JUDGMENT OF THE COURT (First Chamber)

20 September 2007 *

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,

* Language of the case: Dutch.

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.

[Signatures]