II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 20 December 1989

concerning aid granted by the Belgian Government to undertakings in the pharmaceutical industry in the form of programme contracts

(Only the French and Dutch texts are authentic)

(92/327/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty established the European Economic Community, and in particular the first subparagraph of Article 93 (2) thereof,

Having given notice to the parties concerned to submit their comments, in accordance with the abovementioned Article 93, and having regard to such comments,

Whereas :

I

By letter dated 12 May 1986 the Commission asked the Belgian authorities to notify public assistance granted to undertakings in the pharmaceutical industry in the form of programme contracts.

Since the Belgian authorities did not provide the information requested, the Commission took the view that, given the high level of intra-Community trade in the pharmaceutical sector, the measures constituted aid within the meaning of Article 92 (1) and, on the basis of the information at its disposal, considered that the measures did not seem to satisfy the conditions for exemption laid down in Article 92 (3). It therefore initiated the procedure provided for in Article 93 (2) in respect of the aid by decision adopted on 29 July 1986. By letter dated 1 August 1986, the Belgian authorities belatedly provided certain information concerning the programme contract system.

Under the abovementioned procedure, by letter dated 4 August 1986, the Commission gave the Belgian Government notice to submit its comments. In accordance with the provisions of Article 93 (2), the other Member States and other parties concerned were also given notice to submit their comments.

II

The Belgian authorities submitted their comments by letter dated 5 September 1986 ; in the letter, they stated that the programme contract system should be viewed in the context of the setting of prices and of production costs and not as aid to undertakings. The programme contract system, they argued, allowed firms to plan their expenditure forecasts better in relation to their own forecasts of revenue.

By letter dated 21 December 1987, the Belgian authorities announced that they had decided to discontinue the system. Indeed, as far as the Commission is aware, no new programme contract has been concluded. Nevertheless, the existing programme contracts have continued to apply, requiring continued financing of the fund intended for the reimbursement of the additional health insurance costs.

Under the abovementioned procedure, two Member States, eight undertakings and one association of pharmaceutical undertakings submitted their comments. By letter dated 6 October 1989, the Commission passed these comments on to the Belgian authorities, requesting them to submit their observations, which have not, however, been received to date.

Maximum prices for pharmaceutical products are frozen in Belgium; exemptions from the price freeze are possible, but the conditions laid down by the Minister for Economic Affairs for changes to the maximum prices are so strict that the Belgian authorities have themselves felt the need to allow price rises under other conditions and have for this purpose developed the system of programme contracts.

Thus, under Royal Decree No 248 of 31 December 1983 partially extending the Law of 9 July 1975 abrogating Article 62 of the Law of 14 February 1961 on economic expansion, social progress and financial recovery and instituting a system of prices for branded pharmaceuticals and other pharmaceutical products, the Minister for Economic Affairs and the Minister for Social Welfare may jointly conclude with producers, importers or packagers of branded pharmaceuticals and other pharmaceutical products, individually or as a group, or with the sector, programme contracts designed to promote investment, emloyment, basic research and exports.

The programme contracts contain provisions on the trend of prices for branded pharmaceuticals and other pharmaceutical products during a given period within the limits of a budgetary amount set annually in the light of the budget of the Institut National d'Assurance Maladie-Invalidité (INAMI) and taking account of commitments to compensate expenditure in excess of the budgetary amounts set.

Pharmaceutical products covered by a programme contract enjoy two advantages over those not covered by a programme contract.

Firstly, the price of pharmaceutical products covered by a programme contract within the meaning of Article 2 (a) of the Law of 9 July 1975 may be increased, whereas the maximum prices of other pharmaceutical products are frozen under Article 2 of the same Law and may be increased only under the very strict conditions provided for by that Law.

Secondly, pharmaceutical products covered by a programme contract within the meaning of Article 2 (1) of the Law of 9 July 1975 enjoy preferential arrangements as regards eligibility for reimbursement, since they are not subject in this respect to the provisions of Article 5 of the Royal Decree of 2 September 1980 and since they may not be used as a comparative basis for the setting of the reimbursement basis for other products. In practical terms, this means that pharmaceutical products covered by a programme contract are eligible for reimbursement notwithstanding the existence on the market of other less expensive pharmaceutical products, having an equivalent therapeutic effect, such products being in some cases ineligible for reimbursement (1).

So as to prevent the additional burden of the price increases from being borne solely by the budget of Inami which would have to deal with them, Inami is compensated by a fund which was set up under Article 85 of the Law of 1 August 1985 on fiscal and other measures and which is financed by appropriations entered in the budget of the Ministry for Economic Affairs.

The volume of appropriations annually made available to the fund is as follows (2):

— 1986: Bfr 487 million,

— 1987: Bfr 1 128 million,

— 1988: Bfr 1 468 million.

III

The price increases authorized within the framework of the conclusion of programme contracts constitute State aid within the meaning of Article 92 (1), since they enable the beneficiaries to carry out investment and/or research, to take on staff and to promote exports without having to bear the normal costs of such measures. Furthermore, as is shown in detail below, the Community market in pharmaceutical products is highly competitive and involves substantial intra-Community trade (see Chapter V).

IV

Such aid should have been notified to the Commission in accordance with Article 93 (3). Without prior notification by the Belgian Government, the Commission was unable to give a ruling on such measures before their implementation.

This fact meant that they were unlawful under Community law as from the time they were implemented. The failure to carry out the mandatory notification has resulted in a situation which is all the more unfortunate as the aid has been paid since 1986.

(1) As a result of the conditions to which the conclusion of programme contracts is subject, in practice only pharmaceutical products developed and manufactured in Belgium may be covered by a programme contract; since the concept of programme contracts in the pharmaceutical sector is thus fundamentally incompatible with the establishment of a common market, the programme contracts are also the subject of proceedings for infringement of Article 30 of the EEC Treaty — A/86/40.

(2) Budget of the Ministry for Economic Affairs for the financial year 1988 (10), 4/12 — 523/1 — 1988, page 135.

The procedural rules laid down in Article 93 (3), which are a matter of public policy and whose direct effect the Court of Justice recognized in its judgment delivered on 19 June 1973 in Case 77/72, are mandatory. The unlawfulness of the aid derives from the failure to comply with the procedural rules laid down in Article 93 (3). In addition, where aid is incompatible with the common market, the Commission may avail itself of the possibility afforded to it by the Judgment of the Court of Justice delivered on 12 July 1973 in Case 70/72, confirmed by the Judgment of 24 February 1987 in Case 310/85, of requiring Member States to recover from recipients the amount of any aid improperly paid to them.

V

The market for pharmaceutical products has certain characteristics which distinguish it very clearly from the markets for other consumer products. In the first place, the final consumer of a pharmaceutical product has generally only a very limited influence on the choice of the pharmaceutical product, at least as regards those which he consumes on the basis of a medical prescription. In addition, demand for a pharmaceutical product is normally linked to treatment of a given infection, and pharmaceutical products can be substituted one for another to no more than a limited extent. Secondly, the market for pharmaceutical products is characterized by the fact that the social security institutions take the place of consumers to some extent in assuming the medical costs.

Nevertheless, the Community pharmaceutical market is highly competitive and involves substantial intra-Community trade. In 1984, Europeans consumed ECU 25 750 million worth of pharmaceutical products, equivalent to 0,78 % of Community GDP. On average, 43 % of such consumption was supplied by undertakings established within the territory of the 'consuming' Member State, 23 % by undertakings from other Member States and 34 % from non-Community undertakings, principally from the United States or Switzerland (often through subsidiaries established in the Member countries).

Foreign trade statistics (1986) show that there is substantial trade between Member States in pharmaceutical products, the total amount of such trade being ECU 3 700 million. Competition between Member States also takes place on non-Community markets, where Community exports amount to ECU 5 200 million.

Belgium, which is the fourteenth largest pharmaceutical market worldwide, is one of the Community's major producer countries. In 1986, its production totalled Bfr 77 000 million (ECU 1 790 million) (1987 : Bfr 79 500 million). A large proportion of exports, which accounted for 51,6 % of output, went to the other Member States, which in 1986 imported pharmaceutical products worth ECU 575,9 million from the Belgo-Luxembourg Economic Union.

In their letter dated 5 September 1986, the Belgian authorities stated that five firms were involved in the programme contracts system and that there were no definite plans for other undertakings.

However, as far as the Commission is aware, nine undertakings with a total turnover of more than Bfr 24 000 million, or more than one quarter of Belgian pharmaceutical production, have concluded programme contracts. In 1985, their exports to other Member States (EUR 10) amounted to more than Bfr 7 000 million.

In view of the above considerations regarding the situation in the market concerned and the large volume of intra-Community trade, the aid in question is liable to affect trade between Member States and to distort competition within the meaning of Article 92 (1).

Where financial aid granted by a Member State strengthens the position of certain undertakings compared with their competitors in the common market, such competitors must be deemed to be affected by such aid. In the case in point, the aid in the form of permission to increase prices enables the beneficiaries to reduce costs which they would normally have had to bear in full.

The aid has thus distorted and is continuing to distort competition by facilitating the financing of investment (machinery, construction, etc.), research and measures to promote exports and by subsidizing employment costs.

VI

Article 92 (1) lays down the principle that aid having the characteristics which it stipulates is incompatible with the common market ; as regards the exceptions to that principle, those provided for in Article 92 (2) are inapplicable in this particular case, given the nature and the objectives of the aid.

Under Article 92 (3), aid which may be considered to be compatible with the common market must be viewed within the Community context. So as to maintain the smooth functioning of the common market and take account of the principles laid down in Article 3 (f), derogations Article 92 (3) from the principle laid down in Article 92 (1) must be interpreted narrowly in examining individual aid measures.

In particular, the exemptions apply only if the Commission finds that, without the aid, market forces would not in themselves be sufficient to prompt recipients to take action in order to achieve one of the objectives pursued.

Applying the exemptions to cases which do not contribute to such an objective or where the aid is not necessary for this purpose would amount to conferring advantages on the industries or undertakings of certain Member States, whose financial position would be artificially strengthened, and to distorting competition, without any justification based on the common interest as referred to in Article 92 (3).

The Belgian Government has not been able to provide, or the Commission to identify, any reason that would allow the aid to be covered by one of the exemptions provided for in Article 92 (3).

VII

Accordingly, having regard to the provisions of Article 92 (3) (a) concerning aid to promote the development of certain regions, it must be concluded that the regions in which the beneficiaries of the price increases are situated do not suffer from an abnormally low standard of living or from underemployment within the meaning of the exemption provided for in Article 92 (3) (a). The regions concerned are not among the regions eligible for this exemption.

Nor does the aid fulfil the conditions laid down in Article 92 (3) (c) regarding the regional aspecct. The granting of aid to a number of undertakings in a given sector whose production sites are located in different regions is not aimed at facilitating the development of certain areas, nor has the Belgian Government in this case invoked such ground to justify the conclusion of programme contracts. Consequently, the aid is not eligible for this particular derogation.

As regards the exemptions provided for in Article 92 (3) (b), there are no elements whatsoever which indicate that the aid is intended to promote a project of common interest or to remedy a serious disturbance in the Belgian economy, nor has the Belgian Government invoked any such grounds as justification for the aid.

Lastly, as regards the exemption provided for in Article 92 (3) (c) concerning 'aid to facilitate the development of certain economic activities', it should be noted that, although the aid facilitates the development of the undertakings which have concluded programme contracts, it does not facilitate the development of the pharmaceutical industry at Community level and has an impact contrary to the common interest on intra-Community trade.

The system of setting maximum prices and the system of eligibility for reimbursement which are applied in Belgium have the effect of maintaining the prices for pharmaceutical products, and in particular for reimbursed pharmaceutical products, on the Belgian market at an excessively low level, to the extent of creating problems of profitability for a large number of operators.

A large number of pharmaceutical products are marketed in Belgium under precarious conditions of profitability. This fact was noted by the Belgian authorities (1) which, in setting up the fund for the reimbursement of Inami, stated that the need to reduce as far as possible the impact of the cost of the reimbursed pharmaceutical products meant that the Ministry for Social Affairs and Inami had to be very strict as regards the obtaining of a price for a pharmaceutical product eligible for reimbursement and that the consequence of this policy was harming the development of the pharmaceutical industry, which had to bear the costs of research and major investment and was by that very fact preventing certain undertakings from carrying out investment and recruitment of staff.

The conclusion of a programme contract between a pharmaceutical undertaking and the Belgian activities allows the prices of pharmaceutical products to be increased under a system of price setting (without loss of the right to reimbursement by the health insurance fund), leading to a continuous incrase in incomes which is used, depending on the contract concluded, to finance investment, research projects, staff recruitment and/or the promotion of exports.

However, such activities entered into by undertakings which have concluded contracts are in the aid recipients' own interests since they form part of the normal activities of any undertaking in the pharmaceutical industry wishing to maintain or improve its market position.

Given the intensity of competition on the Community pharmaceutical market and the volume of intra-Community trade, the granting of any aid, even indirectly through selective permission to increase prices within the framework of a price setting system, with reimbursement of additional sickness insurance costs by the relevant fund, has a particularly serious effect on competition between the different producers.

Such distortion is amplified by the fact that the Belgian pharmaceutical market is a regulated market. The Belgian authorities themselves have stated that the prices imposed have a serious effect on the profitability of the producers, preventing them in some cases from financing essential investment in research and development, production, the recruitment of staff and even the promotion of sales.

(1) Parliamentary document of the Senate, 1984 - 1985 session, 83, p. 6, 23 May 1985.

Although such activities are in the pharmaceutical undertakings' own interests so as to ensure their medium and long-term viability, because of the abovementioned low level of profitability imposed by the Belgian Government, only the undertakings which have concluded contracts are able to pursue them.

Furthermore, the granting of aid in the form of selective permission to increase prices within the framework of the price setting system has much more serious consequences than the granting of normal aid in the form of a capital grant or an interest subsidy on a loan of limited duration ; contrary to such aid, the permission to increase prices leads to permanent additional revenue equivalent to the regular granting of an annual subsidy amounting to the product of the difference between prices before and after the increase and the volume of the pharmaceutical products sold. In the long term, the additional turnover generated by the conclusion of a programme contract should thus exceed the total costs of the investments and activities which the recipient has carried out.

Allowing aid in the form of contract programmes that enable a limited number of pharmaceutical undertakings to increase their prices on the Belgian market (rather than allowing an increase in the general price level) would amount to imposing on the competitors of such undertakings a disadvantage which might force them to withdraw in whole or in part from the market.

Consequently, the aid does not facilitate the development of the Community sector in question and adversely affects trading conditions to an extent contrary to the common interest, within the meaning of Article 92 (3) (c).

VIII

In conclusion, the aid in the form of programme contracts is unlawful, since the Belgian Government has failed to fulfil its obligations under Article 93 (3). In addition, the aid does not fulfil the conditions laid down in order to qualify for one of the exemptions provided for in Article 92 (2) and (3).

Accordingly, no new programme contract between pharmaceutical undertakings and the Belgian authorities may be concluded and the aid derived from the conclusion of such contracts must be abolished with effect from the date of this Decision,

HAS ADOPTED THIS DECISION :

Article 1

The system of aid in the form of programme contracts for various pharmaceutical undertakings is unlawful since it was introduced in breach of the procedural rules provided for in Article 93 (3) of the EEC Treaty. The aid is, moreover, incompatible with the common market within the meaning of Article 92 of the EEC Treaty.

Article 2

The Kingdom of Belgium shall not conclude any further programme contracts and shall abolish aid derived from contracts concluded in the past with effect from the date of this Decision.

Article 3

The Kingdom of Belgium shall inform the Commission within two months of the date of this Decision of the measures taken to comply with it.

Article 4

This Decision is addressed to the Kingdom of Belgium.

Done at Brussels, 20 December 1989.

For the Commission

Leon BRITTAN

Vice-President