JUDGMENT OF THE COURT (Second Chamber)
12 May 2005 *

In Case C-444/03,

REFERENCE for a preliminary ruling under Article 234 EC from the Verwaltungsgericht Berlin (Germany), made by decision of 28 August 2003, received at the Court on 21 October 2003, in the proceedings

Meta Fackler KG

v

Bundesrepublik Deutschland,

THE COURT (Second Chamber),

composed of C.W.A. Timmermans, President of the Chamber, R. Silva de Lapuerta, C. Gulmann (Rapporteur), P. Kūris and J. Klučka, Judges,

* Language of the case: German.

Advocate General: P. Léger,
Registrar: K. Sztranc, Administrator,

having regard to the written procedure and further to the hearing on 11 November 2004,

after considering the observations submitted on behalf of:

— meta Fackler KG, by T. Fritz, Rechtsanwalt,

— Bundesrepublik Deutschland, by H.G. Schweim and G. Akbarian, acting as Agents,

— the Commission of the European Communities, by B. Schima and B. Stromsky, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 27 January 2005,

gives the following

Judgment

1 The questions referred for a preliminary ruling concern the interpretation of 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 (OJ 2001 L 311, p. 67).

2 That reference was made in the course of proceedings between meta Fackler KG ('meta Fackler') and the Bundesrepublik Deutschland, concerning the dismissal of an application to register a homeopathic medicinal product submitted by that company.

Law

Community legislation

3 The 21st recital in the preamble to Directive 2001/83 states that, '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'.

4 Article 1 of Directive 2001/83 provides:

'For the purposes of this Directive, the following terms shall bear the following meanings:

...

(5) Homeopathic medicinal product:

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.

A homeopathic medicinal product may also contain a number of principles.

...'

5 Article 14 of Directive 2001/83 is worded as follows:

'1. Only homeopathic medicinal products which satisfy all of the 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,

— 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.

At the time of registration, Member States shall determine the classification for the dispensing of the medicinal product.

2. The criteria and rules of procedure provided for in Article 4(4), Article 17(1) and Articles 22 to 26, 112, 116 and 125 shall apply by analogy to the special, simplified registration procedure for homeopathic medicinal products, with the exception of the proof of therapeutic efficacy.

3. The proof of therapeutic efficacy shall not be required for homeopathic medicinal products registered in accordance with paragraph 1 of this article, or, where appropriate, admitted in accordance with Article 13(2).'

6 Article 15 of Directive 2001/83 provides:

'An application for special, simplified registration may cover a series of medicinal products derived from the same homeopathic stock or stocks. The following documents shall be included with the application in order to demonstrate, in

particular, the pharmaceutical quality and the batch-to-batch homogeneity of the products concerned:

— scientific name or other name given in a pharmacopoeia of the homeopathic stock or stocks, together with a statement of the various routes of administration, 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.'

7 The 10th recital in the preamble to 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), repealed and replaced by Directive 2001/83, states that 'it is desirable to provide a special, simplified registration procedure for those traditional 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'.

National legislation

8 Paragraph 39(2) No 7a of the Arzneimittelgesetz (Law on medicinal products, 'the 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.

The dispute in the main proceedings and the questions referred for a preliminary ruling

9 In December 1993 the company 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. That medicinal product is composed of a new combination of homeopathic substances known and described in various monographs published in the *Federal Gazette* (*Bundesanzeiger*).

10 On 30 December 1994 the Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Drugs and Medicinal Products), which is now the competent authority, adopted a decision refusing the application for registration of that medicinal product on the ground that general awareness of its use as a homeopathic medicinal product had not been substantiated. The Bundesinstitut took the view that general awareness of the various substances from which the medicinal product was derived was not sufficient to satisfy the statutory requirements for recognition of the new medicinal combination.

11 Meta Fackler lodged an objection to that decision, arguing essentially that both national law and Community law permitted registration of new medicinal combinations composed of known substances. The Bundesinstitut dismissed that objection by decision of 17 April 1996 on the same grounds as those relied on in the decision of 30 December 1994, adding, in particular, that general awareness of a homeopathic medicinal product necessarily presupposes that it has been the subject of therapeutic experience. The possibility of inferring awareness of the medicinal combination from awareness of its individual components must therefore be ruled out. Like all medicinal combinations it is possible in the case of homeopathic preparations that there are interactions between the various components used. Such an approach is confirmed in the 10th recital in the preamble to Directive 92/73, according to which the simplified registration procedure applies only to 'traditional', that is, generally known homeopathic medicinal products.

12 Meta Fackler has brought an action for annulment of that decision before the Verwaltungsgericht Berlin.

13 The Verwaltungsgericht has observed that the criterion of general awareness is not mentioned in Articles 14 and 15 of Directive 2001/83 among the conditions for the registration of a medicinal product. In fact those provisions simply provide that, in principle, homeopathic medicinal products may be registered where the homeopathic use of stocks is supported by a bibliography. Moreover, the Bundesinstitut has confused the homeopathic character of a medicinal product with its therapeutic efficacy, proof of which is not required in the simplified registration procedure for a homeopathic medicinal product.

14 However, taking account of the 10th recital in the preamble to Directive 92/73, the Verwaltungsgericht Berlin finds it necessary to request clarification as to the interpretation of Articles 14 and 15 of Directive 2001/83. Even if the term 'traditional' is no longer mentioned in the 21st recital in the preamble to Directive 2001/83, the first recital stipulates that the aim of that directive is the codification — and not the modification — of the contents of the earlier directives on that subject. Furthermore, Article 128 of Directive 2001/83 does not prescribe a period for transposition, but retains the period prescribed for each codified directive. Finally, the absence of that amendment in 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) might lead to the conclusion that the absence of the term 'traditional' in the 21st recital in the preamble to Directive 2001/83 is only a drafting error. However, it is possible that that absence indicates that the Community legislature never intended that characteristic of the medicinal product to be a condition for its registration under the simplified procedure, in addition to the conditions listed in Article 7 et seq. of Directive 92/73. Since the Verwaltungsgericht Berlin stated at the outset that, by these legal proceedings, meta Fackler was pursuing its application for registration, it decided to

stay the proceedings and to refer the following questions to the Court for a preliminary ruling:

'Is the rule contained in Paragraph 39(2) No 7a of the AMG compatible with Directive 2001/83/EC ... 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"?

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:

Does the second indent ... 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?'

The questions referred for a preliminary ruling

15 By its questions the national court asks, essentially, whether Articles 14 and 15 of Directive 2001/83 must be interpreted as meaning that they preclude a national provision which does not permit use of the special simplified registration procedure for a medicinal product composed of several known homeopathic substances if its use as a homeopathic medicine is not generally known.

16 Under Article 14(1) of Directive 2001/83, read in conjunction with Article 1(5), a homeopathic medicinal product, that is to say a medicinal product prepared from products, substances or combinations 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, may be subject to the special simplified registration procedure only in so far as it is 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 its safety.

17 Consequently, general awareness of the homeopathic medicinal product, as required by the German law, is not among the conditions which such a medicinal product

must satisfy in order to be eligible for the special simplified registration procedure as provided for in Article 14(1) of Directive 2001/83.

18 The Bundesrepublik Deutschland submits that the second indent of Article 15 of Directive 2001/83 must be interpreted as meaning that the homeopathic character of the medicinal product prepared from one or more stocks must be proved, and cannot simply be deduced from the homeopathic character of the stocks from which it is derived. For that purpose, it is necessary for that medicinal product to be tested so as to identify its effects and, in particular, its safety in homeopathic use. It follows that only a medicinal product generally known, for which an adequate bibliography exists, may be subject to the special simplified registration procedure.

19 That view cannot be accepted.

20 It is clear from Article 15 of Directive 2001/83, which lists the documents which must be included in the application for registration by special simplified procedure for a homeopathic medicinal product, that only the homeopathic stock or stocks from which that combination is derived must be well-known. Thus, the first indent of that provision states that the scientific name or other name given in a pharmacopoeia of the homeopathic stock or stocks is to be stated, together with a statement of the various routes of administration, pharmaceutical forms and degree of dilution to be registered, while the second indent of that provision requires a dossier to be lodged 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. However, a bibliography showing that the effects of the homeopathic medicinal product itself have been identified is not required.

21 As the Commission of the European Communities rightly stated, the safety of such a medicinal product is, generally, in accordance with the third indent of Article 14(1) of Directive 2001/83, ensured primarily by the degree to which it is diluted.

22 As regards proof of therapeutic efficacy, Article 14(3) of Directive 2001/83 expressly states that such proof is not required for homeopathic medicinal products registered in accordance with paragraph (1).

23 The fact that general awareness of the homeopathic medicinal product does not have to be demonstrated in order for it to be registered according to a special simplified registration procedure is not called into question by the fact that the 10th recital in the preamble to Directive 92/73 expressly refers to 'a simplified registration procedure for ... traditional homeopathic medicinal products'.

24 In that connection, it should first be recalled that that directive was repealed and replaced by Directive 2001/83, the 21st recital to which does not repeat the reference to the traditional nature of the homeopathic medicinal products for which it is desirable to lay down a special simplified registration procedure.

25 Second, even if that omission was due, as the Bundesrepublik Deutschland argues, to an oversight by the legislature during the codification into a single text of the various directives concerning medicinal products for human use, the concept of traditional homeopathic medicinal products which are traditional, and therefore generally known, is not consistent, as is clear from the foregoing, with Articles 14 and 15 of Directive 2001/83. The preamble to a Community act cannot be relied on as a ground for derogating from the actual provisions of the act in question (see Case C-162/97 *Nilsson and Others* [1998] ECR I-7477, paragraph 54).

26 It follows that the answer to the questions referred for a preliminary ruling must be that Articles 14 and 15 of the Directive must be interpreted as meaning that they preclude a national provision which does not permit use of the special simplified registration procedure for a medicinal product composed of several known homeopathic substances where its use as a homeopathic medicinal product is not generally known.

Costs

27 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 (Second Chamber) hereby rules:

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 must be interpreted as meaning that they preclude a national provision which does not permit use of the special simplified registration procedure for a medicinal product composed of several known homeopathic substances where its use as a homeopathic medicinal product is not generally known.

[Signatures]