OPINION OF MR ADVOCATE GENERAL MANCINI DELIVERED ON 24 NOVEMBER 1983 [1]

Mr President,
Members of the Court,

1. In this reference for a preliminary ruling the Court is asked to interpret Council Directive 65/65/EEC of 26 January 1965 (Official Journal, English Special Edition 1965-1966, p. 20) on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products. It is a question, essentially, of establishing whether rules which regulate the prices of pharmaceutical products in some way fall within the scope of that directive.

I shall summarize the facts of the case. In 1976 a group of 14 pharmaceutical companies, including Clin-Midy, brought an action before the Conseil d'État [State Council] of Belgium for the annulment of an order made by the Minister for Economic Affairs on 10 February 1976 on the prices of proprietary medicinal products and other drugs. In support of their claim, the plaintiffs argued *inter alia* that the contested rules were contrary to Community law, in particular Directive 65/65. The court submitted the following questions to the Court of Justice for a preliminary ruling under Article 177 of the EEC Treaty:

"1. Does 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 have direct effect in relations between Member States and those subject to their jurisdiction and may the latter plead a breach thereof before a national court?

2. Is Directive 65/65 of 26 January 1965 concerned solely with the approximation of provisions which are intended to protect public health or is it also concerned with the approximation of other provisions relating to proprietary medicinal products, in particular those which are enacted for the purpose of controlling prices?

3. Should Article 21 of Directive 65/65 be interpreted as meaning that an authorization to market a proprietary medicinal product may be refused, suspended or revoked on the ground that rules on prices have not been complied with?"

2. I shall begin by considering briefly the contested provisions. As is clear from its title, the ministerial order of 10 February 1976 is intended to regulate the prices of proprietary medicinal products and other drugs. It provides that proprietary medicinal products and certain other drugs may not be sold to wholesalers, dispensing chemists and hospital establishments at prices higher than those charged on 11 August 1975 (Article 1); it fixes the maximum profit margins of wholesalers and dispensing chemists on sales of proprietary medicinal products (Article 2); it provides

1 — Translated from the Italian.

that, before marketing new products (namely, those not yet on the market on 11 August 1975), manufacturers and importers must obtain approval from the competent authority (the Minister for Economic Affairs) for the price which they intend to charge (Article 3). We are therefore dealing with rules which are concerned directly and exclusively with the prices of pharmaceutical products and which consequently fall within the ambit of national economic policy in the wide sense of the term.

3. I shall now examine the three questions on which the Court is requested to give a ruling. At the heart of the case is the second question, which concerns the scope of Directive 65/65: the national court wishes to know whether it covers only rules which are concerned with the protection of health or whether it also applies to rules relating to prices. Logically, that question must be answered before Question 3, which concerns the interpretation of a single provision of the directive, and before Question 1, which asks what effect the various provisions of the directive have. In fact if Question 2 is answered in the negative, a similar answer will have to be given to Question 3, while Question 1 will become irrelevant.

I will say at once that, in my opinion, the directive at issue is concerned solely with the approximation of rules relating to pharmaceutical products which are intended to protect public health; it therefore does not cover rules relating to price controls. A number of factors lead me to that conclusion.

In the first place, there is the aim of the directive, defined in the preamble. The first recital lays down the basic principle on which any rule concerning the production and distribution of proprietary medicinal products must be based: its "primary purpose ... must be to safeguard public health". That principle is then developed. In particular, the directive states that: (a) that objective must be attained by means which will not hinder the development of the pharmaceutical industry of trade in medicinal products within the Community (second recital); (b) "trade ... is hindered by disparities between certain national provisions ... relating to medicinal products" (third recital) and "such hindrances must accordingly be removed" (fourth recital); (c) this entails approximation of the national rules (fourth recital), to be achieved "progressively"; and (d) priority must be given to eliminating the disparities liable "to have the greatest effect on the functioning of the common market" (fifth and final recital).

Thus the declared aim of the Community legislature is to approximate the national rules from the standpoint of the protection of public health. More important still is the fact that the rules which it has laid down are clearly drafted from the same perspective: those relating to authorization to market (Chapter II) no less than those which deal with the revocation of such authorization (Chapter III) and those which

regulate labelling (Chapter IV). It is sufficient for me to cite in detail Articles 4 and 5. Article 4 defines the procedure for obtaining authorization and requires the persons concerned to supply the competent national authorities with particulars of the constituents of the product, the method of preparation, therapeutic indications, contra-indications, posology, control methods used by the manufacturer and the results of various tests (physico-chemical, biological, pharmacological, toxicological and clinical) to which the medicinal products must be submitted. Article 5 provides that the authorization is to be refused if, after verification of the particulars given, it proves "that the proprietary medicinal product is harmful ... or that its therapeutic efficacy is lacking or is insufficiently substantiated ... or that its ... composition is not as declared".

The same is true of the provisions governing the revocation of authorization: the cases in which revocation is provided for all involve a finding that the product is harmful or dangerous. The provisions on labelling are likewise directed towards the protection of the consumer: the packages must contain particulars such as the "method of administration", "expiry date", "special storage precautions", and so on. Furthermore, the rules on labelling may also be relied on for the sake of a separate argument — which could be described as *a contrario* — in support of my view. Article 19 provides that the rules on labelling "shall not prevent the particulars required by rules other than those to which this directive relates from being given on outer packages or containers". It seems to me that it may be inferred from that that the directive does not deal exhaustively with the subject of proprietary medicinal products. Some aspects remain outside it; and I do not think that it would be far from the truth to state that one of those aspects concerns the prices of such products.

4. I will now consider the question relating to Article 21 of Directive 65/65, which provides that: "An authorization to market a proprietary medicinal product shall not be refused, suspended or revoked except on the grounds set out in this directive". The Belgian Conseil d'État asks whether that rule should be interpreted as meaning that an authorization may be refused, suspended or revoked on the ground that national rules on prices have not been complied with. The reply which I have given to the first question contains the criteria needed to resolve this second question. If it is indeed accepted that rules on prices are outside the scope of the directive, it must also be acknowledged that the failure to comply with such rules does not entitle the competent authorities to refuse, suspend or revoke an authorization.

However, one explanatory remark is needed. The fact that prices are outside the scope of the directive implies that the Member States retain the power to regulate them; it follows that they may also make the authorization to place medicinal products on the market subject to compliance with certain rules on prices and suspend or revoke the authorization if those rules are infringed.

However, it should be added that an authorization which is dependent upon compliance with rules on prices is very different from the authorization provided for by the directive: different both in form, since it emanates from the Member State, whereas the other emanates from the Community, and, more important, in substance. Indeed, the aim of the two types of authorization could not be further apart: the one being intended to promote economic policy and the other to protect health. Naturally, the discretion enjoyed by the State in that area is not unlimited: Article 30 et seq. of the Treaty constitutes the boundary which may never be crossed.

5. Finally, by the third question, the Conseil d'État asks whether Directive 65/65 has direct effect in the Member States and consequently whether individuals may rely upon its provisions before the national courts. The reply which I have given to the preceding questions makes it unnecessary to decide this question, which is too general (since the directive consists of 25 articles). Once it is accepted that national measures relating to prices are outside the scope of the directive, there is no purpose in determining whether or not the provisions of that directive have direct effect.

None the less, for the sake of completeness I would observe that many of those provisions are sufficiently detailed and precise to lead to the immediate conclusion that they are directly applicable. I need only refer to Article 5 on the refusal of authorization, Article 7 on the maximum duration of the procedure for granting an authorization, Article 10, which provides for its renewal, and Articles 11 and 12, which govern suspension and revocation of an authorization.

6. On the basis of all the considerations set out above, I suggest that the Court should reply to the second and third questions asked by the Belgian Conseil d'État by judgment of 22 October 1982 in the action brought by SA Clin-Midy and 13 other undertakings in the pharmaceuticals sector against the Belgian State:

1. *In reply to Question 2:*

   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 must be interpreted as concerning solely national provisions which are intended to protect public health.

2. *In reply to Question 3:*

   Article 21 of Directive 65/65 must be interpreted as meaning that the particular authorization to market a proprietary medicinal product which

is regulated in every respect in that directive may not be refused, suspended or revoked on the ground that national provisions on prices have not been complied with. That does not prevent the Member States from establishing in their own laws, in addition to the authorization provided for in the directive, which is intended purely to ensure the protection of public health, other forms of preventive control designed to protect other interests. In doing so, however, they are bound to comply with the obligations resulting from the Treaty and in particular from Article 30 et seq.

Finally, I consider that, in the light of the replies which I propose should be given to the other two questions, the Court does not need to give a ruling on Question 1.