OPINION OF ADVOCATE GENERAL DARMON
delivered on 15 December 1993 *

Mr President,
Members of the Court,

1. In the context of transposing into national law the obligation on Member States to indicate an expiry date on the packaging of proprietary medicinal products, [1] the German Law of 24 August 1976 [2] restricts for medicinal products within the meaning of Article 2(1) or (2), first paragraph, to two a year — 30 June and 31 December — the dates which may be used for that purpose. That obligation was extended by an Order of 8 March 1985 [3] to other medicinal products, and, without any prior notification being made to the Commission, by an Order of 25 March 1988, [4] to non-reusable sterile medical instruments, which under German law are in any event deemed to be medicinal products. [5]

2. Those measures, which apply without discrimination to domestic products and to those originating in other Member States, prohibit any product which is not labelled in accordance with the law from being placed on the market.

3. By the present action under Article 169, the Court to is asked make a declaration:

— that the duty to amend the labelling of their medicinal products in order to show a biannual validity limit is likely to create barriers to intra-Community trade and that it is therefore incompatible with Article 30 of the EEC Treaty;

— that the failure to communicate to the Commission, before its adoption, the draft text of the Order of 25 March 1988 contravenes the relevant Community provisions.

4. It is necessary, before tackling those two questions on substance, to examine the objection of inadmissibility raised by the defendant State, according to which the Commission has no legal interest in bringing proceedings.

* Original language: French.

1 — Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ, English Special Edition 1965-1966, p. 20).

2 — Law of 24 August 1976 (*Bundesgesetzblatt I*, 1976, p. 2445, 2448) amended on 16 August 1986 (*Bundesgesetzblatt I*, 1986, p. 1296), on 20 July 1988 (*Bundesgesetzblatt I*, 1988, p. 1050) and 11 April 1990 (*Bundesgesetzblatt I*, 1990, p. 717).

3 — *Bundesgesetzblatt I*, 1985, p. 546.

4 — *Bundesgesetzblatt I*, 1988, p. 480.

5 — Article 2(2)(1)(a) of the Law of 24 August 1976, cited above in footnote 2.

5. In that connection, the Commission is criticized, *on the one hand*, for failing to bring its action within a reasonable period from that stated in the reasoned opinion, and, *on the other hand*, for failing to proceed with the default proceedings during consultations leading up to the adoption of Council Directive 92/27/EEC of 31 March 1992 on the labelling of medicinal products for human use and on package leaflets, which harmonizes the subject of expiry dates and which the Federal Republic of Germany is preparing to transpose.

6. With regard to the first ground, suffice it to note that, in default proceedings, the corollary of the Commission's option to bring a matter before the Court is the freedom it has to choose the moment for so doing.

7. As the Court stated in its judgment in *Commission* v *Italian Republic* [6]

'it is for the Commission, under Article 169 of the Treaty, to judge at what time it shall bring an action before the Court; and the considerations which determine its choice of time cannot affect the admissibility of the action, which follows only objective rules'. [7]

8. Similarly, the Court noted the Commission's freedom in that regard in its judgment in *Commission* v *Belgium*, [8] explicitly stating that:

'(...) the rules contained in Article 169 of the Treaty must be applied and the Commission is not obliged to act within a specific period'. [9]

9. Since the Court's case-law on this point has been consistent, the length of time which elapsed between the date of the reasoned opinion (26 March 1990) and that of the application initiating the proceedings (23 July 1992) cannot affect the admissibility of the action.

10. With regard to the second ground of inadmissibility, suffice it to state that, even supposing that the transposition of Directive 92/27/EEC had remedied any failure to comply with Article 30, the period covered by the present action predates the implementation of the directive and that

'the object of an action under Article 169 is established by the Commission's reasoned

6 — Case 7/68 [1968] ECR 423.
7 — P. 428.
8 — Case 324/82 [1984] ECR 1861.
9 — Paragraph 12.

opinion, and even when the default has been remedied subsequently to the time-limit prescribed by paragraph 2 of the same Article, pursuit of the action still has an object'. [10]

11. The objection of inadmissibility must therefore be dismissed and the two claims set out by the Commission in support of its action must be considered.

I — The barrier to intra-Community trade

12. As is stated in the first two recitals to the preamble to Directive 65/65/EEC, 'the primary purpose of any rules concerning the production and distribution of proprietary medicinal products must be to safeguard public health', whilst ensuring that the development of the pharmaceutical industry or trade in medicinal products within the Community is not hindered.

10 — Judgment in Case 39/72 *Commission* v *Italy* [1973] ECR 101, paragraph 9.

13. Article 13 of the directive provides:

'The following particulars shall appear on containers and outer packages of proprietary medicinal products:

...

7. Expiry date in plain language.' [11]

14. Under Article 1, the following definitions apply:

'*1. Proprietary medicinal product:*

Any ready-prepared medicinal product placed on the market under a special name and in a special pack.

11 — This wording follows from the amendment made by Council Directive 83/570/EEC amending Directive 65/65/EEC; the original wording appearing in Directive 65/65/EEC was: '7. Expiry date for proprietary products with a shelf life of less than three years.'

2. *Medicinal product:*

Any substance or combination of substances presented for treating or preventing disease in human beings or animals.

Any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or in animals is likewise considered a medicinal product.'

15. In transposing the provisions of the aforementioned Article 13, the German legislation imposed, for all medicinal products within the meaning of the directive, for veterinary medical products within the meaning of Directive 81/851/EEC [12] and for non-reusable sterile medical instruments, a duty to show, as the expiry date, either 30 June or 31 December. [13]

16. That obligation and its potential consequences as far as the increased cost of products and the reduction in their marketing periods are concerned led the Commission to commence the present proceedings.

17. The explanations given by the Federal Republic of Germany in order to justify that obligation did not satisfy the Commission, which sees it as a measure having equivalent effect to a quantitative restriction on imports.

18. The question which arises is therefore the following: should restricting to two a year the expiry dates which can be used, be deemed to be a measure having equivalent effect to the quantitative restrictions prohibited under Article 30 of the Treaty in so far as it entails an increase in the cost of the products originating in other Member States and a reduction in their marketing period?

19. The Court's case-law warrants an affirmative reply to that question.

20. It has been consistently held since the judgment in *Dassonville*, [14] that the prohibition set out in Article 30 extends to 'all trading rules enacted by Member States which

12 — Council Directive 81/851/EEC of 28 September 1981 on the approximation of laws of the Member States relating to veterinary medicinal products (OJ 1981 L 317, p. 1) which extended to veterinary medicinal products the provisions of Directive 65/65/EEC.

13 — See, for the details of the legislation, the Commission's application, pp. 2 to 6 of the French translation, and the Federal Republic of Germany's defence, pp. 9 to 14 of the French translation.

14 — Judgment in Case 8/74 [1974] ECR 837, paragraph 5.

are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade ...'. [15]

21. The Court's judgment in *Keck and Mithouard* [16] seems to me to have no bearing on this case. The Court simply excluded from the scope of the *Dassonville* judgment national provisions which restrict or prohibit certain rules governing sale provided that they apply to all operators concerned and that they affect domestic products and those originating in other Member States similarly. The Court held that, in such circumstances, the implementation of those provisions is not, for those products, 'such as to prevent their access to the market or to impede access any more than it impedes the access of domestic products'. [17]

22. However, the present case does not involve rules of that type and the provisions contested in these proceedings affect products originating in other Member States more than they affect domestic products.

23. In that connection, it is sufficient, moreover, since the Court's judgment in *Commission* v *Germany*, [18] that the measure be objectively capable of hindering trade without it being necessary to establish that it has actually led to a reduction in imports or that it was such as noticeably to affect intra-Community trade.

24. Moreover, the duty to comply with the contested measure entails mandatory amendment of product labelling and accordingly involves an additional cost which may make sales in the German market more difficult.

25. In its judgment in *Merci convenzionali porto di Genova*, [19] the Court stated that a domestic measure is contrary to Article 30 where it is capable of having a restrictive effect on trade between the Member States, and in particular where the imports of products originating in other Member States are rendered more costly and more difficult.

26. The magnitude of the additional cost entailed by the restrictive measures does not have to be taken into consideration in deciding whether or not they come within the ambit of the prohibition set out in Article 30.

27. Likewise, it is not for a Member State to decide that such a cost may be ignored. It is difficult to see how it could be by economic

15 — See also the judgment of 25 May 1993 in Case C-228/91 *Commission* v *Italy* [1993] ECR I-2701, paragraph 12.

16 — Judgment of 24 November 1993 in Cases C-267/91 and C-268/91 [1993] ECR I-6097.

17 — Paragraph 17.

18 — In Case 12/74 [1975] ECR 181.

19 — In Case C-179/90 *Merci Convenzionali Porto di Genova SpA* v *Siderurgica Gabrielli SpA* [1991] ECR I-5889, paragraph 22.

operators in general, and, more particularly, by a producer or distributor of proprietary medicinal products acting furthermore, it should be recalled, within the scope of a Community regulation which aims, whilst ensuring that public health is safeguarded, to prevent hindrances to the development of the pharmaceutical industry or trade in medicinal products within the Community. [20]

28. However, in addition to the hindrance resulting from the increased cost of imported products, the hindrance arising from the reduction in their marketing period must be noted. Clearly, any change of date, under the conditions imposed by the German legislation, reduces the marketing period for the relevant medicinal products whose validity for a longer period, in so far as their therapeutic value is concerned, is not in dispute.

29. Were it not for an obligation of the kind imposed by the German legislation, importers would have the right to sell their medicinal products until expiry of the period of stability determined in the State of origin on the grant of authorization for placing the product on the market, and could import others whose remaining period of stability, at the time of the request for importation, was short.

30. Moreover, the duty to use 30 June or 31 December as the sole expiry dates can reduce by several months the marketing period for the products concerned.

31. Here again there is an undoubted impact on marketing, which, together with the increase in the cost of the products described above, must be taken into consideration in deciding whether the prohibition in Article 30 applies to the contested measures.

32. The size of that impact is not important. It follows from the judgment in the *Prantl* case [21] that:

'it is sufficient that the measures in question are liable to impede, directly or indirectly, actually or potentially, trade between the Member States. It is not necessary that they should have an appreciable effect on intra-Community trade',

and it was also explicitly stated in the judgment in *Yves Rocher* [22] that:

20 — See above, paragraph 12.

21 — Judgment in Case 16/83 [1984] ECR 1299.

22 — Judgment in Case C-126/91 *Schutzverband Gegen Unwesen in der Wirtschaft e. V.* v *Yves Rocher GmbH* [1993] ECR I-2361, paragraph 21.

'apart from rules having merely hypothetical effect on intra-Community trade, it has been consistently held that Article 30 of the Treaty does not make a distinction between measures which can be called measures having equivalent effect to a quantitative restriction according to the magnitude of the effects they have on trade within the Community'.

33. The German Government's submission that the legislation in question is not incompatible with Article 30 in so far as it only entails a negligible barrier to free movement cannot therefore be accepted.

34. Can it therefore be considered, in order to exclude the barrier from the prohibition in Article 30, that the measure it stems from satisfies mandatory requirements within the meaning of the Court's judgment in the *Cassis de Dijon* case? [23] This submission is put forward in the alternative, by the Federal Republic of Germany.

35. The protection of health was included among the mandatory requirements listed in that judgment. The defendant State relies on that imperative.

36. The case of the protection of health is a special one since it is listed among the mandatory requirements and it also appears in Article 36 of the Treaty. [24] It should be specifically stated here that the area was not harmonized at the material time and that the Court's case-law only precluded reliance on Article 36 after harmonization of the matter concerned. [25]

37. However, the distinction between discriminatory measures and non-discriminatory measures introduced in the *Cassis de Dijon* judgment should be noted. Reliance on mandatory requirements is here linked to the idea of non-discriminatory measures, that is to say, as in the present case, those which apply without distinction to domestic products and to those originating in other Member States.

38. Therefore the question must be examined in the context of Article 30 in view of the reliance placed on the submission relating to the protection of public health.

39. Has the German Government justified the duty to show biannual expiry dates, in the light of Community law?

23 — Judgment in Case 120/78 *REWE-Zentral* [1979] ECR 649.

24 — On that point, see Manfred A. Dauses 'Measures having equivalent effect to quantitative restrictions in the light of the case-law of the Court of Justice of the European Communities', *RTDE* 28 (4), October-December 1992, p. 607, in particular pp. 615 et seq.

25 — See judgments in Case 35/76 *Simmenthal* [1976] ECR 1871 and Case 28/84 *Commission* v *Germany* [1985] ECR 3097, paragraph 25.

40. In the absence of harmonization, the Court accepts that it is for the Member States to decide to what extent they intend to safeguard the protection of health. It is correct to say that the only information required under Community legislation [26] with regard to the duration of validity of products is a clear indication of the expiry date.

41. However, whereas the absence of more specific regulations confers a certain freedom on the German authorities, that does not exempt them from complying with Community rules. In other words, the discretionary powers of the Member States in this regard must be exercised 'having regard however to the fact that their freedom of action is itself restricted by the Treaty'. [27]

42. And whereas, as the Court has noted in its judgment (cited by the defendant State), in the 'Eye lotions' case, [28]

'... it is difficult to avoid the continued existence, for the time being and, doubtless, so long as harmonization of the measures necessary to ensure the protection of health is not more complete, of differences in the classification of products (...)'

and that,

'in those circumstances, (...) it is for the national authorities to determine (...), for each product, (...) the way in which it is used (...)',

none the less, the adoption of measures by a Member State must comply with the requirements of the Treaty on the free movement of goods. Although there is a certain latitude, it is not absolute.

43. This observation applies, as much to medicinal products for human use and medicinal products for veterinary use, for which Directives 65/65/EEC and 81/851/EEC provide merely that the expiry date must be clearly shown, as to non-reusable sterile medical instruments not subject to that requirement under Community legislation.

44. Clearly, imperatives are consonant with the principle of the free movement of goods only if the measures in question are appropriate and necessary for a legitimately pursued aim to be achieved and if they guarantee that it is achieved. It is therefore necessary, in each case, to assess the proportionality of the measures.

26 — Directives 65/65/EEC, 81/851/EEC and 83/570/EEC, cited above.

27 — Judgment in Case 272/80 *Frans-Nederlandse Maatschappij voor Biologische Producten* [1981] ECR 3277, paragraph 12.

28 — Judgment in Case C-290/90 *Commission* v *Germany* [1992] ECR I-3317, paragraphs 16 and 17.

45. The Court noted that principle in its judgment in *Council of the City of Stoke-on-Trent and Norwich City Council* v *B&Q*: [29]

'Appraising the proportionality of national rules which pursue a legitimate aim under Community law involves weighing the national interest in attaining that aim against the Community interest in ensuring the free movement of goods. In that regard, in order to verify that the restrictive effects on intra-Community trade of the rules at issue do not exceed what is necessary to achieve the aim in view, it must be considered whether those effects are direct, indirect or purely speculative and whether those effects do not impede the marketing of imported products more than the marketing of national products.'

46. The Court has consistently held that the principle of proportionality requires in particular that a Member State having a choice between several measures capable of attaining the same objective must 'choose the means which least restrict the free movement of goods'. [30]

47. It would not seem that to restrict to two a year the expiry dates can be justified, taking the principle of proportionality into account, in the light of the desired result, namely the protection of health.

48. The clear indication on the packaging of the proprietary medicinal products, of the expiry dates of those products, as required by law in the State of origin, by the laboratories which produce them, subject to the relevant checks and in particular to marketing authorizations seems to me adequately to satisfy the objective of the protection of the health of users. The essential aim in the present case is to prevent users from coming into contact with expired products.

49. Moreover, all the proprietary medicinal products produced in the Member States feature an expiry date which satisfies that objective and compliance with Community provisions requiring a clear indication of that date on the packaging is manifestly sufficient to protect users.

50. The additional safeguard which may possibly result from biannual dating does not therefore seem necessary to protect health.

51. Likewise, the Federal Republic of Germany's submission that the duration of stability of a medicinal product cannot be determined with certainty at present and that it is necessary therefore to bring the expiry date forward systematically to the beginning of the six month period seems equally unconvincing.

29 — Judgment in Case C-169/91 [1992] ECR I-6635, paragraph 15.

30 — Judgment in Case 261/81 *Rau* v *De Smedt* [1982] ECR 3961, paragraph 12.

52. The Federal Government does not show why it is necessary to bring forward the dates in order to increase safety, and this all the more so since the alleged margin of security is of a different duration according to whether the initial expiry date shown on the product is closer or further from 30 June or 31 December.

53. Furthermore, to add such a margin is also inconvenient in that the different periods of validity of the various proprietary medicinal products are, contrary to what the defendant State maintains, not all of several years' duration.

54. Nor does simplifying the verification of the validity of products appear to me to be capable of affording justification, on grounds of protection of public health, for the obligation of biannual dating. The Federal Government has not shown how the simplification of stock-management for pharmacists, facilitated by restricting to two expiry dates on packaging, was the only measure capable of guaranteeing safety in the distribution of products. As noted by Mr Advocate General Van Gerven in his Opinion in the *Keck and Mithouard* cases, [31]

'the essential element in assessing proportionality continues to be that the restrictive effect of a national regulation cannot go beyond what is necessary to attain *the objective justified under Community law*'.

55. It is worth reiterating that whereas it is for national authorities to choose appropriate measures, it is also for them to establish that they are justified. In my view, that has not been proved by the Federal Republic of Germany which submits merely that it sought to protect public health. The practical implementation of that aim, undoubtedly a legitimate one, involved techniques corresponding clearly to national professional practices for which, however, no evidence was available to suggest that they were necessary in order to attain the desired objective.

56. I conclude, therefore, that the contested measure should be held by the Court to have an equivalent effect to a quantitative restriction on imports, within the meaning of Article 30 of the Treaty.

II — The failure to notify the Commission

57. The Order of the German Ministry of Health of 25 March 1988 ('the Order') extends to non-reusable sterile medical instruments the duty to indicate one of the

31 — Paragraph 11.

two expiry dates provided for in the Law on Medicinal Products of 24 August 1976.

58. Moreover, Directive 83/189/EEC [32] lays down the obligation for Member States, in Article 8(1), to communicate to the Commission any draft technical regulation and to let the Commission have 'a brief statement of the grounds which make the enactment of such a technical regulation necessary, where these are not already made clear in the draft.'

59. The Commission considered that the Federal Republic of Germany, by failing to notify of it of the Order which, it claims, contrary to the view of the defendant State, contains a technical regulation, has contravened Articles 8(1) and 9(1) of Directive 83/189/EEC.

60. That directive provides, in Article 10, that Articles 8 and 9 do not apply where Member States honour their obligations arising out of Community directives or commitments arising out of an international agreement where they result in the adoption of uniform technical specifications in the Community.

61. 'Technical regulation' is defined in Article 1(5) of the directive as:

'(...) technical specifications, including the relevant administrative provisions, the observance of which is compulsory, *de jure* or *de facto*, in the case of marketing or use in a Member State or a major part thereof, except those laid down by local authorities'.

62. The Order clearly provides, *de jure*, that the packaging of the products concerned must feature an expiry date of 30 June or 31 December.

63. It is therefore a national provision introducing a new technical rule and it does not constitute merely a transposition by the Federal Republic of Germany of an obligation arising from an international agreement or a Community directive, since the directive relied upon by the German authorities does not provide for an indication of an expiry date for non-reusable sterile medical instruments.

64. The failure to fulfil obligations which is alleged in this head of claim is therefore established in so far as it is based on Article 8(1) of Directive 83/189/EEC.

32 — Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations (OJ 1983 L 109, p. 8).

65. It does not seem, however, that the Commission's reference to Article 9(1) is relevant.

66. On the one hand, the duty to notify the Commission, in advance of the adoption of any draft technical regulation arises only from Article 8(1) and, on the other hand, Article 9(1) applies only after the communication under Article 8(1), the failure to do so being precisely the default alleged here.

67. My understanding is that it is the Commission's wish that from those two provisions taken together may be drawn all the consequences regarding the rights of individuals to rely on them directly before their national courts so as to oppose the application of the disputed provision. I do not consider however that it is appropriate to address such an issue in the course of the present proceedings.

68. Accordingly, I propose that the Court should:

(1) declare that the Federal Republic of Germany has failed to fulfil its obligations:

— under Article 30 of the EEC Treaty, by making the placing on the market of proprietary medicinal products and non-reusable sterile medical instruments subject to the obligation to use only two dates in the year to indicate their expiry date on the packaging;

— under Article 8(1) of Directive 83/189/EEC of 28 March 1983, by failing to communicate to the Commission, before its adoption, the draft text of the Order of 25 March 1988, amending for the first time the Order on pharmaceutical companies, which extends to non-reusable sterile medical instruments the obligation to indicate an expiry date;

(2) order the Federal Republic of Germany to bear the costs.