# OPINION OF ADVOCATE GENERAL BOT delivered on 24 May 2007 [1]

## I — 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

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.

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

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

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

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]'

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.

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.

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).

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 June 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

12 — Stb. 2004, No 309, 'the Registration Decree'.

13 — Stb. 2000, No 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.

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 accordance 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 medi-

cinal 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

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.

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].

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 95), 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.

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

19 — My italics.
20 — Paragraph 57.
21 — Idem (my italics).
22 — Paragraph 60 (my italics).

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

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).

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 recogni-

tion 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'.

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

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.

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).

## 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.