of that type.

20. Thus, anthroposophic medicinal products prepared by a homeopathic method may be registered under the simplified procedure established by the Homeopathic Products Decree. The normal registration rules put in place by the Registration Decree apply to all other anthroposophic medicinal products. The Netherlands authorities considered that Directive 2001/83 did not permit them to adopt specific rules for non-homeopathic anthroposophic medicinal products.

III – The main proceedings

21. The main proceedings are between the Staat der Nederlanden and Antroposana, Patiëntenvereniging voor Antroposofische Gezondheidszorg (Association of Patients for Anthroposophic Health Care), Nederlandse Vereniging van Antroposofische Artsen (Netherlands Association of Anthroposophic Doctors), Weleda Nederland NV and Wala Nederland NV (14) (hereinafter collectively referred to as ‘the defendants’).

22. The dispute concerns, essentially, the question whether Article 3(4) of the Law may be applied to anthroposophic medicinal products until such time as a specific registration procedure is put in place for that type of medicinal product.

23. The defendants therefore contested, before the Rechtbank te ’s-Gravenhage, the application of Article 3(4) of the Law to anthroposophic medicinal products. In particular, they claimed that the Netherlands legislation was unsuitable and disproportionate inasmuch as, by requiring registration of those products in accor-

dance with the forms and procedures laid down in Directive 2001/83, it made it impossible in practice to market a great many anthroposophic medicinal products in the Netherlands. It is difficult to prove the therapeutic effectiveness of such medicinal products on the basis of the objective criteria applied to traditional medicinal products. Also, many anthroposophic products cannot be registered under the simplified procedure provided for homeopathic medicinal products, since that procedure is based on the description of the product in an officially recognised pharmacopoeia. Anthroposophic medicinal products are described only partially in official pharmacopoeias.

24. The Netherlands authorities replied to that argument by contending, essentially, that Directive 2001/83 carried out a complete harmonisation of the procedures for the issue of marketing authorisations for medicinal products. The Member States are therefore required to follow the harmonised registration procedure in regard to all medicinal products and are not free to apply different procedures, not provided for in the Community rules, to specific categories of medicinal product such as anthroposophic medicinal products.

25. In parallel with those substantive proceedings, the defendants also brought an action against the Netherlands State before the judge hearing applications for interim relief of the Rechtbank te 's-Gravenhage asking for an order restraining the Netherlands State from applying the prohibition contained in Article 3(4) of the Law until judgment had been delivered on the substance of the case. In the alternative, the judge was asked to order the Netherlands State to permit, until that date, the manufacture, sale, delivery, importation and marketing of non-homeopathic anthroposophic medicinal products by Weleda Nederland NV and Wala Nederland NV and the sale and delivery of their products by pharmacists supplied by those undertakings.

26. By decision of 15 April 2003, the judge granted the defendants' alternative application in respect of anthroposophic medicinal products prescribed by a doctor.

27. The Netherlands State appealed to the Gerechtshof te 's-Gravenhage and the defendants lodged a cross-appeal before the same court. By judgment of 27 May 2004, the Gerechtshof te 's-Gravenhage partially quashed the interim order in so far as its scope was limited to anthroposophic medicinal products prescribed by a doctor. For the rest, it upheld the decision of the judge hearing applications for interim measures. The Netherlands State therefore appealed to the Hoge Raad der Nederlanden against the decision of the Gerechtshof te 's-Gravenhage.

IV – The questions referred to the Court

28. Since it considered that an interpretation of Community law was necessary in order to rule on the appeal, the Hoge Raad der Nederlanden decided to refer the following two questions to the Court for a preliminary ruling:

'1. Does Directive 2001/83/EC oblige Member States to make anthroposophic medicinal products which are not at the same time homeopathic medicinal products subject to the requirements in respect of authorisation as set out in Chapter 1 of Title III of that directive?

2. If the answer to Question 1 is in the negative: is the Netherlands statutory provision which makes those anthroposophic medicinal products subject to the aforementioned requirements in respect of authorisation an exception to the prohibition under Article 28 EC which is authorised by virtue of Article 30 EC?'

V – Analysis

A – The first question referred to the Court

29. In its first question, the Hoge Raad der Nederlanden seeks to know, essentially, whether Directive 2001/83 is to be interpreted as requiring the Member States to make anthroposophic medicinal products which are covered neither by the simplified registration procedure for homeopathic medicinal products nor by the simplified registration procedure for traditional herbal medicinal products subject to the general marketing authorisation procedure laid down in that directive.

30. As I pointed out in my introduction, that question calls upon the Court to determine whether Directive 2001/83 is to be regarded as having carried out an exhaustive harmonisation of the national authorisation and registration procedures concerning medicinal products for human use with a view to their being placed on the market in the Member States or whether, on the contrary, the directive is merely a step in the process of harmonisation and leaves the door open to separate national procedures covering categories of medicinal product for which no provision is made in the directive, such as anthroposophic medicinal products which belong neither to the category of homeopathic medicinal products nor to that of traditional herbal medicinal products.

31. It should be noted, first of all, that, in accordance with Article 1(2) of Directive 2001/83, an anthroposophic product is a 'medicinal product' within the meaning of the directive if it comes within the definition of a medicinal product 'by virtue of its presentation' or that of a medicinal product 'by virtue of its function'. (15) This reference for a preliminary ruling concerns only anthroposophic products which are covered by one or other of those definitions.

32. The Italian and Netherlands Governments, and the Commission of the European Communities, propose that the first question be answered in the affirmative, on the ground that Directive 2001/83 carried out a total harmonisation of national procedures concerning marketing authorisation for medicinal products for human use. Anthroposophic medicinal products which are neither homeopathic medicinal products nor traditional herbal medicinal products must therefore be authorised in accordance with the general procedure laid down in Chapter 1 of Title III of that directive.

33. On the other hand, the defendants and the German Government consider that Directive 2001/83 does not carry out a complete harmonisation of the authorisation procedures. They claim, in particular, that the

harmonisation procedure in the field of medicinal products for human use is being carried out in stages. Although homeopathic medicinal products and traditional herbal medicinal products have been brought expressly within the scope of the Community rules, that is not yet the case in regard to anthroposophic medicinal products. Thus, the Member States remain free to adopt or to maintain specific authorisation procedures for certain medicinal products, in parallel with the procedures applicable by virtue of Directive 2001/83, until such time as the directive lays down special and adequate procedures for anthroposophic medicinal products.

34. For the reasons which I will now set out, I consider, as do the Italian and Netherlands Governments and the Commission, that Directive 2001/83 carried out a complete harmonisation of the national marketing authorisation and registration procedures for medicinal products for human use and that, therefore, the answer to the first question should be in the affirmative.

35. The reason for that answer can be deduced from the legal basis, terms, structure and objectives of the directive in question. (16)

1. The legal basis of Directive 2001/83

36. Directive 2001/83 was adopted on the basis of Article 95 EC.

37. Contrary to the defendants' claim in their written pleadings, I do not think that a complete harmonisation of the national marketing authorisation and registration procedures for medicinal products for human use is impossible on the basis of that article.

38. Article 95 EC provides a general legal basis which permits, by way of derogation from Article 94 EC, and save where otherwise provided in the Treaty, the adoption of measures for the approximation of provisions laid down by law, regulation or administrative action in the Member States which have as their object the establishment and functioning of the internal market.

39. It follows from the Court's case law that the measures envisaged by Article 95(1) EC are intended to improve the conditions for the establishment and functioning of the internal market and actually contribute to eliminating obstacles to the free movement of goods or to the freedom to provide services, or to removing distortions of competition. (17)

40. In addition, once the conditions for recourse to Article 95 EC are fulfilled, the Community legislature cannot be prevented from relying on that legal basis on the ground that public health protection is the decisive factor in the choices to be made(18).

41. It is true that that article does not expressly indicate the degree of harmonisation which it seeks to achieve. However, the function of Article 95 EC, which is to reduce, or even eliminate, differences between national provisions which hinder the fundamental freedoms, must permit the Community legislature to carry out an exhaustive harmonisation when it uses that legal basis.

42. Consideration of the terms of Directive 2001/83 will make it possible to verify whether the Community legislature wished to carry out a complete harmonisation of the national marketing authorisation and registration procedures for medicinal products for human use.

2. The terms of Directive 2001/83

43. In Title III of Directive 2001/83, concerning the marketing of medicinal products for human use, the first subparagraph of Article 6(1) provides that '[n]o 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 (EEC) No 2309/93'. (19)

44. The Court interpreted that provision in its judgment in HLH Warenvertrieb and Orthica, cited above. It held that '[i]f a product is correctly classified as a medicinal product for the purposes of Directive 2001/83, its marketing is subject to the issue of marketing authorisation pursuant to Article 6(1) of that directive'(20). It added that '[t]he procedure governing the issue and the effects of such authorisation are set out in detail in Articles 7 to 39 of that directive'. (21) The Court's answer to the national court therefore was that 'a product which constitutes a medicinal product within the meaning of Directive 2001/83 may be imported into another Member State only upon acquisition of a marketing authorisation issued in accordance with the provisions of that directive'. (22)

45. Both the terms of the first subparagraph of Article 6(1) of Directive 2001/83 and the Court's interpretation thereof lead to the conclusion that the Member States have no room to manoeuvre in regard to the adoption of any supplementary procedure for the issue of marketing authorisations in addition to those provided for in the directive. A product coming within the Community definition of a 'medicinal product', and which is not covered by Regulation No 726/2004, may be granted a marketing authorisation in a Member State 'in accordance with the provisions of Directive 2001/83', that is to say, only under the procedures laid down therein. (23)

46. The structure of Directive 2001/83 also argues in favour of the complete harmonisation theory.

3. The structure of Directive 2001/83

47. Directive 2001/83 is structured according to the different subjects which it regulates, that is to say, in particular, the placing on the market of medicinal products for human use (Title III), their manufacture and importation (Title IV), labelling and package leaflets (Title V), classification (Title VI), wholesale distribution (Title VII) and advertising (Title VIII). (24)

48. Providing an answer to the question whether Directive 2001/83 carried out a complete harmonisation in each of those areas requires consideration of the relationship between the provisions in each title of the directive. (25)

49. As I have indicated above, Title III of Directive 2001/83 lays down three types of procedure for the issue of marketing authorisations in respect of medicinal products for human use in the Member States. There is,

on the one hand, the general authorisation procedure (Chapter 1), then there is the special, simplified, registration procedure for homeopathic medicinal products which fulfil the conditions laid down in Article 14(1) of the directive (Chapter 2) and finally, there is the simplified registration system for traditional herbal medicinal products which fulfil all the criteria set out in Article 16a(1) of the directive (Chapter 2a).

50. Several factors show that that system is complete and does not permit the establishment of other specific, national procedures for the issue of marketing authorisations for medicinal products for human use.

51. Thus, Article 16(1) of Directive 2001/83 provides that '[h]omeopathic medicinal products other than those referred to in Article 14(1) shall be authorised and labelled in accordance with Articles 8, 10, 10a, 10b, 10c and 11 [of the directive]'. That provision means that homeopathic medicinal products which do not fulfil all the conditions set out in Article 14(1) of the directive may not be made subject to the special simplified registration procedure but are subject to the general procedure laid down in Chapter 1 of Title III of Directive 2001/83. It follows that the Member States may not establish a special procedure for authorising the marketing of homeopathic medicinal products which cannot be registered under the special simplified procedure laid down in Chapter 2 of the directive.

52. Article 16(2) of Directive 2001/83 certainly permits the Member States to introduce or retain in their territory 'specific rules for the pre-clinical tests and clinical trials of homeopathic medicinal products other than those referred to in Article 14(1) in accordance with the principles and characteristics of homeopathy as practised in [those] Member State[s]'. However, as can be seen from Article 16(1) of Directive 2001/83, such an adaptation, which the Community legislature expressly authorised the Member States to adopt, may be applied only in the context of the general authorisation procedure laid down in Chapter 1 of Title III of the directive.

53. In addition, Article 16a(3) of Directive 2001/83 provides that 'where the competent authorities judge that a traditional herbal medicinal product fulfils the criteria for authorisation in accordance with Article 6 or registration pursuant to Article 14, [Chapter 2a concerning specific provisions applicable to traditional herbal medicinal products] shall not apply'. As the fourth recital in the preamble to Directive 2004/24 indicates, 'this simplified procedure should be used only where no marketing authorisation can be obtained pursuant to Directive 2001/83/EC … It should likewise not apply to homeopathic medicinal products eligible for marketing authorisation or for registration under [that directive]'.

54. To my mind, all of those provisions show that the Community legislature intended to establish an exhaustive procedural framework within which each medicinal product may be authorised or registered according to the procedure which corresponds to its characteristics.

55. Finally, the complete harmonisation theory is confirmed by a consideration of the objectives of Directive 2001/83.

4. The objectives of Directive 2001/83

56. Directive 2001/83 seeks to eliminate hindrances to trade in medicinal products within the Community while protecting public health. Reconciling those two objectives is in accordance with the provision made by Article 95(3) EC, namely that harmonisation on the basis of that article of the Treaty should take as a base a high level of protection of health.

57. In so far as it is to be achieved by the approximation of national provisions concerning medicinal products, the objective of removing hindrances to the movement of medicinal products appears to be intrinsically incompatible with the continued existence of differences between the rules in the various Member States.

58. A total harmonisation of national procedures for the issue of market authorisations and the registration of medicinal products for human use is therefore necessary in order to achieve fully the objective of eliminating hindrances to trade in medicinal products between the Member States.

59. Moreover, only a complete harmonisation of those procedures seems capable of achieving the objective, described as 'essential' by the Community legislature, of protecting public health. In the pursuit of that objective, the existence of different criteria in the Member States for evaluating the safety and effectiveness of certain medicinal products is not the same as the uniform adoption of such criteria at Community level, on the basis of a high level of public health protection.

60. Finally, maintaining or introducing special procedures in the Member States applicable to this or that specific medicinal product would be likely to lead to different assessments by the competent national authorities as to the quality, safety and effectiveness of medicinal products. Such divergences could, in practice, paralyse the implementation of mutual recognition of authorisations, which would run counter to the objective of encouraging such recognition which the Community legislature is seeking to achieve in Directive 2001/83. (26)

5. Final remarks

61. Finally, I would like to dissipate a misunderstanding which is, I think, at the heart of the position both of the defendants and of the German Government. They rely to a large extent on an argument based on the evolution 'in stages' of the Community rules on medicinal products for human use to deny the existence of a complete harmonisation of the national marketing authorisation and registration procedures for such products.

62. However, I do not think that complete harmonisation in a given field means harmonisation which is fixed or definitive. In other words, the fact that harmonisation is exhaustive is not incompatible with its continuing to evolve.

63. In a field such as that which is before the Court, it is absolutely clear that the development of the Community rules at regular intervals is essential, and even unavoidable, having regard to advances in science and the lessons learned from the application of the legal rules in practice.

64. The proof of that can be seen in some of the amendments made to Directive 2001/83 in 2004, such as the insertion of a Chapter 2a in Title III of the directive laying down a simplified procedure for the registration of traditional herbal medicinal products.

65. The introduction of that procedure was justified by the Community legislature as follows in the third recital in the preamble to Directive 2004/24: '[a] significant number of medicinal products, despite their long tradition, do not fulfil the requirements of a well-established medicinal use with recognised efficacy and an acceptable level of safety and are not eligible for a marketing authorisation. To maintain these products on the market, the Member States have enacted differing procedures and provisions. The differences that currently exist between the provisions laid down in the Member States may hinder trade in traditional medicinal products within the Community and lead to discrimination and distortion of competition between manufacturers of these products. They may also have an impact on the protection of public health since the necessary guarantees of quality, safety and efficacy are not always provided at present'.

66. In my view, that demonstrates the pragmatic approach adopted by the Community legislature in regard to medicinal products. Once it realised, on the basis of practical experience, the inadequacy of the general procedure for the authorisation of traditional herbal medicinal products with, along side it, different procedures in the Member States for the authorisation and marketing of that category of medicinal products, (27) the objectives of eliminating hindrances to trade and distortions of competition between producers of medicinal products and of protecting public health made it necessary to adapt the existing procedural framework.

67. In so far as the Community legislature did not expressly permit the Member States to establish special procedures for specific medicinal products, such an adaptation of the procedural system put in place by Directive 2001/83 could only be carried out at Community level.

68. It is in that sense that the harmonisation of the national marketing authorisation and registration procedures for medicinal products for human use must be regarded as exhaustive, although it is, of its nature, evolving. (28)

69. I therefore propose that, in answer to the first question referred to the Court, it should be stated that, inasmuch as Directive 2001/83 carried out a complete harmonisation of the national marketing authorisation and registration procedures for medicinal products for human use, that directive must be interpreted as requiring Member States to make anthroposophic medicinal products which are covered neither by the special simplified procedure for homeopathic medicinal products nor by the simplified registration system for traditional herbal medicinal products subject to the general authorisation procedure laid down in Chapter 1 of Title III of the directive.

B – The second question referred to the Court

70. In light of the fact that I have proposed that the Court should answer the first question in the affirmative, there is no need to consider the second question.

VI – Conclusion

71. In the light of all the foregoing considerations, I propose that the Court should give the following answer to the questions referred by the Hoge Raad der Nederlanden:

Inasmuch as 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 and by Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004, carried out a complete harmonisation of the national marketing authorisation and registration procedures for medicinal products for human use, that directive must be interpreted as requiring Member States to make anthroposophic medicinal products which are covered neither by the special simplified procedure for homeopathic medicinal products nor by the simplified registration system for traditional herbal medicinal products subject to the general authorisation procedure laid down in Chapter 1 of Title III of the directive.

---

1 – Original language: French.

2 – OJ 2001 L 311, p. 67. Directive 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) and, as regards traditional herbal medicinal products, by Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 (OJ 2004 L 136, p. 85, 'Directive 2001/83').

3 – According to this branch of medicine, illness is understood as the result of an imbalance between the four elements of the human being, namely, the physical body, the etheric body (vital force), the astral body (feelings and sensations) and the ego or egotic body (the conscious spirit). The remedies offered by anthroposophic doctors seek to re-establish the balance between those four elements.

4 – Anthroposophic medicinal products have a particular background and method of preparation. They are partially described in an official pharmacopoeia of homeopathic medicinal products. Certain preparations may be diluted in the same way as homeopathic remedies or may form part of phytotherapy.

5 – Second and third recitals in the preamble to Directive 2001/83.

6 – Fourth and fifth recitals in the preamble to Directive 2001/83.

7 – 14th recitals in the preamble to Directive 2001/83.

8 – Idem.

9 – Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (OJ 1993 L 214, p. 1). That regulation put in place a centralised authorisation procedure for the placing of products on the Community market. It was repealed and replaced by Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 (OJ 2004 L 136, p. 1). The centralised procedure is obligatory for the medicinal products in the annex to that regulation.

10 – See Article 8(3)(i) of Directive 2001/83.

11 – Those provisions were initially contained in Council Directive 92/73/EEC of 22 September 1992 widening the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to medicinal products and laying down additional provisions on homeopathic medicinal products (OJ 1992 L 297, p. 8).

12 – Stb. 2004, n° 309, 'the Registration Decree'.

13 – Stb. 2000, n° 467, 'the Homeopathic Products Decree'.

14 – The national court indicates that Weleda Nederland NV and Wala Nederland NV are the largest manufacturers of anthroposophic medicinal products on the Netherlands market and that medicinal products of this kind have been on the Netherlands market for approximately 80 years.

15 – Joined Cases C-211/03, C-299/03 and C-316/03 to C-318/03 HLH Warenvertrieb and Orthica [2005] ECR I-5141, paragraph 49.

16 – In his Opinion, delivered on 13 February 2007 in Case C-374/05 Gintec, pending before the Court, Advocate General Ruiz-Jarabo Colomer expressed his view as to whether the provisions of Directive 2001/83 concerning advertising of medicinal products for human use were intended to carry out a minimum harmonisation or whether they constitute a 'complete system' in which the Member States have no room for manoeuvre and may not therefore add further restrictions beyond those provided for in the directive (point 3). He considered that 'an interpretation of the purpose, structure, terms and legal basis of the directive supports the view that … directive [2001/83] puts in place a system which leaves no room for manoeuvre beyond that expressly authorised' (point 24).

17 – Case C-376/98 Germany v Parliament and Council [2000] ECR I-8419, paragraphs 83, 84 and 9), and Case C-491/01 British American Tobacco (Investments) and Imperial Tobacco [2002] ECR I-11453, paragraph 60. See also, to that effect, Case C-380/03 Germany v Parliament and Council [2006] ECR I-11573, paragraph 37.

18 – See, in particular, Case C-376/98 Germany v Parliament and Council, paragraph 88; British American Tobacco (Investments) and Imperial Tobacco, paragraph 62; and Case C-380/03 Germany v Parliament and Council, paragraph 39.

19 – My italics.

20 – Paragraph 57.

21 – Idem (my italics).

22 – Paragraph 60 (my italics).

23 – I agree with the view expressed by Advocate General Geelhoed in point 33 of his Opinion in HLH Warenvertrieb and Orthica, namely that '[t]he system established by Directive 2001/83 is conclusive where the definition of the notion of medicinal product is concerned; it exhaustively regulates marketing authorisations and the vital – from the standpoint of inter-State trade – issue of mutual recognition, while laying down a sound procedure for resolving differences of opinion between Member States concerning the health risks of permitted medicinal products. Within this framework, Member States are required to formulate their views on health protection in conformity with the detailed provisions of the directive'.

24 – On the other hand, it can be seen from the terms of Directive 2001/83 which areas the Community legislature clearly did not want to harmonise. For example, Article 4(3) of the directive states that its provisions 'shall not affect the powers of the Member States' authorities either as regards the setting of prices for medicinal products or their inclusion in the scope of national health insurance schemes, on the basis of health, economic and social conditions'.

25 – Determining whether Directive No 2001/83 was intended to carry out a complete harmonisation cannot be done in a general manner, but only area by area. It is therefore irrelevant to refer, as the defendants do in support of their position, to the case-law in which the Court held, in particular, that 'the sale of medicinal products to end consumers has not been subject to full Community harmonisation' (Case C-322/01 Deutscher Apothekerverband [2003] ECR I-14887, paragraph 102).

26 – See, in particular, the 12th recital in the preamble to Directive 2001/83 and Chapter 4 of Title III thereof.

27 – By mentioning the existence of such procedures in the Member States, the Community legislature is merely taking note of them, it is not indicating that they are compatible with Directive No 2001/83.

28 – In accordance with that analysis, the 14th recital in the preamble to Directive 2001/83 may not be interpreted as prohibiting, in principle, complete harmonisation in the field governed by the directive. In addition, it is possible to envisage other adaptations of the procedural system put in place by the directive, such as the extension of registration of traditional medicinal products to non-herbal products (see, in that regard, Article 16i of Directive 2001/83).