COMMISSION OF THE EUROPEAN COMMUNITIES

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Proposal for a

COUNCIL DIRECTIVE

relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion within the scope of the national health insurance system

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(submitted to the Council by the Commission)*

EXPLANATORY MEMORANDUM AND REPORT TO THE COUNCIL

on the transparency of measures regulating the pricing of medicinal products for human use and their inclusion within the scope of the health insurance system and on future Community activities in this field

I. GENERAL CONSIDERATIONS

1. The nature of national controls

Within the Community, only about 20% of medicinal products, in terms of value, are directly purchased by the consumer. The remainder are prescribed by a physician and the whole or part of the cost is met by the public authorities through the national health insurance system. Expenditure on pharmaceuticals represents between 10% and 20% of national health care expenditures. In these circumstances, all the Member States have adopted measures to control public expenditures on pharmaceuticals, and in recent years, with the onset of the crisis within the national social security systems, the general trend has been towards the intensification of controls. However, the nature and severity of the controls differs considerably between the Member States.

In five Member States, Belgium, Greece, Spain, Italy and Portugal, a new medicinal product can only be marketed after the national authorities have agreed the price of the product. In these Member States and in France, strict controls are exercised on the range of products covered by the health insurance system, and in general, a new product will not be admitted to the list of products eligible for reimbursement unless the authorities are satisfied that it

offers a significant financial or therapeutic advantage over existing therapies. Moreover, in several of these countries the price of medicinal products already on the market has been subject to freezes and the increases allowed have been less than the level of inflation.

In the United Kingdom, although manufacturers are generally free to set prices for individual products, the overall profits made by firms in their dealings with the national health service are controlled. The authorities have recently introduced a system of "selected lists" which allows for the exclusion from the health insurance system of more expensive products falling within seven therapeutic groups, if cheaper alternatives are available.

In the Netherlands, the price of new medicines is not controlled, although price increases are. Moreover, as in the case of Denmark, provision is made for the exclusion of more expensive medicines from the scope of the health insurance system if cheaper alternatives are available.

In Germany, the price of medicines is uncontrolled, and there is no possibility of excluding products from the health insurance system on the grounds that cheaper alternatives are available. However, in order to make financial savings, a number of therapeutic categories have been entirely excluded from coverage by the health insurance system.

Ireland and Luxembourg are largely dependant on medicines imported from neighbouring countries and prices are fixed by reference to the prices prevailing in those countries, plus an appropriate margin to cover the costs of importation.

It should be noted that, even in those Member States where prices are not directly controlled, pharmaceutical companies will be subject to supervision by the national and Community competition authorities. Moreover, several Member States have attempted to sensitize doctors to the cost of the medicines they prescribe by transparency lists or national formularies, and in some countries there is a system of direct monitoring of doctors prescribing habits.

2. Their effect on the common market

The disparities which exist in the national systems of price and social security reimbursement controls clearly affect intra-Community trade in medicinal products. In fact a survey of pharmaceutical prices carried out by the Statistical Office of the European Communities in 1983 found the existence of wide differentials in the prices of pharmaceuticals between the Member States (TABLE I), and this has been confirmed by two recent studies carried out for the Commission by the Economists Advisory Group[1] and the European Bureau of Consumer Unions[2]. Moreover, the recent increase in the volume of parallel importing of medicinal products into certain Member States itself provides empirical evidence of the existence of wide price differentials for individual products within the Community. On various occasions, the European Parliament, certain Member States, the pharmaceutical industry and consumer groups have all criticised the variations in the prices of medicinal products which exist and the distorting effect which they have on intra-Community trade, albeit from different perspectives.

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[1] The Community's Pharmaceutical Industry, 1985

[2] The Consumer and Pharmaceuticals in the E.E.C., 1984

Decisions to exclude products from the scope of the national health insurance system also effect intra-Community trade, since, in practical terms, a decision to exclude a prescription only drug in this way may be tantamount to its exclusion from the national market.

3. The industrial policy dimension

Hitherto, the European pharmaceutical industry has enjoyed a strong competitive position on world markets and its record of innovation has been good. Recent scientific developments, in particular in the field of biotechnology, hold out the prospect of entirely new perspectives for pharmaceutical research with the possibility of offering effective treatments for hitherto incurable diseases, of offering better treatments for existing diseases with fewer side effects, or of replacing surgical intervention by drug therapy. However, pharmaceutical research is also becoming longer and costlier. At the present time it takes 8 - 10 years to develop a major innovatory product and complete all the tests and trials required, at a total cost of 50 - 100 million ECUs. This research and development expenditure is primarily financed by the industry itself, which devotes 10-15% of its turnover to it.

This phenomenon presents the national authorities with a dilemma since it is clear that the single-minded pursuit of short-term financial economies will effectively undermine the research capacity of the pharmaceutical industry. At the present time, therefore, each Member State must balance the objective of controlling public expenditures on pharmaceuticals against the objective of maintaining a competitive research-based pharmaceutical industry. Hitherto, the reconcilation of these two policy objectives has taken place at national level. Some countries, with a well-established domestic pharmaceutical industry, have adopted policies which are broadly favourable to the development of pharmaceutical research. Other countries, particularly those who are more dependant on pharmaceutical

imports, have tended to give a higher priority to the need for savings. However, in recent years, some of the countries with strict price control systems have recognised the need to encourage pharmaceutical research, and a variety of schemes have been developed for this purpose. Inevitably, such schemes have been developed by reference to national perspectives and they are not always easy to reconcile with the fundamental principles of the EEC Treaty relating to the free movement of goods or to fair competition. There is therefore an urgent need for a Community strategy which will reconcile the need to ensure that reasonable prices are paid for medication with the need to encourage the development of a research-based pharmaceutical industry in Europe.

4. Other disparities in the market for pharmaceuticals

The existence of national systems of controls on the prices charged by the manufacturers of medicinal products and of limitations on the range of medicinal products covered by the health insurance system is undoubtedly a major cause of the price differentials which currently exist. However, other factors are also important. At the present time the market for pharmaceuticals within the Community is characterised by a remarkable degree of diversity. Like prices, levels of pharmaceutical consumption also differ considerably between the Member States (TABLE I). Germany, with arguably the highest prices in the Community, also has the highest consumption rate, at $ U.S. 90 per capita. However, three countries with low prices also have high consumption rates in money terms, France ($ U.S. 80 per capita), Belgium ($ 67 per capita) and Italy ($ 56 per capita). In contrast, three countries with comparatively high prices have relatively low consumption rates in money terms, Netherlands ($ 35 per capita), Denmark ($ 38 per capita) and the United Kingdom ($ 51 per capita). These figures suggest the existence of considerable variations of consumption in volume terms.

Similar differences are reflected in the statistics available for consumption by therapeutic group. Thus, in money terms, the systemic antibiotics accounted for 20% of Greek pharmaceutical consumption, but only 3% of German pharmaceutical consumption in 1982. Medicines affecting the central nervous system, including analgesics and psycholeptics, took 7% of the market in Italy, and 22% of the Danish market[3].

It would be difficult, if not impossible, to know how these differences in consumption rates would affect price formation in the absence of controls. However, it does seem reasonable to presume that such differences will be reflected in the prices Member States allow to be charged for medicinal products, and in particular how an allowance for research and development costs is to be reflected in the price of a specific product.

Another factor which is important when considering differences in the resale price of medicinal products between the Member States are the differences in taxes, and in the margins allowed for wholesalers and retail pharmacists. Thus in 1984, the retail price of a medicinal product with an ex-factory price of 10 D.M. would have varied between 16.10 D.M. in Italy and 22.10 D.M. in Denmark. The effect of such differences on intra-Community trade is, however, much less, and the Commission does not envisage presenting proposals on the manner in which pharmacists are remunerated in the different Member States.

5. The objectives of Community legislation

Following the adoption of five substantive directives[4], considerable progress has been made towards the elimination of

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[3] Economists Advisory Group, The Community's Pharmaceutical Industry, 1985

[4] Council Directive 65/65/EEC, O.J. No. 22, 9.2.65, p. 369/65
Council Directive 75/318/EEC, O.J. L 147, 9.6.75, p. 1
Council Directive 75/319/EEC, O.J. L 147, 9.6.75, p. 11
Council Directive 78/25/EEC, O.J. L 11, 14.1.78, p. 18
Council Directive 83/570/EEC, O.J. L 332, 28.11.83, p. 1

barriers to trade resulting from national public health legislation designed to ensure the quality, safety and efficacy of medicinal products. In accordance with the White Paper on the Internal Market, proposals to eliminate the remaining barriers to trade will be presented by 1989. As the free movement of medicinal products becomes easier, the effects of national price controls are no longer confined to the Member State in question. In recent years a significant parallel trade in pharmaceutical products has developed, with products purchased in the lower price countries being imported into the higher price countries and sold there, sometimes at substantial discounts.

The fundamental aims of Community legislation on price controls and the social security reimbursement of pharmaceuticals should be two-fold.

The first aim must be to ensure that the measures taken by Member States to control pharmaceutical expenditures do not pose a barrier to the creation of a genuine internal market for the pharmaceutical sector by 1992. However, the realisation of the internal market is not an end in itself but the means to the creation of a more favourable environment for stimulating enterprise, competition and trade. As the White Paper "completing the Internal Market" points out, the Commission's approach

> "(...) must aim not simply to remove technical barriers to trade, but to do so in a manner which will contribute to increasing industrial efficiency and competitiveness, leading to greater wealth and job creation" (paragraph 62).

Secondly the Commission considers it important to ensure that Community activity in this sector takes account of the specific need to encourage the future development of the innovatory pharmaceutical industry, while making appropriate provision to ensure that the industry does not make excessive profits in its dealings with the national health services. This is not merely an

economic objective. The maintenance of a high level of public health within the Community will to a large extent depend on the activities of the Community's own pharmaceutical industry. It will not be in the interests of the European patient to become dependant on research conducted in third countries.

In addition, any Community legislation should also contribute towards the realisation of the other objectives of the Treaty in the pharmaceutical sector, in particular the full application of the Treaty rules on competition within the common market (in particular Article 5 in connection with Articles 85 and 86). It must also take properly into account the needs of the Member States in ensuring the availability of an adequate supply of medicines at a reasonable cost for their citizens.

6. A progressive approach

Preceding sections of this note have shown that at the present time there is no consensus on the proper role of the public authorities in regulating pharmaceutical pricing and reimbursement. In certain Member States, very interventionist techniques are used and state regulation has substituted itself for competitive forces. In other Member States, greater reliance has been placed on the effects of competition in restraining price increases. The Commission considers it would be premature at present to propose the full scale harmonisation of national price control and health insurance measures. Instead, the Commission envisages a progressive approach to the problem.

In the first instance, it is considered necessary to ensure that the fundamental principles of the EEC Treaty are fully respected in the operation of national price control and health insurance systems. In its recent Communication on the compatibility with Article 30 of the EEC Treaty of measures taken by Member States relating to price controls and reimbursement of medicinal products, the Commission has explained the conclusions which it has drawn

from the relevant jurisprudence of the Court of Justice. However, it appears desirable to supplement this jurisprudence with certain rules of positive law designed to ensure that national price control and reimbursement systems operate in a fair and transparent manner. The Commission has therefore adopted a proposal for a Council Directive relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion within the scope of the health insurance system. The objectives and content of this proposal are described in Section II.

In addition, the Commission considers that it is necessary to consider the partial approximation of national measures in order to orientate them towards systems which have a less disruptive effect on the operation of the common market and take into account the legitimate industrial policy objectives of the Community as a whole. The Commission intends to engage in a round of intensive consultations with interested parties in order to better define the methods by which these objectives might be achieved. As a basis for discussion, and without in any way prejudicing any future proposals which it might make, the Commission has taken this opportunity to set out several initial reflections on this matter in Section III.

II. THE PROPOSAL FOR A TRANSPARENCY DIRECTIVE

1. Objectives

If the Community's pharmaceutical industry is to remain competitive, it must be protected from discrimination within its own internal market. The Commission's experience in investigating complaints that national measures infringe the free movement of goods rules of the Treaty suggests that there is a lack of transparency in the manner in which the national systems are applied. The "rules of the game" are not clearly defined so that

it is difficult to foresee how a given product will be treated, and even after a decision has been taken, manufacturers are not always sure of the real reasons for that decision. Moreover consumer groups and Members of the European Parliament have criticised the absence of transparency within the pharmaceutical sector.

The basic objective of the proposal for a directive is therefore to enable all concerned to verify that the requirements of Community law are being respected by laying down a series of rules relating to time-limits, the reasoning and publication of decisions, etc., which would be directly effective so that those concerned can defend their interests before the national courts. In addition, the proposal provides for cooperation at Community level. The correct implementation of these provisions will make it easier to detect abuses, whether on the part of industry or the Member States, and will therefore make a limited although significant contribution towards improving the operation of the Common Market in this sector.

In two important cases[5], the Court of Justice has provided guidance on the application of Articles 30-36 of the EEC Treaty to national price control and reimbursement measures affecting medicinal products. The Commission has explained the conclusions it has drawn from this jurisprudence and has explained the policy it will adopt towards allegations of infringements in the Communication referred to above. It is important to emphasise that the present proposal is intended to complement this body of pre-existing law. It is not intended to, and indeed cannot derogate from these fundamental principles. In presenting this proposal, the Commission reserves the right to commence proceedings under Article 169 of the EEC Treaty or to pursue such proceedings as have already been opened against Member States which in its view have failed to fulfil the obligations incumbent upon them in this sector under the EEC Treaty.

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[5] Case 181/82 Roussel /1983/ ECR 3849.
Case 238/82 Duphar /1984/ ECR 523.

A proposal to increase the transparency of national procedures relating to price control and reimbursement of medicinal products must necessarily relate primarily to the obligations of Member States during the decision-making procedure. However, it should not be thought that all the obligations lie on the one side only. If any system of price or reimbursement controls is to operate fairly, it is incumbent upon the manufacturer to provide such information as the authorities may reasonably request and to engage in an open dialogue in which each side takes account of the needs of the other. Thus the proposal requires manufacturers to give reasons for the prices they wish to charge.

2. Price controls on individual medicinal products

In countries where the marketing of a new medicinal product is permitted only after the competent national authorities have approved the price for that product, the following rules would apply. The manufacturer would be obliged to notify the authorities of his intention to market a medicinal product, indicating the price at which he proposed the product be sold and providing appropriate information in support of his proposal. The competent authorities concerned would be required to reach a decision on this notification within 90 days of its receipt. Should the authorities reject the price proposed by the firm, they would be obliged to give a detailed statement of reasons. There would be a right of appeal. Analogous provisions would apply in countries where the price of medicinal products can be increased only with the approval of the authorities.

3. Price freezes

Long term price freezes can have a particularly disruptive effect on the operation of the common market, because they prevent differences in relative inflation rates and currency movements from being reflected in the price of products. The Commission is therefore proposing that in the event of a general freeze on

pharmaceutical prices, the Member State concerned should be required to review and if necessary adjust the overall level of pharmaceutical prices at least once a year, or whenever the national resale price index has increased by 10% since the last review. In addition, any firm should be able to submit an application for a derogation from the freeze and be entitled to a decision from the competent authorities within 90 days.

In reviewing prices, Member States will wish to take a wide variety of factors into account, including not only the economic indicators referred to above but also such factors as changes in the market situation and the gains in efficiency which might be expected.

4. Profit controls

When a Member State resorts to a system of controls on the profitability of pharmaceutical firms, it does not specify a single target rate of profit which is applicable to all companies operating within the sector. The rate of profit allowed is variable, with somewhat higher profits being given to firms which engage in successful pharmaceutical research or which increase their efficiency. Thus the target rate of profit for each firm is fixed individually. Since the rate will depend on such factors as the investment programme of the firm, and its research and development activities, there is a strong body of opinion which suggests that individual profit rates must be confidential. Nevertheless, the Commission considers that it is incumbent on Member States who operate such a system to publish certain information each year so that each company can verify that it is being fairly treated. This information should include the average target profit for the industry as a whole for the year in question, and the minimum and maximum rates, and the criteria used in deciding on the target rate for each firm.

5. Social Security Reimbursement

As noted above, in certain Member States a medicinal product will not be available under the national health insurance system unless it has been included in a positive list, while in other Member States negative lists of products excluded from the scope of the national health insurance system are used.

Where a system of positive lists is used, the Member States should ensure that decisions are reached on applications within 90 days. As the Commission has stated in the Communication, decisions to exclude products from reimbursement must be verifiable by every importer. This means that reasons must be given for national decisions. "When the reason given for exclusion relates to the existence on the market of other products having an equivalent therapeutic effect, the decision must name these products, give their prices and details of the dosage and duration of treatment used to compare prices." Moreover, decisions "must be notified to the firms concerned with an indication of the means of redress open against such decisions and the time-limits within which appeals must be made". Analogous provisions are laid down for a system of negative lists.

6. Classification of products eligible for reimbursement

The classification of medicinal products presents particular difficulties, and several international classifications are available. Nevertheless, within the framework of reimbursement, classification is particularly important because it affects the choice of the reference products which are used to decide whether or not a new product represents value for money. Moreover, in some Member States, differences in classification may affect the

proportion of the cost of the medicine which is reimbursed to the patient. The proposal therefore envisages delegating to the Commission, after consulting a Consultative Committee, the power to issue a directive to harmonise the classification of medicinal products for social security purposes within the Community.

7. "Transfer prices"

For well known economic reasons, the pharmaceutical industry is organised on a multi-national basis. Research and development activities and the manufacture of active principles is often concentrated at a limited number of sites, and the active principle or an intermediate product is taken to the importing country for the manufacture of the final product. In fact trade in intermediate products is of considerable economic significance and much of it consists of transfers within the same group of companies rather than "arms-length" transactions. In any system of price or profit controls, the competent authorities have the difficult task of verifying the reasonableness of these so-called transfer prices. The Commission considers that this is a matter for further consideration at Community level. The Commission is therefore proposing that those Member States which do attempt to verify transfer prices should be required to notify the criteria used to the Commission, and provision is made for the future approximation of these criteria, if necessary.

III. THE FUTURE

1. General

There are those who question the need for any form of control on pharmaceutical pricing or the reimbursement of medicinal products and accordingly argue that price formation in the pharmaceutical sector should be left to market forces. This point of view appears unrealistic. For as long as the public authorities meet a substantial part of the cost of medicinal products through the national health insurance system, the competent authorities will have a legitimate interest in ensuring that good value for money is obtained and in ensuring that companies do not make excessive profits. As mentioned above, in addition to providing support for the Member States, the aims of Community policy must be to ensure that such measures do not adversely affect the operation of the internal market and take due account of the need to maintain a high level of innovation within the Community.

2. Prices of products which are not available under the national health insurance system

The primary justification for imposing controls on pharmaceutical prices is the need to control expenditures in the national health insurance system. This justification does not apply in the case of products which are not available under the health insurance system. In the case of products which can be purchased directly by the consumer, normal competitive prices apply, since the consumer can select the product which represents the best value for money himself, if necessary after consulting the pharmacist. It would therefore seem appropriate to aim for the elimination of controls on these products, although Member States would still be able to impose a freeze on their prices, provided that such a freeze also applied to other sectors of the economy as part of an overall anti-inflation strategy.

3. Price and profit controls

In general terms, it is possible to distinguish between three systems of controls which are used within the Community at the present time: price control based upon costs; price control based upon a comparaison with other products and profit control. All three systems have their disadvantages. In a system of price control based upon the actual costs incurred by the product it is difficult to obtain the information necessary to calculate the overall price. Moreover a cost plus price control system contains no incentive for firms to increase efficiency in production if all the costs actually incurred are taken into account. In a system of price control based upon a comparaison between products, the choice of reference products may be difficult and controversial, particularly in the case of a major innovatory product where there is no obvious substitute. Moreover any system of individual product price controls reduces whatever possibilities for price competition exist within the pharmaceutical sector. On the other hand, while a system of profit control does leave some scope for competitive forces, its administration is complex, and it needs to be carefully adjusted if it is to achieve the objectives of promoting innovation and efficiency while maintaining reasonable prices.

In these circumstances, the Commission does not consider it possible to hold up one or other system as a model for those Member States who wish to operate a price control system. Instead, the Commission intends to enter into consultations with the Member States concerned with a view to identifying those aspects of the national systems which pose the greatest potential problems for the internal market and the manner in which they might be changed.

4. Coverage by the national health insurance system

It is clear that Member States will wish to retain the right to exclude entire categories of medicinal products from their health insurance system, on the grounds, for example, that such products may be purchased by the consumer without a medical prescription, or that the products are intended for the symptomatic relief of minor and self-limiting ailments.

The application of price criteria in deciding whether to exclude individual products from the scope of the health insurance system gives rise to difficulties resulting from the interpretation of the notion of therapeutic equivalence. Within the framework of medicines licensing (marketing authorization), the concept of therapeutic equivalence has a relatively clear meaning: the same pharmaceutical form and route of administration together with bio-equivalence. However if this approach is applied to reimbursement, it means that the vast majority of medicinal products are automatically eligible for reimbursement unless a generic or branded generic copy is available. For this reason, in the framework of reimbursement, the authorities take a wider view of equivalence, looking at the ability of the medicine to treat a particular disease at a given cost (cost/benefit evaluation). Such an approach inevitably gives rise to difficulties of interpretation and evaluation.

It therefore appears necessary to try to achieve a greater degree of coordination of national decisions. In the first instance, it may be desirable to consider the establishment of a Community level forum in which the therapeutic advantages of new medicinal products could be discussed, having regard to their indications, contra-indications, side effects, etc. The national health authorities would then be able to use an opinion from this forum as the basis for determining the status of a product within the national health insurance system.

TABLE I - INDICES OF LEVEL OF PRICES OF MEDICINAL PRODUCTS + PER CAPITA CONSUMPTION

PRICES	DE	DK	NL	IRL	BE	UK	FR	GR	IT
EC Statistical Office, 1983 EC Average = 100	169	159	149	118	106	103	78	75	59
Health Econ., 1982 UK = 100	143	143	129		66	100	57		66
EFPIA, 1985 B = 100	170		160		100	142	109		103

PER CAPITA CONSUMPTION IN $ U.S., ECONOMISTS ADVISORY GROUP, 1982	90	38	35	37	67	51	80	36	56

PROPOSAL FOR A COUNCIL DIRECTIVE RELATING TO THE TRANSPARENCY OF MEASURES REGULATING THE PRICING OF MEDICINAL PRODUCTS FOR HUMAN USE AND THEIR INCLUSION WITHIN THE SCOPE OF THE NATIONAL HEALTH INSURANCE SYSTEM

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100 thereof,

Having regard to the proposal from the Commission[1],

Having regard to the opinion of the European Parliament[2],

Having regard to the opinion of the Economic and Social Committee[3],

Whereas marketing authorizations for proprietary medicinal products issued pursuant to Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products[4] may be refused only for reasons relating to the quality, safety or efficacy of the proprietary medicinal product concerned;

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4 OJ No. 22 of 9.2.1965, p. 369/65

Whereas Member States have adopted measures of an economic nature on the marketing of medicinal products in order to control or reduce public health expenditures on medicinal products; whereas such measures include direct and indirect controls on the prices of medicinal products and limitations on the range of products covered by the national health insurance system;

Whereas the primary objective of such measures is the promotion of public health by ensuring the availability of adequate supplies of medicinal products at a reasonable cost; whereas however such measures should also be intended to promote efficiency in the production of medicinal products and to encourage research and development into new medicinal products, on which the maintenance of a high level of public health within the Community ultimately depends;

Whereas disparities in such measures may hinder or distort intra-Community trade in medicinal products and thereby directly affect the functioning of the common market in medicinal products;

Whereas as a first step towards the removal of these disparities, it is urgently necessary to lay down a series of requirements intended to ensure that all concerned can verify that the national measures do not constitute quantitative restrictions on imports or exports or measures having equivalent effect thereto; whereas, however, these requirements do not effect the policies of the Member States who rely primarily upon free competition to determine the price of medicinal products;

Whereas the further approximation of such measures must take place progressively;

HAS ADOPTED THE FOLLOWING DIRECTIVE:

Article 1

1. Member States shall ensure that any national measure, whether laid down by law, regulation or administrative action, to control the prices of medicinal products for human use or to restrict the range of medicinal products covered by their national health insurance systems complies with the requirements of this Directive.

2. The definition of "medicinal products" laid down in Article 1 of Council Directive 65/65/EEC of 26 January 1965 shall apply to this Directive.

3. Nothing in this Directive shall permit the marketing of a proprietary medicinal product in respect of which the authorization provided for in Article 3 of Council Directive 65/65/EEC of 26 January 1965 has not been issued.

Article 2

The following provisions shall apply if the marketing of a medicinal product is permitted only after the competent authorities of the Member State concerned have approved the price of the product:

1. Member States shall ensure that a decision on the price which may be charged for the medicinal product concerned is adopted and communicated to the applicant within 90 days of the receipt of an application submitted in due form. In the absence of such a decision, the applicant shall be entitled to market the product at the price proposed.

2. Should the competent authorities decide not to permit the marketing of the medicinal product concerned at the price proposed by the applicant, the decision shall contain a detailed statement of reasons. In addition, the applicant shall be informed of the remedies available to him under the laws in force and the time-limits allowed for applying for such remedies.

3. At least once every six months the competent authorities shall publish in an appropriate official publication and communicate to the Commission a list of the medicinal products whose price has been fixed during the relevant period together with the prices which may be charged for such products.

Article 3

Without prejudice to Article 4, the following provisions shall apply if an increase in the price of a medicinal product is permitted only after prior approval has been obtained from the competent authorities:

1. Member States shall ensure that a decision is adopted on an application submitted in due form to increase the price of a medicinal product and communicated to the applicant within 90 days of its receipt. In the absence of such a decision, the applicant shall be entitled to apply in full the price increase requested.

2. Should the competent authorities decide not to permit the whole or part of the price increase requested, the decision shall contain a detailed statement of reasons and the applicant shall be informed of the remedies available to him under the laws in force and the time-limits allowed for applying for such remedies.

3. At least once every six months the competent authorities shall publish in an appropriate official publication and communicate to the Commission a list of the medicinal products for which price increases have been granted during the relevant period together with the new price which may be charged for such products.

Article 4

1. In the event of a freeze being imposed on the prices of all medicinal products or certain categories of medicinal products, Member States shall ensure that prices are reviewed, and where appropriate adjusted, at least once a year or when the national resale price index has increased by ten per cent since the last review, whichever is the sooner. Within 90 days of the commencement of this review the competent authorities shall announce what increases or decreases in prices are being made.

2. Any person who is responsible for marketing a medicinal product may apply for a derogation from a price freeze, stating his reasons in detail. Member States shall ensure that a reasoned decision on any such application is adopted and communicated to the applicant within 90 days. In the absence of such a decision, the applicant shall be entitled to apply in full the price increase requested. Should the derogation be granted, the competent authorities shall forthwith publish an announcement of the price increase allowed.

Article 5

Where a Member State adopts a system of direct or indirect controls on the profitability of manufacturers and importers of medicinal products, the Member State concerned shall publish the following information in an appropriate official publication and communicate it to the Commission:

a) the method or methods used to define profitability; return on sales and/or return on capital,
b) the criteria according to which target rates of profit are accorded to individual manufacturers or importers together with the criteria according to which manufacturers or importers will be allowed to retain profits above their given targets,
c) the range of target profit, including the average target rate of profit for manufacturers or importers for the previous year and the current year,
d) whether any company failed to reach their allocated target,
e) the maximum percentage profit which any manufacturer or importer has been allowed to retain above their target.

This information shall be updated at least once a year.

Where, in addition to a system of direct or indirect controls on profits, a Member State operates a system of controls on the prices of certain types of medicinal products, which are excluded from the scope of the profit control scheme, the provisions of Articles 2 - 4 shall apply to such price controls. However, Articles 2 - 4 shall not apply where the normal operation of a system of direct or indirect controls on profits results exceptionally in a price being fixed for an individual medicinal product.

Article 6

The following provisions shall apply if a medicinal product is covered by the national health insurance system only after the competent authorities have decided to include the medicinal product concerned in a positive list of medicinal products covered by the national health insurance system.

1. Member States shall ensure that a decision on an application submitted in due form to include a medicinal product in the list of medicinal products covered by the health insurance system is adopted and communicated to the applicant within 90 days of its receipt. An application under this Article may be made before the competent authorities have agreed the price to be charged for the product pursuant to Article 2.

2. Any decision not to include a medicinal product in the list of products covered by the health insurance system shall state in detail the reasons upon which it is based. In addition the applicant shall be informed of the remedies available to him under the laws in force, and the time-limits allowed for applying for such remedies.

3. Before the date referred to in Article 11(1) of this Directive the Member States shall publish in an appropriate official publication and communicate to the Commission the criteria which are to be taken into account by the competent authorities in deciding whether or not to include medicinal products on the lists.

4. Within one year of the date referred to in Article 11(1) of this Directive, the Member States shall publish in an appropriate official publication and communicate to the Commission a complete list of the products covered by their health insurance system, together with their prices. This information shall be updated at least once every six months.

Article 7

The following provisions shall apply if the competent authorities of a Member State are empowered to adopt decisions to exclude individual or categories of medicinal products from the coverage of its national health insurance system (negative lists).

1. Any decision to exclude a category of medicinal products from the coverage of the national health insurance system shall state in detail the reasons on which it is based and be published in an appropriate official publication.

2. Before the date referred to in Article 11(1) of this Directive, Member States shall publish in an appropriate official publication and communicate to the Commission the criteria which are to be taken into account by the competent authorities in deciding whether or not to exclude an individual medicinal product from the coverage of the national health insurance system.

3. Any decision to exclude an individual medicinal product from the coverage of the national health insurance system shall state in detail the reasons on which it is based. Such decisions shall be communicated to the person responsible, who shall be informed of the remedies available to him under the laws in force and the time-limits allowed for applying for such remedies.

4. Within one year of the date referred to in Article 11(1) of this Directive, the competent authorities shall publish in an appropriate official publication and communicate to the Commission a list of the individual medicinal products which have been excluded from the scope of its health insurance system. This information shall be updated at least every six months.

Article 8

1. Before the date referred to in Article 11(1) of this Directive, the Member States shall communicate to the Commission any therapeutic classification of medicinal products which is used by the competent authorities for the purposes of the national social security system. If it considers it necessary, the Commission may, after considering the opinion of the Committee referred to in Article 10, adopt a directive on the approximation of national provisions relating to the classification of medicinal products for social security purposes.

2. Before the date referred to in Article 11(1) of this Directive, the Member States shall communicate to the Commission the criteria which are used by the competent authorities in verifying the fairness of the prices charged for transfers within a group of companies of active principles or intermediate products used in the manufacture of medicinal products. If it considers it necessary, the Commission may, after considering the opinion of the Committee referred to in Article 10, adopt a directive or issue guidelines on the approximation of national criteria for the verification of the fairness of such prices.

Article 9

1. In the light of experience, the Commission shall, not later than two years after the date referred to in Article 11(1) of this Directive, submit to the Council a proposal containing appropriate measures leading towards the abolition of any remaining barriers to or distortions of the free movement of proprietary medicinal products.

2. The Council shall decide on the Commission proposal not later than one year after its submission.

Article 10

1. A Committee called the Consultative Committee on Pharmaceutical Pricing and Reimbursement shall be set up and attached to the Commission.

2. The tasks of the Committee shall be:

   - to examine any question relating to the application of this Directive which is brought up by its chairman either on his initiative or at the request of a Member State;

   - to discuss and provide an opinion on matters referred to it by the Commission pursuant to Article 8 of this Directive or in accordance with the provisions of any future directive. When seeking the opinion of the Committee, the Commission may set a time-limit within which such an opinion shall be given. No vote shall be taken. However any member of the Committee may demand that his views be set down in the minutes.

3. The Committee shall consist of one representative from each Member State. There shall be one deputy for each representative. This deputy shall be entitled to participate in meetings of the Committee.

4. A representative of the Commission shall chair the Committee.

5. The Committee shall adopt its rules of procedure.

Article 11

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 January 1989 at the latest. They shall forthwith inform the Commission thereof.

2. Before the date referred to in paragraph 1, Member States shall communicate to the Commission the texts of any law regulations or administrative provisions relating to the pricing of medicinal products, the profitability of manufacturers of medicinal products and the coverage of medicinal products by the national health insurance system. Amendments and modifications to these laws, regulations or administrative provisions shall be communicated to the Commission forthwith.

Article 12

This Directive is addressed to the Member States.

FINANCIAL STATEMENT

relating to the Commission proposal for a Council Directive relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion within the scope of the national health insurance system

Although the measures proposed do not strictly constitute new actions, they will result in new responsibilities for the Commission department concerned (DG III/A/3 "Pharmacy and Veterinary Medicines").

1. Budget headings

N° 1100 salaries of officials and temporary agents
N° 2510 travelling expenses of members of institutionalised committees
N° 2600 expenses of studies, experts and consultants
N° 1301 missions

2. Legal basis

Article 100 (100 A) of the EEC Treaty

3. Description of the project

3.1. General objective

- to ensure that national systems to limit public health expenditures on medicinal products do not disrupt the operation of the internal market

3.2. Specific objectives

a) to study the detailed effects of national price control and reimbursement systems on the operation of the common market and make detailed proposals for appropriate adjustment;

b) to coordinate certain aspects of the operation of national price control and reimbursement systems in particular the classification of medicines for reimbursement purposes and the assessment of the reasonableness of transfer prices;

c) to assess the impact of divergencies in price control and reimbursement systems on industrial efficiency and innovation within the framework of the Commission's programme of research into the"cost of non-Europe".

4. Justification of the project

4.1. Justification of the type of project proposed

There are wide disparities between national systems of price control and reimbursement of medicinal products within the Community. These differences result from fundamental differences in political and economic philosophy and it is not realistically feasible to undertake the full-scale approximation of national price control systems at present. The resources presently available to the Commission service responsible are not adequate to undertake the detailed studies and negotiations with Member States which are required.

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4.2. Interest of the project at Community level

The operation of national systems of price control and social security reimbursement are resulting in major disparities in the price of pharmaceuticals, which are resulting in distortions of intra-Community trade, and are being criticised by the European Parliament, the Industry and consumer groups.

5. Financial implications for personnel and operating appropriations

a) Additional personnel for DG III/A/3 "Pharmacy and Veterinary Medicines" from 1988:

- 1 economist with knowledge of the problems of price formation in the pharmaceutical sector (A7)
- 1 secretary (C3)

b) Allowance for meetings of institutional committees from 1988:

- 4 meetings of national experts on price control per annum (travelling expenses for 2 experts per Member State - ± 40.000 ECU/p.a.)

c) Appropriations for outside consultants, multi-client studies and economic documentation on pharmaceutical pricing and reimbursement (± 100.000 ECU/p.a.)

d) Appropriations for missions to the competent national authorities

STATEMENT OF IMPACT ON SMALL AND MEDIUM-SIZED FIRMS AND EMPLOYMENT

1. ADMINISTRATIVE OBLIGATIONS ARISING FROM THE APPLICATION OF THE LEGISLATION FOR FIRMS

   The proposal will not increase the obligations on firms which result from national price control procedures.

2. ADVANTAGES FOR THE FIRM

   - YES/NO

   - WHICH - greater transparency in national decision-making procedures relating to price control and reimbursement of medicines

3. INCONVENIENCE FOR THE FIRM

   XES/NO

   CONSEQUENCES

4. EFFECT ON EMPLOYMENT

   No direct effects.

5. HAS PRIOR CONCERTATION WITH THE SOCIAL PARTNERS TAKEN PLACE?

   YES/NO - consultation of pharmaceutical industry

   OPINION OF SOCIAL PARTNERS - generally favourable

6. IS THERE A LESS RESTRICTIVE ALTERNATIVE?

   No.