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Report

drawn up on behalf of the Committee on Economic and Monetary Affairs

on the manufacture, distribution and use of pharmaceutical preparations

Rapporteur: Mr P. DE KEERSMAEKER

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PE 57.189/fin.

English Edition

At its sitting of 11 April 1978 the European Parliament, pursuant to Rule 25 of the Rules of Procedure, referred the motion for a resolution tabled by Mr Fellermaier, on behalf of the Socialist Group, on the manufacture, distribution and use of pharmaceutical preparations (Doc. 18/78) to the Committee on Economic and Monetary Affairs.

On 28 April 1978 the Committee on Economic and Monetary Affairs appointed Mr De Keersmaeker rapporteur.

The committee considered the draft report at its meetings of 25 and 26 September, 21 and 22 November 1978, 23 and 24 January and 27 and 28 February 1979 and approved it at the last of these meetings by 16 votes with 2 abstentions.

Present: Mr Notenboom, acting chairman; Mr De Keersmaeker, rapporteur; Mr Ansquer, Lord Ardwick, Mr Cifarelli, Mr Damseaux, Mr Deschamps, Mr Glinne, Mr Van der Gun, Mr Lange, Mr Leonardi, Mr Normanton, Mr Prescott, Sir Brandon Rhys Williams, Mr Ripamonti, Mr Spinelli, Mr Starke and Mr Stetter.

C O N T E N T S

A

The Committee on Economic and Monetary Affairs hereby submits to the European Parliament the following motion for a resolution, together with explanatory statement:

MOTION FOR A RESOLUTION

on the manufacture, distribution and use of pharmaceutical preparations

The European Parliament,

- having regard to the motion for a resolution (Doc. 18/78)[1],
- having regard to the report of the Committee on Economic and Monetary Affairs (Doc. 664/78),

1. Notes that the structure of the pharmaceutical industry is characterized by a substantial concentration of supply in certain categories of therapeutical products and that, where a structure of this nature obtains, the possibility of the rules of competition being infringed, for instance in the matter of price fixing, cannot be ruled out;

2. Stresses that such a structure calls for great vigilance on the part of the Commission as regards compliance with the rules on competition laid down by the EEC Treaty;

3. Notes with satisfaction the Commission's successful efforts to ensure compliance with the rules on competition laid down by the Treaty; points, however, to the need for the Commission constantly to consider ways of detecting distortions of competition for example, with respect to the methods of fixing transfer prices even more efficiently and quickly;

4. Is aware of the restrictions imposed by Articles 85 and 86 of the EEC Treaty and of the interpretation of those articles when distortions of competition are being dealt with;

5. Urges, as it has repeatedly done in the past, the Council to approve as quickly as possible the Commission's proposal on the control of concentrations between undertakings;

6. Considers that in view of the low price elasticity, which provides opportunities for abuse in price fixing, and in view of the heavy burden borne by the social security systems, supervision at national and Community level of the prices charged for pharmaceutical preparations may prove beneficial;

1 Motion for a resolution tabled by the Socialist Group

7. Stresses, however, that the price control measures taken by the Member States should be compatible with the Treaty and that they should not restrict intra-Community trade;

8. Calls on the Commission to undertake a careful investigation into the compatability with the Treaty of the various national price control systems for pharmaceutical products and to submit its findings to Parliament; reminds the Commission of its responsibility for ensuring compliance with the provisions of the Treaty and, accordingly, to take immediate action should particular national price control systems prove to be incompatible with the Treaty;

9. Feels that in the case of the categories of therapeutical products on which there is marked concentration, the Commission should keep a close watch on price differences and that, in accordance with the task it set itself in the Fourth Report on competition policy, it should investigate instances of notable price differences and determine whether these are not in part due to a breach of the rules on competition;

10. Considers that if an understanding of the price situation in the Community is to be gained, the cooperation of the national authorities is absolutely essential; regrets, however, that more often than not, such cooperation is inadequate;

11. Requests the Commission to consider how consultations with national price bodies might be arranged and to draw up an appropriate proposal;

12. Points out that while the Directives already approved for the elimination of barriers to intra-Community trade in pharmaceutical products, under which licences for marketing are issued at national level, certainly constitute an important step towards free trade in pharmaceutical products, they do not eliminate all barriers to such trade;

13. Requests the Commission, therefore, to submit as quickly as possible a new proposal for the mutual recognition by the Member States of national licences or for the introduction of a Community licence for the marketing of pharmaceutical products, so that free trade in pharmaceutical products is fully implemented;

14. Requests the Commission to submit as soon as possible an amended proposal on advertising and information in the pharmaceutical industry, in particular with a view to combating the misuse of pharmaceutical preparations;

15. Instructs its President to forward this resolution and the report of its committee to the Council and Commission of the European Communities and to the governments and parliaments of the Member States.

B

EXPLANATORY STATEMENT

I. The structure of supply

1. The pharmaceutical industry is characterized by a large number of producers and a large number of products; a small number of producers and products, control most of the market. However, no single group or product controls a very large share of the market. The pharamceutical industry cannot therefore be said to be oligopolistic, despite the marked trend towards concentration. This assessment has to be qualified, since investigation of the relative competitive position of the various therapeutic groups has shown that some of these groups control a substantial part of the market, one example of this being the position of Hoffmann-La Roche on the tranquillizer and vitamin markets.

2. During the discussions on this matter, reference was made to the major multinational undertakings active in the pharmaceutical industry. A number of major multinational undertakings do indeed operate in this industry. There is, therefore, a real danger that certain multinationals may infringe Articles 85 and 86 of the Treaty and thus realize excessive profits. This problem is not, however, peculiar to this sector. The possibility of infringements of the rules on competition cannot be ruled out in any sector with a market structure of this nature.

Initially, the committee was unable to agree on how the pharmaceutical industry's structure might affect compliance with the rules on competition laid down by the Treaty, in particular the profits realized in this sector. In order to obtain more information which might provide a basis for a consensus, the committee decided to invite one representative from the Trade Unions involved and one from the industry. Mr LEVINSON, Secretary-General of the International Federation of Chemical, Energy and General Workers Unions, and Mr TIEFENBACHER, until recently the chairman of the International Federation of Pharmaceutical Manufacturers Associations, each made a statement to the committee on this subject on 21 and 22 November 1978.

3. How did this hearing contribute to a solution of the problem on which the committee had been unable to reach agreement and for which the hearing was organized : i.e., the level of profit realized in this sector? A brief summary of the two statements will help to answer that question.

Mr LEVINSON began by describing the specific nature of the product and then went on to the second feature which he felt was central to the

pharmaceutical industry, its multinational character. He gave a detailed analysis of the problems posed by the multinationals in general: the new economic order, the inadequacy of supervision by national governments, the economic crisis, inflation, price fixing in terms of wage costs and investment, the impact of technology on employment, the selection of place of business and geographical mobility, the division between production and distribution, the application of transfer prices and the profits realized, the significance of the high level of depreciation entailed by rapid technological progress, financial finagling, etc., Mr LEVINSON'S statement gave for the most part a general picture of multinational undertakings as such, with the occasional comment that, since the pharmaceutical industry was largely in the hands of the multinationals, it, too, must be guilty of such practices. It was not possible, however, on the basis of this statement, to pass judgement on certain practices in the pharmaceutical industry. And no clear answer was given to the problem on which the committee had been unable to reach a consensus, namely whether or not the profit margin exceeded a reasonable level. Mr LEVINSON's answer may be summed up as follows : Only if we have a clear picture of how prices are determined, can we assess fairly whether the profit margin is justified or not, due regard being had to the risks involved, research, etc., Only if we have a clear picture of the structure of the transfer prices and know exactly what margin is added at the various stages after production, can we assess whether or not the profit margin is justified. To this end, the provisions relating to the notification and publication of the undertakings' balance sheets as submitted to the tax authorities should be harmonized. There is, however, no sign of this happening, and the possibility of evading these obligations by the utilization of tax havens makes it impossible for this information to be obtained and, consequently, for the acceptability of the profits realized to be assessed. Nonetheless, Mr LEVINSON felt that profits in the pharmaceutical industry were at a very high level.

In his statement, Mr TIEFENBACHER referred to the way in which the pharmaceutical industry was hampered by the absence of any harmonization between the various national laws regulating this sector. Consequently, trade in these products between the Member States was seriously impeded and a common market in these products was still a long way off. He emphasized the need for progress to be made at an early date towards such harmonization and hence towards the establishment of a common market in these products.

As for the industry's profits, Mr TIEFENBACHER emphasized that production costs constituted only a small part of total costs, in which research and development, monitoring costs and so forth were becoming increasingly significant. Profit could not be defined simply as the difference between the price and production costs. He also referred in this context to the fact that current profit and price controls made it difficult to realize excessive profits.

4. What conclusions can be drawn from these two statements with respect to the profits realized in the pharmaceutical sector? No proof was forthcoming that excessive profits were being made in this sector. Mr LEVINSON's statement emphasized the opportunities for abuse in price fixing, which would then be reflected in the profits realized by an industry dominated by the multinationals. Since the pharmaceutical industry was characterized by such a structure, such abuses could not be ruled out. There is, however, no concrete evidence to prove that such is the case. Paragraph 1 of the motion for a resolution therefore refers to the danger inherent in such a structure. This danger is not restricted to price fixing, but relates more generally to all practices which restrict competition.

Given the type of structure involved in this sector, the Commission should therefore be extremely vigilant in enforcing the rules on competition laid down by the Treaty. In its answer to the questions put by your rapporteur, the Commission summarizes the action taken against pharmaceutical undertakings on the basis of Articles 85 and 86. Some of the cases cited concern abuse of a dominant position, such as the Hoffmann-La Roche case, in respect of both the therapeutic vitamins group and the tranquillizer group. In the Zoja case in 1972 the Commission also took action against a multinational undertaking, the Commercial Solvents Corporation, because this undertaking, which had a partial monopoly of nitropropane, refused to resume supplies of this substance to the Italian company Zoja.

5. Some of these infringements are not, however, entirely attributable to the multinational nature of the undertakings concerned. If most of the supply is controlled by a limited number of undertakings in a particular therapeutic group, there is nothing to stop these undertakings concluding agreements on the distribution of the market, prices etc. For such agreements to be made it is not necessary for the undertakings involved to be multinational concerns; the number of undertakings involved must not be too big, but it is quite possible for several undertakings which each manufacture their products in a single Member State to come to

an agreement. An example of this was the 'quinine' case; one Dutch. two German and three French undertakings, which were the biggest suppliers of quinine on the Community market and in certain third countries, had reached an agreement fixing the terms on which they were to purchase raw materials and sell quinine on all the markets.

6. It is clear from the Commission's list of cases in which it has applied Articles 85 and 86 of the Treaty to the pharmaceutical industry that it is making every effort to ensure that the rules on competition laid down by the Treaty are observed in this sector. But the Commission should be constantly devising more efficient and more rapid ways of detecting and dealing with possible distortions of competition and abuses of power within the meaning of Articles 85 and 86 of the Treaty. The Commission must, however, be provided with the necessary material resources to achieve these ends.

7. Articles 85 and 86 contain certain constraints, however, by which the Commission is bound. These include, for example, the need to prove that a dominant position exists. In order to do so it has to be shown that no substitute product exists, a difficult task, given the large number of products manufactured in this industry.

8. Further, it is axiomatic that the Commission can take action in accordance with Article 85 and 86 only when trade between the Member States is adversely affected and competition distorted or when there is abuse of a dominant position on a large part of the Community market. Other distortions of competition fall within the jurisdiction of national authorities.

9. Finally, the Council should again be urged in this context to take rapid action on the Commission proposal on merger control, which urgently needs to be applied to the pharmaceutical industry where mergers are extremely common.

II. Special features of the pharmaceutical industry

10. Given that pharmaceutical products are required for health care and that their cost is largely reimbursed through social security systems, there is very little price elasticity in this sector. Competition does not operate at the level of prices in the pharmaceutical sector. A certain amount of control over prices may therefore be a good thing so as to ensure that this freedom to fix prices is not misused, especially as most of the cost of pharmaceutical products is borne by social security systems and thus constitutes a heavy burden on national budgets. This

price control must, however, be sufficiently flexible as the cost of research must be met from the profits made from pharmaceutical preparations which have already become firmly established on the market.

11. As these costs are borne by national budgets and not by the Community budget, it is logical that this control function should be entrusted to the national governments and not to the Community. Indeed, it would be impossible to exercise price control at Community level. Price differences between the various Member States are not so much due to a distortion of competition as to a whole series of other factors, such as distribution, the granting of patents, exchange rates, rates of taxation, etc., It is planned to harmonize a number of these factors, and indeed for some of them, e.g. admission of a pharmaceutical preparation on to the market, harmonization has already commenced, but such factors as social security systems will not be harmonized. The exercise of Community price control in the nine Member States is therefore virtually unfeasible, and any attempt to implement it would founder in a tangle of red tape.

12. The measures which the Member States take in order to ensure a reasonable price level for pharmaceutical products must not, however, infringe the provisions of the Treaty. In this connection the Commission stated, in reply to Written Question No. 808/76 by Mr Cousté on the freeze in the price of pharmaceutical products[1]: 'these measures must however be kept within certain limits, notably as prescribed by the Articles of the Treaty (30 et seq.). In this context, the Court of Justice of the European Communities has ruled[2] that the institution by a Member State of a maximum price - insofar as it applies to imported products - constitutes a measure of equivalent effect to a quantitative restriction on imports within the terms of Article 30 where it is fixed at such a low level, taking into account the general situation of imported products as compared to national ones, that prospective importers can only import and market at a loss.

The extent to which national price control systems for pharmaceutical products are compatible with the provisions of the Treaty came up for discussion again not long ago in connection with the publication of Prof. E.J. Mestmäcker's 'Vereinbarkeit von Preisregelungen auf dem Arzneimittelmarkt mit dem Recht der Europäischen Wirtschaftgemeinschaft' (Compatibility of price controls on the market in pharmaceutical products with the law of the European Economic Community). In statements made apropos of this document, representatives of the industry complained that some national price control systems for pharmaceutical products were incompatible with the Treaty and impeded free trade in these products.

1 OJ No. C. 84, 4.4.1977, p. 15

2 Case 65/75 and 88-90/75 (OJ No. C 136, 17.6.1976, p. 6)

However, the Commission was taking no action against these breaches of the Treaty and was accepting the continued existence of these price control systems without demur. This being the case, the Committee on Economic and Monetary Affairs considers that the Commission should, as a matter of urgency, undertake a detailed investigation into the compatibility with the Treaty of the various national price control systems and subsequently submit its findings to Parliament. Should the Commission find that certain national price control systems are in fact incompatible, it should take immediate action to ensure that they are withdrawn as quickly as possible. After all, under Article 155 of the Treaty, it is the Commission's responsibility to ensure compliance with the provisions of the Treaty.

13. Investigations into possible infringements of the Treaty's rules on competition used to begin when evidence of violations came to light. In its Fourth Report on competition policy[1] the Commission also assumed for itself the responsibility of investigating any wide price disparities and finding out, while making allowance for any other possible causes, whether these price disparities were not at least partly due to non-compliance with the rules on competition. In the Normanton report[2], which was not, however, adopted by Parliament, the Committee on Economic and Monetary Affairs supported the Commission's initiative and urged it to amplify its investigations and extend the number of goods in respect of which price comparisons were carried out.

This raises the question whether the markets of certain therapeutic groups with a high degree of concentration and substantial price disparities, the two criteria set by the Commission, should not be the subject of an investigation into the causes of these disparities.

14. This presupposes, however, that the Commission is aware of the existence of any major price disparities between certain pharmaceutical products in the various Member States. For this purpose it needs to have sufficient information concerning the prices of the large range of products manufactured by the pharmaceutical industry in the various countries.

The Commission cannot possibly obtain a complete picture of the price situation from existing Community price surveys. The latter are merely Community surveys of retail prices carried out annually since 1970 by the Statistical Office of the European Communities with a view to comparing purchasing power parities in the various Member States. For certain

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1 Doc. 108/75

2 Doc. 164/75

commodities, however, these statistics may contain interesting data from the point of view of competition. The retail prices of pharmaceutical preparations were, however, only investigated in the 1970 survey. The prices of about 20 products were investigated and published; this provoked a strong protest from the Member States and from the pharmaceutical industry. Pharmaceutical preparations were again covered in the 1975 price survey, which has still not yet been published. This survey covered between 15 and 20 categories of products, each of which contained various pharmaceutical preparations, giving a total of 101 pharmaceutical preparations. The Statistical Office does not intend to publish these prices, but merely the weighted average calculated on the basis of these individual prices; this will then be used to calculate purchasing power parities. Even if these data are not published, they should still be made available to the Commission's Directorate-General for Competition.

15. To obtain a picture of the price situation as regards this large number of products in the various Member States, the Commission needs the cooperation of the national authorities. This cooperation is, however, rarely satisfactory. The Committee on Economic and Monetary Affairs stated its position on such cooperation in the Normanton report[1], which was not adopted by the European Parliament. It is impossible for the Commission to detect abnormal disparities between prices in the various Member States, because of the wide range of products manufactured by the pharmaceutical industry, without the cooperation of the national authorities. The Committee on Economic and Monetary Affairs therefore urges that the necessary measures be taken so that this cooperation may be improved as quickly as possible. The problem of cooperation between the national authorities and the Commission has been simplified to a certain extent by the setting up of the Pharmaceutical Committee and the Committee for Proprietary Medicinal Products. However, it might also be useful to establish consultation between the various national authorities responsible for price control and the Commission.

This would enable the national authorities to improve their price control methods on the basis of experience with methods applied in the other Member States. Moreover, the national market is too restricted for a proper assessment to be made of the prices of certain medicinal products, and the availability of information concerning the situation in other Member States may be extremely useful. Finally, the Commission might obtain, in this context, the cooperation from the national authorities necessary for its price comparisons.

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[1] Doc. 164/75

16. Although price comparisons have on several occasions revealed distortions of competition, it must be borne in mind that the matter is somewhat more complex than that. As pointed out above, differences in price are determined by so many economic and legal factors that substantial differences are possible without a distortion of competition necessarily being responsible for them. This prompts the Commission to quote in its reply a passage from H. COOPER's study 'European Pharmaceutical Prices 1964-1974': 'International comparisons of prices are at best extremely hazardous undertakings. Any results which emerge need heavy qualification and cautious interpretation. Small changes in methodology and in the sample size and composition can produce dramatic changes in the results. In no country are all prices consistently higher than in another.'

In its Sixth Report on competition policy the Commission states : 'so far none of the studies carried out in various industries where sharply differing prices between Member States were found to exist has shown that the differences resulted from restrictive agreements or concerted practices within the meaning of Article 85 of the Treaty, or from abuse of dominant positions within the meaning of Article 86'.

17. However, despite the difficulties involved in carrying out price comparisons, the Commission seems determined to use this method to expose distortions of competition. In reply to questions put by your rapporteur, the Commission refers to an investigation that is now in progress into the causes of the price distortion in the various Member States in respect of the medicinal product 'allopurinol', sold under the trade mark 'Zyloric', for which a higher price is charged in Germany than in most of the other Member States.

18. As regards the application of Article 86 in the event of substantial price disparities, the judgment of the Court of Justice in Case 78-70 (Deutsche Grammaphon Gesellschaft v Metro-SB-Grossmärkte) of 8 June 1971 constitutes a crucial step forward: in this judgement it was assumed that a considerable price disparity, in the absence of any objective justification, may be regarded as important evidence of abuse of a dominant position within the meaning of Article 86. The Commission recently referred to this judgment in its decision against United Brandt. The disparity between the prices charged by this undertaking for bananas in the various Member States amounts to over 100%. According to the Commission, not even half of this price disparity can be explained by differences in quality or by advertising costs. The Commission's decision is not based on a detailed cost-price analysis but on an analysis of the market situation, the prices charged by United Brandt, the prices charged by competitors etc. The judgment of the Court of Justice in this Case will be of crucial importance for the Commission's future ability to combat abuses in price fixing on the basis of Article 86.

III. The free movement of pharmaceutical preparations in the Community

19. In the absence of genuine price competition, efforts should be made to intensify competition between products. The realization of the common market in pharmaceutical preparations would intensify competition on this market. To that end, the current barriers to trade hampering the free movement of pharmaceutical preparations should be eliminated by the harmonization of national legislation on pharmaceutical preparations.

The Council has so far adopted a number of Directives on the approximation of legal and administrative provisions relating to pharmaceutical preparations.

Directive 65/65/EEC[1] : This Directive makes the placing of a proprietary medicinal product on the market of a Member State subject to authorization by the competent authority of that Member State. This Directive has been in force since 1.1.1967.

The following Directives came into force at the end of November 1976.

Directive No. 75/318/EEC[2]: This Directive, adopted in May 1975, lays down the rules with which particulars and documents concerning the results of tests carried out with proprietary medicinal products, for which an application for a marketing authorization has been made, must comply. These particulars are to be produced pursuant to the abovementioned Directive No. 65/65/EEC.

Directive No. 75/319/EEC[3]: This Directive lays down the qualifications required of persons drawing up documents and particulars concerning control methods and results of tests which should be submitted to the competent authorities in accordance with the abovementioned Directive. Further, this Directive determines the manner in which applications for marketing authorizations should be made and supervision exercised over the application of the legal provisions.

The marketing authorization is granted at national level. The authorization must first be granted in the country of production, following which authorization may be applied for in respect of the other Member States. However, applications are to be submitted in the same manner in the various Member States, and the criteria applied in granting the authorization are Community criteria. This Community system is applied at national level. In order to facilitate the adoption of a common position by the Member States regarding the granting of marketing authorizations, a Committee for

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1 OJ No. 22, 9.2.1965, p. 369/65

2 OJ No. L 147, 9.6.1975, p.1

3 OJ No. L 147, 9.6.1975, p.13

Propriety Medicinal Products was set up under Directive 75/319/EEC. This management committee can give an opinion on applications to bring a particular pharmaceutical product on to the market whenever a Member State has doubts about the innocuousness or efficacy of the product. If several Member States have adopted conflicting decisions concerning the granting or revoking of an authorization, one of the Member States concerned may refer the matter to the Committee.

Finally, Directive 75/319/EEC makes authorization obligatory for manufacture and imports from third countries. Imports from third countries and manufacture should be supervised, but if supervision is exercised in a Member State over the manufacture or importation of products from third countries such supervision need not be repeated if the products are imported into another Member State. It should, however, be pointed out that Article 39 provides that this Directive should not be applied to proprietary medicinal products placed on the market by virtue of previous provisions before 15 years have elapsed.

Decision 75/320/EEC[1]: This Council Decision set up a Pharmaceutical Committee, intended primarily to deliver opinions to the Commission. In the Pharmaceutical Committee the persons responsible for national public health policy may give opinions to the Commission on matters in which they believe Community harmonization to be desirable, on measures deemed necessary by the Commission and on new Commission proposals in this area.

20. These Directives represent significant progress towards greater freedom of movement in intra-Community trade in pharmaceutical products and in the protection of the health of consumers. The planned transitional period before the entry into force of the authorization arrangements for proprietary medicinal products placed on the market by virtue of previous provisions is, however, extremely long. The last remaining obstacle to free trade in pharmaceutical products is the fact that the Community system of authorization is implemented at national level. Standardization on a Community basis of the particulars to be supplied in order to obtain an authorization considerably simplifies the application procedure for obtaining authorization in the various Member States. Further, the setting up of a Committee for Proprietary Medicinal Products and a Pharmaceutical Committee is an initial step towards coordination of decisions regarding authorizations and constitutes the beginnings of cooperation between the national authorities.

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[1] OJ No. L 147, 9.6.1975, p. 23