1. **Declares that, by reserving the marketing of medicinal preparations to pharmaceutical undertakings having their headquarters in the area in which the German Law on Medicinal Preparations is applicable, the Federal Republic of Germany has failed to fulfil its obligations under Article 30 et seq. of the EEC Treaty;**

2. **Orders the defendant to pay the costs.**

Mertens de Wilmars Koopmans Bahlmann
Pescatore Mackenzie Stuart Bosco Due

Delivered in open court in Luxembourg on 28 February 1984.

P. Heim
Registrar

J. Mertens de Wilmars
President

OPINION OF MR ADVOCATE GENERAL MANCINI DELIVERED ON 17 JANUARY 1984 [1]

Mr President,
Members of the Court,

1. This dispute arises out of an application brought by the Commission under Article 169 of the EEC Treaty against the Federal Republic of Germany. That Member State is said to have infringed Article 30 of the Treaty by reserving the placing of medical preparations on the market to pharmaceutical undertakings having their headquarters in the Federal Republic of Germany.

Through the "Gesetz zur Neuordnung des Arzneimittelrechts" of 24 August 1976, the German legislature re-shaped the law of proprietary medicinal products (BGBl. I, p. 2445). Article 1 of that Law contains the "Gesetz über den Verkehr mit Arzneimittel" (known as the "Arzneimittelgesetz" and hereinafter referred to as "the AMG"), Paragraph 9 (2) of which provides that only pharmaceutical undertakings having their headquarters in the Federal Republic of Germany may place medical preparations on the market. This provision is part of a

1 — Translated from the Italian.

rigorous system of prior examination and subsequent surveillance of the marketing of pharmaceutical products which includes the undertaking's liability without fault and the imposition of penal or administrative sanctions on it for failure to carry out its obligations. Its specific purpose is to make it possible to identify and trace at any time the person who has placed medicinal preparations on the market.

Since it was convinced that the headquarters requirement limited the freedom of pharmaceutical undertakings established in other Member States and therefore restricted the free movement of goods, the Commission initiated the procedure under Article 169 on 28 February 1979 by addressing to the German Government a letter calling for its observations which, however, remained unanswered. On 11 February 1980 the Commission issued the prescribed reasoned opinion. At this point, the Federal Republic informed the Commission on two occasions (10 April and 24 October 1980) that it had asked the Länder not to apply the disputed provision to medical preparations from other Member States and that it had presented an amendment to the Bundestag which would modify Paragraph 9 (2) of the AMG, to that effect. On 9 March 1981, the Commission asked the Federal Republic to keep it informed of the progress of this initiative, but, as it received no reply, it brought the matter before this Court by an application registered on 10 September 1981. At the request of the Federal Republic, the proceedings were suspended since there were grounds for hoping that the amendment to the Law would be passed. After the Bundestag had rejected the Government's amendment, the proceedings were resumed.

2. The legislation of which the provision under consideration forms part is very similar to the Belgian Decree of 5 June 1975 which was the subject of the judgment delivered by this Court on 2 March 1983 in Case 155/82. That decree, dealing with the storage, marketing and use of pesticides and phtyo-pharmaceutical products, made the sale of such products subject to an approval which could be obtained only if the person responsible for the marketing was established in Belgium (Article 12). The Commission considered that such a requirement placed manufacturers established in other Member States at a disadvantage by impeding the free movement of goods and this Court accepted its argument and held: "The requirement that a representative be established on national territory is not ... such as to provide, with a view to the attainment of the objective of the protection of public health, [a justification for] an exception to the prohibition contained in Article 30 ... and ... constitutes a restriction on intra-Community trade" (paragraphs 16 and 17 of the decision).

It is remarkable that a precedent which is both so close and so recent was discussed by the parties only during the oral procedure and then only as a result of a question posed by a Member of the Court. The Agent of the Federal Republic of Germany sought to prove that between the two cases there were differences of such a nature as to make it impossible to apply to this case the principles laid down in the other. He contended that in this respect there were two decisive factors: the different purposes of the Belgian and German provisions, and the different risk to health presented by the products to

which they referred. Both, he said, provide for checks on the marketing of such products; but those carried out under the AMG are predominantly *a posteriori* whereas those carried out under the Belgian Decree are essentially preventive. The dangers to health presented by medical preparations intended for human consumption are more serious and more direct.

These arguments seem to me to be without foundation. The first is contradicted by the proceedings in Case 155/82, which show clearly that the surveillance of pesticides already placed on the market was also one of the objectives of the Belgian Decree. The second founders on a point of plain common sense. Medicinal preparations are designed to cure and pesticides to kill. Although the former may be dangerous, the latter are so by definition. But that is not all. At the time of the proceedings in Case 155/82, the pesticides and phyto-pharmaceutical products sector was subject, at Community level, to a lesser degree of harmonization that that applicable to proprietary medicinal products today. In regulating the latter, therefore, the Member States are subject to stricter limits than those which applied to the former.

3. Those considerations, properly developed, are probably sufficient in themselves to demonstrate the illegality under Community law of Paragraph 9 (2) of the AMG. It seems more correct, however, to review the arguments relating to Articles 30 and 36 of the Treaty that the German Government advanced to defend the headquarters requirement.

That requirement, it claims, does not infringe the first of those articles or if it does, only to an insignificant degree. The provision which lays it down does not in fact require undertakings from the Member States to set up headquarters in Germany with the high costs that this entails. It merely requires that, for the marketing of their products, they should appoint a responsible person resident in the Federal Republic. It subjects them therefore to an obligation which does not involve any great expense and, what is more important, corresponds to a choice which for reasons of commercial strategy and in view of requirements relating to the distribution of goods they would make in any event.

That argument does not accord with the facts. As will shortly be seen, in order to show that the provision in dispute is justified under Article 36, the defendant Government has been constrained to emphasize the considerable extent of the obligations imposed upon the person responsible for placing products on the market. From this I infer that that person will be adequately rewarded; if that is the case, the burden of employing him will come to constitute a significant impediment to imports, at least "for ... small or medium-sized undertakings" (judgment of 2 March 1983, paragraph 7 of the decision). Legally, that makes it a measure having an effect equivalent to a quantitative restriction, which, in this case, is prohibited not only by Article 30 but also by Commission Directive 70/50 of 22 December 1969, (Official Journal, English Special Edition, 1970 (I), p. 17). To be included among such measures, according to Article 2 (g), are those

which "make access of imported products to the domestic market conditional upon having an agent or representative in the territory of the importing Member State".

4. Let us turn to Article 36. Starting from the premise that the procedures for the surveillance of medicinal preparations placed on the market are not harmonized, the German Government relies on that article in four respects. The presence of a representative of the undertaking on the territory of the Federal Republic is, it claims, indispensable for the protection of health because: (a) it enables the competent authorities to obtain all the information necessary for assessing the product before it is placed on the market; (b) it enables them to subject it to further analyses and, if these show that it is harmful, to order its immediate withdrawal after it has been placed on the market; (c) it facilitates actions for compensation for damage caused by harmful medicinal preparations; and (d) it ensures the effectiveness of criminal proceedings in the case of an offence against the legislation.

In comparing this case with Case 155/82, I have already made a number of references to the high degree of harmonization in the sector involved in this case and I will return to this point later. For the moment I will confine myself to remarking that, however far apart the national rules remain, the Court regards as justified under Article 36 only those internal measures which are strictly necessary for the protection of public health, for which there are no alternatives less restrictive of intra-Community trade and which do not entail arbitrary discrimination or disguised restrictions on trade between the Member States. The provision which requires the employment of a representative on the territory of the Federal Republic penalizes only foreign undertakings, by discriminating against them as compared with national undertakings. As regards the questions whether that provision is indispensable and whether there are no measures which could achieve the same ends by less restrictive means, I should like to put forward the following considerations.

The first argument: The requirement laid down by that provision, it is said, must be met before the product is placed on the market because the direct contact which that requirement renders possible between the national authorities and the representative of the undertaking makes it easier for the authorities to obtain the information on the basis of which they establish whether it is appropriate to authorize the marketing of the product. This argument would carry weight were it not for the fact that the rules of Community law deal with this very point in the most detailed way. According to Article 4 of Council Directive 65/65 of 26 January 1965 (Official Journal, English Special Edition, 1965-1966, p. 20) any person wishing to obtain an authorization must provide the competent authority of the Member State with information on the composition of the product, the method of preparation, the therapeutic indications, the contra-indications, the posology, the control methods employed by the manufacturer and the results of the tests (physico-chemical, biological, pharmacological, toxological and clinical) to which the medicinal preparation has been subjected.

Nor is that all. According to a later directive (75/318 of 20 May 1975, Official Journal L 147, p. 1) the information relating to the method of preparation must include at least a

"mention of the various stages of manufacture, so that an assessment can be made of whether the processes employed in producing the pharmaceutical form might have produced an adverse change in the constituents" (Annex, Part 1, B). What more information the national authorities need in order to decide whether the authorization can be granted, I cannot imagine. Assuming, however, that they did need more information, there would be nothing to prevent them from seeking it from the applicant. The latter will, as a rule, be the manufacturer of the medicinal preparation and thus the person who best knows its characteristics. From that point of view, whether or not there is a person responsible for marketing resident in Germany is totally irrelevant.

The second argument: Such a person, so the argument continues, is indispensable even after the authorization to place the product on the market has been granted, for example when the competent authorities consider it appropriate to subject the product to new tests or when, having established that it is dangerous, they intend to withdraw it immediately from the market. Let me distinguish between these two situations. In the first, it seems to me, there are no grounds of urgency which prevent the competent authorities from addressing themselves to the foreign manufacturer. In the second, the possibility of being able to contact a person resident in Germany would undoubtedly facilitate their task. However, it seems to me that it is going too far to say that the immediate withdrawal of the dangerous medicinal product is the *only* means of protecting the health of consumers. As the Commission has pointed out, there are other ways and means of ensuring that consumers do not use it, for example, by warning them of the danger through the mass media (press, radio, television).

The third argument: It is further contended that a person who consumes a harmful medicinal product can bring an action for damages more easily against a representative of an undertaking residing in the Federal Republic of Germany. That argument is in itself correct, but it misses the point. I do not believe that the exemption under Article 36 goes so far as to cover measures which protect consumers not *against the use* of harmful medicinal products, but *against having used them.* The requirement to which the German Government has expressly drawn attention is covered by other Community texts, such as the Brussels Convention on Jurisdiction and the Enforcement of Judgments in Civil and Commercial Matters.

The fourth argument: Finally, it is asserted that the presence in the Federal Republic of a person responsible for marketing renders more effective criminal proceedings instituted for offences against provisions relating to the protection of health. This is also correct, but of no value for our purposes, as this Court itself observed in its judgment of 2 March 1983 when it stated that "questions of criminal liability are relevant to the objective of Article 36 only in so far as the application of criminal provisions may have a preventive effect" and added that "even though criminal penalties may have a

deterrent effect as regards the conduct which they sanction, that effect is not guaranteed and, ... is not strengthened, in the case of a manufacturer in another Member State ..., solely by the presence on national territory of a person who may legally represent the manufacturer" (paragraph 15 of the decision). In my opinion there is no reason for the Court now to depart from that approach.

5. In the light of the foregoing considerations, I propose that the Court's decision on the action brought by the Commission of the European Communities against the Federal Republic of Germany by application lodged at the Court Registry on 10 September 1981 should be as follows:

The Federal Republic of Germany, by reserving the marketing of medicinal preparations to pharmaceutical undertakings having headquarters on the territory of the Federal Republic of Germany, has adopted a measure which is not justified under Article 36 of the EEC Treaty and has thus failed to fulfil its obligations under Article 30 of that Treaty.

Since the Federal Republic of Germany has failed in its submissions, it must bear the costs of the action.