gations to be granted from the general rules on price control and places the products that benefit from the system at an advantage as regards approval for reimbursement, constitutes an infringement of Article 30 of the Treaty. That system is such as to place imported products at a disadvantage and, therefore, constitutes a measure having an effect equivalent to a quantitative restriction prohibited by that provision.

REPORT FOR THE HEARING
in Case C-249/88 *

I — Summary of the national legislation at issue and the course of the dispute

A — *The Belgian legislation on the prices of medicinal products and the approval of those products for reimbursement by social security*

1. *The pricing arrangements for proprietary pharmaceuticals and other medicinal products*

(a) The *Law of 9 July 1975* (*Moniteur Belge* of 30 July 1975, p. 93280) empowers the Minister for Economic Affairs to fix maximum prices for proprietary pharmaceuticals and other medicinal products in general, and for each proprietary pharmaceutical or other medicinal product in particular.

Under Article 3 of the Law, the Minister, who is required to consult the committee on prices for proprietary pharmaceuticals provided for in Article 4, must in the exercise of his powers have regard to 'criteria laid down by the King in a decree deliberated upon by the Council of Ministers, after consultation with the Committee on prices for proprietary pharmaceuticals . . . Those criteria relate both to initial price formation and the subsequent trends in the prices of medicinal products. On the one hand, they are to take account of the health, socio-economic, technical and scientific interests of the community and, on the other, of the industrial and profitability conditions of Belgian undertakings, whilst at the same time taking into consideration those conditions abroad and in particular in the Member States of the EEC'.

Under Article 6 thereof, the Law was applicable until 31 December 1977 but its validity was extended on several occasions by laws (of 22 December 1977, 24 November 1978, 23 December 1980) and then, in part, by royal decrees (decrees of 9 December 1982 and 31 December 1983).

(b) The *royal decree* specifying the criteria provided for in Article 3 of the Law of 9

* Language of the case: French.

July 1975 for fixing the prices of proprietary pharmaceuticals and other medicinal products was adopted on *11 December 1975* (*Moniteur Belge* of 16 December 1975, p. 15989).

The decree of 11 December 1975 distinguishes between two sets of criteria which the Minister for Economic Affairs must take into consideration, in 'fixing maximum prices in general for pharmaceutical products', on the one hand, and 'in fixing maximum prices for pharmaceutical products in particular', on the other.

With regard to the fixing of maximum prices in general, the criteria are as follows:

— trends in quantities sold on the Belgian market and in the corresponding turnover;

— trends in sickness insurance expenditure;

— impact on consumer prices;

— cost of factors of production, importation or distribution;

— level of publicity, medical information expenses and selling expenses;

— distribution and delivery margins;

— effect of rates of value added tax;

— research and investment;

— effect on the profitability and the industrialization of all the undertakings in the sector;

— health interests of the population.

As regards the fixing of maximum prices for different specific products, account must be taken of the following criteria:

— components of ex-producer or ex-importer price;

— effect of distribution and delivery margins;

— effect of value added tax;

— balance sheets, including profit and loss accounts of the undertaking and operating accounts of the undertaking and/or of the relevant division where the undertaking carries on various activities, regard being had to any interaction with the parent group;

— relationship between the number of units contained in each package and the dosage per unit;

— investment and employment;

— market and competitive conditions and impact on exports;

— comparison with prices charged for identical or comparable products in the other countries having a similar standard of living;

— comparison with prices charged in Belgium for pharmaceutical or medicinal products and for magistral preparations which are comparable and are available on the market;

— health interests, including the therapeutic value of the medicinal product, socio-economic and technical and scientific interests of the community.

(c) By the *Royal Decree of 31 December 1983* (*Moniteur Belge* of 21 January 1984, p. 850), an Article 2a was inserted into the Law of 9 July 1975 empowering the Ministers for Economic Affairs and Social Welfare to conclude with producers, importers or packagers of pharmaceutical products 'programme contracts entailing undertakings *inter alia* on investment, research, employment and exports, in exchange for authorized prices and reimbursements'.

Under the second paragraph of that article, the programme contracts are to contain provisions relating to the trends in prices of pharmaceutical products over a specified period and within the limits of an overall budget established each year on the basis of the budget of the Institut National d'Assurance Maladie-Invalidité (National Sickness and Invalidity Insurance Institute) (INAMI).

2. *The Belgian system of reimbursement of pharmaceutical products*

(a) Under Articles 24 and 25(2) of the Law of 9 August 1963 laying down and organizing a scheme of compulsory insurance against sickness and invalidity two royal decrees were adopted, *the first, of 1 September 1980, laying down the personal contribution by recipients to the cost of medicinal products refunded under the scheme of compulsory insurance against sickness and invalidity* which, in particular, provides for proprietary pharmaceuticals to be classified in different categories depending upon the rate of reimbursement granted (*Moniteur Belge*, 30 September 1980, p. 11106), *the second, of 2 September 1980, laying down the conditions in which compulsory insurance against sickness and invalidity is to contribute to the cost of pharmaceutical supplies* (*Moniteur Belge*, 30 September 1980, p. 11107).

Under the latter decree, pharmaceutical products are subject to reimbursement by INAMI only if they appear on the lists of reimbursable medicinal products.

Under Article 3 of the decree, in order to be admitted to those lists, 'proprietary pharmaceuticals must satisfy criteria for approval

relating to composition and price and must present an interest from the social point of view'.

By virtue of Article 4 of the decree, the *criteria for approval as regards composition and dosage* are laid down in Annex II. However, to be admitted to the list, it is not sufficient for a particular product to belong to a defined therapeutic category; it is for the technical committee on proprietary pharmaceuticals to 'assess the usefulness of admission to the category concerned'. Finally, the criteria for admission are classified in categories corresponding to the different reimbursement arrangements provided for in the Royal Decree of 1 September 1980, regard being had to the factors set out in the fourth subparagraph of that article:

— degree of therapeutic interest of the medicinal product in question and whether it is the only product available;

— degree of social interest of either the group or a part of the group of medicinal products in question, or of the applications, in whole or in part, of the product in question;

— probable duration of the treatment and frequency of administration;

— conformity of the price of the medicinal product in question with the provisions of Article 5 of the decree and cost of the resulting treatment;

— nature of the various products which can be utilized in similar therapeutic situations and resulting possibilities of substitution.

Article 5 of the decree *lays down the criteria for admission as regards prices.* Accordingly, proprietary pharmaceuticals may not be admitted 'whose price for sale to the public exceeds a percentage calculated on the basis of a comparison of economic, therapeutic and social data relating to a similar proprietary pharmaceutical or magistral preparation'. The percentage is given in the text. Finally, the last paragraph of that article states that the provisions thereof 'may not however mean that the same bases of reimbursement may not be laid down in respect of proprietary pharmaceuticals whose active ingredients are the same and whose galenic form is comparable'.

Under Article 6 the basis on which the intervention by the sickness insurance scheme is calculated is the price for sale to the public which meets the conditions laid down in Article 5. Where the price of a pharmaceutical product is increased pursuant to price-control rules issued by the Minister for Economic Affairs, such increase may be taken into account in the context of the sickness insurance scheme only in so far as the increased price continues to comply with the provisions of Article 5 of the decree.

(b) By *Royal Decree of 14 October 1985* (*Moniteur Belge*, 21 November 1985, p. 17137), Article 5 of the Royal Decree of

2 September 1980 was supplemented in order to take account of the introduction of the scheme of programme contracts under the Royal Decree of 31 December 1983, mentioned above.

Under the terms of a new paragraph added to Article 5 of the Royal Decree of 2 September 1980, the prices of proprietary pharmaceuticals covered by a programme contract 'do not fall within the sphere of application of this article. Nor may they be used as a basis for comparison in determining the basis for reimbursement of proprietary pharmaceuticals or of products whose price was fixed in accordance with Article 2 of the Law of 9 July 1975'.

B — *The course of the dispute*

In two letters before action of 1 August 1983 (SG (83) D/9821) and 20 June 1984 (SG (84) D/7894), the Commission informed the Belgian Government that the Belgian system of price control for medicinal products and of reimbursement of those products by social security were contrary to Article 30 of the EEC Treaty. The Belgian authorities stated their position in letters of 24 October 1983 (NA/SO4/90/1323/8815) and of 25 September 1984 (H/SO4/90/1412/92321) respectively, whereupon the Commission issued two reasoned opinions dated 21 March 1984 (SG (84) D/3869) and 2 October 1985 (SG (85) D712504) respectively and directed to the Kingdom of Belgium. The Belgian Government made its position known by letters of 20 April 1984 (NA/SO4/90/1550/90932) and 27 November 1985 (H/SO4/90/1412/98227).

On 12 March 1986 the Commission addressed to the Belgian Government a letter before action (SG (86) D/3011) in which it informed the Belgian Government that it took the view that the system of programme contracts introduced by the Royal Decree of 31 December 1983 infringed Article 30 of the Treaty. The Belgian authorities made known their position in a letter of 4 July 1986 (P/11/91/1323/1813).

In a reasoned opinion of 30 September 1987 (SG (87) 11716), the Commission informed the Belgian Government that both the rules on the fixing of maximum prices for pharmaceutical products and the rules governing approval for reimbursement of those products, together with the system of programme contracts in the pharmaceutical sector, were incompatible with Community law, and requested the Kingdom of Belgium to comply with that reasoned opinion within two months of its notification.

Since the Belgian Government did not comply with that opinion, the Commission brought an action before the Court under the second paragraph of Article 169 of the EEC Treaty, by application lodged at the Court Registry on 9 September 1988.

C — *Procedure before the Court*

Upon hearing the report of the Judge-Rapporteur and the views of the Advocate General, the Court decided to open the oral procedure. It also requested the Commission and the Kingdom of Belgium to reply to several questions.

II — Forms of order sought by the parties

1. The *Commission* claims that the Court should:

(a) Declare that the Kingdom of Belgium has failed to fulfil its obligations under Article 30 of the EEC Treaty:

— by laying down criteria for determining the maximum prices of pharmaceutical products which refer to factors peculiar to the Belgian market and do not permit account to be taken of the specific cost components of imported products;

— by freezing the prices of pharmaceutical products at a level so low that the marketing of certain imported products is impossible or unprofitable;

— by not permitting the pharmaceutical undertakings concerned to know the criteria on which the decisions fixing the maximum prices of their products or adjusting those prices are based;

— by adopting decisions to allow or not to allow reimbursement on the basis of criteria which are not objective or verifiable;

— by refusing to allow reimbursement of certain pharmaceutical products unless the prices of the products are reduced;

— by placing imported pharmaceutical products, whose prices are frozen, at a disadvantage by the conclusion of programme contracts which permit price rises subject to conditions which can be satisfied only by domestic products;

— by favouring, as regards approval for reimbursement, domestic pharmaceutical products which benefit from programme contracts, while imported products cannot so benefit;

(b) Order the Kingdom of Belgium to pay the costs.

2. The *Kingdom of Belgium* contends that the Court should dismiss the Commission's application as unfounded.

III — Summary of the observations of the parties

A — *The market in pharmaceutical products*

1. *Trends in the prices of pharmaceutical products on the Belgian market*

(a) The *Commission* puts forward a number of factors to demonstrate that prices of pharmaceutical products on the Belgian market are falling or are increasing only very slightly.

The Commission begins by taking as its starting point a 'basket' of 50 of the products most sold on the Belgian market in 1975 in order to trace the trends in their prices between that year and 1985. The total price of those products fell, according to the Commission, from BFR 17 183 in 1975 to BFR 15 802 in 1985, that is to say by 7.5%. With regard solely to products eligible for reimbursement the reduction is as great as 11%.

The Commission then goes on to compare the trends in the prices of pharmaceutical products with trends in prices in general. Starting from a 100 index in 1975, prices of medicinal products had fallen by 1985 to 92.4, whereas the level of prices in general stood at 190.9.

The Commission considers that the criticisms made by the Belgian Government of the methods of assessment employed by the Commission are unfounded.

In reply to the criticism that it is not sufficient to consider the trend of prices of the same 50 products between 1975 and 1985 and that it would be more meaningful to examine the trend of prices of the 50 products most sold in 1975 with the prices of the 50 products most sold in 1985, the Commission states that such reasoning is unacceptable because the products concerned would then be too different. Having said that, the Commission observes that even under the method proposed by the Belgian Government a comparison of the prices of the 18 products appearing in the 1975 list with the price of the same products still appearing in the 1985 list, account being taken of changes in packaging, shows that the price per milligram fell by 7.5%, whereas the Belgian Government's method shows an increase of 27.8%.

The Commission also considers that the observations of the Belgian authorities to the effect that the number of units sold increased over a ten-year period, as did turnover and the average price of special products (76.5% increase), are not relevant in assessing the trend of prices of proprietary pharmaceuticals.

With regard, finally, to the new product most sold in Belgium, the Commission demonstrates, in a table, that its Belgian price is lower than the price charged in seven other Member States.

The Commission also stresses that the Belgian authorities themselves acknowledge that the pricing policy adopted is harmful to the profitability of the pharmaceutical industry and that the decisions taken are based on national considerations and do not take account of the cost components of the products, in particular when they are imported.

(b) The *Kingdom of Belgium*, for its part, highlights the special nature of the market in pharmaceutical products which is characterized by the small degree of consumer influence on its development and of product substitution. The public authorities are therefore justified, also in view of the highly concentrated nature of the pharmaceutical products sector, to pursue a pricing policy in order, in particular, to secure for the public access to the largest possible range of medicinal products.

As far as prices are concerned, account must be taken of the commercial policy pursued by the undertakings. The Kingdom of Belgium observes that the prices of medicinal products are not frozen. In that respect it challenges the method used by the Commission, based on a list of the 50 products most sold in 1975, to analyse trends in prices. That is not a representative sample and does not enable changes affecting the market to be taken into account. Moreover, products reimbursed are over-represented in the sample in comparison with those not reimbursed. Finally, the fall in prices concerned mainly antibiotics and antirheumatic products which account for 13 out of the 16 cases of price reduction in the Commission's list. The Commission's method is therefore open to criticism and it would be better to take into consideration all products available on the market during a reference period. According to the Belgian Government, that method would show that the average level of prices on the Belgian market for medicinal products increased by 81% from 1975 to 1986. If the trend of prices of medicinal products is contrasted with the movements of the general price index, the year 1975 representing 100, the average price of medicinal products stood at 181 in 1986, whereas the general price index stood at 193.7, figures which are very different from those put forward by the Commission.

2. *The comparison of prices on the Belgian market with those on the markets of the other Member States*

(a) With a view to comparing prices of pharmaceutical products in Belgium with prices in the other Member States, the Commission examines the 20 proprietary pharmaceuticals most sold in Belgium. According to its figures, the price of those products in the other Member States lies somewhere between 119.2 and 172.8% of their price in Belgium. A comparison of the total price of the 'basket' containing those 20 proprietary pharmaceuticals reveals that their price in France is 115.8% of the price in Belgium, whereas it is 166.9% in the Netherlands, 195.6% in the Federal Republic of Germany, 143.4% in the United Kingdom and 121.7% in Italy.

Analysing, finally, the prices of 10 new products marketed since 1984 and most sold in Belgium, the Commission puts forward figures to show that their prices in the other Member States are always higher than in Belgium, except in the case of two products which, specifically, are not reimbursed in Belgium by social security.

(b) The *Kingdom of Belgium* considers that it is not sufficient to examine price trends on the basis of a sample of 20 of the most sold products in Belgium in order to compare price levels in that country with those in other Member States. Referring to studies by the European Bureau of Consumers' Unions and the Economist Advisory Group, the Belgian Government considers that Belgium occupies a middle position in the matter of prices. Moreover, the Kingdom of Belgium criticizes the fact that the Commission's comparison covers only five other Member States.

(c) The *Commission*, for its part, argues that the figures put forward by the Belgian Government may be explained by the fact that the figures used by the Commission itself used were those relating to industrial prices whereas the European Bureau of Consumers' Unions referred to retail prices.

Similarly, although the Belgian Government criticizes the fact that the Commission compared only the prices on the Belgian market with those prevailing in five other Member States, the Commission considers that to have taken into consideration the four other Member States would scarcely have altered the overall results.

3. *The profitability threshold of the prices of pharmaceutical products*

(a) The *Commission* considers that the Belgian authorities themselves acknowledge that their pricing policy is harmful to the profitability of the Belgian pharmaceutical industry and that decisions on the pricing of medicinal products are taken on the basis of considerations which ignore the cost components of the products.

Although the Kingdom of Belgium observes that the prices of national products have not evolved more favourably than prices of imported products and that the volume of imports from other Member States has increased, it is nevertheless true, in the Commission's view, that prices of imported medicinal products are frozen and changes in production costs and monetary fluctuations cannot be reflected in them.

(b) The *Kingdom of Belgium* contends that, from the difference between the price asked by the undertaking and the price allowed by the State authorities, it is not possible to draw the inference that a product is not profitable. The market is dominated by international undertakings which operate differentiated pricing policies, and it is impossible to know precisely the true profitability threshold. Moreover, the Commission is not putting forward an analysis of the costs of the products in order to infer therefrom a profitability threshold, but is merely working on the basis that the prices of medicinal products are higher abroad or that undertakings offered to sell at higher prices and refrained from selling their products on the Belgian market because those prices were not granted to them. None of this, however, enables the inference to be drawn that the prices imposed by the Belgian authorities are unprofitable.

It goes on to observe that the rules governing the fixing of prices and those governing approval for reimbursement of pharmaceutical products do not place imported medicinal products at a disadvantage since the proportion of turnover attributable to the consumption of imported medicinal products reached about 60% of overall turnover in 1986, as in 1975, and the share of imports originating in the Member States of the EEC increased during those ten years from 71.6 to 74.4%.

Finally, price differences from one country to another are without significance. First of all, as regards certain products mentioned by the Commission, Belgian prices are now no longer lower than those charged in other Member States; secondly, there is no shortage of examples of prices charged by undertakings for a product which are lower than the prices charged by those same undertakings for the same product abroad. That is the consequence of the differentiated economic and commercial strategies pursued by the undertakings in question. There is therefore no correlation between the level of the price of a medicinal product and the threshold of profitability.

B — *The Commission's allegations and the arguments of the Kingdom of Belgium*

1. *The fixing of maximum prices*

(a) According to the *Commission*, the Minister for Economic Affairs imposes on importers prices which are too low and therefore unremunerative. It observes, indeed, that it is very difficult to establish the level at which a price is remunerative but it considers that it is sufficient in that connection to note, on the one hand, that the prices imposed in Belgium are in general lower than those charged on the market in the other Member States, and on the other hand, that the decisions taken by the Minister have repeatedly led undertakings to abandon the marketing of certain products in Belgium and to withdraw other products from the Belgian market. That is attributable to the fact that the Minister bases his appraisal primarily on a comparison of prices charged with the prices of products already on sale on the Belgian market, whilst referring in general terms to the criteria 1 to 10, taken as a whole, set out in Article 3 of the Royal Decree of 11 December 1975.

According to the *Kingdom of Belgium*, the prices of imported products are generally higher than those of Belgian products, and the fact that the undertaking in question requested that a higher price should be charged or has abandoned the marketing of the product in question on the Belgian market, does not justify the conclusion that the price of a pharmaceutical product is not remunerative, having agreed to the very diverse commercial policies pursued by undertakings.

(b) The *Commission* observes, with regard to the method for fixing prices, that the Member States are empowered to fix the prices of the products on condition that the legislation enacted is compatible with Article 30 et seq. of the Treaty, as stated in the Commission's notice of 4 December 1986 (Official Journal C 310, p. 7).

The Commission criticizes the methods used by the Belgian Government to fix the prices of medicinal products in three respects:

— First, the criteria adopted in the legislation refer to features peculiar to the Belgian market and do not take account of the specific cost components of imported products. The Commission refers to the judgment of the Court in Case 181/82 (*Roussel* [1983] ECR 3849);

— Secondly, the Belgian legislation, by reason of its particular features, inevitably has the effect of freezing prices at such a low level that the disposal of imported products proves to be impossible, because it is unprofitable. The criteria contained in Article 3 of the Royal Decree of 11 December 1975 for granting price rises make no provision for increases in imported products to be taken into consideration in the sale prices. That is true, in particular, of increases due to monetary fluctuations. It also caused certain withdrawals of products from the Belgian market by undertakings. The Commission refers here to the judgment in Joined Cases 16/79, 17/79, 18/79, 19/79 and 20/79 (*Danis* [1979] ECR 3327);

— Finally, the decisions on prices adopted by the Minister give no indication of the criteria applied in each specific case, since they refer generally to criteria 1 to 10 of the Royal Decree of 11 December 1975. However, it is clear from the case-law of the Court that the criteria used must be objective and reviewable in accordance with the judgment in Case 238/82 (Duphar [1984] ECR 523).

The Commission submits that the Belgian Government has been unable to refute the various examples of abandonment of marketing or withdrawals of products by undertakings from the Belgian market. It also claims that although price adjustments are theoretically possible the Belgian legislation in reality operates as a price-freezing mechanism. With regard to the lack of transparency in the decisions adopted by the Minister for Economic Affairs, the Commission observes that the Kingdom of Belgium, has, in the final analysis, given no explanations concerning the various specific cases which the Commission had taken as examples and that, since the grounds on which the decisions were based were stated in extremely general terms, the practice 'thus reveals the exercise of a discretionary power incompatible with Article 30 of the EEC Treaty'.

The *Kingdom of Belgium* observes first of all that, in so far as the Commission seeks to maintain that price-fixing rules enabling the individual prices of products to be determined are, as such, contrary to Community law, this amounts to a new plea in law and is therefore inadmissible.

It goes on to refute each of the allegations put forward by the Commission:

— In the first place, it is incorrect to claim that the criteria adopted in the Royal Decree of 11 December 1975 concern in their entirety the national market. The only criteria which truly concern that market are criteria 9 and 10, relating respectively to the comparison with prices charged on the Belgian market for similar products and to the health, socio-economic and technical and scientific interests of the community. Criteria 6 and 7, relating to investment and employment and to market conditions, competition and the effect on exports are practically never considered. Moreover, it is perfectly normal in the context of criterion 9 to take account of prices charged on the Belgian market for comparable products and there are, moreover, no grounds for saying this criterion is predominantly taken into account.

— In so far as the Commission seeks to criticize the very existence in the legislation of certain criteria concerning the Belgian market, the Kingdom of Belgium makes the following observations: first, a comparison with the prices of existing, similar products is justified by an imperative requirement within the meaning of the abovementioned judgment in the *Duphar* case, that is to say the financial management of the sickness insurance scheme. It is also pointed out that the price comparison with other products sold on the Belgian market is not discriminatory inasmuch as both national and imported products are considered. The legislation is therefore applicable without distinction;

— Secondly, it considers that the Commission adduces no evidence that the price imposed by the Belgian authorities is unremunerative. That would require an analysis of costs structure so as to determine the profitability threshold, which the Commission does not undertake; the examples of disparities between prices on the Belgian market and in other countries are not convincing since such disparities may result from the economic strategy of the pharmaceutical companies;

— Finally, the Belgian Government observes that the undertakings to which decisions on prices are addressed are aware of the specific criteria applied on by the Minister, on the one hand because, as a result of various judgments of the Conseil d'État between 1981 and 1983, he indicates the criterion or criteria on which his decision was based, and on the other as a result of the discussion between the authorities and the undertaking concerned in the course of the price-fixing procedure.

2. *Approval for reimbursement of pharmaceutical products*

(a) Price levels

The *Commission* observes that approval for reimbursement of a pharmaceutical product is often subject to a reduction in the price of the product proposed by the undertaking concerned. Since the prices determined by the Minister for Economic Affairs under his powers under the Law of 9 July 1975 are already very low, an additional reduction in those prices causes the undertakings either to forego reimbursement or to agree to sell their products at an unremunerative price. That situation is all the more worrying since the products approved for reimbursement represent 65% of the pharmaceutical products market. The Commission gives a number of examples of products withdrawn from the market for those reasons.

Although it is true that the price of the reference product used for the comparison provided for in Article 5 of the Royal Decree of 2 September 1980 may be either the price of a domestic product or that of an imported product and, consequently, the system of comparison is not discriminatory, the system as a whole has the effect of impeding imports.

Finally, although the Royal Decree of 2 September 1980 was amended by a royal decree of 20 April 1988 (*Moniteur Belge*, 29.4.1988, p. 6118) so that, thenceforth, the notification to the firm concerned of the unfavourable opinion of the technical committee on proprietary pharmaceuticals may no longer be accompanied by recommendations for price adjustments, the Commission considers, nevertheless, that the substantive problem remains in its entirety, since the amendment of the decree does not necessarily entail a change in the practice of requiring a price reduction in order for approval for reimbursement to be granted. Moreover, it observes that the third paragraph of Article 5, in its new version, provides that the changeover to a larger format packaging of a pharmaceutical product involves a mandatory price reduction of 20%.

The *Kingdom of Belgium* considers that the Commission is confusing the power to fix prices with approval for reimbursement. In its view the Member States may exclude certain products from reimbursement, which means that they clearly have the power to approve pharmaceutical products only for partial reimbursement. Moreover, the Kingdom of Belgium no longer imposes price reductions after the entry into force of the abovementioned decree of 20 April 1988.

Although the question of the profitability of the price of the products in question is, according to the Kingdom of Belgium, not an issue, it is however pointed out that the Commission adduces no evidence that the prices imposed in the context of approval for reimbursement are unprofitable. In fact, it gives only examples of cases where a price reduction was required in relation to the maximum price allowed by the Minister for Economic Affairs. The Belgian Government takes issue with the various examples given by the Commission. In any event, the Belgian Government considers that it is for INAMI to examine the cost of new products in relation to those already on the market and approved for reimbursement.

(b) The criteria for approval for reimbursement

According to the *Commission*, decisions on approval for reimbursement are not based on objective and verifiable criteria, whereas this is an essential requirement laid down in the *Duphar* judgment, cited above. The Commission stress the highly discretionary nature of the Belgian system. In the Commission's view, an applicant cannot know in advance the criterion which will be applied to him, especially since INAMI adapts the criteria according to specific situations which have already been examined. Finally, no clear rules have ever been laid down to govern the classification of the pharmaceutical products in the four categories of reimbursement.

Although it is true that the Royal Decree of 20 April 1988 amended Article 5 of the decree of 2 September 1980 by rendering the approval-for-reimbursement procedure more transparent, the criteria for acceptance were not amended and the Commission considers that the Belgian system of approval for reimbursement continues 'to pose certain problems with respect to Article 30 of the EEC Treaty'.

For its part, the *Kingdom of Belgium* considers that the criteria for approval for reimbursement are objective and verifiable. They result from Article 4 of the Royal Decree of 2 September 1980 within which two categories of provisions must be distinguished. The first relates to the composition and the dosage of pharmaceutical products. It involves a comparison with existing products which is manifestly justified and is effected without discrimination since both products of Belgian origin and imported products may be excluded on the basis of the comparisons made. As regards the stress laid by the Commission points on the discretionary nature of the system, it should be pointed out that, although reimbursement may be subject to 'restrictive or exceptional measures', the conditions governing those restrictions or derogations are laid down in Articles 8, 9, 11, 12 and 13 of the decree of 2 September 1980 to which Article 2 of the same decree refers.

A second category of provisions in Article 4 concerns the classification of approval criteria in order to determine the amount at which reimbursement for pharmaceutical products is to be fixed. The Kingdom of Belgium contends that the undertakings are clearly informed of the characteristics of the products used for purposes of comparison, if only through discussions within the technical committee on proprietary pharmaceuticals. Moreover, the Commission itself acknowledges that the criteria have been verifiable since the decree of 20 April 1988. The criteria are, moreover, undergoing modification, certain amendments having already been made by a royal decree of 21 March 1989 (*Moniteur Belge*, 30.3.1989, p. 5516).

3. *The system of programme contracts*

The *Commission* considers that the programme contracts entered into under Article 2a added to the Law of 9 July 1975 by the Royal Decree of 31 December 1983 are fundamentally irreconcilable with the rules of the Common Market. According to the Commission, systems of programme contracts place at a disadvantage sales of imported medicinal products whose prices remain frozen, since the approval of any increase in the context of a programme contract is governed by conditions which may only be satisfied by Belgian undertakings.

On the other hand, domestic products are placed at an advantage as regards acceptance for reimbursement. Under the Royal Decree of 14 October 1985 the price of medicinal products subject to a programme contract is no longer taken into account for approval for reimbursement, so that medicinal products whose price has increased continue to be approved for reimbursement whereas other less expensive products remain excluded from reimbursement.

Moreover, medicinal products subject to a programme contract may not, under the decree of 14 October 1985, be used for purposes of comparison in the determination of the basis for reimbursement of pharmaceutical products whose price is determined in accordance with the general rules. Such a system, apparently not discriminatory as set out in the text of the legislation, is manifestly so in fact.

Finally, although the Belgian Government has put an end to the system of programme contracts and although, therefore, new contracts are no longer being concluded, it is nevertheless the case that contracts already entered into continue to produce effects. Thus, for the implementation of the system of programme contracts BFR 1 486 million were allocated to INAMI in the 1988 budget.

The *Belgian Government* observes that, following the reasoned opinion issued by the Commission on 30 September 1987, it undertook no longer to enter into programme contracts. It was decided not to renew existing contracts, but to allow them to run for their duration.

Article 2a inserted in the Law of 9 July 1975 by the Royal Decree of 31 December 1983 was repealed by a framework law of 30 December 1988 (*Moniteur Belge*, 5.1.1989, p. 75), and no appropriations for the implementation of the system of programme contracts were included in the 1989 budget.

IV — Replies to the questions put by the Court of Justice

A — *Reply by the Commission to the questions put by the Court of Justice*

(a) First question put to the Commission

On page 43 of its application, the Commission states that the Belgian authorities' argument to the effect that the average price of proprietary pharmaceuticals increased by 76.5% between 1975 and 1985 does not appear to it to be relevant in assessing the trend in prices of pharmaceutical products on the Belgian market.

The Commission is requested to inform the Court of the precise reasons for which it considers that factor to be without significance.

The Commission's reply

The Commission explains that the method which it used was to take the price of a given product at a given time and to contrast it with the price of the same product after a certain time. To use another method, which would be to compare the price of the most sold product at a given time with the price of the most sold product — which may be different — some time afterwards would, in the Commission's view, be meaningless.

Without challenging the calculations carried out by the Belgian authorities on the basis of the latter method, the Commission considers that it in no way enables the trend in prices to be ascertained over a given period of time. In the Commission's view, the method which it itself uses is also used by all statisticians and in particular by the Belgian national statistics institute.

The Commission points out, moreover, that the Belgian authorities did not challenge the graph produced on page 36 of its application which was drawn up on the basis of data supplied by the national statistics institute and seeks to show that the price of pharmaceutical products approved for reimbursement increased more slowly than the price of products not subject to reimbursement.

(b) Second question put to the Commission

In order to demonstrate that the price of medicinal products in Belgium is generally lower than in other Member States, the Commission takes, *inter alia*, the example of the prices of the 20 most sold proprietary pharmaceuticals in Belgium which reveals the price of those products in the other Member States to be higher. However, the Kingdom of Belgium demonstrates the contrary by taking the 20 following products. By way of reply the Commission states only, on page 45 of its application, that it 'continues to believe that the methodology adopted by it is the correct one'.

The Commission is requested to state the grounds on which it considers that the figures supplied by the Belgian Government are not convincing.

The Commission's reply

The Commission recalls that in order to compare the price levels of pharmaceutical products in Belgium and the other Member States, it took the 20 most frequently sold proprietary pharmaceuticals in Belgium in the most common packaging and took into account their industrial price. The comparison was carried out as between the following countries: Belgium, France, Netherlands, Germany, United Kingdom and Italy.

The Commission observes, on the one hand, that the Kingdom of Belgium arrived at different results only by comparing prices with those prevailing in France and Italy and by taking into account the 20 subsequent products and, also, by taking into account the smallest packaging format. It holds that method to be questionable on the grounds that the Kingdom of Belgium took the 20 subsequent products instead of the 40 most sold products, that it did not state which were the products in question, that it did not indicate its sources and that it did not state whether it had based its comparisons on industrial or retail prices.

On the other hand, the Commission wonders why the Belgian authorities gave the results of the comparisons only in respect of France and Italy and why it took the price of the product in its smallest format packaging, although under the Belgian rules that packaging is in fact the most expensive. Accordingly, the Commission persists in considering the method which it used to be the more correct one.

On the other hand, the Commission states that it draws no inference in law from the data on comparative price levels of pharmaceutical products in the Member States. Those comparisons are merely intended to illustrate the economic consequences of the contested measures.

Finally, the Commission gives a comparison of prices carried out in the middle of June 1990 which demonstrates that the prices of the 20 medicinal products most sold in Belgium are in that country 34% below the average price for those same products in five neighbouring States (France, Italy, Netherlands, Federal Republic of Germany and the United Kingdom), and that in respect of the next 20 most sold medicinal products the Belgian prices are 30% below the average price for those same products in the other Member States.

(c) Third question put to the Commission

The Commission is requested to give precise particulars of the criticisms it makes of the 'criteria for approval' for reimbursement of the medicinal products listed in an annex to the Royal Decree of 2 September 1980, together with the specific inferences which it draws therefrom.

The Commission's reply

The Commission considers that the 'criteria for approval' for reimbursement mentioned in Article 4 of the Royal Decree of 2

September 1980 are in actual fact a list of pharmaco-therapeutic categories, chemical classifications or even of products, and do not therefore constitute objective criteria verifiable by the traders in question. They are in reality an enumeration of the medicinal products approved for reimbursement in the four reimbursement categories.

That method would not appear questionable to the Commission if the criteria for approval relates to pharmaco-therapeutic categories and the conditions for the inclusion of a product in one or the other category were known. However, according to the Commission, the criteria are defined in an arbitrary manner since they represent at times a therapeutic category or a chemical category, or at other times even a product. That system thus enables the Belgian authorities to classify a product in accordance with an existing criterion or to apply a new criterion to it with no possibility of accounting for the choice made. For example, in the area of anti-infectious medicinal products, six new criteria were created in 1984 whereas there were already 79. Of those six new criteria four relate to products and two to chemical categories.

That system also enables the Belgian authorities to move a product from one criterion to another, thus enabling a different mode of reimbursement to be determined.

Finally, it allows price comparisons of medicinal products with the same therapeutic effect to be distorted.

B — *Questions put by the Court of Justice to the Kingdom of Belgium*

(a) First question

The Kingdom of Belgium is requested to state the difference between the determination of prices of pharmaceutical products 'in general' and their determination 'in specific cases' and to indicate under what circumstances prices are determined 'in general', and to give examples, and to state the relationship between the two methods of price determination.

Reply by the Kingdom of Belgium

The Kingdom of Belgium begins by defining the concept of maximum price. It is a ceiling price which may not be exceeded and which, consequently, in no way restricts the freedom of undertakings to charge lower prices.

As regards the concept of 'maximum price in general' the Kingdom of Belgium states that that is a maximum sectoral price applicable to all undertakings within a given sector. Such a price may be established in various ways: either by determining profit margins at various distribution stages, or by allowing those concerned to fix the prices themselves within a framework laid down by the authorities, or by fixing the prices at a level reached on a reference date, or, finally, by determining the maximum price of a group of products by reference to the price charged for the products of another group.

Finally, the Kingdom of Belgium defines the concept of 'maximum price in particular'. That is a specific maximum price decreed with regard to a named undertaking. The Minister for Economic Affairs is empowered to lay down maximum prices, with regard both to reimbursable and non-reimbursable medicinal products. According to the circumstances, the Minister is required to consult first the committee on prices of proprietary pharmaceuticals or the committee on price regulation and to submit his draft decree for an opinion of the Conseil d'État.

The Minister has principally had recourse to the technique of specific maximum prices which is a system of individual price approval. In his decrees of 10 February 1976 and 28 December 1982, the Minister determined the procedure for examining individual requests for price determinations and also adopted certain measures determining general maximum prices.

(b) Second question put to the Kingdom of Belgium

The Kingdom of Belgium is requested to state the significance and precise consequences of the table appearing in annex 5 to its defence entitled 'proportion of requests granted for price rises of proprietary pharmaceuticals in Belgium'.

Reply by the Kingdom of Belgium

The Kingdom of Belgium states that the table in question indicates the rate of growth in prices expressed in terms of the rate of growth in global turnover, where quantities sold of those products only which were the subject of a request for a price rise remained constant. It thus enables the effects of price controls to be evaluated and the results of the study of the average trend in prices for all products to be corrected. According to the Government of Belgium the rate of growth in prices thus determined remains greater than the rate of inflation for each year considered as from 1980.

(c) Third question put to the Kingdom of Belgium

The Kingdom of Belgium is requested to state the reasons for which, by the Royal Decree of 20 April 1988, 'it had discontinued approval for reimbursement subject to a price reduction in relation to the maximum price'.

Reply by the Kingdom of Belgium

The Kingdom of Belgium argues that the Royal Decree of 20 April 1988 abrogated approval for reimbursement subject to a price reduction, in order to meet the complaints made by the Commission of the European Communities with regard to that practice. It observes that the Commission acknowledges, moreover, that the new provisions go some way to meeting its objections.

F. Grévisse
Judge-Rapporteur