REPORT FOR THE HEARING
delivered in Case 56/87 *

I — Facts and procedure

1. Following the submission of complaints, the Commission commenced (in 1971, 1978 and 1981) the pre-litigation procedure laid down in Article 169 of the Treaty against the Italian Republic on the ground that the prices of pharmaceutical products were fixed at a level which was too low in order to allow normal imports into Italy of products from other Member States. However, it decided not to bring the cases before the Court owing to the measures adopted by the Italian Government.

2. In meetings between the parties which took place in 1981 the Italian Government undertook to adjust the prices at least once a year and each time that the consumer price index increased by 10%.

3. On 18 April 1984 an average increase of 10% of the prices subject to control, with the exception of those of pharmaceutical products, was decreed, whilst on 29 July 1984 a decree-law suspended all increases in the prices of pharmaceutical products pending the introduction of a new method of calculation.

4. On 24 October 1984 the new method was approved by a decision of the Interministerial Committee for Prices (*Gazzetta Ufficiale della Repubblica Italiana* No 298 of 29.10.1984). According to section 1 of the decision, the factors to be taken into account in the calculation of prices are the following:

'1.1. Raw materials.

1.2. Preparation and packaging materials.

1.3. Overall processing and marketing costs and overheads:

Labour;

Added industrial value;

Total processing costs;

Cost of products made non-marketable;

Cost of free samples;

Cost of medical and scientific information.

1.4. Research at company and product level.

1.5. Return on capital.

1.6. Launch of newly-registered products.'

* Language of the Case: Italian.

In section 1.1. on raw materials, the decision provides *inter alia* that:

'Proper attention must also be given to the pursuit of the objectives of promoting productive investment on national territory'.

5. The new method is also based on a decision of the Interministerial Committee for Economic Planning of 11 October 1984, published as an annex to the aforesaid decision, which also provides as follows:

'A — Guiding principles

A.1. The method of fixing prices must . . . also be oriented towards the objectives of promoting the national pharmaceutical industry, which is an industry which may bring positive benefits to the economy of the country in terms of productive investment, research, innovation, employment and exports.

. . .

B — Specific directives

. . .

B.4. Costs of research . . .

B.4.1. . . . The rate adopted, which normally must not exceed 10% of the industrial product net of VAT, may be increased to 12% if the research leads to considerable investment in the national territory, subject to proper verification.

. . .

B.4.2. To pharmaceutical specialities considered to be particularly original and innovative (research at the product level) shall apply a rate of increase in the sales product net of VAT which may amount to 20% in ordinary cases and 40% in the case of products which are the result of research carried out entirely on national territory . . .'

6. On 8 February 1985 the Commission commenced the procedure under Article 169 of the Treaty by sending to the Italian Government a letter in which it complained that prices had not been adjusted after the review of 1 April 1983 and in which it also criticized the new method of calculation.

7. By a telex message of 1 July 1985 the Italian Government drew the Commission's attention to the average increase of 8% in the prices of pharmaceutical products decided on by the Interministerial Committee for Prices on 21 December 1984.

8. The Commission repeated its complaints regarding the new method of calculation in its reasoned opinion of 19 March 1986.

9. On 12 July 1986 the Italian Government replied that the options to be submitted to the bodies empowered to take the appropriate decisions would be determined at the next interministerial meeting of the ministers concerned, in the light of preliminary studies being undertaken at the Interministerial Committee for Prices.

10. By application registered at the Court on 24 February 1987 the Commission brought this action. Upon reading the report of the Judge-Rapporteur and hearing the views of the Advocate General the Court decided to open the oral procedure without any preparatory inquiry.

II — Conclusions of the parties

1. The Commission claims that the Court should:

Declare that, by adopting and applying the new method for fixing the prices of pharmaceutical products, the Italian Republic has failed to fulfil its obligations under Article 30 of the Treaty;

Order the defendant to pay the costs.

2. The Italian Government has not submitted any express conclusions.

III — Submissions and arguments of the parties

1. The Commission submits that the new method contravenes Article 30 of the Treaty in so far as it is designed to favour domestic production and consequently makes the marketing of imported products more difficult than that of domestic products.

2. It points out that one of the objectives of the new method is 'the promotion of the national pharmaceutical industry' (point A.1. of the decision of the Interministerial Committee for Economic Planning). Furthermore, certain criteria are manifestly discriminatory since they allow, for the purposes of calculating prices, a greater proportion of the costs if activities are carried out on 'national territory' (points B.4.1. and B.4.2. of the aforesaid decision and point 1.1. of the decision of the Interministerial Committee for Prices).

3. Secondly, the method takes no account of the particular situation of imported products in so far as there is no reference to the supplementary costs and charges inherent in importation or to the dynamics of the various cost factors in the other Member States.

4. The Commission points out that Commission Directive 70/50/EEC of 22 December 1969 based on the provisions of Article 33 (7) of the Treaty, on the abolition of measures which have an effect equivalent to quantitative restrictions on imports and are not covered by other provisions adopted in pursuance of the EEC Treaty (Official Journal, English Special Edition 1970 (I), p. 17), covers measures which:

'(d) preclude any increase in the price of the imported product corresponding to the supplementary costs and charges inherent in importation;

(e) fix the prices of products solely on the basis of the cost price or the quality of domestic products at such a level as to create a hindrance to importation' (Article 2 (2)).

5. It also points out that, according to the judgment of the Court of 29 November 1983 in Case 181/82 *Roussel Laboratoria BV* v *Netherlands* [1983] ECR 3849, Member States have the possibility of 'combating inflation and adopting measures intended to control increases in the price of medicines, whatever their origin, on condition that they do so by means of measures which do not place imported medicines at a disadvantage'.

6. Finally, the Commission points out that the judgment of the Court of 29 January 1985 in Case 231/85 *Henri Cullet* v *Centre Leclerc* [1985] ECR 305 is a case of the application of the principle that, in price-fixing matters, Member States may not base decisions on factors specific to the national situation and ignore the situation of imported products.

7. The Italian Government, referring to the first complaint in the formal notice requiring it to submit observations, points out that under Decision No 12 of the Interministerial Committee for Prices of 26 March 1987 there was an average increase of 7% in the prices of pharmaceutical products. That complaint has therefore lost its purpose.

8. As regards the new method, the Italian Government, which does not dispute the Commission's complaints, only states that the competent authorities will propose amendments to its decision of 11 October 1984 to the Interministerial Committee for Economic Planning as soon as possible in order to eliminate any suspicion of discrimination against imported products in the method of determining the prices of pharmaceutical products.

O. Due
Judge-Rapporteur