European Communities

# EUROPEAN PARLIAMENT

# Working Documents

1982-1983

5 December 1982 DOCUMENT 1-979/82

REPORT

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

on the production and use of pharmaceutical products in the Community

Rapporteur: Mr G. DELEAU

PE 77.856/fin.

English Edition

At its plenary sittings of 18 June 1980 and 16 January 1981 the European Parliament referred :

- the motion for a resolution tabled by Mr Ghergo and others, pursuant to Rule 25 of the Rules of Procedure on the state of implementation of the EEC directives on proprietary medicinal products and measures to be adopted for the free movement of pharmaceuticals between Member States (Doc. 1-243/80) and

- the motion for a resolution tabled by Mrs Krouwel-Vlam and others, pursuant to Rule 25 of the Rules of Procedure,[1] on the production and use of pharmaceutical products (Doc. 1-817/80),

to the Committee on Economic and Monetary Affairs as the committee responsible, and to the Committee on the Environment, Public Health and Consumer Protection for its opinion.

At its meetings of 21 October 1980 and 18 February 1981, the Committee on Economic and Monetary Affairs appointed Mr Deleau rapporteur on these two motions for resolutions.

The Committee on Economic and Monetary Affairs considered the draft report at its meetings of 23 and 30 November 1982. At its meeting of 30 November 1982, it unanimously adopted the motion for a resolution.

Present: Mr Jacques MOREAU, chairman; Mr DELEAU, vice-chairman and rapporteur; Mr BONACCINI, Mr CAROSSINO (deputizing for Mr LEONARDI), Mrs DESOUCHES, Mr FRANZ, Mr de GOEDE, Mr HERMAN, Mr HOPPER, Mrs LIZIN (deputizing for Mr SCHWARTZENBERG), Mr MORELAND (deputizing for Mr de FERRANTI), Mr MÜLLER-HERMANN (deputizing for Mr COLLOMB), Mr PURVIS (deputizing for Miss FORSTER), Mr VAN ROMPUY, Mr VERGEER, Mr WELSH and Mr von WOGAU.

The opinion of the Committee on the Environment, Public Health and Consumer Protection is attached.

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[1] currently Rule 47

CONTENTS

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 production and use of pharmaceutical products in the Community

The European Parliament,

- having regard to its motions for resolutions (Docs. 1-243/80 and 1-817/80),

- having regard to the report of the Committee on Economic and Monetary Affairs and the opinion of the Committee on the Environment, Public Health and Consumer Protection (Doc. 1-979/82),

1. Considers that the European pharmaceutical industry constitutes an important industrial sector that has been able, in spite of the economic crisis, essentially to maintain its competitivity, employment levels and export capacity;

2. Stresses both the potential and the special situation of the Community's pharmaceutical industry, and considers that its activities must, in view of their implications for public health and the volume of public health-care expenditure, be rigorously assessed, albeit in a constructive spirit;

3. Considers that in the context of global industrial strategy, a European strategy for the pharmaceutical industry must be worked out;

this must reconcile the promotion of this sector, confronted as it is with high research costs and stiff international competition, with the implicit EEC Treaty objective of improving public health at the lowest cost and in the best conditions possible;

- production guidelines

4. Stresses that the future of the pharmaceutical industry will depend principally on its capacity for innovation; that in view of the growing cost of research, the pharmaceutical industry must therefore establish its priorities and should orient its research effort accordingly; that the Community institutions, without substituting their own activities for the responsibilities of private research laboratories, must henceforth assume a coordinating function in this sector of research;

5. Calls in particular on the Commission to provide the incentives necessary in order to carry the various existing pharmaceutical research programmes to their conclusion, and to establish basic guidelines for pharmaceutical research in areas that have hitherto been neglected but where real needs exist;

   Calls on the Commission to conduct a review of the various national pharmaceutical research programmes to see whether coordination is possible so as to avoid duplication and fill any gaps that may be found to exist;

6. Notes that legal protection for pharmaceutical inventions is in practice attenuated by the length of test-periods, and calls on the Commission to investigate, possibly on the lines of procedures envisaged in the United States, effective means of strengthening this indispensable legal protection and also means of extending the facilities for product testing and screening;

7. Calls on the Commission to develop the Common Market in pharmaceutical products in such a way as to enable ethical, generic and mass consumption products to find their natural balance in response to the needs of the market and the interests of public health;

8. Insists that the Community contribute to establishing the necessary conditions for the development of an authentic external trade policy, which would be of considerable value to the European pharmaceutical industry; also calls on the Commission to seek, in the appropriate international bodies, basic arrangements for cooperation with developing countries that can reconcile, in the pharmaceutical field, the needs

of these countries, which consume less than 20% of world production, their requirements, and the concern of the pharmaceutical undertakings for basic stability and profitability;

9. Calls on the Commission to ensure that the quality standards required of pharmaceutical products in the Community countries will apply to all exported products and will be subject to appropriate scrutiny jointly with the World Health Organization;

- securing market conditions

10. Recalls that the pharmaceutical industry is characterised by a high level of concentration on the part of producers and a high incidence of monopoly purchasers. This makes it particularly important for the Commission to monitor vigilantly the application of the rules of competition in this sector, in regard to both the private companies and the public agencies,

Calls on the Council speedily to adopt the proposal for a regulation on the control of concentrations as a means of securing the position of SMUs, which have their special place in the sector of generic drug production and mass-consumption products, and are a dynamic and innovating element;

11. Believes that the market for pharmaceutical products is vulnerable to disruption by parallel imports and that this could best be solved by opening the market to cross-border transfers from single European production centres. Such a liberalization would help small and medium-sized undertakings to make a dynamic contribution to the production of general drugs and mass consumption products by making it impossible for national authorities to restrict purchasing and distribution;

12. Stresses that it will be in the joint interest of consumers and the industry for the pharmaceutical industry to benefit from the opening up of the European market;

Calls on the Commission vigorously to pursue its work of harmonization of legislation in this field, and on the Council to assist, in particular by adopting without delay the recent proposal for a directive on the

harmonization of marketing authorizations, as the essential first step towards a market in pharmaceuticals genuinely open to the free movement of goods;

Considers that it would make a significant impact on the Community public if harmonization of legislation on the issuing of pharmaceuticals on prescription were to be introduced, and calls on the Commission to submit an appropriate proposal;

Calls on the Commission to oppose all unjustified attempts to wall off markets;

13. Considers it indispensable to bring about real transparency of the market in pharmaceuticals, both from the legal point of view, in particular as regards parallel imports, and from the fiscal point of view;

In this connection again asks the Commission to submit a proposal on transfer prices as an indispensable instrument for equalization of competition and rationalization of undertakings;

14. Considers that price formation on the market in pharmaceuticals is unsatisfactory;

Considers that the considerable disparities in prices, whether they are the result of non-observance of the rules of competition, of the diversity of national price-fixing arrangements and drug prices, or of variations in wholesalers' and pharmacists' margins as between Member States, violate the basic Treaty objective of securing a balanced market that meets the need to provide the highest standard of public health care at the lowest cost and in the best conditions possible;

15. Therefore calls on the Commission to proceed as soon as possible, as requested by the European Parliament in its previous resolution, with a study of the compatibility with the EEC Treaty of the different national systems for monitoring the prices of pharmaceuticals;

16. Also calls on the Commission to seek with more determination that it has hitherto shown arrangements for coordination with the national authorities responsible for monitoring the prices of drugs, with a view to harmonizing national systems, since artificial importing channels will otherwise be perpetuated;

- monitoring the use of drugs

17. Stresses that any European strategy on pharmaceuticals aimed at improving public health must also concentrate on the conditions under which drugs are used, whilst taking account of the often decisive influence of social protection systems, and help to improve training and information for practitioners and drug users;

18. Calls on the Commission to consider arrangements for the general introduction in the Community of compulsory post-graduate and follow-up courses to provide doctors with training in the therapeutical field and in the field of drug control, and for wider access to relevant data banks;

19. Also calls on the Commission to study the possiblity of implementing, with the cooperation of the national authorities, an information and education campaign covering the proper use of pharmaceutical products, taking due account of the different practices in the use of drugs as between Member States;

20. Points out that in view of the particular nature of drugs, advertising for pharmaceuticals must be subject to special rules;

Therefore again calls on the Commission to submit a proposal in this area;

Considers that abusive trading practices by certain laboratories must be severely condemned;

21. Calls on the Commission to study the prospects and scope for self-medication;

Calls also on the Commission to produce full and harmonized statistics on the pharmaceuticals sector as a whole, so that the use of drugs and their impact on health and on public health expenditure in the Community can be monitored and compared in precise detail in future;

22. Instructs its President to forward this resolution to the Council, the Commission and the parliaments of the Member States of the Community.

B.

## EXPLANATORY STATEMENT

### INTRODUCTION

The two motions for resolutions[1] on the pharmaceuticals sector underlying this report relate to a wide range of questions such as the structure of competition, the volume of pharmaceutical production, production guidelines, price formation, advertising, information for practitioners and users and ways of securing effective free movement of drugs in the EEC.

The European Parliament adopted in 1978 a report[2] on the subject dealing in some depth with a number of matters, including in particular the suppty structure in the sector and price and profit levels. One of the conclusions reached in this report and the hearings that preceded it was that, given the special situation of the pharmaceuticals industry, it would be appropriate to adopt a position of well-informed vigilance before coming to any conclusions as to the guidelines to be followed in this sector.

It is therefore clear that if this new report by the Committee on Economic and Monetary Affairs on the production and use of pharmaceutical products is to prove its worth and avoid duplication on certain matters or controversies that have already been highlighted, it must combine a study of matters previously raised, such as price levels, advertising and competition, with an overall view of the future of the pharmaceutical industry in the EEC.

The purpose of this report is therefore to consider the production and use of pharmaceuticals in the wider context of a European pharmaceuticals policy comprising, as far as possible:

- promotion of this major industrial sector, confronted as it is with high research costs and international competition, and
- the improvement of public health at the lowest cost and in the best conditions possible.

The new report should thus constitute an appraisal of the matters raised in the report adopted in 1978 and an analysis of future prospects for the sector.

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1 Docs. 1-243/80 and 1-817/80

2 Report on the manufacture, distribution and use of pharmaceutical preparations by Mr DE KEERSMAECKER (Doc. 664/78)

We shall consider in turn production guidelines, marketing conditions and the circumstances in which drugs are used.

## I. PRODUCTION GUIDELINES

The pharmaceutical industry in the Community is an important traditional sector that has so far succeeded in maintaining its dynamism. Indeed, the European pharmaceutical industry now occupies a major position in world trade, and its activities account for a very high export volume. It is a sector with a very high added value, is a low polluter, a low energy consumer, and employs some 315,000 individuals in the EEC, a high proportion of them highly qualified.

However, the European pharmaceutical industry today faces a double set of difficulties. The first arises from the growing cost of research. While pharmaceutical research went through a period of major expansion until into the sixties, it is becoming increasingly difficult to invent useful new medicines. Each therapeutic breakthrough presupposes an extended period of long and costly research before any marketable product can be produced.

At the same time the European pharmaceutical industry is beginning to be exposed to international competition, in particular competition from Japan, which is likely to prove intensive. In fact the Japanese industry, the volume of whose exports has hitherto been modest, is now investing heavily in this sector.

It therefore seems appropriate, especially when the implications of pharmaceutical production for the social security expenditure of the states is taken into account, to implement, before it is too late, a European strategy for the pharmaceutical sector that reconciles as far as possible the improvement of public health, the vitality of the sector, and the need to restrain public spending and uphold the rules of competition laid down in the Treaties.

This strategy could be pivoted on the following four basic approaches:

### 1. Research promotion

The essential characteristic of the pharmaceutical industry is that competition takes the form of innovation and the substitution of one product for another. This highlights the important role played by research in the sector. The implementation of a European research strategy in the field of pharmaceuticals presupposes the establishment of appropriate facilities and guidelines.

(a) Research financing

Research financing is a major item in the budget of pharmaceutical undertakings, or at least of those that undertake research activities and do not confine themselves to manufacturing and distributing generic or mass-consumption products. The need to devote large sums to research must also be taken fully into consideration when evaluating the profits realized by the industry.

Research costs, given their overwhelming importance in the present context of competition, obviously call for an element of coordination. A high level of coordination of research investment in European pharmaceutical industries is clearly desirable. In fact, the Commission notes in a recent communication on scientific and technical research in the Community[1] that a certain dissipation of effort is characteristic of this field. The Commission should, therefore, without in any sense substituting its own activity for the responsibility, free choice and risks of the industries concerned, encourage the latter to establish research priorities. As the Commission recommends in its communication on a Community strategy to develop Europe's industry[2], 'long-term projections ... must be prepared, and essential industries ... must have the technologies they need in good time so that they can continue to be a source of wealth and employment'.

The coordination of investment in research should also apply to pharmaceutical laboratories and private and government research establishments, as the motion for a resolution states[3].

It would be appropriate to determine whether the Commission now has sufficient resources[4] to play an effective coordinating and pioneering role in the research sector.

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1 COM(81) 574 final: Scientific and technical research in the European Community;

2 COM(81) 639 final, p.10;

3 Doc. 1-817/80, paragraph 7;

4 The Community budget now devotes some 1.6% of appropriations to research and development. Within CREST there is a committee on medical and public health research; a Council decision of 18.3.1980 - OJ L 78, p.24 - drew up a research programme in the field of medical and public health research consisting of four concerted multi-annual projects. A research programme on methodological research to improve drug control and monitoring of pharmaceutical products has also been forwarded by the Commission to the Council.

(b) Research guidelines

The Community can also orient research in the pharmaceutical field to the future needs of the industry, having regard to its competitive position, and also to the public health objectives implicit in the EEC Treaty.

Freedom of research in laboratories is indispensable to the very success of their research effort, the complexity of which is well known. It often happens, however that research in pharmaceutical laboratories tends to be oriented to criteria of profitability, either in developing drugs for treating widespread illnesses, or turning out products not significantly different from existing drugs, but having the advantage of relative novelty.

It would, however, be going too far to say that the numbers of drugs marketed was growing uncontrollably.In France, for example, the number of drugs has gone from 25,000 in 1930 to 8,500 in 1977 and, according to INSEE statistics, between 1971 and 1979 consumption of pharmaceuticals increased by only 7.1% in volume terms per year. It is the rising cost of hospitalization that accounts for the growth in health care expenditure, rather than strictly pharmaceutical expenses.

It remains the case, however, that the effort should be made to determine how the Community can play a guiding role in research, particularly in the less profitable fields such as rare diseases or tropical diseases in the developing countries.

2. Legal protection for pharmaceutical inventions

At present the period of legal protection under patent pursuant to the Munich Convention of 5 October 1973 on the issue of European patents and the Luxembourg Convention on European patents for the Common Market of 15 February 1975 is 20 years. This seemingly long period is in fact considerably shortened by lead times of up to 10 years that can elapse between discovery and sale of a product, given the growing number and severity of tests that must be carried out before a drug is marketed. If the period of exclusive rights is too short, the profitability of an invention is therefore considerably reduced, and this in turn inhibits the research effort.

The question therefore arises, given the special situation of the pharmaceutical sector, as to whether the EEC should introduce the so-called 'stop the clock' system now under study in the United States and consisting of suspending expiry of the 20-year period during the entire test period to a maximum of 7 years[1].

[1] PATENT RESTORATION ACT, 1981

This extra protection seems all the more indispensable in that, although the European Court of Justice can affirm the existence of the right of patent, the exercise of this right is often attenuated by the fact of the rules of free movement of goods and the exhaustion of patent rights, especially in the case of parallel imports. It is hardly acceptable that parallel importers should sometimes benefit from substantial windfall profits when they contribute nothing to the research effort.

3. Balanced production of pharmaceuticals, generic and mass-consumption products

Production breaks down into three main groups of products: pharmaceuticals, generic drugs and mass-consumption drugs, each of which meets a particular set of needs.

Pharmaceuticals, in the form of patented inventions essential to public health care,are certainly the major element in production and a sign of the competitivity of the industry.

However, by no means negligible, resources are devoted to the production of generic drugs, i.e. drugs that are now standard products and can be freely manufactured without a trade-name. It is certain that this sector of production has been unduly neglected for obvious reasons of profitability. Since they are sold at a lower price, having become a standardized product (approximately 30% cheaper) these products are evidently less attractive to laboratories and pharmacies. It would therefore be appropriate to give an impetus to the production of generic drugs in those cases where the same therapeutic effect can be obtained at a lower social-security cost. It would be wrong, however, to believe that demand could be satisfied by generic drugs alone; this would be to take a short-term view that would compromise future prospects in return for a purely financial immediate saving in public expenditure. To orient production exclusively on generic drugs would irreversibly compromise the future prospects and competitivity of the industry, and would be detrimental to health care in the long run.

The same problem arises with mass-consumption of 'family' products, as opposed to ethical products. The representatives of the industries stress the economies that this type of drug makes possible. Self-medication should not, however, be encouraged except within reasonable bounds, taking the level of information available to the user and the risk to health of drug abuse into account.

Careful consideration of the delicate subject of the balance in pharmaceuticals production, bearing in mind that the future as well as the present state of the industry is at stake, will be necessary to pinpoint the measures that will be needed in terms of advertising, training of medical practioners (who are often unaware of the existence of generic drugs), the control of drugs, their inclusion/non-inclusion in social-security reimbursement lists, and harmonization of regulations on compulsory prescriptions, if an optimum balance is to be obtained in the production of these three groups of drugs.

4. External trade policy for the pharmaceutical sector

The recent Commission communication on a strategy to develop Europe's industry[1] stresses that the Commission does not at present have any mechanism for promoting either exports or external investment. But the Community cannot be satisfied with separate initiatives and must try to step up coordination of its efforts. This general rule obviously applies to the pharmaceutical sector.

Clearly an effort should be made to step up exports of European pharmaceuticals to the USA and Japan.

As to the developing countries, the Community should approach the appropriate international organizations such as UNCTAD or WHO with a view to reconciling the needs of these countries, their requirements, and the pharmaceutical undertakings' concern for minimum stability and profitability. At present 80% of world pharmaceutical production is consumed in the industrialized countries and less than 20% in developing countries.

II. MARKET CONDITIONS

The success of a European strategy for the pharmaceutical industry that will help to maintain competitivity in the sector and meet public health requirements at lowest cost presupposes that the right conditions obtain to securing an open, transparent and orderly market.

1. The special situation of the market in pharmaceutical products

Without going into a detailed analysis of the special structure of the market in pharmaceutical products[2] it will be useful to recall some of the salient features.

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1 COM(81) 639 final 2, p.14

2 See report by Mr DE KEERSMAEKER, Doc. 664/78

By virtue of its considerable research costs, the sector displays a growing tendency to concentration. The pharmaceutical industry is characterized by the fact that a limited number of producers and products alone account for a very large part of the market[1].

This oligopolization and concentration of the industry under large transnational undertakings obviously entails the risks of a dominant position, the more so in that the prices of pharmaceutical products are highly inelastic.

It should therefore again be stressed that this structure makes it necessary for the Commission to pay particularly close attention to the observance of the rules of competition of the Treaties. And it does so; moreover, the judgments of the European Court of Justice in this field have been extremely consistent and a substantial body of case law is accumulating year by year.

However, the fairly unique and relative character of oligopolization in the pharmaceutical field must be stressed. In fact, dominant positions in this sector arise from the fact of the importance of innovation itself, an essential factor in competition, albeit a precarious one that is confined to a single product or a specific therapeutic area.

Moreover this situation is not necessarily prejudicial to public health since it stimulates research and leads to new inventions by competing companies in turn.

It is to be hoped nevertheless that the regulation on the control of concentrations will soon be adopted by the Council in the amended version that has just been submitted. This regulation could in fact play a useful role in guaranteeing the viability of the SMUs which, if not in the research sector, then at least in the production of generic and mass-consumption drugs, play an important role.

2. An open market

The relative uniqueness of the pharmaceutical sector is by no means an obstacle to the opening up of the market. As in other sectors of industry, it is essential for the European pharmaceutical industry to have the advantages of an effective European market.

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[1] In France the number of laboratories fell from 2,000 to 350 in the space of 30 years.

The Member States have too often maintained walled-off markets on the pretext of public health requirements. The application of Article 36 of the EEC Treaty, which has been diverted from its real objective, has often led, as Parliament's motion for a resolution (Doc. 1-243/80)[1] points out, to an actual reduction in health care standards, either because the opportunity for the entire population of the Community to use new and more effective products to treat disease is prevented or considerably delayed, or because products remain in circulation after some Member States have found them to be potentially harmful.

It will therefore be essential to pursue the objective of harmonizing national legislation governing undertakings on the initiative of the Commission as regards the production, authorization, registration and distribution of pharmaceuticals. Here, the recent Commission proposal for a directive on the mutual recognition of marketing authorizations[2] would constitute an important step in this direction, and the European Parliament can only ask the Council to adopt this proposal without delay.

It would also make a significant public impact in the Community if harmonization of legislation on the availability of drugs without prescription were to be introduced in the near future.

Similarly the Commission's recent proposal for a regulation establishing a Community trade-mark[3] should be adopted. Trade protection for the quality of a product during and beyond the protection provided by patent is indispensable, particularly in the health field. The existence of a Community trade-mark can only facilitate the exercise of this right in the Community as a whole, and would constitute a factor tending to the equalization of conditions of competition and the opening up of markets; it would of course be for the European Court of Justice to sanction any trade-mark or patent abuses leading to the walling-off of markets.

3. A transparent market

As a corollary of the condition of an open market, transparency is necessary both for observation of the rules of competition and in the interests of the consumer.

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1 Motion for a Resolution Doc. 1-243/80, third recital

2 Report by Mr von WOGAU, Doc. 1-246/81

3 COM (80) 635 final

The requirement of transparency should apply mainly on one technical side to the composition of pharmaceuticals, as a means of outlawing changes in composition having no real therapeutic value, or artificial changes in denomination that make monitoring of the market more difficult and heighten the danger of drug confusion.

Transparency must also apply with regard to parallel imports, which must be open to all importers provided they fulfil the required conditions set out in the Commission's communication[1], in order to forestall all efforts to monopolize trade in these products.

Finally, transparency will also be necessary from the fiscal point of view for multinational pharmaceutical undertakings, as for all multinationals. It is regrettable that the Commission has still not submitted any proposals on transfer prices, since this would be an indispensable mechanism for equalizing competition and rationalizing undertakings.

4. An orderly market

The formation of pharmaceutical prices is somewhat peculiar, since it results from interaction between a number of suppliers and one principle customer, namely the social security system, given the predominant role played by the public authorities in fixing prices and listing drugs as eligible for reimbursement. This results in considerable price disparities in the Community. Whether they are attributable to the non-observance of the rules of competition by producers, to the various national price fixing systems for pharmaceuticals, or to variations in the margins of wholesalers and pharmacists, these price disparities are unacceptable in terms of health protection and health improvement. Moreover, current price disparities, aggravated by exchange rate variations, act as an impetus to parallel import channels between Member States resulting in a flow of windfall profits primarily to the importer. Moreover when prices are too low, pharmaceutical research possibilities are reduced.

It is regrettable that the requests made by Parliament in its previous resolution[2] have resulted in hardly any action being taken.

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[1] COM(81) 803 final

[2] Report by Mr DE KEERSMAEKER, Doc. 664/78, paragraphs 8, 9, 10 and 11

(a) Study of the compatibility of different national pharmaceutical price monitoring systems with the EEC Treaty

As the Commission points out[1], fixing a price which is too low or excluding a drug from reimbursement constitute as effective a barrier as the refusal of a marketing authorization. The Commission has not yet reported to the European Parliament on the study it was asked to provide of the compatibility of the different national pharmaceutical price monitoring systems. This omission is regrettable, and the Commission, in addition to its specific projects in this field, should inform the European Parliament on developments as a whole, and make whatever proposals it deems necessary.

(b) Coordination with national authorities responsible for price monitoring

The European Parliament had also asked the Commission to study ways in which coordination with national authorities responsible for price monitoring could be organized. In response, the Commission set up a group of experts on drug prices which met infrequently and irregularly[2]. This committee recognized the need for information exchanges, cooperation between the authorities at Community level, and harmonization of national systems. More determined action in this field is obviously necessary.

## III. GENERAL FEATURES OF DRUG USE

A pharmaceutical is more than just another product. Its cost can have a considerable impact on public expenditure through the social security system, and while ill-considered drug use can be dangerous to health, in certain cases self-medication can be highly desirable. The basic features of drug use therefore merit serious attention, since they are an integral part of a European pharmaceuticals policy geared to improving public health, an implicit objective of the EEC Treaty.

### 1. Training of medical practitioners

The prescription of drugs in large numbers and for prolonged periods should require more intensive training for medical practitioners than they generally receive. At Community level it would be appropriate to envisage post-graduate training in therapeutic techniques and drug control so as to enable Community doctors to acquire the necessary expertise and benefit periodically from follow-up courses.

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[1] Proposal for a Directive COM(80) 789 final, p.5

[2] The last meeting of the group was held on 21 November 1980. A CREDOC study at the request of the Directorate-General for the Internal Market concerning comparisons of the prices of pharmaceutical products in EEC countries will also be published shortly.

The inadequacy of present training entails the risk of ineffective excessive or contradictory prescriptions, and of drug-induced illness. The development of data banks on drugs, readily accessible to practitioners, would also be of considerable value.

2. User information

There should also be improvements in the information available to drug users. Here the request made in Parliament's motion for a resolution (Doc. 1-817/80)[1] for the Commission to submit a proposal on a well-conceived information and education campaign covering the proper use of pharmaceutical products and the limits to be placed on their use should be reiterated. However, to be effective, any such campaign would need to be sufficiently decentralized and take account of the varying attitudes from one Member State to another of drug users to drugs or to certain types of drugs.

3. Monitoring of distribution methods

The distribution of pharmaceutical products is frequently criticised. A study of current commercial practices in this sector should be carried out in order to identify the abuses and eliminate waste due to excessive use of pharmaceutical products, harmful side effects and the extra burden on social security systems.

In its previous resolution[2] Parliament asked the Commission to submit as soon as possible an amended proposal on information and advertising in the pharmaceutical industries. The same request was also made in Lord KENNET's report[3] on a directive on the approximation of legal provisions in the Member States on unfair and misleading advertising.

The Commission's delaying tactics in this field should cease and a specific proposal on misleading advertising of pharmaceuticals should be submitted.

As to information disseminated by pharmaceutical company representatives, it appears that this remains indispensable at present levels of training of medical practitioners. However, improvements in post-graduate training of doctors in therapeutic techniques and drug control, together with easier access to data banks, could reduce the scope for this type of information in future. Abuses by medical laboratories, in particular

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1 Doc. 1-817/80, paragraph 11

2 Report by Mr DE KEERSMAEKER, Doc. 664/78, resolution paragraph 14

3 Report by Lord KENNET, Doc. 36/79, resolution paragraph 3

the dubious practice of sending gift packages[1], should at all events be severely condemned, and it will be primarily for the Member States to take appropriate counter measures under national legislation.

4. Self-medication

Finally, a strong case can be made for self-medication. The advantages of self-medication are manifest: simplicity, lower cost, prophylactic effect. But the risks should not be under-estimated. Self-medication presupposes a minimum of information and understanding on the part of the user, and should in no circumstances be a substitute for prescription by a medical practitioner. A Commission study of the advantages and disadvantages of self-medication, the standards that should be applied in this sector, and specific rules of advertising would be welcome. In general, the Community should have access to harmonized and full statistics in the pharmaceutical sector as an indispensable tool in providing regular and accurate information on the use of pharmaceuticals and the impact on public health.

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[1] Written question No. 1710/80 on marketing techniques in the pharmaceutical sector - OJ No. C 78, 6.4.81, p.19; Written question No. 1709/80 on the boycotting of non-proprietary medicines, OJ C 78, 6.4.81, p.18.

ANNEX I

MOTION FOR A RESOLUTION DOCUMENT 1-243/80

tabled by Mr GHERGO, Mr DEL DUCA, Mr SASSANO, Mr DALSASS, Mr BARBAGLI, Mr NARDUCCI, Mrs SCHLEICHER and Mrs CASSANMAGNAGO CERRETTI

pursuant to Rule 25 of the Rules of Procedure

on the state of implementation of the EEC directives on proprietary medicinal products and measures to be adopted for the free movement of pharmaceuticals between Member States

The European Parliament,

- whereas one of the primary aims of the Community is by appropriate measures to ensure the free movement of goods between Member States by removing barriers, including non-tariff barriers, which may constitute a de facto obstacle to the export and import of products,

- whereas the effective application of these principles in the field of pharmaceutical products has so far been seriously hindered by the application of the derogations provided for under Article 36 of the Treaty of Rome relating to the protection of health and life of humans,

- whereas, in contrast with the principles underlying the provisions of Article 36 of the Treaty of Rome, the application of these derogations in the pharmaceutical field often leads to an actual reduction in the protection of health, either because the opportunity for the entire population of the Community to use new and more effective products to treat diseases, is prevented or considerably delayed or because products remain in circulation in some Member States after other Member States have found them to be potentially harmful,

- whereas Article 100 of the Treaty of Rome provides a means of overcoming these barriers by the harmonization of national legislation,

- whereas the Council has so far adopted four important directives in the pharmaceutical sector covering inter alia the procedures for bringing

products on to the market, the standards and technical documents required for proprietary medicinal products, the labels and instructions for use of these products and the setting up of the Committee for Proprietary Medicinal Products,

- having particular regard to the important role of this committee in implementing Article 14 of Directive 75/319 regarding consultations at Community level by individual Member States before they reach a decision on a marketing authorization for a medicinal product or its revocation,

- whereas, under Article 15 of Directive 75/319, the Commission has to submit proposals to the Council by the end of 1980 containing all appropriate measures leading towards the abolition of any remaining barriers to the free movement of proprietary medicinal products, and whereas it would be extremely desirable for these proposals to be given their first consideration at the next meeting of the Council of Ministers of Health,

- noting that the obstacles to the free movement of medicinal products affect the availability of some products which are needed to treat serious, though perhaps rare, diseases, since the limited size of the market and of consumption does not encourage research and experimentation into such substances nor their production,

- recognizing, therefore, the need to remove the barriers which have arisen to the free movement of proprietary medicinal products,

- recognizing also the need for the European Parliament, as the expression of popular will in the Member States, to be better informed about all the issues concerned with the free movement of these products, in view, for example, of the close links this has with the protection of health,

1. Requests the Commission to submit a full report at the earliest opportunity on the state of implementation of the directives which have already been adopted in the pharmaceutical sector, giving particular attention to any difficulties or obstacles which may have arisen in the operation of the Committee for Proprietary Medicinal Products;

2. Considers that further measures need to be taken in this area so as to permit the free movement of pharmaceuticals within the Community even if this has to be done in stages;

3. Considers that to this end further steps must be taken towards the harmonization of Member States' legislation on the production, authorization-registration and distribution of proprietary medicinal products;

4. Considers that, as part of this general process, measures should be adopted as a matter of urgency to make Community action more effective in regard to decisions taken by the Member States on authorizations for proprietary medicinal products or revocations thereof particularly where there are good grounds for believing that products may be harmful;

5. Identifies as one of the first measures to be adopted - until such time as liberalization is achieved and as part of the progress in stages referred to above - a directive to permit the free movement within the Community of medicines required for the treatment of serious, but rare diseases, by including them on a special, limited list of products to be drawn up and brought regularly up to date by the Commission with the aid of specialized advisory technical bodies;

6. Requests the Commission in conclusion to draw up with the greatest possible urgency suitable proposals on the subjects indicated above, so as to allow Parliament to express its opinion on them and the Council to adopt at the earliest possible time the relevant measures which should have a binding force on the Member States.

MOTION FOR A RESOLUTION DOCUMENT 1-817/80

tabled by Mrs KROUWEL-VLAM, Mr COLLINS, Mrs SEIBEL-EMMERLING, Mr ADAM, Mrs FUILLET, Mr MUNTINGH, Mr O'CONNELL, Mrs ROUDY, Mrs WEBER

on behalf of the Socialist Group

pursuant to Rule 25 of the Rules of Procedure

on the production and use of pharmaceutical products

The European Parliament,

- whereas the right to optimum health care is a fundamental right,

- whereas public health falls with the scope of the Treaties

- whereas it is the task of Member States and the Community to provide themselves with structures guaranteeing the best possible health care,

- whereas the growing use of pharmaceutical products leads to high costs for social security systems,

- whereas pharmaceutical production is in the hands of a few large undertakings which occupy a dominant position and make enormous profits at the Community's expense,

- whereas the Community directives adopted on this subject chiefly concern the free movement of pharmaceutical products, which is, however, still seriously impeded by technical barriers to trade,

1. Is concerned at the uncontrolled increase in the number of pharmaceutical products being put on the market and the variety of forms in which they appear, without any evidence that this quantitative increase is producing a perceptible improvement in the quality of health or health protection;

2. Considers that measures need to be taken against the overconsumption of pharmaceutical products due to commercial practices, in particular advertising by pharmaceutical laboratories, so as to prevent the wastage, harmful side effects and extra burden on the social security systems;

3. Stresses the need for a transparent market for pharmaceutical products by means of quality and price controls in order to put a stop to excessive profits;

4. Points out the existence of, and trade in, illegally imported products and urgently requests the Commission to start the necessary investigation and to take effective action;

5. Is of the opinion that the price of pharmaceutical products ought not to be allowed to become a social obstacle to the right to optimum health care;

6. Stresses therefore the need for the strict application on the rules of competition;

7. Recalls the need to reorientate policy regarding pharmaceutical products so that industrial interests are no longer the only matter to which importance is attached but also coordination between pharmaceutical laboratories, private and government research institutes and the doctors concerned, in the interests of the consumer;

8. Urges the rapid harmonization and raising of standards in registration of pharmaceutical products so that the differences between Member States as regards what products are available on or off prescription cease to exist;

9. Is of the opinion that the consumer is entitled to verified information on the packaging and enclosures;

10. Requests the Commission to proceed without delay with its proposal on misleading advertising for pharmaceutical products;

11. Considers it essential that a proposal be received from the Commission in the near future on a well-conceived information and education campaign covering the proper use of pharmaceutical products and the limits to be placed on their use;

12. Urges that more attention be paid to the points mentioned above in training and further training courses for doctors, nursing staff and pharmacists, so that all persons using or prescribing medicines have available all the necessary information on the therapeutic value of the products proposed to them;

13. Deplores the way in which many pharmaceutical companies, through their medical representatives, frequently see fit to offer their products for sale to doctors by means of samples, gifts and loans, and calls on the Commission to draw up a proposal designed to prevent the use of these improper sales practices in the various Member States;

14. Considers that pharmaceutical products exported to developing countries must satisfy the same safety and quality standards as those applicable in the Member States of the Community;

15. Instructs the Commission to harmonize the statistical information completely and to analyse this in a report on the pharmaceutical sector, so that a sound overall picture may be gained of the consumption of pharmaceutical products and the consequences thereof for public health.

## OPINION

of the Committee on the Environment, Public Health and Consumer Protection

Draftsman: Mr SHERLOCK

On 12 March 1981 the Committee on the Environment, Public Health and Consumer Protection appointed Mr SHERLOCK draftsman.

The draft opinion was considered at its meetings of 25 May and 23 June 1982 and adopted unanimously on 23 June 1982.

The following took part in the vote: Mr Collins, chairman; Mr McCartin, vice-chairman; Mr Johnson, vice-chairman; Mr Sherlock, draftsman; Mr Bombard, Mr del Duca, Mr Forth, Mr Ghergo, Mrs Krouwel-Vlam, Mrs Lentz-Cornette, Mr Muntingh, Mrs Schleicher, Mrs Seibel-Emmerling, Mrs Spaak, Mrs van Hemeldonck and Mr Verroken (deputizing for Mr Alber).

## I. INTRODUCTION

1. The Committee on the Environment, Public Health and Consumer Protection has been asked for its opinion on the production and use of pharmaceutical products in the Community as a result of the motions for resolutions submitted by Mr Ghergo and Mrs Krouwel-Vlam pursuant to Rule 25 (Doc. 1-243/80 and 1-817/80).

2. In the case of Mr Ghergo's motion for a resolution the committee has already set out its position during consideration of the amendments proposed by the Commission to Directives 65/65/EEC, 75/318/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (see Doc. 1-246/81/Ann.).

3. As regards the motion for a resolution by Mrs Krouwel-Vlam, the committee would like to point out that the above-mentioned directives on medicinal products in the European Community already govern the following:

a. conditions for the granting, suspension and withdrawal of authorizations for the marketing of proprietary medicinal products;

b. the conditions with which each product for which an authorization is granted must comply;

c. the specifications for testing and investigating applications for authorizations for the marketing of proprietary medicinal products;

d the specifications for labels and accompanying information;

e the tasks of the public authorities responsible for checking and supervision;

The Council Decision of 10 May 1978 (78/319/EEC) provided for the creation of a Committee on Proprietary Medicinal Products to guarantee cooperation between appropriate national authorities and the Council Decision of 20 May 1975 (75/320/EEC) provided for the creation of a Pharmaceutical Committee made up of senior civil servants from the Member States whose job it is to advise the Commission on general questions concerning proprietary medicinal products.

## II. PRODUCTION AND USE OF MEDICINAL PRODUCTS

5. The Committee on the Environment, Public Health and Consumer Protection would like to start by recalling its frequently expressed view that any regulation concerning the production and distribution of medicinal products must have as its prime aim the protection and fostering of public health, even though the industrial and commercial aspects may be very influential.

6. The committee takes it as read that medicinal products must be as effective as possible, have the minimum negative effects and be as economical as possible. Without going into greater detail on this point, it seems obvious to the committee that these three objectives cannot be achieved without sufficient encouragement of the necessary scientific research.

7. Consequently we should also recall the meeting of 16 November 1978 of the Council of Ministers of Health which noted with interest the three studies carried out by the Commission on the cost of health services. One of these concerned the consumption of pharmaceutical products and was compiled by Mr B. Abel-Smith and Mr P. Grandjeat[1].

8. The remarkable study contains three important findings for the present debate:

a. that during the period under review (1966-1975) there was a decrease in the total consumption of prescribed pharmaceutical products expressed as a proportion of total health service costs in seven Member States (no statistics were available for Ireland and Belgium) (Annex 1);

b. that an unusually large disparity was ascertained in the average number of medicinal products prescribed per person per annum which varied from 4.5 in the Netherlands (1974) to 21.5 in Italy (1975) (Annex II, Table II);

c. the following reasons were given for the increase in the cost of pharmaceutical products:
   - population growth
   - expansion of health insurance schemes
   - change in the population age pyramid
   - changes in production and distribution costs
   - the replacement of older medicinal products by newer, more expensive ones
   - changes in the number of consultations
   - changes in medical practice.

9. Taking account of these elements and the fact that supply and demand is anything but transparent in the pharmaceuticals sector, and that market splitting and sometimes a great divergence in prices are more in evidence than a common market, the Committee on the Environment, Public Health and Consumer Protection believes that there is every justification for further investigation of the situation.

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[1] Studies: Social policy series 1978 - N° 3

10. It therefore asks the committee responsible to recommend the following in its report:

a. an investigation into whether the trends in the pharmaceuticals sector ascertained for the period 1966-1975 also apply to the period 1976-1981;

b. an investigation into how a start can be made on the sale of medicinal products under generic names, so as to benefit consumers in terms of both price and availability;

c. in view of very divergent national views, an appraisal of whether a sectoral directive on advertising of pharmaceutical products is necessary;

d. [illegible] products which the patient can buy freely (self-medication) and those which should be strictly subject to prescription;

e. a guarantee that, in promoting the free movement of pharmaceutical products, the element of protection of public health should not be lost by allowing possibly less stringent legislation on the admissibility, supervision or prohibition of certain medicinal products or conflicting decisions on the approval of dosages, instructions and contra-indications for medicinal products;

f. an investigation into ways of curbing excessive consumption;

g. an investigation into whether a European information and action programme on the prescription and use of medicinal products could improve public health and save costs;

h. an investigation into what results from the Council of Europe's deliberations could be used in European legislation;

i. a request to the Commission to report each year on progress in the harmonization of pharmaceutical products;

j. an instruction to the Commission to work out a system whereby the statistical information on the costs and use of pharmaceutical products in the Member States can be compared

CONCLUSION

11. The Committee on the Environment, Public Health and Consumer Protection believes that, with a view to the realization of a common market in the interest of public health, the question of the production and use of pharmaceutical products, which naturally has considerable financial implications, calls for considerable further investigation and is in fact too dependent on the different social security schemes in the Member States. At the same time it believes that existing Community provisions must be amplified in the near future to cover the mutual recognition of more stringent national decisions,

common names for pharmaceutical products, a methodology for the compilation of statistics, self-medication and proper information on the use of medicines.

Estimates of total consumption of prescribed pharmaceuticals (including tax) as a percentage of estimates of the current cost of health services (1) (including tax) - EEC 1966-1975

Percentages

| | Denmark | Germany | France | Italy(2)(3) | Luxembourg(2) | Netherlands(4) | United Kingdom (England & Wales only) |
|---|---|---|---|---|---|---|---|
| 1966 | 12.6 | 14.3 | 24.3 | 51.1 | 39.2 | - | 12.4 |
| 1967 | 12.9 | - | 24.5 | 49.4 | 39.6 | - | 12.3 |
| 1968 | 12.8 | 15.6 | 24.8 | 49.7 | 39.8 | - | 12.0 |
| 1969 | 12.5 | - | 24.2 | 47.4 | 40.1 | - | 12.1 |
| 1970 | 12.0 | 16.0 | 24.3 | 42.6 | 34.7 | (11.0) | 11.8 |
| 1971 | 12.0 | - | 24.4 | 39.9 | 38.1 | - | 11.8 |
| 1972 | 11.8 | 14.9 | 23.8 | 37.8 | 36.6 | (11.0) | 12.0 |
| 1973 | 10.9 | - | 22.7 | 38.6 | 36.0 | (10.6) | 11.8 |
| 1974 | 10.4 | 13.9 | 21.8 | 28.9 | 34.2 | ( 9.9) | 10.9 |
| 1975 | 10.6 | 13.3 | 21.0 | 34.5 | 26.1 | ( 9.7) | 10.5 |

(1) Excludes products made up by pharmacists

(2) Includes cost of hospital pharmaceutical departments in whole or part

(3) Includes only registered products in the case of non-prescription medicines

(4) Excludes drugs prescribed in hospital.

Doctors per 10.000 population, average prescription items per person per year, and pharmaceutical consumption as a proportion of the cost of health services

| | Doctors per 10,000 population (1) (1975) | Prescription Items Per Person per year under Health Insurance or the Health Service (1975) | Pharmaceutical Consumption as a Percentage of Cost of Health Services (1975) |
|---|---|---|---|
| Netherlands | 16.0 | 4.5 (1974) | 9.5 (2) |
| United Kingdom (England & Wales) | 13.1 | 6.3 | 13.8 |
| Denmark | 16.2 (1972) | 6.9 (1976) | 11.7 (1974) |
| Belgium (3) | 18.9 | 9 | 19.5 |
| France (3) | 14.7 | 10.5 | 25.5 |
| Germany | 19.4 (1974) | 11 (1973) | 18.8 (1974) |
| Italy (3) | 19.9 (1973) | 21 (4) | 34.6 |

(1) Sources - WHO, Annual Statistical Summaries 1965 and 1977

(2) Only covers prescription drugs outside hospital

(3) Including doctors practicing dentistry of specialists in odontology

(4) For doctors paid on fee-for-service basis