OPINION OF MR ADVOCATE GENERAL TESAURO
delivered on 30 January 1991 *

Mr President,
Members of the Court,

1. In these proceedings the Commission seeks a declaration that the Kingdom of Belgium has failed to fulfil its obligations under Article 30 of the Treaty as regards legislation on pharmaceutical products. Three aspects of the national legislation are contested by the Commission: the rules for fixing maximum prices, [1] the rules governing approval for reimbursement by social security [2] and finally the system of 'programme contracts' established in the sector in question. [3]

Those rules are described in detail in the Report for the Hearing to which reference is made; they will be referred to in this Opinion only in so far as is necessary in order to analyse the specific allegations made by the Commission.

A — Rules on the fixing of maximum prices

2. As a preliminary matter I would point out that the determination maximum prices for pharmaceutical products, as provided for under the Belgian legislation, may concern both products in general and procuts 'in particular', that is to say products considered individually. It is in fact the latter technique which is principally used by the Minster for Economic Affairs whose task it is to fix maximum prices after prior consultation wiht the committee on prices for proprietary pharmaceuticals.

In its reply, the Commission has argued that the technique of fixing the price of each individual product makes it possible to intervene according to the origin of the products themselves and is therefore in itself capable of restricting the possibilities of importation.

In that regard I would point out at once that, since the Commission, neither during the pre-litigation stage nor during the proceedings themselves, has challenged the compatibility *per se* of such a system of fixing prices with Article 30 of the Treaty, this is a new plea in law raised in the course of the proceedings and is therefore inadmissible, as the Belgian Government has in fact argued.

On the other hand, although it is true that such a system, by allowing an individual product to be specifically affected, may give rise to arbitrary practices, it is nevertheless also the case that it constitutes a body of rules which, from a formal point of view,

* Original language: Italian.

1 — Law of 9 July 1975 (*Moniteur Belge*, 30 July 1975, p. 9328) and royal decree of 11 December 1975 (*Moniteur Belge*, 16 December 1975, p. 15989).

2 — Royal Decree of 1 September 1980 (*Moniteur Belge*, 30 September 1980, p. 11106) and Royal Decree of 2 September 1980 (*Moniteur Belge*, 30 September 1980, p. 11107).

3 — Royal Decree of 14 October 1985 (*Moniteur Belge*, 21 November 1985, p. 17137).

are applicable without distinction. The decisive factor is the manner in which they are applied, which will be discussed below, although the rules *per se* are not incompatible with Community law.

3. Having said that, I would first of all recall the words of Commission Directive 70/50/EEC,[4] Article 2(3)(d)(e) of which deems to be incompatible with Article 30 of the Treaty measures which 'preclude any increase in the price of the imported product corresponding to the supplementary costs and charges inherent in importation'; or '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'.

The interpretation of Article 30 given in the directive has been upheld by the consistent case-law of the Court.[5] With regard more specifically to the fixing of maximum prices the Court held in the *Tasca* case[6] that in principle, 'although a maximum price applicable without distinction to domestic and imported products does not in itself constitute a measure having an effect equivalent to a quantitative restriction, it may have such an effect, however, when it is fixed at a level such that the sale of imported products becomes, if not impossible, more difficult than that of domestic products. A maximum price, in any event in so far as it applies to imported products, therefore constitutes a measure having an effect equivalent to a quantitative restriction, especially when it is fixed at such a low level that, having regard to the general situation of imported products compared to that of domestic products, dealers wishing to import the product in question into the Member State concerned can do so only at a loss'.

It follows from that decision that a national system of maximum prices infringes Article 30 of the Treaty whenever it does not enable a producer or an importer to include in the selling price the various elements of the cost of the product in question, including additional amounts inherent in importing.

In the light of the foregoing, I now turn to an examination of the individual allegations made by the Commission in regard to the system in question, namely:

— the predominant criteria for fixing prices;

— the unremunerative level, in regard to imported products, of the prices so fixed;

— the lack of transparency in the application of the criteria themselves.

The predominant criteria for fixing prices

4. Prices 'in particular' are fixed on the basis of a series of criteria, 10 in all, certain

4 — OJ English Special Edition 1970 (I), p. 17.

5 — See judgments in Case 181/82 *Roussel* [1983] ECR 3849, paragraph 17; Case 231/83 *Cullet* [1985] ECR 315, paragraph 23; Case 56/87 *Commission* v *Italy* [1988] ECR 2919, paragraph 6

6 — Judgment in Case 65/75 *Tasca* [1976] ECR 291

of which include consideration of factors relating also or solely to imported products (for example ex-producer or ex-importer price components, the impact of sales and delivery margins, the impact of value added tax, the comparison with prices charged for like products in the other countries having a similar standard of living), whilst others relate to factors peculiar to the national market (for example, investment and employment, market and competitive conditions and the effect on exports, comparison with prices charged in Belgium for pharmaceutical products or medicinal products comparable from a therapeutic point of view and to be found on the market). The abovementioned criteria in principle permit the specific components of the cost of imported products to be taken into account.

However, as the Court held in its judgment in *Cullet*,[7] 'in order to avoid any disadvantageous effect on the distribution of imported products on the market, those criteria (for fixing prices) must take due account of the ex-refinery prices of all traders, regardless of the origin of the goods', I would also point out that the existence of criteria relating solely to national products is not in itself of such a nature as to entail incompatibility with Article 30 of the Treaty.[8] Once again, what matters is the actual application of the criteria in question.

The Commission submitted that in the fixing of prices disproportionate importance is attached to criteria which relate exclusively to factors specific to the Belgian market and that therefore that situation is likely to impede imports. In essence, the Commission merely sets out the *quid demonstrandum* (namely that the prices do not take account of the costs relating to imported products) but does not explain the reasons on which that conclusion is based except by way of illustrations which cannot be regarded as convincing.

The proposition that the criterion mainly used in price-fixing decisions is the comparison with prices charged in Belgium for therapeutically comparable proprietary pharmaceuticals is not in fact proved; on the contrary, it is merely an inference, especially since the Commission itself admits that 'it does not necessarily follow from the reasons indicated in the letters addressed by the Minister to the undertakings' (p. 10 of the reply).

Nor does the mere inference drawn by the Commission (point II of the reply) to the effect that in many cases costs are not covered and that this is borne out by the fact that certain undertakings have given up importing their products into Belgium because the prices are too low prove that the criteria relating to the costs of the imported products were not taken into consideration, even where the price-fixing decisions expressly refer to those criteria.

Having regard to the foregoing considerations, I do not think that the Commission

7 — Cited above, paragraph 26.

8 — See in that connection the judgment in Case C-347/88 *Commission* v *Greece* [1990] ECR I-4747.

has proved that the criteria taken into consideration in fixing prices are exclusively or principally those which take account solely of factors relating to the national market.

Fixing of prices at an unremunerative level

5. The Commission itself acknowledges that to demonstrate the unremunerative nature of certain prices involves a 'detailed analysis of the cost of the product in question' (p. 8 of the application). Yet it carries out no analysis of the costs of the products but infers the lack of profitability from the mere fact that the prices of pharmaceutical products are higher in other countries and from the fact that certain undertakings have abandoned the marketing of their products in Belgium because the prices imposed were so low as to be unremunerative.

In that connection it is not disputed that the market share of imported pharmaceutical products has reached 60% (the same percentage as in 1975) and that the share of imports from Member States has increased. Moreover the Commission acknowledges that the average price of imported products is higher than the average price of domestic products.

In order to demonstrate the lack of profitability of imported products, the Commission merely asserts that the level at which the Belgian authorities fix prices for products placed for the first time on the Belgian market '*gives reason for thinking* that the contribution of such products to the undertaking's general profitability is either very limited or non-existent' (p. 12 of the reply). An assertion of this kind requires no comment, in view of the undeniable burden of proof which it is for the Commission to discharge in proceedings of the kind now before the Court.

With regard to products already on the market, the Commission challenges the Belgian rules by arguing that since prices already fixed may not be increased without the prior agreement of the Minister, those rules have the effect of freezing prices at such a low level that the marketing of imported products becomes impossible.

The Commission in fact maintains that the abovementioned criteria, laid down in Article 3 of the Royal Decree of 11 November 1975, preclude increases in the costs of imported products from being taken into account in granting price increases. That is particularly so in the case of increases due to monetary fluctuations.

The Belgian Government disputes that the pricing system in question has the effect of freezing prices since provision is made for regular adjustments, and an undertaking may request an increase in the price of the product in question on economic grounds.

Irrespective of the abstract question whether a pricing system affording the possibility of an increase in the prices in question may be regarded as frozen, I consider that such a system is likely to have a restrictive effect only if it does not enable prices to be

adapted in good time to variations in costs occurring on the market.

As was held in the judgment in *Danis*,[9] a system of that kind is not incompatible with Community law when prices are frozen at a level which does not place imported products at a disadvantage and price increases are granted where justified.

As regards, in particular, the case of monetary fluctuations, it should be said that a change in exchange rates does not necessarily in itself have to entail an increase in prices. It will always be necessary to establish, in each particular case, that the level of prices imposed, regard being had to the additional costs inherent in importing, render the sale of the products impossible, or in any event less advantageous, than that of domestic products.

In the present case the Commission has made no allusion to any specific instance of devaluation of the Belgian franc and, in any event, has not demonstrated what monetary fluctuations have in fact had the alleged consequences and to what extent.

The foregoing considerations lead me to the view that the allegation which has just been considered has not been sufficiently proven.

6. For the sake of completeness, I nevertheless think it useful to mention the analysis of price levels carried out by the Commission for the purpose of demonstrating that the system in question impedes imports and in particular that the prices so fixed are not remunerative for importers.

Essentially, the Commission took as its basis a 'basket' of 50 of the products most sold in Belgium in 1975 and compared them with the same products 10 years later. That analysis shows that the total price of the products in question fell by 7.5%, or by 11% if one takes only reimbursable products.

The Belgian Government vigorously contests that method of analysis and by comparing instead the prices of the 50 most sold products in 1975 with those of the 50 products most sold in 1986, it demonstrates that those prices have increased by 54.1%.

We are presented with two completely different methods neither of which, however, in my opinion are entirely convincing in view of the particular nature of the pharmaceutical sector. In particular, the method used by the Commission, although theoretically more suited to verifying trends in prices over a period of time, does not pay sufficient heed to the fact that the market in question is constantly changing as a result of pharmaceutical research and the substitution on that market of certain products by other more effective products is a very common occurrence.

Indeed, to compare the same 50 pharmaceutical products over a period of 10 years may not be indicative of anything, in so far

9 — Judgment in Joined Cases 16/79 and 20/79 *Danis* [1979] ECR 3327.

as, precisely, certain products may disappear from the market once and for all whereas others are superseded by new and more effective products, so that if they continue to be marketed their price remains unchanged or is even reduced.

The other analyses and the other statistical method employed by the Commission, and sharply contested by the Belgian Government, are those relating to the comparison of prices on the Belgian market with those on the markets in other Member States, in order to demonstrate that prices on the latter markets are substantially higher than in Belgium.

I do not think it even necessary to examine the method and the results of that comparison since this would in no way alter the conclusions which I have reached; the Commission itself has honestly and expressly acknowledged that it draws no inferences in law from the data relating to the compared level prices of pharmaceutical products in the Member States of the Community.

Lack of transparency in the application of the criteria

7. Article 3 of the Decree of 11 December 1975 provides that, in notifying his decision fixing the price, the Minister for Economic Affairs is to inform the undertaking concerned of the criteria on which he based himself. The Commission has maintained that in the majority of cases the decisions in question merely mention that account was taken of criteria 1 to 10. That practice thus does make it possible to know, in each particular case, the criteria on the basis of which the Minister fixed the maximum price of the products in question or, *a fortiori*, to appraise the grounds of his decision.

The Belgian Government maintains that that practice was abandoned following a series of judgments of the Conseil d'État.[10] The Minister has therefore changed the manner of giving the reasons for his decisions, in which the criteria taken into account are now explicitly stated. I should point out in this respect that the Commission, whilst acknowledging that the contested practice is today less frequent than in the past, observes that it is still in use. However, the only example given by the Commission in support of its arguments predates the abovementioned judgments of the Conseil d'État.

The Belgian Government further maintains that the fact the committee on prices of proprietary pharmaceuticals includes a representative of the pharmaceutical industry means that the undertakings are aware of the reasons which led to the fixing of the price for the individual product under consideration.

Having said that, I would first point out that the Court held in its judgment in *Duphar*,[11] with respect to the criteria for approval for reimbursement by social security, that the criteria in question must, *inter alia*, be 'verifiable by any importer'.

10 — Judgments Nos 20.987 and 20.993 of 27 February 1981, and Nos 23215 and 23220 of 6 May 1983.

11 — Case 238/82 *Duphar* v *Netherlands* [1984] ECR 523

In the Commission's view that requirement is also essential with regard to pricing decisions.[12] In that regard, the opportunity for the traders in the sector, in particular importers, to ascertain which criteria were applied cannot be considered to have been afforded by a mere enumeration of the criteria applied or by the presence of a representative of the industry or the committee on prices. In that respect, the Belgian practice, although amended following the abovementioned judgments of the Conseil d'État, is not, according to the Commission, capable of enabling importers to ascertain the manner in which the criteria were applied, and in particular the impact of each of those criteria on the determination of the price of the relevant product.

8. In that connection I would point out first of all that a duty to provide a statement of reasons is certainly indispensible where, as in the present case, the legislation merely lists the applicable criteria and leaves the competent Minister to determine, after consultation with the committee on prices of proprietary pharmaceuticals, which of those criteria should be taken into account in each individual case, and the impact of each of them.

The existence of such a discretionary power, albeit in the presence of criteria which are objective in the sense that, taken as a whole, they take account of the specific costs of the imported products, in my view requires that the decision not to permit the marketing of a specific product at the price proposed by the importer must clearly explain the grounds on which it is based.

On the basis that there is a lack of transparency in the application of the criteria in question, a fact which, moreover, is not really contested by the Belgian Government so far as notification of the reasons to the undertakings is concerned, it should be determined whether that lack of transparency is such as to constitute in itself an infringement of Article 30.

I consider that it does, inasmuch as a system of price-fixing such as that in the present case, when applied to 'products in particular', that is to say individual products, may give rise to arbitrary practices and, therefore, to discrimination according to the origin of the products. Consequently, any measure which may have the effect of restricting imports must be accompanied by a statement of reasons that makes it possible to verify whether the criteria in question were applied in such a manner as not to constitute a restriction on imports.

Furthermore, the Court has on several occasions affirmed that the competent national authorities are obliged to give reasons for an individual measure where that measure has an impact on the effective protection of rights directly conferred on individuals by the Treaty.[13] That obligation

12 — This is a requirement which is moreover now codified in Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems (OJ L 40, p. 8).

13 — See in this connection the judgment in Case 222/86 *UNECTEF* v *Heylens* [1987] ECR 4097, paragraphs 15 and 16, in which the principle in question was upheld in relation to freedom of movement for workers.

is imposed in order, in particular, to ensure the effectiveness of judicial review, a requirement which constitutes a general principle of Community law.

The solution adopted is moreover consistent with the principles specifically laid down by the Court in the judgment in *Duphar*, cited above, in the sense that the existence of objective and verifiable criteria is considered to be an essential prerequisite for the conformity of such rules with Community law.

Having regard to the foregoing considerations, I therefore consider that the allegation that a lack of knowledge of the manner in which the criteria are applied is capable of impeding imports and thus constitutes an infringement of Article 30 is well founded.

B — The rules governing approval for reimbursement

9. The Belgian legislation contested by the Commission provides that only products contained in a relevant list may be reimbursed. Admission to those lists is carried out on the basis of a certain number of criteria relating to the composition, the price and the social interest of each product.

The Commission, on the basis of certain concrete cases which were reported by certain undertakings and which are said to show that those undertakings have been compelled to lower the prices of their products below the threshold of profitability or to forgo reimbursement, with consequent exclusion from the market, maintains that the system in question is incompatible with Article 30.

The Commission makes two allegations against the system in question: lack of transparency with regard to the criteria for approval for reimbursement; and, in many cases, approval for reimbursement made conditional on a reduction of the price charged by the undertaking concerned.

Before examining whether those allegations are well founded, I consider it essential to clarify certain matters.

It is apparent from the Commission's own application to the Court that, after the period prescribed in the reasoned opinion had expired and before the action was brought, the Belgian rules were amended by the Royal Decree of 20 April 1988.[14] Whilst acknowledging that the changes made by that decree are such as to eliminate the majority of the shortcomings complained of, the Commission nevertheless considers that the system of approval for reimbursement 'continues to raise certain doubts as to its compatibility with Article 30 of the Treaty' (page 24 of the application).

Inasmuch as the Commission has not withdrawn its allegations and since, in accordance with the well-established case-law of the Court,[15] the purpose of an application under Article 169 is to obtain a declaration that the State concerned has failed to fulfil its obligations under the Treaty and has not brought its infringement to an end within the period prescribed in the Commission's reasoned opinion, the

14 — *Moniteur Belge* 29 4 1988, p 5118

15 — See, most recently, the judgment in Case 347/88 *Commission* v *Hellenic Republic* [1990] ECR 4747, paragraph 40

situation existing on the expiry of the period allowed to the Kingdom of Belgium to comply with the reasoned opinion must be taken into consideration for the purposes of the present action.

The criteria

10. According to the Commission the decisions on approval for reimbursement are not based on objective and verifiable criteria, a requirement held by the Court in its judgment in *Duphar* to be essential. [16]

The Commission challenges the criteria for approval, criticizing the absence of clear rules for the classification of pharmaceutical products in the four reimbursement categories provided for in the legislation. In particular, the criteria as to composition constitute in substance a mere enumeration of therapeutic categories, chemical classifications, or of products. The criteria are therefore arbitrary inasmuch as, in the Commission's view, they enable a product to be moved from one category to another, thus escaping comparison with products of the same therapeutic value. This is so precisely because the system theoretically enables products having the same therapeutical effect to be classified in different categories.

Furthermore, the decisions on approval for reimbursement do not provide an adequate statement of the reasons on which they are based and thus do not permit the undertakings to make known their point of view.

The Belgian Government challenges the abovementioned allegations, maintaining that the criteria in question are objective, inasmuch as approval for reimbursement is based essentially on the therapeutic value of the product in question in relation to other products of the same category. In that connection, the Belgian Government remarks that the classification in different reimbursement categories of products intended for treating the same pathological condition is justified by reason of the varying therapeutic efficacy of the products in question. In any event, the criteria do not give rise to discrimination between imported products and domestic products, especially since domestic products are also excluded from reimbursement.

According to the Belgian Government, these criteria are also verifiable, inasmuch as the undertakings are certainly kept informed by means of the discussions within the technical committee on proprietary pharmaceuticals.

It should be borne in mind in that connection that in the *Duphar* judgment, cited above, the Court stated that, in view of the special nature of 'the trade in pharmaceutical products, namely the fact that social security institutions are substituted for consumers as regards responsibility for the payment of medical expenses, legislation of the type in question cannot in itself be

16 — Judgment cited above, at paragraph 22.

regarded as constituting a restriction on the freedom to import guaranteed by Article 30 of the Treaty if certain conditions are satisfied'. [17] And it added that 'for such legislation to be in conformity with the Treaty the choice of the medicinal preparations to be excluded must be free of any discrimination to the detriment of imported medicinal preparations. To that end, the exclusionary lists must be drawn up in accordance with objective criteria, without reference to the origin of the products, and must be verifiable by any importer'. [18]

Since in the present case the Commission in no way shows that the contested legislation has the effect of discriminating against imported products, I would observe that it emerges from the Commission's arguments on this point with regard to the lack of objectivity of the criteria on which the decisions on approval for reimbursement are based that it is challenging the application *in concreto* of the legislation in question, in so far as it is liable to entail discrimination, rather than the criteria themselves. In any event, the factors and arguments put forward by the Commission do not seem to me to provide sufficient proof of lack of objectivity of the criteria in question.

On the other hand, the allegation that the decisions refusing approval for reimbursement do not contain an adequate statement of the reasons on which they are based or, more precisely, that they did not do so before the adoption of the Royal Decree of 20 April 1988, should be upheld. In that connection the same observations are applicable as those relating to the lack of transparency in the application of the criteria for fixing prices.

In view of the foregoing considerations and in the light of the *Duphar* judgment, I consider that the criteria for approval for reimbursement are not verifiable by the undertakings and that, accordingly, in that respect, the legislation in question is such as to impede imports and thus infringes Article 30.

Request for a price reduction

11. The second allegation in this matter concerns the fact that frequently approval for reimbursement is made subject to a reduction in prices by the undertaking concerned. In a system of prices that are already low that situation is said to induce undertakings to forgo reimbursement or to sell at unprofitable prices. The Commission cites a series of examples of products withdrawn from the market on those grounds, and these examples are specifically refuted by the Belgian Government.

The Commission itself acknowledges, moreover, that the system is not in itself discriminatory but claims that the mechanism as a whole has the consequence in practice of impeding imports, precisely on account of the resulting lack of profitability for certain imported products; accordingly, the mechanism is, in that respect, incompatible with Article 30.

17 — Paragraph 20.
18 — Paragraph 21

Such an argument, which is contested by the Belgian Government (which maintains *inter alia* that the problem of the profitability of prices forms no part of the dispute concerning approval for reimbursement), cannot however be accepted, since the Commission has not demonstrated that the prices in question are unremunerative.

The Commission does not analyse the costs of the products in question, which alone could show the prices of those products to be unremunerative by reason of subsequent reduction imposed on the undertakings in order for them to be eligible for the reimbursement in question.

I therefore consider that the allegation in question should be rejected.

C — The system of programme contracts

12. The Commission considers that the system of programme contracts in the medicinal products sector discriminates against imported products in two respects.

First, in view of the conditions specified, only products manufactured in Belgium qualify for such contracts and can thus benefit from price increases which, conversely, are excluded in the case of imported products.

Secondly, with regard to approval for reimbursement, domestic products enjoy a further advantage, inasmuch as they continue to be eligible for reimbursement even if they increase in price and no longer satisfy the conditions laid down by the rules governing approval for reimbursement. At the same time, however, prices of imported products continue to be frozen. Moreover, medicinal products which are subject to a programme contract cannot be used as a reference for determining the basis of reimbursement for products whose price is fixed in accordance with the general rules. That factor makes the system in question even more discriminatory in practice.

This is a manifest case of discrimination which, moreover, is not disputed by the Belgian Government. That Government merely states that the legislation in question was repealed by a framework law of 30 December 1988 [19] following the reasoned opinion of 30 November 1987 and that, consequently, in this respect the application to the Court has been deprived of its purpose. Indeed the Belgian Government has undertaken no longer to enter into programme contracts and not to renew existing ones. Nevertheless, the contracts still in force continue to produce their effects.

The Commission therefore considers that the infringement alleged against the Belgian Government has not yet been terminated. Further, according to the well established case-law of the Court the subject-matter of proceedings brought under Article 169 is fixed by the reasoned opinion and, even where the infringement has been brought to an end after the period prescribed by the Commission, the pursuit of the action retains an interest. [20]

19 — *Moniteur Belge* of 5.1.1989, p. 75.

20 — See *inter alia* the judgment in Case 154/85 *Commission* v *Italy* [1987] ECR 2717.

13. In the light of the foregoing considerations I therefore conclude by proposing that the Court should:

(i) declare that, by basing decisions fixing the maximum prices of pharmaceutical products and decisions on approval for reimbursement of those products upon criteria which are not verifiable, and by introducing the system of programme contracts, the Kingdom of Belgium has failed to fulfil its obligations under Article 30 of the Treaty;

(ii) dismiss the remainder of the application;

(iii) order the defendant to pay the costs.