JUDGMENT OF THE COURT (First Chamber)
21 March 1996 *

In Case C-297/94,

REFERENCE to the Court under Article 177 of the EC Treaty by the Belgian Conseil d'État for a preliminary ruling in the proceedings pending before that court between

Dominique Bruyère and Others

and

Belgian State

on the interpretation of Article 4(2) of Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products (OJ 1981 L 317, p. 1), in its original version and as amended by Council Directive 90/676/EEC of 13 December 1990 (OJ 1990 L 373, p. 15),

THE COURT (First Chamber),

composed of: D. A. O. Edward, President of the Chamber, P. Jann and L. Sevón (Rapporteur), Judges,

* Language of the case: French.

Advocate General: M. B. Elmer,
Registrar: L. Hewlett, Administrator,

after considering the written observations submitted on behalf of:

— Dominique Bruyère and Thierry Charlier and Union Syndicale Vétérinaire Belge (Belgian Professional Association for Veterinary Practitioners), by Denis Philippe and Jean-Paul Lagasse, of the Brussels Bar;

— Eric Basseleer and others, by André Renette and Bernard André, of the Liège Bar;

— the Belgian State, by Pierre Legros, of the Brussels Bar;

— the Commission of the European Communities, by Richard Wainwright, Principal Legal Adviser, and Jean-Francis Pasquier, a national civil servant on secondment to the Commission's Legal Service, acting as Agents,

having regard to the Report for the Hearing,

after hearing the oral observations of Dominique Bruyère and Thierry Charlier and Union Syndicale Vétérinaire Belge, represented by Denis Philippe; Eric Basseleer and others, represented by André Renette; the Belgian State, represented by Philippe Coenraets and Delphine de Norre, of the Brussels Bar, and the Commission, represented by Richard Wainwright, at the hearing on 6 July 1995,

after hearing the Opinion of the Advocate General at the sitting on 17 October 1995,

gives the following

Judgment

1 By judgment of 12 October 1994, received at the Court on 4 November 1994, the Belgian Conseil d'État (Council of State) referred for a preliminary ruling under Article 177 of the EC Treaty two questions concerning the interpretation of Article 4(2) of Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products (OJ 1981 L 317, p. 1), in its original version and as amended by Council Directive 90/676/EEC of 13 December 1990 (OJ 1990 L 373, p. 15).

2 Directive 81/851 is intended to harmonize the legislation of the Member States on veterinary medicinal products and, in particular, the conditions governing the issue of authorization for their marketing. The first recital in the preamble states that the primary purpose of any rules for the production and distribution of veterinary medicinal products must be the safeguarding of public health. The 11th recital stresses that the directive is only one stage in the achievement of the aim of freedom of movement of veterinary medicinal products and that new measures will prove necessary, in the light of experience gained, for the removal of the remaining barriers to freedom of movement.

3 That directive was amended by Directive 90/676, which seeks *inter alia* to enable a veterinary medicinal product, manufactured and placed on the market in one Member State on the basis of harmonized provisions, to be allowed into the other Member States, taking due consideration of the initial authorization (fourth recital

in the preamble), and subsequently by Council Directive 93/40/EEC of 14 June 1993 amending Directives 81/851/EEC and 81/852/EEC (OJ 1993 L 214, p. 31), which was adopted in parallel to 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). Directive 93/40 seeks in particular to ensure that authorization to place a veterinary medicinal product on the market in one Member State is in principle recognized by the competent authorities of the other Member States (third recital in the preamble).

4 Article 4 of Directive 81/851 was worded as follows:

'1. No veterinary medicinal product may be marketed in a Member State unless authorization has previously been issued by the competent authority in that Member State.

2. No veterinary medicinal product may be administered to animals unless the authorization referred to above has been issued, except for tests of veterinary medicinal products referred to in point 10 of Article 5.'

5 That article was amended as follows by Article 1(4) of Directive 90/676:

'1. No veterinary medicinal product may be placed on the market in a Member State unless authorization has previously been granted by the competent authority of that Member State.

However, where the health situation so requires, a Member State may authorize the placing on the market or administration to animals of veterinary medicinal products which have been authorized by another Member State in accordance with this Directive.

In the event of a serious disease epidemic, the States may provisionally allow the use of immunological veterinary medicinal products without an authorization for placing on the market, in the absence of a suitable medicinal product and after informing the Commission of the detailed conditions of use.

...

3. No veterinary medicinal product may be administered to animals unless the authorization referred to above has been issued, except for ... tests of veterinary medicinal products ...

...

5. Notwithstanding paragraph 3, Member States shall ensure that veterinarians providing services in another Member State can take with them and administer to animals small quantities of ready-made veterinary medicinal products not exceeding daily requirements other than immunological veterinary medicinal products which are not authorized for use in the Member State in which the services are provided (host Member State), providing that the following conditions are satisfied:

...'

6 In Belgium, the provisions applicable to medicinal products are contained in the Law on Medicinal Products of 25 March 1964 (*Moniteur Belge* of 17 April 1964), Article 6(2) of which provides that

'... before being placed on the market, all medicinal products must be registered with the Ministry for Public Health and Family Affairs in accordance with such conditions and detailed rules as the King shall prescribe.'

7 Article 6a(2) of that Law provides that

'An unregistered medicinal product may be imported, for the purpose of making up a medical prescription, by a dispensing pharmacist. The conditions and detailed rules under which such a product may be imported, together with any restrictions thereon, shall be laid down by the King.'

8 In implementation of that provision, a Royal Decree was adopted on 29 January 1987 (*Moniteur Belge* of 4 April 1987) which added, *inter alia*, an Article 48a to the Royal Decree of 6 June 1960 on the Manufacture, Preparation, Wholesale Distribution and Dispensing of Medicinal Products (*Moniteur Belge* of 22 June 1960). Article 48a provided that

'A medicinal product not registered for veterinary use may not be imported by a dispensing chemist unless the following conditions are fulfilled:

1. There may not be on the market any medicinal product having the same composition in terms of active ingredients or having an equivalent therapeutic effect;

2. The product must be prescribed by a veterinarian licensed to practise veterinary medicine in Belgium;

3. The prescription must be dated and signed by the prescribing veterinarian and must bear the following indications:

...'

9 By Royal Decree of 20 December 1989 (*Moniteur Belge* of 3 February 1990), Article 48a was repealed with effect from 1 March 1990 (*Moniteur Belge* of 15 March 1990). However, a Royal Decree of 14 February 1990, which also took effect on 1 March 1990, reintroduced the possibility of importation. Article 1 of that Royal Decree provides that

'A dispensing chemist may, for the purpose of making up a medical prescription in his possession, dated and signed by a veterinarian, import unregistered medicinal products provided that they contain, as their sole or major active ingredient:

[the Decree lists six chemical components]'.

This Royal Decree was amended by a Royal Decree of 16 January 1992 (*Moniteur Belge* of 18 March 1992), which added eight further chemical substances to that list.

10 The applicants in the main proceedings are, *inter alia*, veterinarians, dispensing chemists, a non-profit-making association known as Union Syndicale Vétérinaire Belge and a company which specializes in supplying to Belgian dispensing chemists, on production of prescriptions from Belgian veterinarians, veterinary medicinal products which are not registered in Belgium but are registered in France.

They instituted various proceedings before the Conseil d'État in which they sought the annulment of the Royal Decree of 20 December 1989, which lays down the principle of a total prohibition of imports of unregistered medicinal products, the Royal Decree of 14 February 1990, which provides for an exception to this principle for six molecular substances, and the Royal Decree of 16 January 1992, which increased that number to 14.

11 After it had joined the various cases, the Conseil d'État stayed the proceedings and submitted the following two questions to the Court for a preliminary ruling:

'1. Is Council Directive 81/851 of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products, in particular Article 4(2) thereof, to be interpreted as implying a prohibition of the administration of a medicinal product without the authorization of the competent authority of a Member State and thus a prohibition of the importation of such a product when it is not placed on the market in that Member State and consequently has not previously been authorized by the authority of that Member State?

2. Is Council Directive 81/851 of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products, in particular Article 4 thereof as replaced by Council Directive 90/676 of 13 December 1990, to be interpreted as implying a prohibition of the administration of a medicinal product without the authorization of the competent authority of a Member State and thus a prohibition of the importation of such a product when it is not placed on the market in that Member State and consequently has not previously been authorized by the authority of that Member State and when, in addition, it has not been authorized by another Member State?'

12 Those questions raise only one issue, namely whether it is possible for a Member State to prohibit the import of a medicinal product, the marketing of which has not been the subject of prior authorization by the competent authority. Accordingly, they should be considered together.

13 The applicants in the main proceedings do not deny that the Royal Decrees are consistent with Article 4 of Directive 81/851, even after its amendment by Directive 90/676. They submit, however, that those Decrees have to be considered in the light of Articles 30 and 36 of the EC Treaty on the ground that, since it represents only one stage in the achievement of the aim of freedom of movement of veterinary medicinal products, Directive 81/851 does not provide for full harmonization of all national measures and thus leaves room for the application of Articles 30 and 36 of the Treaty. They also argue that some veterinary medicinal products, such as serums, do not come within the scope of Directive 81/851 and that the latter covers only the placing of medicinal products on the market, that is to say, their distribution by pharmaceutical companies, and not the import by a dispensing chemist, pursuant to a prescription issued by a Belgian veterinarian, of a medicinal product which has not been registered in Belgium. Lastly, they aver that animal owners are dependent on the good will of the pharmaceutical companies, which refuse to place certain veterinary medicinal products on the Belgian market because of the formalities and costs associated with the procedure for requesting authorization and also by reason of the low profits which they can expect to earn on such products in a market as small as that of Belgium. The prohibition on importing certain medicinal products for which no equivalent exists on the Belgian market thus endangers the health of both animals and humans in view of the risk of transmission of certain diseases.

14 The Belgian State and the Commission both take the view that the wording of Article 4 of Directive 81/851 is clear in so far as it authorizes a Member State to prohibit the marketing, administration and consequently also the import of a medicinal product which has not been the subject of prior authorization.

15 So far as concerns the reference to Articles 30 and 36 of the Treaty, the Commission takes the view that the Conseil d'État was correct, by virtue of the principle *lex specialis generalibus derogat*, to request an interpretation only of Directive 81/851, which seeks to harmonize the conditions governing the marketing and administration of veterinary medicinal products by making it compulsory for the competent authorities of the Member State in question to issue authorization. It is only in the case of medicinal products not covered by Directive 81/851 that Article 30 could possibly apply, in which event it would then be necessary to determine whether the national rules could be justified on one of the grounds mentioned in Article 36.

16 For its part, the Belgian Government does not address the question whether its legislation is in conformity with Articles 30 and 36 of the Treaty.

17 The arguments put forward by the applicants in the main proceedings cannot be accepted.

18 Although Directive 81/851 describes itself as 'one stage in the achievement of the aim of freedom of movement of veterinary medicinal products' (11th recital in the preamble), it cannot be inferred from this that, for medicinal products coming within its scope, the directive leaves room for the application of Articles 30 and 36 of the Treaty. As the development of Community law shows, that wording means only that the system of multiple national authorizations for the marketing of products, first introduced by Directive 81/851, was destined to be replaced by a system under which account was to be taken of authorizations granted by other Member States (Directive 90/676) and subsequently by a system for the mutual recognition in principle of such authorizations (Directive 93/40).

19 With regard to any medicinal products not covered by Directive 81/851 to which Articles 30 and 36 of the Treaty should be applied, it should be recalled that it is solely for the national courts before which actions are brought, and which must bear the responsibility for the subsequent judicial decision, to determine in the light of the particular facts of each case both the need for a preliminary ruling in order to enable them to deliver judgment and the relevance of the questions which they submit to the Court (see, in particular, Case C-472/93 *Spano and Others* v *Fiat Geotech and Fiat Hitachi Excavators* [1995] ECR I-4321, paragraph 15), and that the parties cannot alter the wording of those questions (Case 5/72 *Grassi* v *Italian Finance Administration* [1972] ECR 443, paragraph 4).

20 Since the Conseil d'État has not requested an interpretation of Articles 30 and 36 of the Treaty, it is unnecessary to give a ruling in that regard.

21 As for Article 4 of Directive 81/851, to which reference must consequently be made as far as the medicinal products which it covers are concerned, its scope is clear in so far as it makes both the marketing and the administration of a medicinal product within the territory of a Member State subject to the prior issue of authorization by the competent authority of that State. The fact that it is prohibited to market and administer a medicinal product means that it is prohibited to import that product for one of those purposes. Consequently, the importation, by a pharmacist in a Member State, of a medicinal product prescribed in that State by a veterinarian in order to cater for a specific need is also covered by that provision.

22 As the Advocate General states at point 17 of his Opinion, the derogation introduced in Article 4(5) by Directive 90/676 for veterinarians providing services would be redundant if the import of a medicinal product for the purpose of administering it was not prohibited in principle. Moreover, to authorize the import of a medicinal product lacking prior authorization with a view to marketing or administering it would destroy the system set in place by the directive.

23 It cannot be argued against this that, in its judgments in Case 215/87 *Schumacher* v *Hauptzollamt Frankfurt am Main-Ost* [1989] ECR 617 and Case C-62/90 *Commission* v *Germany* [1992] ECR I-2575, the Court, ruling in respect of Articles 30 and 36 of the Treaty, permitted the importation of medicinal products into a Member State. Those two judgments were concerned with medicinal products authorized in the Member State of importation which were imported for personal needs by individuals who had themselves purchased those products in a pharmacy in another Member State.

24 As for the arguments of the applicants in the main proceedings that they are dependent on the pharmaceutical companies' good will and that the prohibition on importing certain medicinal products for which no equivalent exists endangers the health of both animals and humans, the Court simply finds that, in adopting the contested Royal Decrees, the Belgian State was acting within the sphere of

competence which Community law recognizes it as having. It is therefore only in the light of the rules of national law that the public-health policy pursued might fall to be assessed.

25 It follows from the whole of the foregoing that Article 4 of Directive 81/851, in its original version and as amended by Directive 90/676, must be interpreted as prohibiting the importation into a Member State of a medicinal product covered by that directive with a view to placing it on the market of that State or of administering it there in the absence of prior authorization issued by the competent authority of that Member State.

Costs

26 The costs incurred by the Commission of the European Communities, which has submitted observations to the Court, are not recoverable. Since these proceedings are, for the parties to the main proceedings, a step in the proceedings pending before the national court, the decision on costs is a matter for that court.

On those grounds,

THE COURT (First Chamber),

in answer to the questions referred to it by the Belgian Conseil d'État, by judgment of 12 October 1994, hereby rules:

Article 4 of Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products, in its original version and as amended by Council Directive

90/676/EEC of 13 December 1990, must be interpreted as prohibiting the importation into a Member State of a medicinal product covered by that directive with a view to placing it on the market of that State or of administering it there in the absence of prior authorization issued by the competent authority of that Member State.

Edward Jann Sevón

Delivered in open court in Luxembourg on 21 March 1996.

R. Grass

Registrar

D. A. O. Edward

President of the First Chamber