OPINION OF ADVOCATE GENERAL ELMER

delivered on 17 October 1995 *

Introduction

1. In this case, a number of questions concerning the interpretation of Article 4 of Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Members States relating to veterinary medicinal products [1] (hereinafter 'the directive') have been referred to the Court for a preliminary ruling.

2. The directive was adopted pursuant to Article 100 of the Treaty, and the recitals in its preamble provide *inter alia* that the primary purpose of any rules for, among other things, the distribution of veterinary medicinal products must be the safeguarding of public health (first recital). Approximation of the Member States' provisions on veterinary medicinal products is of importance in removing hindrances to trade in medicinal products within the Community (second, third and fourth recitals). The directive, however, represents only one stage in the achievement of the aim of freedom of movement of veterinary medicinal products (11th recital).

3. Article 4 of the directive provides 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.'

4. The directive also contains highly detailed rules concerning, *inter alia*, the conditions governing applications for authorizations to market veterinary medicinal products, including rules on the documentation and information to be provided, on the processing of such applications and on authorizations and their renewal. In addition, the directive establishes a Committee for Veterinary Medicinal Products in order to facilitate

* Original language: Danish.

1 — OJ 1981 L 317, p. 1.

the adoption of a common position by the Member States with regard to marketing authorizations. The directive also sets out rules on the manufacture of veterinary medicinal products and on the supervision of products granted marketing authorization, along with sanctions, including withdrawal of marketing authorization, in cases where, *inter alia*, the product proves to be harmful or lacking in the therapeutic effect claimed.

5. Council Directive 90/676/EEC of 13 December 1990 amending Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products [2] (hereinafter 'the amending directive'), adopted pursuant to Article 100a of the Treaty, amended Article 4 of the directive with effect from 1 January 1992. Article 4 now reads as follows:

'*Article 4*

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.

...

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

...

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:

(a) the authorization to place the product on the market provided for in paragraph 1 has been issued by the competent authorities of the Member State in which the veterinarian is established;

...'.

Proceedings before the national court

6. Dominique Bruyère, a veterinary practitioner, along with a number of other

2 — OJ 1990 L 373, p. 15.

veterinary practitioners and dispensing chemists, all of whom are established in Belgium, brought proceedings before the Belgian Conseil d'État (Council of State) seeking the annulment of three Royal Decrees of 20 December 1989, 14 February 1990 and 16 January 1992, which they consider to be contrary to Community law.

7. According to the judgment making the reference, the first Royal Decree, that of 20 December 1989, provided that it would, from 1 March 1990, no longer be possible to import into Belgium veterinary medicinal products that had not been approved by the Belgian authorities.

8. The Decree of 20 December 1989 was replaced, from 1 March 1990, by the Royal Decree of 14 February 1990, with the result that the Royal Decree of 20 December 1989 never actually entered into force. The new Decree retained the prohibition of importing into Belgium veterinary medicinal products that had not been approved by the Belgian authorities, but also introduced an exception to that rule, allowing a dispensing chemist to import unregistered medicinal products for the purpose of making up a medical prescription in his possession, dated and signed by a veterinary practitioner, provided that those medicinal products contained as their sole or major active ingredient one of a number of specified substances.

9. The Royal Decree of 16 January 1992 added a number of additional substances to the list of active substances permitted as ingredients in unregistered medicinal products which could be imported under the rules in the Decree of 14 February 1990.

The questions submitted for a preliminary ruling

10. By judgment of 12 October 1994, the Belgian Conseil d'État referred the following 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 September 1990, [3] 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?'

11. The two questions in reality constitute one single question. The first concerns Article 4 of the directive, as originally worded. The second relates to the wording of Article 4 which results from the amending directive, and specifies, presumably in order to indicate that it is not seeking an interpretation of the provision in Article 4(5), inserted by the amending directive, that an answer is requested only in regard to cases where the product has not been authorized in another Member State. Common to both questions, therefore, is the fact that the national court is seeking a ruling from the Court as to whether Article 4 must be interpreted as prohibiting the administration of veterinary medicinal products that have not been authorized by the competent authorities of the Member State in question, and whether the provision must therefore be interpreted as containing a prohibition of the importation of such medicinal products. In what follows, the questions will be considered together.

Proceedings before the Court of Justice

12. Mr Bruyère and the other applicants in the main proceedings contend that Article 4 of the directive does not cover occasional imports effected pursuant to a prescription from a veterinary practitioner. In their view, such imports must be considered on the basis of Articles 30 and 36 of the Treaty. They argue that the Court should therefore take account of Articles 30 and 36 of the Treaty in its reply.

13. The Belgian State points out that the directive leaves it to each Member State to determine which veterinary medicinal products may be marketed and administered within its territory. According to the directive, the fact that a product has been authorized in one Member State does not mean that it may be marketed and administered in a second Member State prior to its authorization by that second Member State. The

3 — This should read 13 December 1990.

prohibition in the directive of marketing and administering unauthorized products also covers the importation of such products.

14. The Commission takes the view that the national court properly limited its questions to the interpretation of the directive in so far as the text of the directive clearly addresses the question of the importation of unauthorized medicinal products by veterinary practitioners. If the main rule in the directive on the prohibition of marketing and administration of unauthorized medicinal products did not also imply a prohibition of the importation of such medicinal products, it would not have been necessary to implement the derogating provision in Article 4(5), in the version resulting from the amending directive, regarding entitlement to import and administer such products in connection with veterinary services provided outside the Member State of establishment.

Analysis

15. The provisions of Article 4(1) and (2) of the directive, and Article 4(1) and (3) of the directive in the version resulting from the amending directive, expressly lay down the main rule that no veterinary medicinal product may be marketed or administered to animals unless the competent authorities in the Member State in question have given prior authorization for the product to be marketed. The directive contains a derogation from this rule in so far as Article 4(2) allows certain products to be tested on animals under the conditions set out in point 10 of Article 5. In the amending directive, this derogating rule on the use of unauthorized products for the purpose of tests is retained in Article 4(3); however, Article 4(5) also contains a further derogating rule, under which veterinarians providing services in another Member State can, 'notwithstanding paragraph 3', take into and administer in the host Member State small quantities of products which have not been authorized in the host Member State, on condition that the competent authorities in the Member State of establishment have authorized the products in question.

16. These derogating rules concern very specific situations and, in the light of the construction of Article 4, there can scarcely be any doubt that Member States must, outside the scope of these specific derogations, comply with the main rule outlined above and prohibit the marketing and administration of unauthorized products. It is precisely this main rule that constitutes the basis underlying gradual harmonization of the protection accorded by Member States to public health in this area, since it is thereby guaranteed that the product will be assessed in accordance with the rules of the directive before it can lawfully be marketed and administered to animals.

17. As the Commission stresses, the inclusion of Article 4(5) by the amending directive would also have been redundant if it did not follow from the main rule in the directive that unauthorized products may not be imported or administered in the situations referred to in Article 4(5). The provision expressly features as a (new) derogation from the general rule in Article 4(3), as evidenced by the words 'notwithstanding paragraph 3'. If Article 4(5) — as a derogation from Article 4(3) — expressly addresses the issue of the conditions under which veterinary practitioners providing services in another Member State can *take with them* and administer products that are authorized for use in the Member State in which they are established, but not in the host Member State, it must accordingly be assumed and specified that such importation and administration of unauthorized products is otherwise prohibited under the main rule in the first subparagraph of Article 4(1) and the first subparagraph of Article 4(3), as introduced by the amending directive, which, moreover, corresponds closely to the previous wording of Article 4(1) and (2) of the directive.

18. The need to ensure that the main objective of the directive, namely the protection of public health, is attained also argues in favour of such a result. Why would dispensing chemists or veterinary practitioners import unauthorized veterinary medicinal products if not to market them and administer them to animals without following the rules of the directive on prior authorization from the Member State in question? If the main rule in the directive on the prohibition of marketing and administration of unauthorized veterinary medicinal products did not also include prohibition of the importation of such products, it would not in practice be possible to counteract breaches of the rules and the Community-law regulation of this area would thus remain ineffective in practice and fail to achieve its objective of protecting public health.

19. It must be pointed out in this connection that the national court making the reference expressly confined its second question on the interpretation of Article 4 of the directive, in the version resulting from the amending directive, to cases in which no authorization had been granted for the marketing of the product in any Member State. It is in such cases particularly evident that concern for the protection of public health makes it necessary to interpret the prohibition of marketing and administration of unauthorized veterinary medicinal products as also including a prohibition of the importation of such products.

20. It follows from the foregoing that the questions can be answered on the basis of the harmonizing directive and — as the national court also assumed — a discussion of the bearing of Articles 30 and 36 of the Treaty is not relevant.

Conclusion

21. I accordingly propose that the Court should reply as follows to the questions submitted by the Belgian Conseil d'État by judgment of 12 October 1994:

(1) Article 4(1) and (2) of Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Members States relating to veterinary medicinal products must be understood as meaning that each Member State must prohibit the marketing and administration, as well as the importation, of veterinary medicinal products, the marketing of which has not been the subject of prior authorization by the competent authorities of the Member State in question.

(2) The first subparagraph of Article 4(1) of Council Directive 81/851/EEC on the approximation of the laws of the Members States relating to veterinary medicinal products, along with the first subparagraph of Article 4(3), in the version resulting from Council Directive 90/676/EEC of 13 December 1990, must be understood as meaning that each Member State must prohibit the marketing and administration, as well as the importation, of veterinary medicinal products, the marketing of which has not been the subject of prior authorization by the competent authorities of either the Member State in question or of any other Member State.