JUDGMENT OF THE COURT
1 June 1994 *

In Case C-317/92,

Commission of the European Communities, represented by Richard Wainwright, Legal Adviser, and Angela Bardenhewer, of the Legal Service, acting as Agents, with an address for service at the office of Georgios Kremlis, also of its Legal Service, Wagner Centre, Kirchberg,

applicant,

v

Federal Republic of Germany, represented by Ernst Röder, Ministerialrat in the Federal Ministry for Economic Affairs, and Claus-Dieter Quassowski, Regierungsdirektor in the same ministry, acting as Agents, assisted by Dietrich Ehle, Rechtsanwalt, Cologne, with an address for service in Luxembourg at the German Embassy, 20-22 Avenue Emile Reuter,

defendant,

APPLICATION for a declaration that, by restricting to two a year (30 June and 31 December) the expiry dates which may be indicated on the packaging of medicinal products and of non-reusable sterile medical instruments and by not communicating to the Commission a draft of a regulation introducing new technical regulations for the marketing of those medical instruments, the Federal Republic of Germany has failed to fulfil its obligations under Article 30 of the EEC Treaty and under Article 8 of Council Directive 83/189/EEC of 28

* Language of the case: German.

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),

THE COURT,

composed of: O. Due, President, J. C. Moitinho de Almeida and M. Diez de Velasco (Presidents of Chambers), C. N. Kakouris, F. A. Schockweiler, F. Grévisse, M. Zuleeg, P. J. G. Kapteyn and J. L. Murray (Rapporteur), Judges,

Advocate General: M. Darmon,
Registrar: J.-G. Giraud,

having regard to the report of the Judge-Rapporteur,

after hearing the Opinion of the Advocate General at the sitting on 15 December 1993,

gives the following

Judgment

1 By application lodged at the Court Registry on 22 July 1992 the Commission of the European Communities brought an action under Article 169 of the EEC Treaty for a declaration that,

— by restricting to two a year (30 June and 31 December) the expiry dates which may be indicated on the packaging of medicinal products and of non-reusable sterile medical instruments, and

— by not communicating to the Commission a draft of a regulation introducing new technical regulations for the marketing of those medical instruments,

the Federal Republic of Germany has failed to fulfil its obligations under Article 30 of the EEC Treaty and under Article 8 of 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).

Admissibility of the actions

2 The German Government contests *in limine* the admissibility of the action on the ground

— that the procedure has been initiated for amending German law in order to make it consistent with the Community legislation and that administrative instructions have been sent, as a provisional measure, to the competent national bodies with a view to ensuring unrestricted entry for medicinal products which originate in other Member States;

— that the institution of the proceedings constitutes an infringement of the principle of protection of legitimate expectations since the Commission did nothing for two years after sending the reasoned opinion (26 March 1990) and did not formally raise the subject of the failure to fulfil obligations at a bilateral meeting held in the interim;

— and that the institution of the proceedings interferes with the negotiations, at present in progress within the Council, on the harmonization of national rules on labelling of medicinal products.

3 With regard to those various arguments, it should first be noted that the amendment of the national rule at issue, now under way, is insufficient to eliminate the failure to fulfil obligations since the subject-matter of the proceedings in an action for failure to fulfil obligations is limited in time to the end of the pre-litigation phase (see the judgment in Case C-361/88 *Commission* v *Germany* [1991] ECR I-2567). Furthermore, mere administrative measures, by their very nature open to amendment at the will of the administration and lacking sufficient publicity, cannot be regarded as constituting valid compliance with the Treaty obligations (see judgment in Case C-236/91 *Commission* v *Ireland* [1992] ECR I-5933, paragraph 6).

4 Secondly, it is for the Commission to judge at what time it will bring an action for failure to fulfil obligations; the considerations which determine its choice of time cannot affect the admissibility of the action (see judgment in Case 7/68 *Commission* v *Italy* [1968] ECR 423). That being so, the fact, on the one hand, that no action was taken further to the reasoned opinion, either immediately or shortly afterwards, and, on the other hand, that the subject of the failure to fulfil obligations was not formally raised at a bilateral meeting, could not confer on the Member State concerned a legitimate expectation that the procedure was at an end.

5 Lastly, it should be noted that the right to choose the time for bringing an action is not affected by the fact that negotiations on harmonization are in progress within the Council, and that in any event such negotiations do not exempt the Member States from compliance with the applicable Community provisions so long as the provisions under discussion have not entered into force.

6 The action is therefore admissible.

The barrier to intra-Community trade

7 Article 13 of 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), as amended in particular by Council Directive 83/570/EEC of 26 October 1983 amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action (OJ 1983 L 332, p. 1), that any proprietary medicinal products — that is to say any ready-prepared medicinal product placed on the market under a special name and in a special pack (Article 1) — must show its expiry date:

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

...

7. Expiry date in plain language.

...'

8 In accordance with the Community legislation, the German Law on medicinal products (Arzneimittelgesetz, BGB1. I, p. 2445, as amended by the Law of 16 August 1986, BGB1. I, p. 1296), provides that the packaging must show the expiry

date and, although the directive contains no additional obligation on the point, provides, in Paragraph 10, point 7, as follows:

'The expiry date to be shown must be 30 June or 31 December of a year, unless the duration of validity calculated from the date on which the pharmaceutical undertaking puts the product on the market is less than one year ...'

9 By regulation of 25 March 1988, the Federal Minister for Health extended to non-reusable sterile medical instruments the obligations applicable to medicinal products with regard to labelling, in particular the obligation to use one of the two dates mentioned above in order to show the expiry date.

10 According to the Commission, the restriction of the expiry dates to two a year creates a barrier to intra-Community trade, in so far as, on the one hand, importers are obliged to alter the original packaging in order to make it conform with the German provisions, and, on the other hand, marketing of the products must cease at the start of the six-month period during which their validity would expire if the provision at issue did not exist (for example 30 June for a product normally valid until 15 November).

11 The German Government contends that importers must in any event alter the packaging in order for the information on it to be given in German and that the fixing of the expiry date at the start of the six-month period corresponds to the practice of German pharmacists, who cease selling a product several months before its expiry date in order to allow the consumer a sufficient period to use it or because other, more effective, products have appeared on the market.

12 In that connection, it should be noted, without its being necessary to consider the costs which may be involved in altering the packaging, that the measure in question, relating to the conditions to be satisfied by products, is likely to affect intra-Community trade in so far as it may reduce the period of marketing of imported products and that for that reason, it constitutes, according to settled case-law, a measure having equivalent effect to a quantitative restriction, prohibited by Article 30 of the EEC Treaty (see judgment in Cases C-267/91 and C-268/91 *Keck and Mithouard* [1993] ECR I-6097). The fact that that measure may correspond to a national practice does not mean that it ceases to be restrictive in nature, since it constitutes, *per se*, the expression of an obligation which requires importers to alter expiry dates.

13 The German Government maintains that the measure is justified on the ground of protection of public health.

14 In that connection, it should be noted that in the absence of specific Community requirements the Member States may choose the means which they consider appropriate to protect public health on their territory (see judgment in Case C-290/90 *Commission* v *Germany* [1992] ECR I-3317).

15 Directive 65/65, cited above, merely requires that the expiry date be shown in plain language but does not prohibit Member States from specifying the means which may be employed for the purpose. Therefore there is nothing to prevent the Member States from specifying those means, so long as they comply with the principle of proportionality (see, in particular, the judgment in Case 261/81 *Rau* v *De Smedt* [1982] ECR 3961).

16 The German Government states that the contested measure is designed to prevent consumption of expired products by reducing the period of duration of their validity, which is necessary because that period is fixed according to criteria that are unreliable and are defined by the undertakings themselves.

17 That argument cannot be upheld. The mere advancing of an expiry date does not constitute, in itself, a measure capable of protecting public health. It does not involve any check on the date fixed by the undertaking but instead is based on that date, and merely brings it forward. Advancing the date therefore does not enable any mistake to be rectified, still less so since the alleged safety margin differs in duration according to how far the real expiry date is from 30 June or 31 December.

18 Furthermore, under the system established by Directive 65/65, the expected shelf life of the product must be communicated to the competent authority of the Member State of origin before the product is placed on the market (Article 4, point 6), that the authority must have specifically authorized that product to be placed on the market (Article 3) and that if, after verification of the information supplied, it appears that the product is harmful in the normal conditions of use, the authorization must be refused (Article 5). With respect to those provisions, the German Government has failed to show, and has not even put forward anything to suggest, that there were reasons to doubt the reliability of the expiry date, fixed in the Member State of origin on the basis of the product's expected shelf life.

19 The German Government further contends that the restriction of the expiry dates to two a year simplifies the checking of the products and thus reduces the number of errors which may result in the use of expired products.

20 That argument cannot be upheld either. Admittedly, the standardization of expiry dates makes it easier to sort products, but the resulting economic advantages for traders does not constitute a ground of justification recognized in Community law. Furthermore, the German Government has not shown that the contested measure was the most appropriate means of reducing the risk of consumption of expired products, whilst being the least restrictive of intra-Community trade.

21 It must therefore be held that, by restricting to two a year (30 June and 31 December) the expiry dates which may be shown on the packaging of medicinal products and non-reusable sterile medical instruments, the Federal Republic of Germany has failed to fulfil its obligations under Article 30 of the Treaty.

The failure to communicate a draft of a regulation

22 The Commission considers that the regulation of 25 March 1988 by which the Federal Minister of Health extended to non-reusable sterile medical instruments the obligations relating to labelling of medicinal products should have been communicated to it before it was adopted, as required by Article 8(1) of Directive 83/189/EEC, cited above, which provides:

'Member States shall immediately communicate to the Commission any draft technical regulation, except where such technical regulation merely transposes the full text of an international or European standard, in which case information regarding the relevant standard shall suffice.'

23 'Technical regulation' is defined in Article 1(5) of the same 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 major part thereof, except those laid down by local authorities'

24 The German Government considers that the regulation of 25 March 1988 merely extends existing rules to certain products and thus does not itself contain any new technical regulation.

25 That argument cannot be upheld. The German regulation in question constitutes a new technical specification within the meaning of Article 1, cited above, since non-reusable sterile medical instruments may henceforth be marketed or used in Germany only if certain obligations are fulfilled the application of which was formerly confined to the labelling of medicinal products. The application, to given products, of a rule which previously only affected other products, constitutes, with regard to the former, a new regulation and must therefore be notified in accordance with the directive.

26 That finding is not called in question by the fact that, as contended by the German Government, the extension of the scope of the rule is based on an enabling provision which was previously communicated to the Commission. That enabling measure, taken as such, does not require to be notified on the basis of Article 8 aforesaid since it does not constitute a new specification. The situation is different as regards the implementation of that measure, which does constitute a new specification which must be notified.

27 It must therefore be held that, by not notifying to the Commission a draft of a regulation introducing new technical regulations for the marketing of non-reusable sterile medical instruments, the Federal Republic of Germany has failed to fulfil its obligations under Article 8 of 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.

Costs

28 Under Article 69(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs. Since the Federal Republic of Germany has been unsuccessful, it must be ordered to pay the costs.

On those grounds,

THE COURT

hereby:

1. Declares that, by restricting to two a year (30 June and 31 December) the expiry dates which may be indicated on the packaging of medicinal products and of non-reusable sterile medical instruments and by not notifying to the Commission a draft of a regulation introducing new technical regulations for the marketing of those medical instruments, the Federal Republic of Germany has failed to fulfil its obligations under Article 30 of the EEC Treaty and under Article 8 of 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;

2. Orders the Federal Republic of Germany to pay the costs.

Due Moitinho de Almeida Diez de Velasco

Kakouris Schockweiler Grévisse

Zuleeg Kapteyn Murray

Delivered in open court in Luxembourg on 1 June 1994.

R. Grass O. Due

Registrar President