META FACKLER

OPINION OF ADVOCATE GENERAL LÉGER

delivered on 27 January 2005 [1]

1. The controversy sparked by homeopathy is no longer confined to medical circles. It extends to the legal sphere, as is shown by this question referred for a preliminary ruling by the Verwaltungsgericht Berlin, Germany. However, the argument always tends to revolve around one recurring issue, the proof of the efficacy of homeopathic medical products.

I — Legal framework

2. Since Directive 92/73/EEC, [2] which was codified by Directive 2001/83/EC, [3] Community law has taken the particular characteristics of homeopathic medical products into account by making them subject, provided they fulfil certain conditions, to a special simplified registration procedure. By these questions referred for a preliminary ruling, the Verwaltungsgericht Berlin asks the Court to interpret the Community provisions governing this particular registration procedure.

A — *Community law*

3. Directive 2001/83 introduces a Community code relating to medicinal products for human use. Title III establishes the rules for placing a medicinal product on the market in a Member State of the European Community.

4. The principal aims of Directive 2001/83 are to remove obstacles to trade in medicinal products within the Community and to safeguard public health. The latter aim is

1 — Original language: French.

2 — 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).

3 — 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). By way of guidance, I would point out that this directive has recently been 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). These last two directives must be transposed by the Member States by 30 October 2005 at the latest. Under Article 128 of Directive 2001/83, Directive 92/73 is repealed.

described as 'essential' by the Community legislature. [4]

5. The 21st recital in the preamble to Directive 2001/83 states:

'Having regard to the particular characteristics of these homeopathic medicinal products, such as the very low level of active principles they contain and the difficulty of applying to them the conventional statistical methods relating to clinical trials, it is desirable to provide a special simplified registration procedure for those homeopathic medicinal products which are placed on the market without therapeutic indications in a pharmaceutical form and dosage which do not present a risk for the patient.'

6. In comparison, the wording of the 10th recital in the preamble to Directive 92/73 was identical, except that it referred to homeopathic medical products described as 'traditional'.

7. According to the 23rd recital in the preamble to Directive 2001/83, 'it is desirable in the first instance to provide users of these homeopathic medicinal products with a very clear indication of their homeopathic character and with sufficient guarantees of their quality and safety'.

8. Under Article 1(5) of the directive, a homeopathic medicinal product is defined as 'any medicinal product prepared from products, substances or compositions called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the *European Pharmacopoeia* or, in absence thereof, by the pharmacopoeias currently used officially in the Member States'. It is also stated that 'a homeopathic medicinal product may also contain a number of principles'.

9. Chapter 2 of Directive 2001/83 contains the specific provisions applicable to homeopathic medicinal products. Under Article 14 (1), only homeopathic medicinal products which satisfy the three following conditions may be subject to a special simplified registration procedure:

'— they are administered orally or externally,

— no specific therapeutic indication appears on the labelling of the medicinal product or in any information relating thereto,

4 — Second recital.

— there is a sufficient degree of dilution to guarantee the safety of the medicinal product; in particular, the medicinal product may not contain either more than one part per 10 000 of the mother tincture or more than 1/100th of the smallest dose used in allopathy with regard to active substances whose presence in an allopathic medicinal product results in the obligation to submit a doctor's prescription'.

10. Article 14(2) of Directive 2001/83 states that the criteria and rules of procedure laid down in a series of other provisions of the directive 'shall apply by analogy to the special simplified registration procedure for homeopathic medicinal products, with the exception of the proof of therapeutic efficacy'.

11. Also, Article 14(3) of the directive provides that 'proof of therapeutic efficacy shall not be required for homeopathic medicinal products registered in accordance with paragraph 1 of this article ...'.

12. Finally, the aim of Article 15 of Directive 2001/83 is inter alia to list the documents which must be enclosed with the application for special simplified registration 'in order to demonstrate, in particular, the pharmaceutical quality and the batch-to-batch homogeneity of the products concerned'. Those documents are as follows:

'— scientific name or other name given in a pharmacopoeia of the homeopathic stock or stocks, together with a statement of the various routes of use, pharmaceutical forms and degree of dilution to be registered,

— dossier describing how the homeopathic stock or stocks is/are obtained and controlled, and justifying its/their homeopathic nature, on the basis of an adequate bibliography,

— manufacturing and control file for each pharmaceutical form and a description of the method of dilution and potentisation,

— manufacturing authorisation for the medicinal product concerned,

— copies of any registrations or authorisations obtained for the same medicinal product in other Member States,

— one or more specimens or mock-ups of the outer packaging and the immediate packaging of the medicinal products to be registered,

— data concerning the stability of the medicinal product'.

B — *National law*

13. Article 39(2) No 7a of the Arzneimittelgesetz (Law on Medicinal Products, 'AMG') does not permit registration of a medicinal product composed of bibliographically identified homeopathic constituents if its use as a homeopathic medicinal product is not generally known.

II — Facts and procedure

14. In December 1993 the company meta Fackler KG ('meta Fackler') applied to the Bundesgesundheitsamt (Federal Health Authority), the competent authority at that time, for registration of a homeopathic medicinal product called 'metaipecac', in accordance with the provisions of the AMG. This medicinal product is a new combination of active substances known in homeopathy and described in various monographs published in the *Bundesanzeiger* (*Federal Gazette*).

15. In a ruling of 30 December 1994 the Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Drugs and Medicinal Products, 'the Bundesinstitut'), which is now the competent authority, rejected the application for registration on the ground that general awareness of its use as a homeopathic medicinal product had not been substantiated. The Bundesinstitut thus held that the — undisputed — general awareness of the various active substances of which the medicinal product was composed did not satisfy the statutory requirements for recognition of the new combined preparation.

16. Meta Fackler lodged an objection against that ruling, claiming that registration of new combinations of known substances was permitted by both national and Community law. By a decision of 17 April 1996 the Bundesinstitut dismissed that objection on the same grounds as the initial ruling. It added, in particular, that the criterion of being generally known necessarily presupposed therapeutic experience with the homeopathic medicinal product concerned.

17. The Bundesinstitut maintains that the possibility of inferring awareness of the combined preparation from awareness of its individual constituents should therefore be ruled out. This approach is supported by the 10th recital in the preamble to Directive 92/73, which provides that the special simplified registration procedure applies only to 'traditional', that is to say generally known, homeopathic medicinal products.

18. Meta Fackler has brought an appeal against that decision before the Verwaltungsgericht Berlin. The national court points out that in those proceedings the claimant in the main action is pursuing its application for registration. [5]

III — The reference for a preliminary ruling

19. The national court is in doubt as to the interpretation to be given to the Community provisions concerning the special simplified registration procedure for homeopathic medicinal products and has referred the following questions to the Court of Justice for a preliminary ruling:

'1. Is the rule contained in Paragraph 39(2) No 7a of the AMG compatible with Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 in so far as it does not permit registration of a medicinal product composed of bibliographically identified homeopathic constituents if its "use as a homeopathic ... medicinal product is not generally known"?

2. In particular:

(a) Are only "traditional" homeopathic medicinal products subject to the special simplified registration procedure under Article 14 et seq. of Directive 2001/83/EC?

(b) If the answer to this question is in the affirmative, can a medicinal product also be considered to be "traditional" if it is manufactured using bibliographically identified homeopathic stocks without having been in actual homeopathic use in that combination prior to the registration applied for,

or:

5 — Order for reference, p. 4.

Does the second indent of the second sentence of Article 15 of Directive 2001/83/EC permit a Member State to require that, for registration of a homeopathic medicinal product which is manufactured using a number of homeopathic stocks, a bibliography must be produced that refers to the combined preparation as such?'

IV — Assessment

20. It should be stated, first, that Chapter 2 of the codifying directive, Directive 2001/83, which is entitled 'Specific provisions applicable to homeopathic medicinal products', preserves almost unchanged the provisions of Directive 92/73 laying down the conditions to be fulfilled and the documents to be enclosed under the special simplified registration procedure for homeopathic medicinal products. [6]

21. Furthermore, as I have already pointed out, it is apparent from the order for reference that meta Fackler is not only asking the national court to quash the contested ruling of the Bundesinstitut, but is also pursuing its application for registration before that court.

22. I therefore consider that, even though the directive in force on the date on which the contested ruling of the Bundesinstitut was adopted, 17 April 1996, was Directive 92/73, the interpretation of Directive 2001/83 may conceivably help the national court to deal fully with the action brought by the claimant in the main proceedings.

23. It is therefore permissible for questions to be put to this Court regarding the interpretation of the relevant provisions of Directive 2001/83.

24. At the same time, I think I should focus my assessment on the main question to emerge from the various queries raised by the national court, that is: should Articles 14 and 15 of Directive 2001/83 be interpreted as precluding a national provision which refuses registration under the special simplified procedure for a medicinal product composed of a number of known homeopathic substances if its use as a homeopathic medicinal product is not generally known?

25. In order to reply to this question it will be necessary not only to specify the meaning and scope of the term '"traditional" homeopathic medicinal product', but also to establish whether Community law allows a

6 — The only variations between the two series of provisions are for the most part procedural and are attributable to the process of codification itself.

Member State to require a trader who wishes to register a homeopathic medicinal product under the special simplified procedure, to submit a bibliography which refers to the new combined preparation as such.

26. Having thus established the framework for my assessment, I must now set out the various arguments involved.

A — *The arguments involved*

27. The Bundesinstitut considers that although the Community provisions do not mention general awareness of the homeopathic medicinal product as such as a condition for registering the product under the special simplified procedure, that condition must nevertheless be satisfied by traders.

28. In its written observations it states that although Directive 2001/83 expressly excludes the need for proof of the therapeutic efficacy of the medicinal product, it does not preclude the requirement of proof of the efficacy of the medicinal product as a homeopathic remedy. This reasoning is based on the premiss that 'without experience of its use, a medicinal product cannot ... be described as homeopathic in accordance with the principles of that discipline'. [7] It is therefore not enough that the medicinal product is manufactured in accordance with homeopathic methods, since the testing of the medicinal product in order to determine its efficacy is an integral part of the homeopathic tradition.

29. This specific feature of homeopathy was taken into account by the authors of Directive 92/73, as is apparent in particular from its 10th recital, which provides for a special simplified registration procedure for homeopathic medicinal products described as 'traditional'. Furthermore, the removal of the adjective 'traditional' in the codifying directive, Directive 2001/83, is not inconsistent with this assessment, since the absence is probably due to an editorial oversight. [8]

30. The Bundesinstitut points out, finally, that the use of an untested medicinal

7 — The last sentence of point 29 of the observations of the defendant in the main proceedings.

8 — The Bundesinstitut adds that the 18th recital in the preamble to Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ 2001 L 311, p. 1) provides that the special simplified registration procedure applies to 'traditional' homeopathic medicinal products. The Bundesinstitut argues that, if the removal of the term 'traditional' in Directive 2001/83, which concerns medicinal products for human use, were not regarded as an editorial oversight, that would mean that 'the safety requirements in respect of medicinal products for animals would be stricter than in respect of those for humans' (point 20 of the observations of the defendant in the main proceedings).

product provides no guarantee that its use in homeopathic therapy will be safe, contrary, inter alia, to the aim of safeguarding public health, described as 'essential' by the Community legislature. [9]

31. The Commission's view is that the authors of Directive 92/73, and subsequently of Directive 2001/83, took a neutral position with regard to homeopathy and the controversies to which it gives rise. Accordingly, the compromise found in those directives is based on the notion that it is desirable not only to guarantee the safety and quality of homeopathic medicinal products, but also to ensure that patients have free access to the medicinal products of their choice.

32. The problem of proving the efficacy of homeopathic products was resolved by not requiring such proof in the case of a medicinal product placed on the market without therapeutic indications.

33. The Commission also states that the criterion of general awareness of the use of the medicinal product as a homeopathic medicinal product set out in Article 39(2) No 7a of the AMG is not required under the Community provisions relating to the special simplified registration procedure. Furthermore, the conditions to be met in order to be eligible for this procedure are listed exhaustively, as are the documents to be enclosed with the application for registration.

34. Moreover, the Community definition of homeopathic medicinal product calls only for a preparation from homeopathic stocks and a homeopathic manufacturing process. It makes no mention, by contrast, of the criterion of general awareness of the use of the medicinal product as a homeopathic medicinal product.

35. That condition relating to general awareness of the use of the homeopathic medicinal product likewise cannot be inferred from the 10th recital in Directive 92/73 in which the adjective 'traditional' appears, since the preamble to a Community act has no binding legal force and cannot be relied on as a ground for derogating from the actual provisions of the act in question. [10]

36. The Commission therefore considers that Member States which apply a special

9 — See the second recital in Directive 92/73 and the second recital in Directive 2001/83.

10 — In support of this argument, the Commission refers to the judgment in Case C-162/97 *Nilsson and Others* [1998] ECR I-7477, paragraph 54.

simplified registration procedure for homeopathic medicinal products are not justified in making application of the procedure subject to conditions which are more restrictive than those expressly laid down by Directive 2001/83.

37. As regards the risks connected with possible interactions between the various substances contained in a homeopathic medicinal product which is not generally known as such, the Commission considers that the safety of that homeopathic medicinal product is guaranteed by its method of administration and by its degree of dilution. Moreover, safe use of the homeopathic medicinal product means that its use is risk-free. Since the conditions laid down by the Community provisions are fulfilled, it may be concluded that the homeopathic medicinal product is safe.

38. Finally, Articles 26 and 116 of Directive 2001/83 are applicable by analogy to the special simplified registration procedure. It is apparent from the application by analogy of Article 26 that registration must be refused if, after verification of the particulars and documents, it proves that the medicinal product is harmful in the normal conditions of use. Article 116 stipulates that the authorities must revoke registration if the medicinal product proves to be harmful.

39. The view expressed by meta Fackler at the hearing largely concurs with that of the Commission.

B — *The suggested reply*

40. The questions raised by the national court seek to ascertain, in essence, whether Articles 14 and 15 of Directive 2001/83 must be interpreted as precluding a national provision which does not permit registration under the special simplified registration procedure for a medicinal product composed of a number of known homeopathic substances if its use as a homeopathic medicinal product is not generally known.

41. It is clear from the arguments it puts forward that the Bundesinstitut takes a firmly empirical approach to homeopathy. This point of view leads it to read in the provisions of Directive 2001/83 conditions regarding the experience required of the efficacy of the homeopathic medicinal products submitted for registration.

42. The Commission, on the other hand, argues that the Community legislature is neutral as to the efficacy of homeopathic medicinal products.

43. Meta Fackler follows this line of argument, maintaining that it is above all the special manufacturing process which gives a medicinal product its homeopathic nature.

44. In my view, both the wording and scheme of Directive 2001/83 and the aims which it is designed to achieve support the argument upheld by the Commission and meta Fackler.

45. Before examining more closely the legal definition of homeopathic medicinal product in Community law and the wording of the relevant provisions of Directive 2001/83, I think it would be helpful to have in mind some of the characteristics of homeopathy.

46. Homeopathy (from the Greek 'homoios', similar, and 'pathos', disease) is the name given to a 'therapy which consists in treating an ill person with infinitesimal doses of substances which, in a well person, would cause disorders similar to those suffered by the ill person'. [11]

11 — See *Le Petit Larousse*, large format, 1993. The opposite of homeopathy is allopathy (from the Greek 'allos', other, and 'pathos', disease) which is a 'method of treatment which uses medicines having opposite effects to the symptoms of the disease'.

47. Homeopathy, which was founded by Samuel Hahnemann (1755-1843), is therefore based on the principle of similarity ('like cures like'), according to which any substance capable of developing characteristic symptoms in a healthy person may cure an ill person who already has those same characteristic symptoms.

48. Two other principles are an intrinsic feature of homeopathy: the principles of dilution and potentisation, according to which gradually diluting the substance and shaking it removes its toxicity and renders it able to cause certain reactions in the body.

49. These special characteristics of homeopathy lie at the heart of Directive 92/73, and subsequently of the codifying directive, Directive 2001/83.

50. Under Article 1 No 5 of Directive 2001/83, a homeopathic medicinal product is defined as 'any medicinal product prepared from products, substances or compositions called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the *European Pharmacopoeia* or, in absence thereof, by the pharmacopoeias currently used officially in the Member States'.

51. Of the medicinal products covered by this definition, the special simplified registration procedure may be applied only to those which satisfy the three conditions laid down in Article 14(1) of Directive 2001/83 and summarised as follows:

— they are administered orally or externally,

— no specific therapeutic indication appears on the labelling of the medicinal product or in any information relating thereto,

— and, finally, there is a sufficient degree of dilution to guarantee the safety of the medicinal product.

52. A straightforward reading of those provisions suffices to show that the aforementioned conditions, which are unquestionably exhaustive, do not include the requirement, contained in the German legislation, that the homeopathic medicinal product should be generally known.

53. There is likewise no indication of a requirement that a medicinal product as such should have been subject to experience and research ensuring that it is generally known in Article 15 of Directive 2001/83, the aim of which is to list — also exhaustively — the documents to be enclosed with the application for special simplified registration.

54. However, the Bundesinstitut considers that the provision contained in the second indent of Article 15, according to which it is necessary to enclose with the application a 'dossier describing how the homeopathic stock or stocks is/are obtained and controlled, and justifying its/their homeopathic nature, on the basis of an adequate bibliography', should be interpreted as meaning that it is necessary to prove the homeopathic nature of the medicinal product obtained from one or more stocks.

55. The Bundesinstitut also claims that the homeopathic nature of the medicinal product cannot simply be inferred from the homeopathic nature of the stocks of which it is composed; the medicinal product must also have been *tested so as to determine its efficacy when administered in homeopathic therapy.* [12]

56. It is clear from this argument that the condition imposed by the German legislation that the medicinal product to be generally

12 — Points 27 and 28 of the written observations of the defendant in the main proceedings.

known, and the application of that condition by the Bundesinstitut, is in practice designed to require the applicant to show, by submitting a bibliography referring to the homeopathic medicinal product as such, that the efficacy of the medicinal product composed of known homeopathic substances has been tested, so that there is a sufficient degree of scientific knowledge of that medicinal product.

57. I cannot support that argument, which goes well beyond what is stated in the second indent of Article 15 of Directive 2001/83. That provision requires only the submission of a dossier describing how *the stocks* from which the medicinal product is made are obtained and controlled and justifying their homeopathic nature: it by no means requires the submission of a bibliography showing that the *efficacy of the homeopathic medicinal product itself* has been proved. [13]

58. Furthermore, the terms in which Article 15 is couched indicates the role of the documents which have to be enclosed with the application for registration, namely 'to demonstrate, in particular, the pharmaceutical quality and the batch-to-batch homogeneity of the products concerned'. Those documents are not therefore intended to prove the efficacy of the medicinal product when used in homeopathic therapy.

59. In that regard, the argument put forward by the Bundesinstitut is also rebutted by Article 14(2) and (3) of Directive 2001/83, which expressly excludes proof of therapeutic effect from the conditions laid down for registering homeopathic medicinal products under the special simplified procedure. [14]

60. Finally, I would point out that Article 14 (2) of Directive 2001/83, which provides for the application by analogy of certain criteria and certain general rules of procedure to the special procedure applicable to homeopathic medicinal products which satisfy the conditions laid down in Article 14(1), does not refer expressly to Article 10(1)(b) of that directive, thereby effectively excluding its application to those homeopathic medicinal products.

13 — I do not think that this analysis is affected by the new wording of the second indent of Article 15 introduced by Directive 2004/27, according to which the application for registration must be accompanied by a 'dossier describing how the homeopathic stock or stocks is/are obtained and controlled, and justifying its/their homeopathic *use*, on the basis of an adequate bibliography,' (emphasis added). In my view, it is still a question of referring to studies showing the use of *the stocks* concerned in homeopathy and in accordance with homeopathic procedures.

14 — I note in this regard that Directive 2004/27, amending Directive 2001/83, removes Article 14(3). None the less, the exclusion of proof of the therapeutic effect is retained in Article 14(2).

61. This observation is important in the context of the present case, since Article 10 (1)(b) of Directive 2001/83 provides that 'in the case of new medicinal products containing known constituents not hitherto used in combination for therapeutic purposes, the results of toxicological and pharmacological tests and of clinical trials relating to that combination must be provided, but it shall not be necessary to provide references relating to each individual constituent'.

62. In the case of a new homeopathic medicinal product which fulfils the conditions laid down in Article 14(1) of Directive 2001/83, the reasoning is quite simply reversed: since such a medicinal product does not have to contain specific therapeutic indications and since its degree of dilution ensures that it is safe, it is not required to have been the subject of medical trials. The application for registration of this new medicinal product, on the other hand, must be accompanied by documentation in respect of the homeopathic *stocks* of which it is composed.

63. Therefore, examination of the wording of the Community provisions on the special simplified registration procedure for homeopathic medicinal products and the scheme of Directive 2001/83 tend to preclude the interpretation to the effect that it is necessary to prove that the medicinal product is generally known in order to be able to register it under that procedure.

64. I do not think that this assessment can be seriously contradicted by the argument which has been put forward by the Bundesinstitut, and which to a large extent lies at the heart of the questions referred by the national court for a preliminary ruling, that since the 10th recital in the preamble to Directive 92/73 expressly refers to 'a special simplified registration procedure for those *traditional* homeopathic medicinal products', [15] Directive 2001/83, which has only a codifying role, could have neither the aim nor the effect of extending that procedure to homeopathic medicinal products other than 'traditional' ones.

65. Admittedly, the presence of that adjective in the relevant parent directive could, on first analysis, lead to the conclusion that the Community legislature intended, in any event at the beginning, that the special simplified registration procedure should apply only to homeopathic medicinal products which had been in medical use for long enough to be recognised as effective and as having a reasonable level of safety.

66. From this perspective, it is interesting to refer to the recent Directive 2004/24, which has the aim inter alia of inserting into

15 — Emphasis added.

Directive 2001/83 special provisions applicable to *traditional herbal medicinal products*. Under Article 16c(1)(c) of Directive 2001/83, as amended, those provisions relate to medicinal products which have been 'in medicinal use throughout a period of at least 30 years preceding the date of the application [for registration], including at least 15 years within the Community'.

67. The benefit of this 'traditional-use registration', to use the expression employed by the Community legislature in Directive 2004/24, is therefore expressly reserved to herbal medicinal products which satisfy several criteria, one of which is the requirement that 'the period of traditional use as laid down in Article 16c(1)(c) ...' has elapsed. [16]

68. It must be stated that the title, preamble and content of that directive are in perfect accord: the simplified registration procedure introduced by the directive applies only to traditional herbal medicinal products, meaning medicinal products which may 'rely on a sufficiently long medicinal use in the Community'. [17]

16 — Article 16a(1)(d) of Directive 2001/83, as amended.

17 — Seventh recital in the preamble to Directive 2004/24.

69. On the other hand, in Directive 92/73, the adjective 'traditional' appeared in only one recital, it was not defined, and nowhere did the content of the directive mention the length of time for which the homeopathic medicinal product had been in medicinal use as a legal condition for its registration under the special simplified procedure.

70. Although, as a general rule, the preamble of a directive gives the Court of Justice information about the legislature's intention and provides it with useful guidelines for determining the meaning to be given to its provisions, if a concept stated in a recital is not given concrete expression in the body of the directive, or even conflicts with it, it is the content of the directive, in my view, which must predominate.

71. I believe that this reasoning accords with the view taken by this Court, according to which 'the preamble to a Community act has no binding legal force and cannot be relied on as a ground for derogating from the actual provisions of the act in question'. [18]

18 — *Nilsson and Others*, cited above, paragraph 54. In the Opinion he delivered on 5 May 1998 in that case, Advocate General Mischo explained this position as follows: 'The recitals in the preamble state the reasons for the contents of the rule and can sometimes help with its interpretation, but they cannot form the basis of a derogation from one of the directive's express provisions' (point 92).

72. In the light of these factors, I think that the presence in the 10th recital in the preamble to Directive 92/73 of the adjective 'traditional' to describe the homeopathic medicinal products qualifying for the special simplified registration procedure should not permit the inference that only generally known homeopathic medicinal products could be subject to that procedure.

73. I consider that the use of the adjective 'traditional' was superfluous, having regard to the scheme of Directive 92/73 and the fact that it was intended, at the very most, to designate medicinal products obtained by homeopathic manufacturing processes and derived from stocks traditionally used in homoeopathy, in accordance with the clear meaning of that directive.

74. The absence of that adjective from the preamble to the codifying directive, Directive 2001/83, confirms that it was superfluous and removes any ambiguity in that regard. I do not believe it can be an omission due to an editorial oversight, as the Bundesinstitut claims.

75. At this stage in my assessment, I am therefore inclined to consider that the provisions of Directive 2001/83, in particular Articles 14 and 15, should be interpreted as precluding a national provision which does not permit registration under the special simplified registration procedure for a medicinal product composed of a number of known homeopathic substances if its use as a homeopathic medicinal product is not generally known.

76. Consideration of the main objectives of Directive 2001/83 supports this interpretation.

77. First, the essential aim of safeguarding public health requires that sufficient guarantees be given of the quality and safety of the medicinal products registered under the special simplified procedure.

78. The provisions of Articles 14 and 15 of that directive enable that objective to be achieved since they apply only to homeopathic medicinal products with a sufficient degree of dilution to guarantee their safety and the documents to be enclosed with the application for special simplified registration have to demonstrate the pharmaceutical quality and batch-to-batch homogeneity of the medicinal products concerned.

79. The fact that safeguarding public health was an essential aim even led the legislature to provide for the applicability by analogy to homeopathic medicinal products of the general rules of procedure concerning the rejection, suspension or revocation of an authorisation to place a medicinal product on the market where that product proves to be harmful in the normal conditions of use. [19]

80. In the light of these factors, nothing permits the inference that the registration under the special simplified procedure of a homeopathic medicinal product which is not generally known, but which satisfies the objective conditions laid down by Directive 2001/83, is contrary to the aim of safeguarding public health.

81. Secondly, the removal of obstacles to trade in homeopathic medicinal products within the Community means that a Member State which introduces such a special simplified registration procedure must require traders of the Member States to fulfil the conditions expressly laid down in Article 14(1) of Directive 2001/83 and cannot require them to provide documents for which provision is not made in Article 15 of the directive. To allow Member States freely to add conditions and procedural requirements for registering medicinal products under the special simplified registration procedure would not only be contrary to the necessary harmonisation of the national legislations of the Member States, but would complicate a procedure whose distinctive feature is, on the contrary, that it is simplified in comparison with the procedure for authorising the placing on the market of 'classic' medicinal products.

82. All these factors lead me to propose that the Court reply to the Verwaltungsgericht Berlin that Articles 14 and 15 of Directive 2001/83 should be interpreted as precluding a national provision which does not permit registration under the special simplified procedure for a medicinal product composed of a number of known homeopathic substances if its use as a homeopathic medicinal product is not generally known.

83. In particular, the second indent of Article 15 of Directive 2001/83 should be interpreted as precluding a Member State from requiring that, for registration under the special simplified procedure of a homeopathic medicinal product made from a number of homeopathic stocks, a bibliography must be produced that refers to the new combined preparation as such.

19 — See Articles 26 and 116 of Directive 2001/83.

V — Conclusion

84. In the light of the foregoing considerations, I propose that the Court give the following reply to the Verwaltungsgericht Berlin:

(1) Articles 14 and 15 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 should be interpreted as precluding a national provision which does not permit registration under the special simplified procedure for a medicinal product composed of a number of known homeopathic substances if its use as a homeopathic medicinal product is not generally known.

(2) In particular, the second indent of Article 15 of Directive 2001/83 should be interpreted as precluding a Member State from requiring that, for registration under the special simplified procedure of a homeopathic medicinal product made from a number of homeopathic stocks, a bibliography must be produced that refers to the new combined preparation as such.