

Pharmaceutical Prices: A continental view

Some economic aspects of pharmaceutical pricing
on a national and international level

KLAUS VON GREBMER

Office of Health Economics

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Foreword

It has not normally been OHE policy to reprint articles which have previously been published elsewhere. However, it seemed desirable to make an exception for this paper by Dr Klaus von Grebmer which has been published in two parts in German in *Die Pharmazeutische Industrie*. This is because it is a useful compilation of many arguments relating to pharmaceutical pricing, which deserves to be available in the English language as well as in German.

It is also useful for British readers to be able to view some of the current problems of pharmaceutical pricing 'through European eyes', as it were. For these reasons OHE is grateful to Dr von Grebmer and to the Editor of *Die Pharmazeutische Industrie* for permission to publish this booklet. The responsibility for the views expressed, however, must remain that of Klaus von Grebmer rather than OHE.

GEORGE TEELING-SMITH

Basic problems

Struggle for shares in the gross national product

In recent years the costs of health care have risen at a faster rate than the gross national product in all Western industrialised countries. In the period from 1970 to 1975 alone health care costs have more than doubled in every country belonging to the European Community (EC). Illustrated in Figure 1 is the extent to which the increase in the payments made by the statutory sickness insurance funds outstripped the growth in gross national product in the Federal Republic of Germany in the years 1970-76.

Up to the end of 1973 both gross national product and expenditure on health care were increasing – although the rate of growth was more marked in the case of the latter. The advent of the recession in 1973-74 was accompanied in all EC countries by a further growth in health care expenditure, which, however, now had to be financed from a gross national product that had shrunk in real terms. Figure 2 clearly shows that all the EC countries were affected by this 'sag' in the growth curve of the gross national product. The disproportionately high rates of increase in expenditure on health care would inevitably have led sooner or later to a struggle for a greater share of the gross national product; but, as a result of the recession, this struggle started earlier than it would otherwise have done, and it assumed a more acute form.

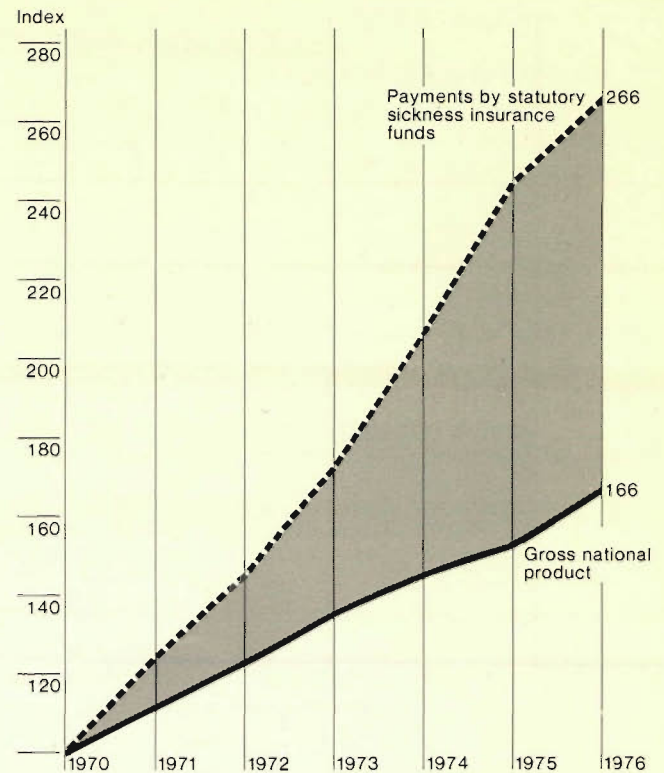
Use of 'public money'

The money expended on health care is often thought of as public money; in actual fact, however, all that the State does in many countries is to organise a rate assessment system for the compulsory levying of private health insurance contributions. Obviously, the State is anxious to supervise the uses to which its money, or the money it levies, is put. The regulatory and controlling influences exerted by the State on the utilisation of health care money are consequently very pronounced in many EC countries. The pharmaceutical industry too – as one of the suppliers of goods and services in the health care sector – is becoming more and more exposed to State intervention.

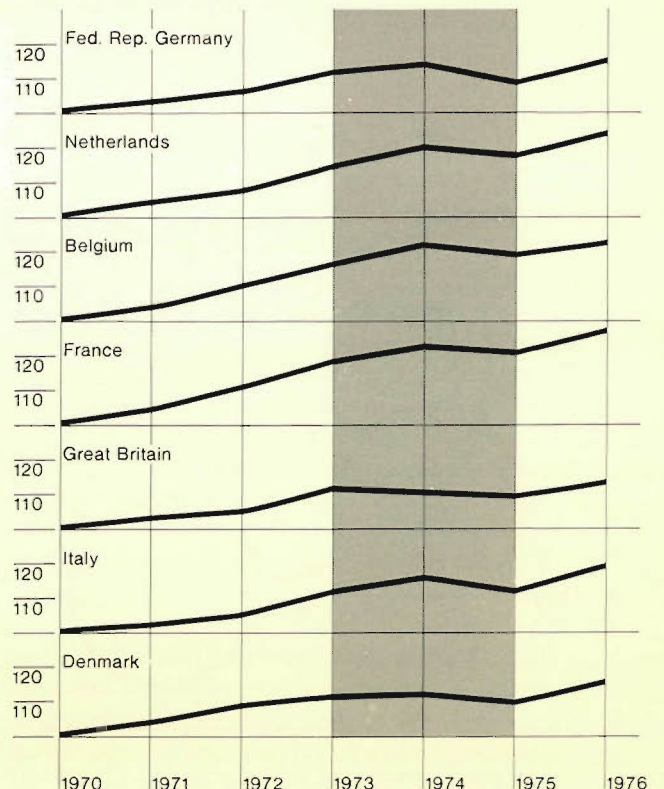
Lack of ideas on the subject of political reform

None of the EC countries has yet summoned up sufficient courage to reform its health care system. Instead of looking for more efficient ways of organising their health services (by modifying the structure of their reimbursement or payment modalities, as well as their financing methods, etc), the political authorities in virtually all EC countries are confining their efforts to alleviating the

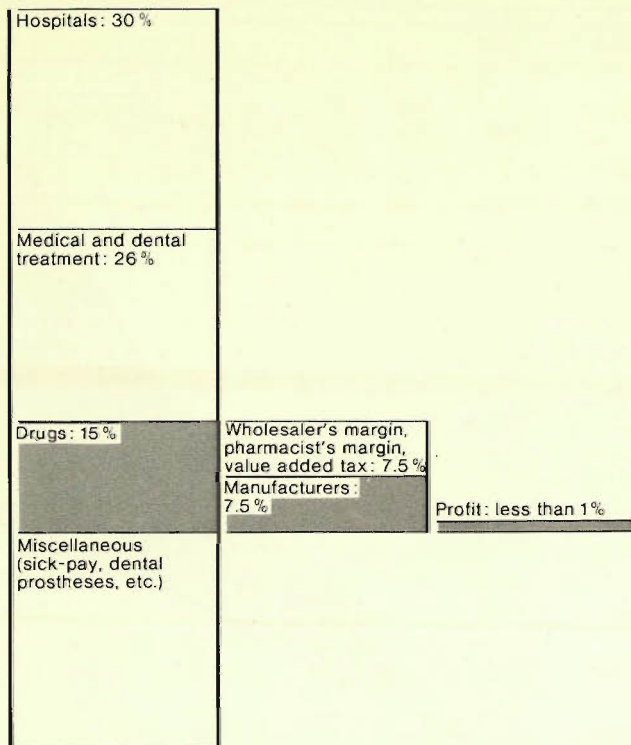
1 Federal Republic of Germany. Indices of health care costs and gross national product in 1970-76



2 European Community. The 1973-74 'sag' in the growth curve. Index of gross national products, expressed in terms of 1970 price levels

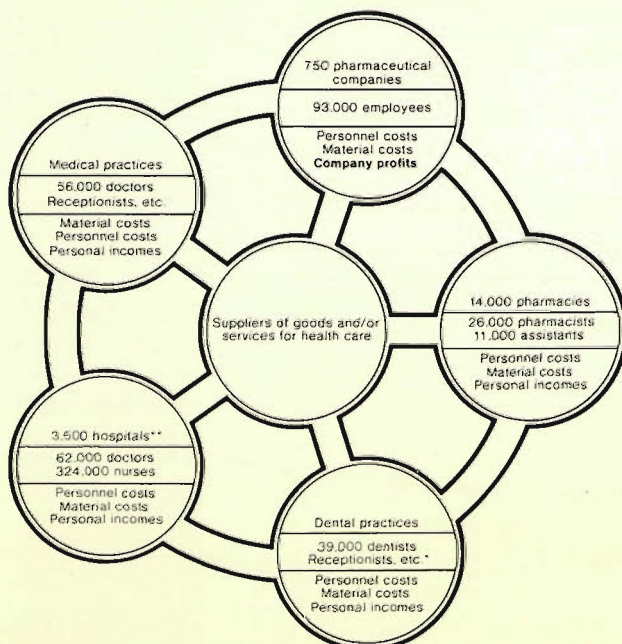


3 Federal Republic of Germany. Breakdown of payments made in the health care sector in 1976



Maximum saving achievable if all profits of the pharmaceutical industry were to be deleted: 1%

4 Federal Republic of Germany. More than 1,000,000 people work for the health services, but only the pharmaceutical companies show any return on investment



**No statistics available

**Total number of persons employed in hospitals: 709,000

symptoms provoked by increases in costs. Against the background of an ever more intense struggle for a share in the money spent on health care, the pharmaceutical industry has become the main target for political measures aimed at alleviating these symptoms. In a public opinion poll conducted in the Federal Republic of Germany in 1977 drug prices were named as the main factor responsible for the 'explosion in health costs'. From the political standpoint, therefore, it might appear that this explosion in costs could be tackled simply by imposing increasingly strict controls on pharmaceutical markets. But the imposition of such controls would be out of all proportion to the savings it could achieve in real terms. Shown in Figure 3 is a breakdown of the expenditure on health care in the Federal Republic of Germany (the breakdowns for other EC countries would, within certain limits, present a similar picture): medicines account for 15 per cent of the total sum of money paid out by the statutory sickness insurance funds. If one deducts from this 15 per cent the pharmacist's margin, the wholesaler's margin, and value added tax, the share left over for the industry works out at 7.5 per cent of the total sum. Assuming further – that the profits of the pharmaceutical industry – at a generous estimate and without including any extra allowance to cover either the risks involved or interest computed for accounting purposes – amount to 15 per cent of sales, the maximum saving to be achieved by deleting all profits made by drug manufacturers would be less than 1 per cent of the total sum paid out. To ban the pharmaceutical industry from making any profit at all, however, would certainly be a drastic step.

The pharmaceutical industry as the only supplier of goods or services in the health care market to show a return on investment

It may perhaps be precisely because of the profit it makes that the pharmaceutical industry is being subjected to growing public criticism and political pressure in all the countries of the European Community. As can be seen from Figure 4, the pharmaceutical industry is the only supplier of goods or services in the health care market to earn a return on investment. As regards all the other suppliers, the difference between sales and/or services on the one hand and expenditure on the other goes to make up their 'personal' income; in the case of the pharmaceutical industry, by contrast, this difference is merely an 'abstract' quantity which is used either for the payment of dividends or for self-financing purposes. If profit in any shape or form is already regarded with suspicion, then criticism is bound to increase when the profit in question is made 'at the expense of the sick' and

Pricing in the national market

when, in order to cover the risks of research, it is in addition higher than the average in other industries.

Complexity of the economic factors involved

It is partly for the reasons already mentioned above that the pharmaceutical industry has been forced into a state of siege in the EC countries. The situation is exacerbated by the fact that discussions on reforms in the health care system and in the field of medicines are not always conducted without polemics. The next part of this *exposé* deals – from the economic standpoint – with problems relating to the pricing of medicines in national markets and within the European Community. The economics of the pharmaceutical industry and the mechanisms employed for the pricing of its products are already complex enough on a national plane. But the difficulties and problems involved multiply when account has to be taken not only of national but also of international factors. We do not propose here to attempt to justify price differences within a given country or between countries; instead, our intention is to portray the basic economic characteristics of the pharmaceutical industry and to indicate the problems they entail in connection with national and international pricing in Europe. In so doing, we also hope to place the discussion of the price of medicines on a more objective footing.

Research-based pharmaceutical companies display a number of characteristic features which clearly distinguish them from other business undertakings.

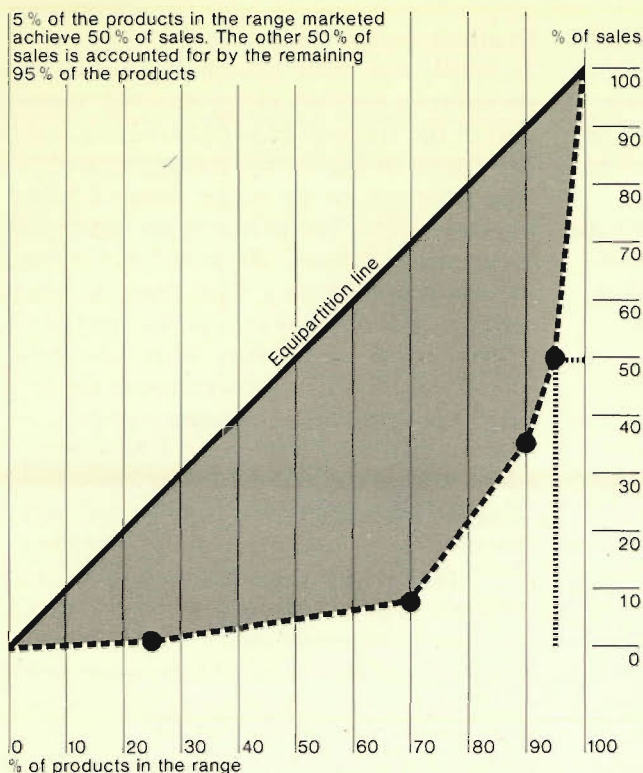
Product range structure

In hardly any other branch of industry does one encounter a product range structure resembling that of the research-based pharmaceutical industry. Illustrated in Figure 5 is the aggregated product/sales structure for ten major research-based pharmaceutical companies in an EC country: 50 per cent of these companies' sales are achieved by only approximately 5 per cent of their product range, and the remaining 50 per cent of sales by 95 per cent of the product range. Owing to the special nature of the costs structure in the research-based pharmaceutical industry, the only economically reasonable accounting procedure to adopt is to calculate for each product a so-called 'contribution margin' (=price minus directly chargeable costs) which includes an extra percentage to cover general costs. This procedure, however, means that the 'best sellers' contribute in absolute terms considerably more to general costs and profits than the bulk of the other products in the range. It is a procedure which is often improperly understood, with the result that it is precisely the best sellers that become singled out as targets for public criticism and political intervention. Fears are expressed that the consumer is being exploited by these products, because they earn 'larger' contribution margins, in absolute terms, than the rest of the product range. A cut in the prices of these best sellers is then demanded, without any consideration being given to the fact that such a step is bound to cause severe confusion in the price relationships of the product range as a whole, in the basic principles on which price calculations are made in order to keep these relationships in balance, and in the overall costs structure of the company concerned.

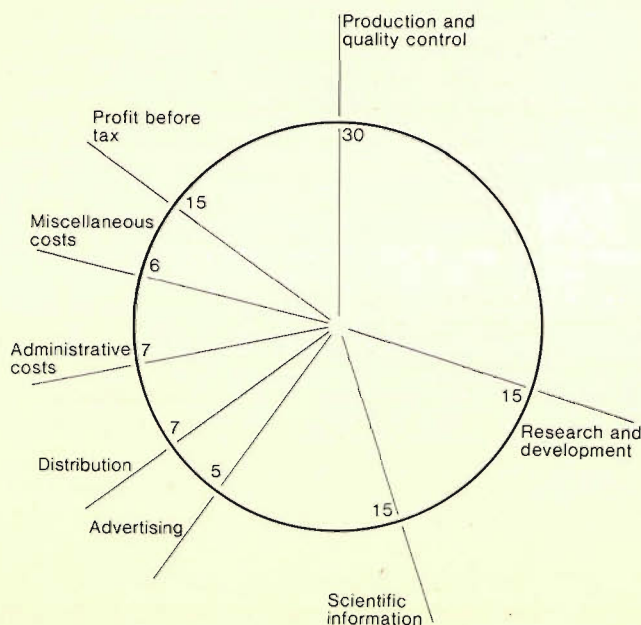
Structure and allocation of costs

Reproduced in Figure 6 by way of an example is the possible costs structure (in percentages) of a research-based pharmaceutical company active on an international plane: the items 'Research and development', 'Scientific information', 'Promotion', 'Marketing', and 'Administrative costs' represent general expenses which cannot, on a strict causal basis, be assigned directly to individual pharmaceutical products, but have to be borne by the product range as a whole. How, for instance, can the 'failures' encountered in one field of research reasonably be debited to a single product? What proportion of administrative costs should be borne by a single product? Furthermore, not even the total costs of production and quality control

5 High sales achieved with only a few products in the range marketed (Lorenz curve)



6 Costs structure (in per cent of sales) of a research-based pharmaceutical company. (Example of a possible costs structure)



can be directly charged to individual products or product groups. Assuming that the directly chargeable costs amount to 20–30 per cent of sales, then between 70 per cent and 80 per cent of the sales figure goes towards general costs and profit.

If a company takes the view that, for the above-mentioned reasons, general costs as a rule cannot be charged to individual products, it is accused of ‘refusing to furnish information’ or of ‘secretiveness’ – even when it is prepared to divulge the total profit of its pharmaceutical business. On the other hand, if the company attempts to assign the full costs of a given product to that product by means of a coding system, it likewise exposes itself to criticism, levelled first of all at the method of allocating costs to a product (ie at the code employed). Should the company perhaps succeed in refuting this criticism, then the next step is to question the individual cost items themselves on the grounds that they are too high (eg in the case of research and development) or even not justified at all (eg in the case of promotion).

Figure 6 shows that, out of every Deutsch-Mark – or its equivalent – that a pharmaceutical manufacturer earns from the sale of his products he spends 15 Pfennigs on research and development – a proportion that is several times higher than in other branches of industry. The productivity of research (=output in relation to expenditure) is currently decreasing. Hence, the man in the street is tending more and more to question the ‘justification’ for high expenditure on research and development – that is, if he does not already classify expenditure on research and development as coming *a priori* under the heading ‘utilisation of profits’.

Moreover, competition within the research-based pharmaceutical industry compels many companies to conduct research in the same fields; this is described as a ‘squandering of resources’. But competition should imply variety, and so it is held to be only right that arrangements made between companies about the lines of research to be pursued should immediately be investigated in case they infringe the laws governing cartels. The research-based pharmaceutical company finds itself in a difficult position here, because the public wants to enjoy the advantages of competition without having to bear the costs involved. Illustrated below are the methods by which the prices of pharmaceuticals are arrived at in a freely competitive market and in a State-regulated market.

Pricing in a freely competitive market

In a freely competitive market there is no guarantee that a company will manage to obtain prices which cover its costs. Profits – especially high profits – are

the driving force behind the system of free competition. If a company achieves high profits by introducing innovations in certain fields, then its competitors will divert resources to these same fields, so as to share in the profits. The advent of new competitors in these fields has the effect of eroding the profits of the company that pioneered the innovations (ie the company holding a monopoly in the process or processes concerned). In other words, even during the period in which a new innovative product still enjoys patent protection, research-based pharmaceutical companies already attempt to attack the innovator by introducing substitute products. Once the patent has expired, any competitor can offer for sale products containing the identical active substance – ie homogeneous competition then begins. Both competition by means of substitute products and the subsequent phase of homogeneous competition thus ensure that the market remains dynamic, that profits are eroded, and that the consumer is protected against ‘exploitation’ or ‘excessive’ prices (Hoppmann).

The following EC countries have hitherto been content with a pharmaceutical market run, in principle, in accordance with the laws of free competition: the Federal Republic of Germany, the Netherlands, and Denmark. The authorities in these three countries, however, are making steadily increasing efforts to introduce stricter price controls in the pharmaceutical market. It is therefore of interest to examine the question as to what – apart, perhaps, from political opportunism – has given rise to the view that, in the pharmaceutical market in particular, free competition, and especially price competition, are doomed to failure. The tripartite subdivision of the demand for medicines (the doctor selects the medicine, the patient consumes it, and the sickness insurance fund pays for it) is the argument most frequently advanced to explain why the doctor is allegedly not interested in prices. According to this argument, moreover, demand is largely inelastic, (because the patient needs his medicine immediately) and the individual company is therefore able to charge high prices without let or hindrance. Hence, so the argument runs, the maxim found in economic textbooks to the effect that demand falls as prices rise and rises as prices fall does not apply to the pharmaceutical market: demand can to all intents and purposes be regarded as an unvarying factor and must be satisfied at any price.

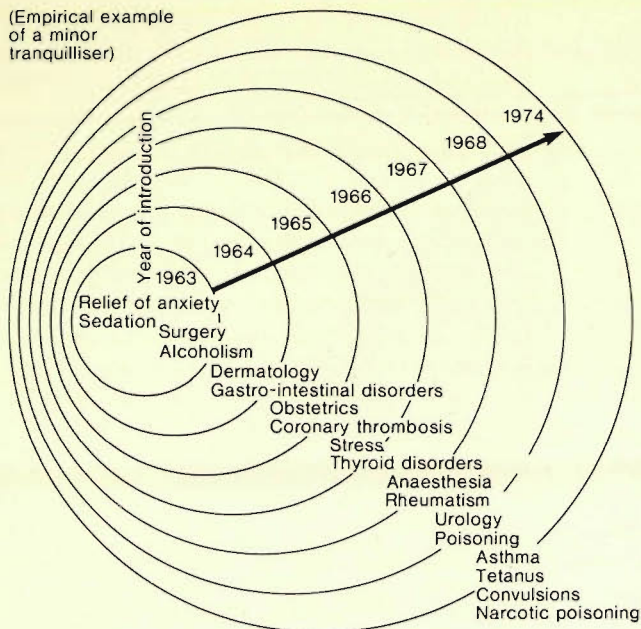
The thesis that demand is inelastic may be valid as regards the overall demand for certain drug treatments. Within the overall demand for a particular type of treatment, however, the various products that could be used for the purpose are in competition with one another. If a company,

when establishing the price of its product, were to start from the assumption that the demand is inelastic in respect of prices, then that company would certainly be in for a shock. The type of demand curve with which an individual research-based pharmaceutical company is most likely to be confronted in the case of a product enjoying patent protection is one that sooner or later develops a ‘sag’ (ie kinked demand curve). As far as its price policy with regard to the product is concerned, the company is free to manoeuvre within certain limits, but this freedom remains subject to the laws governing competition. Although it is possible for the company to raise the price of a product by a certain percentage without running the risk that doctors or consumers will switch to rival preparations, as soon as the upper limit of the price range (the ‘economic stimulus threshold’) is exceeded, the company will lose a considerable amount of its sales to its competitors: as a result of this disproportionate decline in sales, the product’s contribution margin will diminish in absolute terms. The same applies to reductions in price, which are most unlikely to lead to any major increase in sales volume as long as they remain within certain limits. If, however, a company brings down the price of a product, while maintaining its quality, to a level appreciably below that of rival preparations, this will produce a disproportionately high increase in sales volume and, consequently, an increase in the product’s contribution margin in absolute terms. One factor not taken into account in this argument is the time factor: even price variations ‘within certain limits’ will give rise to reactions in the market in the long term.

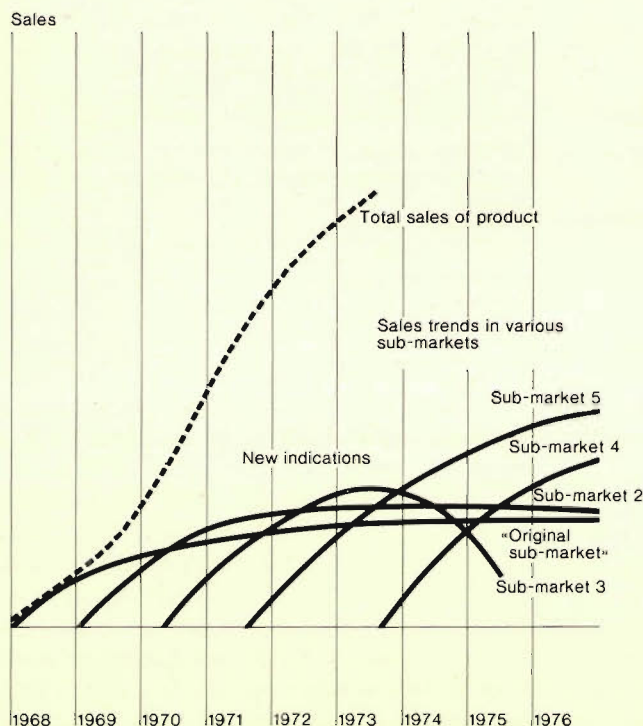
Since the market for pharmaceutical products does not exist as a single entity, but is made up of a series of sub-markets in each of which companies offering medicines for particular indications or groups of indications compete with one another, it is basically wrong to speak of competition in ‘the’ pharmaceutical market. As pricing and price trends are dependent on the sub-market concerned, on the features peculiar to this sub-market, on the alternatives available to the consumer, and on the phase through which the sub-market is passing at the time (phase of experimentation, expansion, or maturation), the intensity of the competition is bound to vary from one sub-market to another. Even in one and the same sub-market, moreover, the medical treatments (ie products and active substances) competing with one another are not, for the most part, of an identical (homogeneous) kind but are extremely varied (heterogeneous). It is above all for these reasons that no really satisfactory solution has yet been found to the problem of defining, in terms appropriate to the

7 Expansion of a drug's range of indications between 1963 and 1974

(Empirical example of a minor tranquilliser)



8 Total sales and sales in respect of new indications (greatly simplified)



purpose of assessing the type and degree of competition involved, the exact nature of a 'relevant' pharmaceutical market.

Introduction of a product on the market does not signify by any means that developmental work on that product has been completed. Conventional consumer goods pass through various stages, the first of which might be labelled 'more information needed' and the last 'no problems': radios, television sets, cameras, and electronic pocket calculators are good examples of products which rapidly approach the 'no problems' stage. Medicines, by contrast, remain in the 'more information needed' stage for the whole of their useful life. This situation is illustrated in Figure 7 by reference to a minor tranquilliser: in 1963, the year of its introduction, this preparation had only two known indications that were medically documented: by 1974, as a result of continuous research and development, the number of its indications had increased to eighteen. This growth in therapeutic usefulness (=expanding field of indications) also meant, however, that the medical profession had repeatedly to be informed about every new use for the medicine (=permanent necessity for more information).

Generally speaking, therefore, products with multiple therapeutic uses do not have an overall sales curve, but a series of sales curves each relating to a particular sub-market. Figure 8 shows that the total sales of a product are made up of its sales in widely disparate sub-markets. In the original sub-market and in Sub-market 2 sales stagnated relatively soon after the product's introduction: in Sub-market 3 they began to decline only three years after introduction, whereas in Sub-markets 4 and 5 they were still in the growth phase at the end of the period under analysis.

Once again, though, the opening up of every new sub-market for an already introduced product calls for expenditure on research and development, launching, and information. It also calls for a decision regarding the choice of sub-market on which to base the price of the product. Can an identical pack be sold at different prices in one and the same country? Must an identical substance be sold under different trade marks in different sub-markets? These are questions to which free competition can provide an answer, but to which an official body cannot.

Since research and development costs and information costs (cf Figure 6) account for a large proportion of total costs, increasing sales cannot lead to marked economies of scale in the case of a pharmaceutical product, as they do, for example, in that of consumer products. This difference between the two types of product is illustrated in Figure 9. Assuming that the total costs of a

pharmaceutical product increase by approximately 12 per cent as a result of inflation, even a 30 per cent reduction in production costs would not permit any change to be made in the price of the product.

On the other hand, a 30 per cent reduction in the production costs of a consumer product – assuming the same rate of inflation of approximately 12 per cent for total costs – would make it possible to reduce the price by 10 per cent (cf Figure 10).

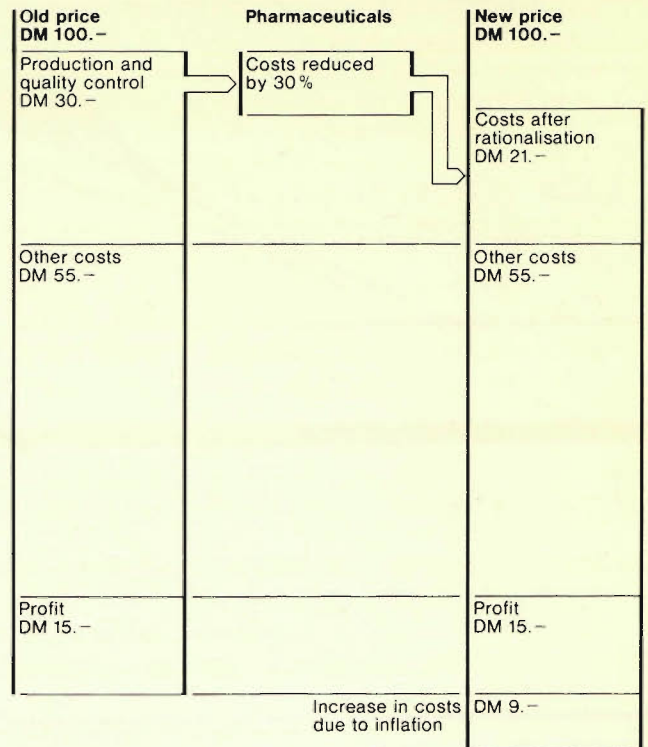
The proportion of total costs accounted for by production costs is much higher in the case of consumer goods than in that of pharmaceutical products. Since, as far as ‘services’ are concerned, rationalisation measures in the pharmaceutical sector are extremely difficult to implement and call for the investment of a considerable amount of capital, the total costs curve for a medicine ‘sticks’ very close to the total sales curve. In the case of consumer goods, by contrast, the sales curve detaches itself from the costs curve as the sales volume increases, thus allowing room for price reductions (cf Figure 11).

Exceptions merely prove this rule. In cases where production costs have accounted for a very high proportion of the total costs of medicines (eg antibiotics) and where these production costs have been drastically lowered by rationalisation measures (=synthesis), considerable price reductions have become possible in the course of time and have in fact been implemented.

Under a system of free competition the manufacturer has a certain freedom to choose the price strategy he intends to pursue when introducing his product. This strategy will depend not only on the expected or predictable useful life of the product (cf Figure 12), but also on the plus points (in respect of quality, additional field or fields of use, reliability, etc) which it displays in comparison with other drugs already introduced. The more advantages his product has to offer over preparations already available on the market, the higher the price he can charge relative to that of these rival preparations.

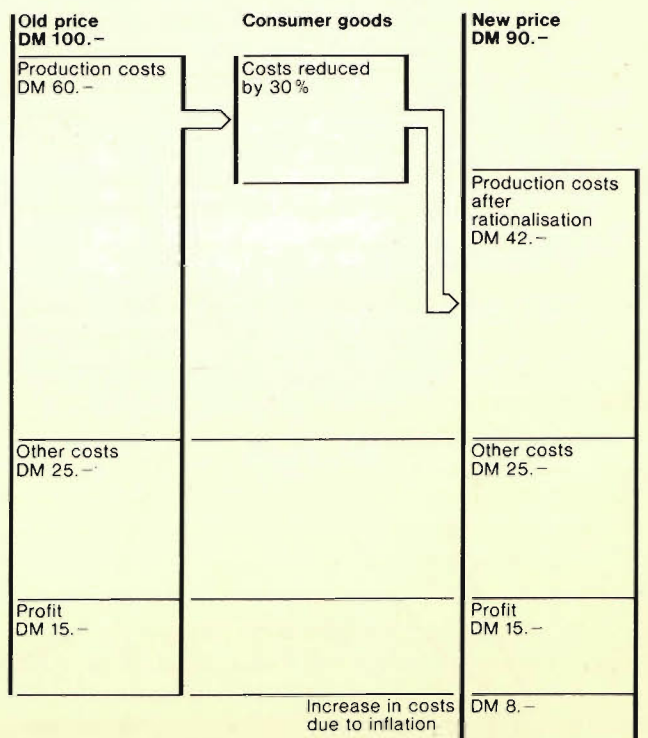
In principle, he can adopt either of the two strategies outlined in Figure 13. He can enter the market with a comparatively high price and then reduce this price gradually during the useful life of the product (=skimming pricing). If he selects this method, his sales volume will be initially very low. If, on the other hand, he adapts the price of his product – which, being an innovation, has considerably more advantages to offer – to the prices of preparations already being marketed, he will usually achieve very rapid penetration of the market (=penetration pricing). Calculated on the basis of the useful life of the product, total sales and total profit might in the final analysis quite

9 Cost-induced price reductions hardly possible in the case of pharmaceuticals (greatly simplified)



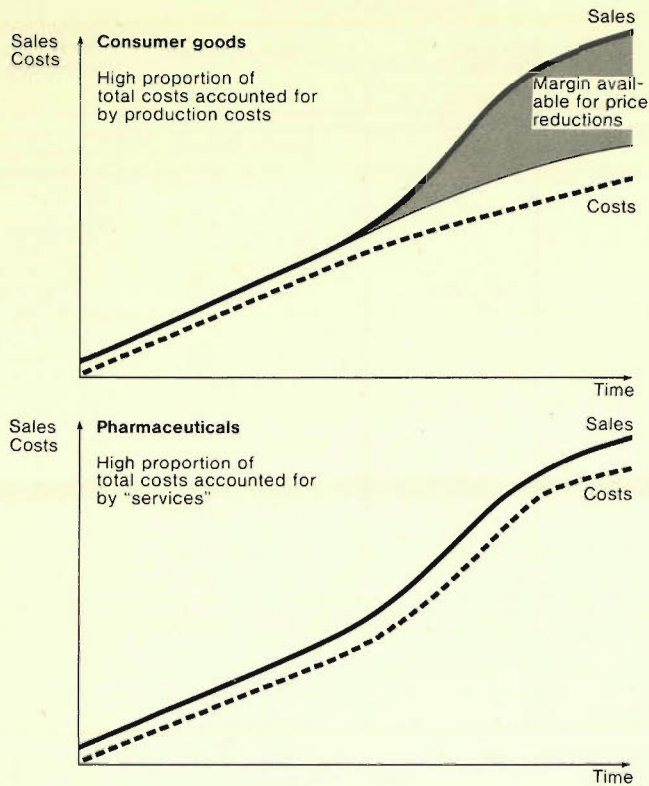
Assumptions: No change in other costs or profit
Rate of inflation: 12%

10 Cost-induced price reductions in the case of consumer goods (simplified)

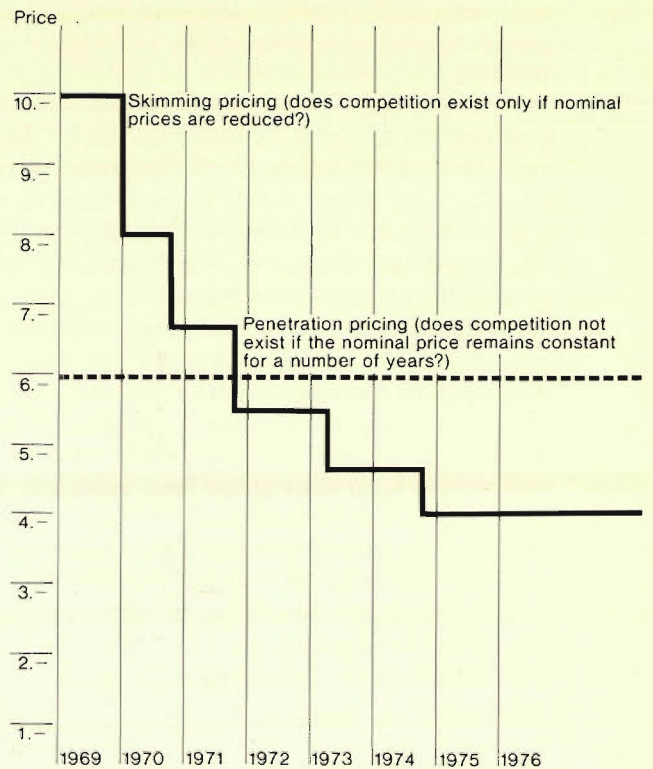


Assumptions: No change in other costs or profit
Rate of inflation: 12%

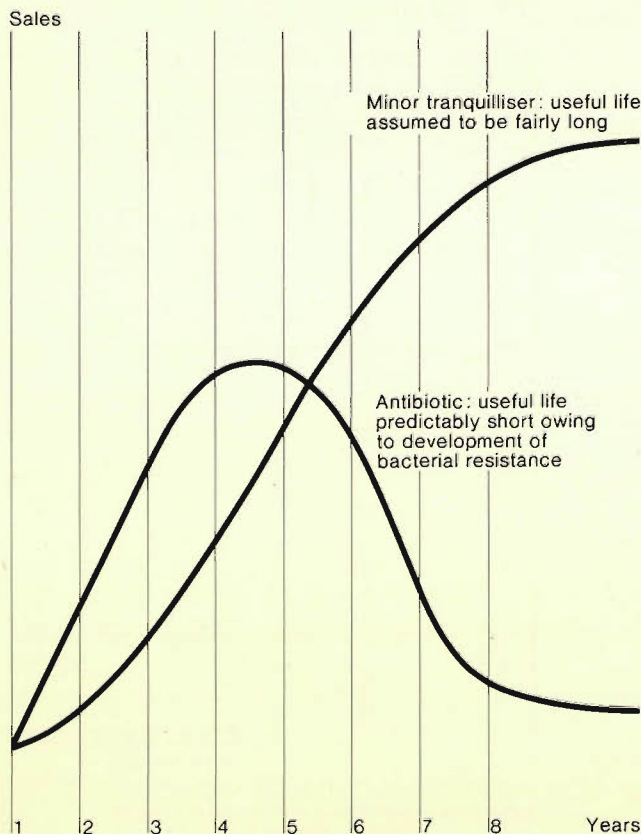
11 Relationship of sales to costs (greatly simplified)



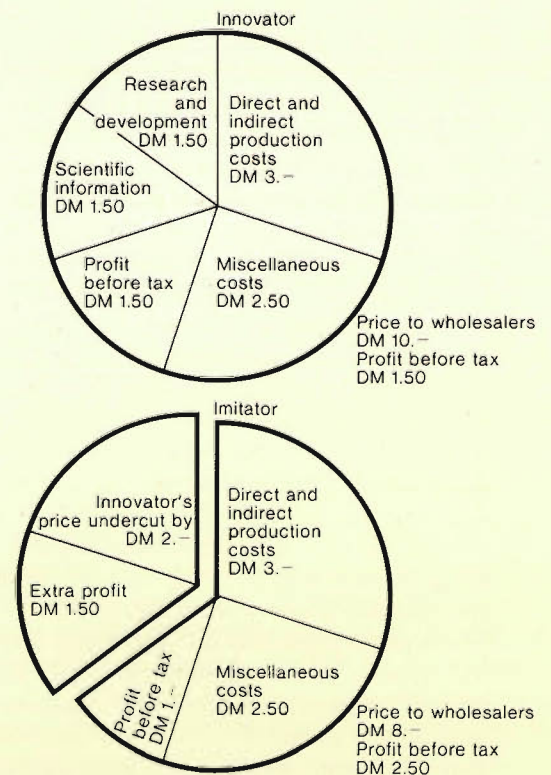
13 'Skimming pricing' and 'Penetration pricing' (greatly simplified)



12 Expected useful life



14 Innovator and imitator: costs – profits – prices



well be identical, irrespective of which of these two approaches is adopted. Hence, both are rational from the point of view of company policy and politically defensible in a system of free competition. Viewed from the standpoint of the laws governing a system of free competition, however, the method of 'skimming pricing' seems to be yielding rapidly growing rewards. This may appear paradoxical, but the explanation is that frequently price competition is assumed to be operating only in cases where the nominal prices of a product are lowered (involved here is the principle that competitive pricing, like justice, has to be seen to be done). The marked improvements constantly being made in the quality of already introduced products, however, are tantamount in fact to a drastic reduction in the prices of these products, even though their nominal price remains unchanged: in other words, price competition can also be ensured by stepping up the quality of products instead of by changing their prices.

Once the patent on a medicine expires, imitators appear on the scene – provided the medicine in question is still an interesting commercial proposition. The manufacturers of generics thus initiate homogeneous competition and thereby curtail the profits made by the innovator who pioneered the medicine. The innovator is compelled to develop new innovations if he is not to fall behind in the competitive race. Theoretically, the research-based company could defend its market share, even after expiry of the patent, by effecting price reductions. Such a strategy, however, involves the danger of its tying down a growing proportion of its resources as a company to this generics market and thus weakening its capacity for research and development.

A more likely attitude for the innovative company to adopt is to allow itself to be priced out of the market once its patent has expired. During this phase the prices charged by the research-based and the non-research-based companies are apt to differ considerably. In view of its costs structure and contribution calculations the research-based company would have no chance at all of keeping abreast of the imitating firm in respect of prices. Figure 14 shows, once again by reference to a model example, what advantages the imitator enjoys over the innovator with regard to costs. The imitator has no costs to bear for research and development or for scientific information. Since he needs much less capital with which to operate, and since the capital that he does invest shows a faster turnover rate than in the case of the research-based company, his sales return can be set at a level one-third lower than that of the research-based company. In other words, the imitator could easily undercut the prices charged by the innovator

by at least 35 per cent and still probably achieve a higher profit than the latter. If consideration is also given to the interest, calculated for accounting purposes, on the capital invested in research and development, then by virtue of these differences in costs alone the imitator is in a position to undercut the innovator by far more than 50 per cent and still make the same percentage profit on the capital invested.

If the research-based company were to be allowed to finance its research and development costs solely from the prices it charges for its new products, it, too, would be able to compete with the imitating firm. In that event, however, one would have to accept a drastic increase in the prices of patented preparations. 'Official sanction' by the authorities for such a re-allocation of costs would introduce an element foreign to the whole idea of free competition; under the conditions of free competition, there is in fact no guarantee that costs will be covered.

In the pharmaceutical market, too, official interference with the mechanisms by which free competition operates and with the companies' freedom to set their own prices would very soon lead to a situation where price control would be followed by increasingly wider controls affecting costs and the companies' entire approach to business management. The experiments which some EC countries have already tried in the field of price controls on medicines certainly do not appear to be worth imitating.

Pricing in State-regulated markets

Price controls as such are nothing new; Lactantius Firmianus, a contemporary of the emperors Diocletian and Constantine, reports as follows on the effect of an edict on maximum prices (*edictum de pretiis*) promulgated in AD 310: 'Dear goods did not become cheap, but cheap goods became dear, even though it was a capital crime to charge more than the maximum permitted prices'. (Börner, page 21). Nevertheless, the belief that price regulation in the pharmaceutical market can produce lower prices than those obtainable by the control mechanisms inherent in a system of free competition is still firmly held today, almost 1,700 years later. Within the European Community, price regulation is being implemented in two different ways – by the imposition of controls, firstly, on the company itself and, secondly, on its products.

1 Controls imposed on the company

In Great Britain, under the terms of the PPRS (Pharmaceutical Price Regulation Scheme), the business operations conducted by a company in the pharmaceutical field are analysed in their entirety. The total return on capital invested in

pharmaceutical activities must not exceed a certain percentage. If a company engages in such activities as research, export trade, etc, it is, as it were, rewarded by being placed in a category where the permissible return on invested capital is both higher and individually assessed. How the total return allowed is distributed among the company's various products is a matter of no interest to the authorities. Corrections to the permissible return on invested capital are carried out with a certain time-lag. Provided a company has 'marketable' products, government must ensure that the company does not increase its costs almost at will, because it is allowed to compensate for a reduction in total return on investment by means of price increases. In cases where the return permitted is too low, incentives may disappear. Of the two possible forms of price regulation mentioned above, the PPRS provided the profit allowed is economically reasonable, constitutes the lesser evil.

Even the PPRS, however, offers no solution to the basic economic problem which underlies any system of regulation and which can be defined as follows: if the controls imposed are too strict, capital will be diverted into other, more attractive fields of business; if, on the other hand, they are too lax, the branch of industry concerned will be receiving what amounts to 'intervention subsidies' which have to be paid for by the consumer.

2 Controls imposed on products

We have seen that controls imposed on the company itself leave considerable scope for the exercise of discretion. This applies with far greater force to the problem of assessing or determining the appropriateness of the prices of individual products in terms of their so-called 'costs'. Owing to changes occurring in economically relevant variables (wage increases, rising prices of raw materials, etc), as well as to the fact that, with respect both to technicalities and to timing, the debiting of certain costs to individual products calls for some freedom of judgement (especially also as regards the extent to which transfer prices are recognised as contributing to costs), attempts to control the price of an individual product inevitably involve a process of haggling with the authorities that is worthy of an oriental bazaar. Currently in force in Italy, France, and Belgium is a system of calculating prices for individual pharmaceutical products. In these countries, both the local and the international pharmaceutical companies have had to contend with financial difficulties. One result is that the pharmaceutical industry is being faced with a crisis of which the increasing numbers of mergers and liquidations are but one symptom. There is even a tendency to

abandon research and development in order to concentrate purely and simply on imitating new preparations which have been developed by those companies that are still undertaking research. Despite appreciable losses, pharmaceutical companies in these countries continue to offer their products for sale. These companies are hoping for reforms which will serve to improve their present invidious position. A company withdrawing from the market would also find it difficult to regain its lost business if and when conditions in the country change for the better. Moreover, since in a number of instances extensive investments have been made in the past in these countries, it is – for the moment at least – more economic to remain in the market than to effect a complete or partial withdrawal.

Although the research-based pharmaceutical companies are sometimes operating at a loss in these price-regulated markets, they are still managing to meet their direct costs. What they are not able to cover are all their fixed costs and general expenses. Over a limited period of time this situation can be tolerated, but already on a medium-term basis it is bound to necessitate entrepreneurial compromises, because a company confronted with an increasing shortfall in finance to meet its fixed costs will be less willing and, indeed, less able to remain active in these markets. Concern on the part of pharmaceutical companies to maintain their system of contribution margins both on the national and on the international plane has hitherto prevented them from withdrawing products from certain markets or from abandoning these markets altogether. It remains to be seen whether this policy can be upheld *ad infinitum*. Just how complex entrepreneurial decision-making becomes when one leaves the national scene will be apparent from the following analysis of the decisions facing a research-based pharmaceutical company in connection with the international pricing of its products in the European Community.

European prices for drugs?

Harmonisation and entrepreneurial objectives

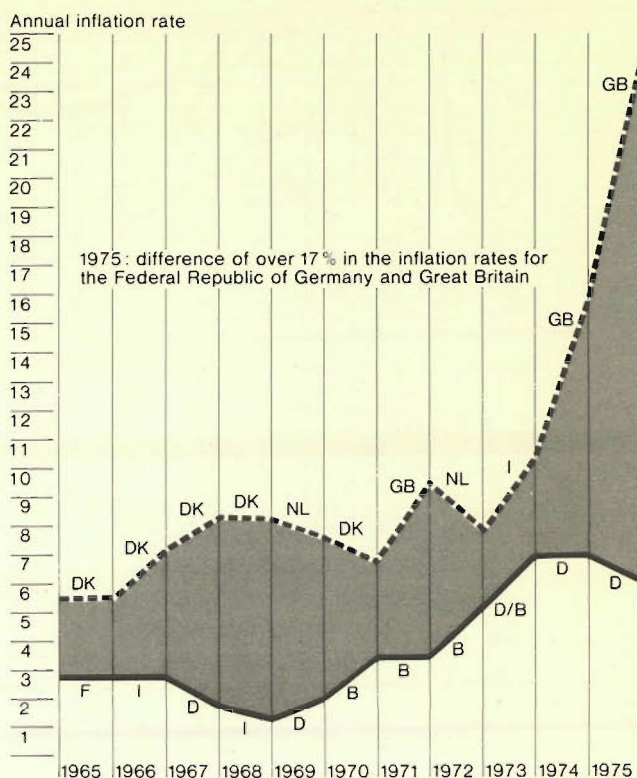
The creation of larger geographical markets, the dismantling of trade barriers, and economic and statutory measures serving to overcome structural differences all facilitate the conduct of business operations. Rational forms of international harmonisation serve to simplify matters in general and are therefore welcomed by commercial enterprises.

The European Community has now been in existence for over twenty years; one of its aims is to establish step by step a common market for its nine member countries. The efforts at harmonisation which have already been made to this end should in theory have rendered it easier to do business in the EC countries. Even today, however, the European Community still has no common industrial policy: the individual EC countries have nevertheless been forced to restructure many branches of their industry. The European Community still lacks an overall economic and monetary policy sufficiently integrated to constitute a genuine common policy. It is thus hardly surprising that the economic policies of the nine member countries now diverge even more widely than they did before the inception of the European Community, although the whole aim of the exercise was to achieve greater congruence. Today there is an acute danger that some of the EC countries may revert to a policy of protectionism – a danger posing a particular threat to the pharmaceutical industry. The dilemma now facing the pharmaceutical industry arises from the fact that, on the one hand, it is exposed to interventionist measures in the individual EC countries (especially with regard to the pricing of its products), whereas, on the other hand, these very same national interventionist measures are being increasingly accepted by the legal authorities of the European Community as norms applicable to the common pharmaceutical market which the Community is striving to create.

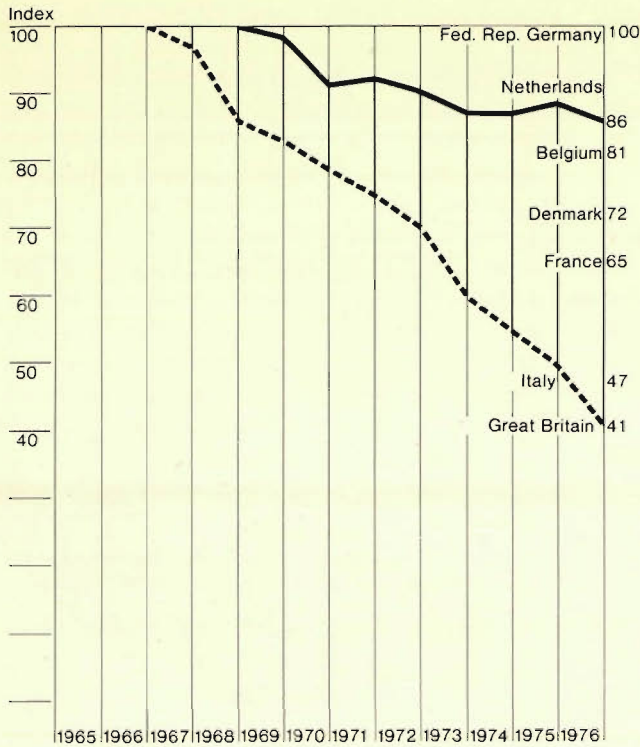
Economic realities in the European Community

Under a rational system of European harmonisation, the divergences between the member countries in terms of national economic variables should progressively diminish, ie the major differences previously existing between them should in theory have narrowed to a point after the manner of a nozzle: in fact, however, the national economic variables have shown a pattern of divergence shaped more like a trumpet than a nozzle. Plotted in Figure 15, by way of an example, are annual inflation rates in the individual EC countries. To avoid making this figure unnecessarily complicated, only those countries are shown which, in each of

15 European Community. Highest and lowest annual inflation rates in the EC countries during the years 1965–75



16 European Community. Alterations in exchange rates for the DM during the years 1965-76 (Index 100)

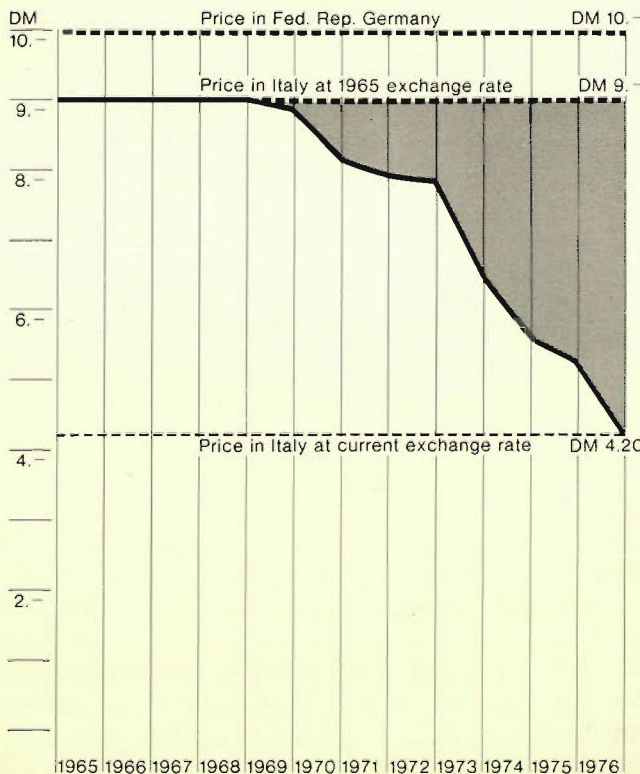


the years indicated, had the highest and lowest inflation rates. Whereas in 1965 the difference between these two extremes was barely 3 per cent, by 1975 it had widened to over 17 per cent. The lack of any jointly coordinated economic and monetary policy has inevitably also been reflected in an erratic development of exchange rates within the European Community. Shown in Figure 16 is the way in which exchange rates for the Deutsch-Mark altered over the period from 1964 to 1976. Here once again, no trend towards the elimination of old or new discrepancies is discernible: instead, we have the familiar 'trumpet syndrome'. For internationally distributing pharmaceutical enterprises operating in the European Community these monetary disparities in particular have had serious consequences of which a typical example will be given below.

Causes of international price differences

Three of the pharmaceutical markets in the European Community (those of the Federal Republic of Germany, the Netherlands, and Denmark) are to some extent organised on the basis of free competition. The remaining six EC countries, on the other hand, have regulated markets in which the pricing of pharmaceuticals is subject to government intervention of either a global or a specific type. In Belgium, France, and Italy, for instance, general freezes have been imposed on the selling prices of pharmaceutical products over periods of several years.

17 Structural differences and the influence of exchange rates as illustrated by the example of the Federal Republic of Germany and Italy



An example illustrating the repercussions of such price-pegging in the presence of erratically evolving exchange rates is given in Figure 17, which is based on the hypothetical case of a product introduced in 1965 at a price of DM 10 on the German market and at a price equivalent to DM 9 on the Italian market. The fact that the Italian price in 1965 was 10 per cent less merely reflects the lower labour costs which are a structural feature of the economy in Italy. Although the national selling price of the product remains the same in each country, the Italian price in 1976 is in fact 58 per cent lower than the German price. Having had no possibility of raising the price in Italy, the company marketing the product is then, in 1976, accused by the European Community of practising international price discrimination. It should be added that, to simplify this example, the assumption has been made that costs in the two countries remained constant during the years in question. If we abandon this assumption, it follows that additional price increases would have been necessary in both countries – whereupon structurally determined price differences and price differences due to alterations in the exchange rate become inextricably intertangled.

In the presence of pegged selling prices and erratic exchange rates, the emergence of international price differences is only a question of time. This in itself would not be all that bad. The real trouble begins when attempts are made to achieve harmony in the pricing realm *ex post* without having harmonised the economic structures *ex ante*. In this case, whichever EC country has been most ruthless in freezing its prices and has had the highest devaluation rate becomes the model upon which to base a common European price structure for pharmaceuticals.

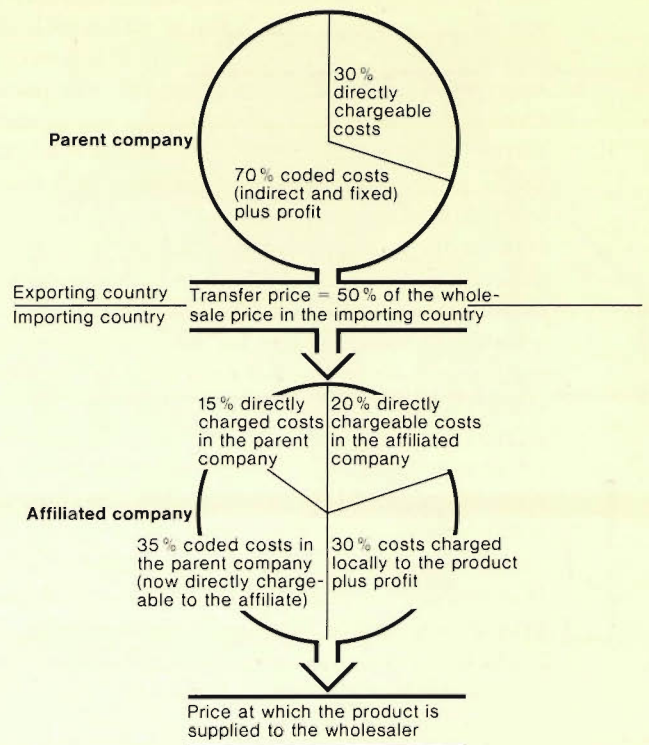
Recent statements issued by the EC Commission, as well as judgments made by the European Court of Justice, indicate a desire to impose harmonisation on the Community's pharmaceutical market without first having created the structural prerequisites for such harmonisation. This is a state of affairs to which the pharmaceutical industry has no alternative but to accommodate itself. Here, however, the pharmaceutical industry also finds itself in something of a quandary, insofar as those with whom it has to negotiate about national prices are the national authorities, whereas, even supposing that it reaches agreement with each of the respective national authorities, it still has no guarantee that the prices thus agreed upon will be accepted by the supranational EC authorities. On the other hand, in Brussels there is neither a body with whom it could negotiate nor an authority that has the power to impose a 'European' price on all the EC countries. In disregard of economic realities, the European Community is taking as its guiding juridical maxim the free international exchange of goods – a fiction upheld at the expense of industry.

National and international costs (transfer prices)

Research-based pharmaceutical enterprises active on an international scale make it a practice to decentralise a number of their operational functions while centralising certain others. In the case of research and development in particular, there are – if only for reasons of efficiency – limits on the degree to which decentralisation is feasible. To some extent pharmaceutical enterprises have deliberately resorted to decentralisation in their own economic interests, and to some extent they have been forced to do so by the existence of national laws stipulating that certain operational functions be carried out in the country concerned (eg the legislation prescribing local manufacture in France).

Costs arising from services rendered by a company's central headquarters should be equitably apportioned on a factual basis and debited by the country supplying them to the country receiving

18 Allocation of costs and prices



them. The money charged by the parent company for such services should be duly accounted for in the costing system of the affiliated company making use of the services. The 'vehicle' via which these service charges are offset between the parent company and its affiliates is the transfer price. Generally speaking, transfer prices are always suspect: the specific costs structure of research-based pharmaceutical companies is such that international transfer prices in particular repeatedly give rise to conjecture.

Figure 18 clearly demonstrates why the allocation of general costs, which already poses problems on a national basis, creates far greater problems in connection with international pricing. Besides the research and development work it performs, the parent company also provides its affiliates with other services which have to be paid for via the transfer price. The countries supplied from the parent company protest against the size of the transfer price on the following grounds: (1) that it is based on a distorted productwise cost-coding system, (2) that, through the transfer price, their country is having to make an excessively large contribution towards the defrayal of centrally incurred costs, and (3) that the transfer price serves not only to cover these costs but also to enable appreciable profits to be transmitted from the local affiliate to the parent company. Thus, in addition to the aforementioned difficulties involved in allocating general costs in a national market, trading between one country and another also poses the problem of the international allocation of costs.

Assuming for the sake of argument that at a given point in time an 'equitable' transfer price has been agreed upon, any drastic devaluations in the currency of the country to which the product is exported are bound to lead to considerable increases in costs if the transfer price is invoiced in the currency of the exporting country. Where alterations in the exchange rate entail increases in transfer prices, however, the importing countries strictly refuse to recognise these increases as a reason for an affiliated company to raise its prices. With each fresh devaluation, the affiliated company in the importing country thus incurs higher losses, which the parent company has to meet in order to prevent its affiliate from going bankrupt. The refusal to make allowances for shifts in exchange rates in connection with pricing is resulting in ever-increasing distributional injustices between the EC countries with a strong currency and those with a weak one.

The peculiarities of their national and international costs structure are one of the factors which in the past have almost invariably induced the pharmaceutical companies to adopt an attitude of

compromise towards price interventions on the part of national authorities. Whereas in the case of purely national industries such price interventions have direct and immediate repercussions on profits, in the case of international enterprises the economic effect of price freezing imposed by a national authority is *de facto* shifted into the country from which the goods are being imported. This is all well and good so long as the total earnings of the parent company are still sufficient to enable it to finance the central services it provides. The important point to note, however, is that even in the European Community situations have thus arisen in which some of the member countries have to make a bigger contribution to the financing of central services than others, despite the fact that these services are made available to all the EC countries in the same manner.

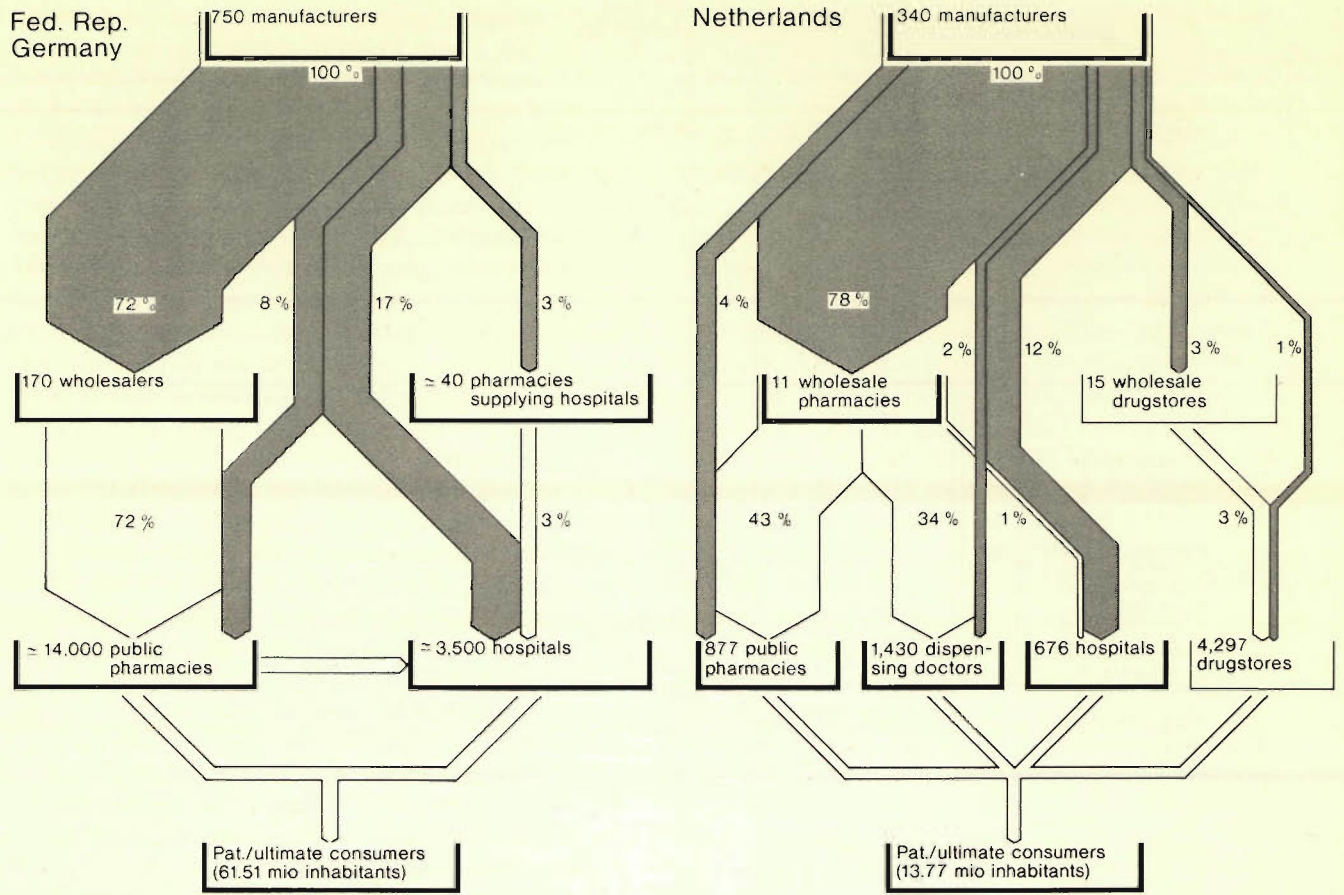
Structural differences and pricing

When determining the prices he proposes to charge for his pharmaceutical products in a national market in which free competition exists, the manufacturer must make allowances for all economically relevant factors on both the supply and the demand side. Recent publications (Prognos Study, Cooper) have clearly indicated which factors are likely to be economically relevant: the population level and its trend, the 'size' and the 'potential' of the national market, prescribing habits, medical schools, taxation systems, purchasing power, marketing systems, trade mark-ups, and value added tax. The manufacturer has to take account of all these national factors on the demand side in his competitive pricing calculations. Presented in Figure 19 is an example illustrating differences existing between the Federal Republic of Germany and the Netherlands with regard to the distribution network via which pharmaceutical products find their way from the manufacturer to the patient. Whereas, for instance, in the Netherlands doctors who do their own dispensing represent one of the main distribution channels, in the Federal Republic of Germany there are no such doctors. This explains why on the Dutch market large dispensing packs (containing 2,000–5,000 tablets) are offered for sale, from which the pharmacist or the dispensing doctor can supply the patient with the required number of tablets. On the German market, by contrast, medicines are normally sold in small standard packs (containing as a rule anything between 20 and 100 tablets).

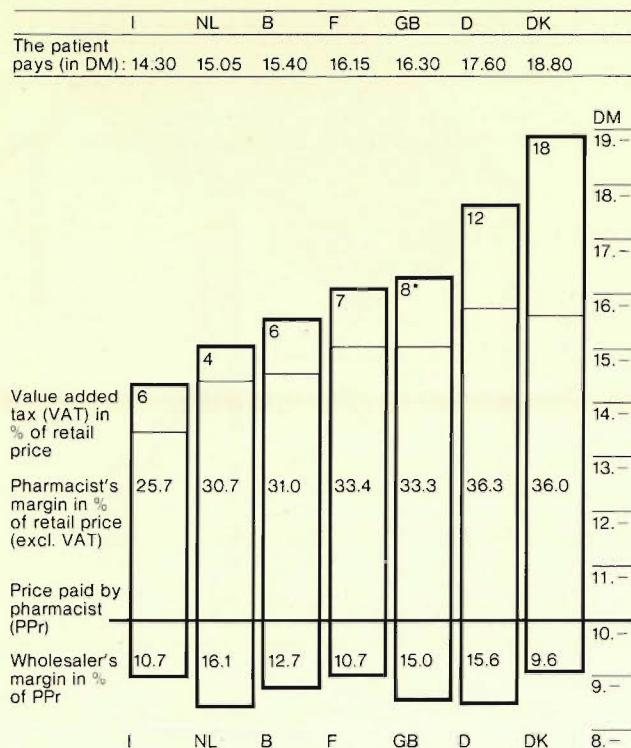
Impossibility of a 'European' price for pharmaceuticals

Even assuming that it would be possible to arrive at a uniform European manufacturer's price, it by no means follows that a European retail price for

19 Distribution networks for pharmaceutical products



20 European Community. How the retail price is arrived at in the case of a prescription preparation for which the pharmacist pays the equivalent of DM 10



*National Health Service drugs are not subject to VAT

pharmaceuticals could be established. Owing to differences in wholesalers' margins, in pharmacists' margins, and in the amount of value added tax that has to be paid in the various EC countries, there are still considerable price discrepancies at the consumer level. For a product which the pharmacist purchases at a price equivalent to DM 10, for example, the consumer has to pay the equivalent of DM 14.30 in Italy and DM 18.80 in Denmark. The extent to which wholesalers' margins, pharmacists' margins, and the value added tax differ in the EC countries is clearly apparent from Figure 20, in which the comparisons are uniformly based on the price paid by the pharmacist, because in most of the countries it is upon this price that the pharmacist's mark-up depends.

To ensure that the consumer pays the same price for a given pharmaceutical product in all the EC countries, one would have to make the manufacturer sell his product at different prices in the individual member countries of the Community; otherwise it would be impossible to achieve a uniform retail price.

On the other hand, if the objective were to ensure that the manufacturer charges a uniform price throughout the European Community, then – owing purely and simply to differences in trade mark-ups and taxation rates – the German or Danish consumer, for example, would have to pay more than one-and-a-half times as much for his medicine as the Italian consumer.

Finally, if the aim were to standardise both the manufacturer's price and the retail price throughout the European Community, this would mean that not only the manufacturer's price but also the wholesaler's margin, the pharmacist's margin, and the rate for the value added tax would have to be absolutely identical in each of the member countries.

Squaring the circle

If the manufacturer adapts the price of his pharmaceutical products to conditions prevailing on the market, he must of necessity make due allowances for differing national statutory and economic factors in the individual countries. Since – as already explained – conditions in the individual national markets of the European Community differ very widely, it is impossible with a market-oriented pricing system to achieve a uniform 'European' price for pharmaceuticals.

Because the Community has thus far failed to evolve a common economic and monetary policy, and because of differences in the economic structures of its member countries, there are still appreciable differences in costs within the Community. An analysis of these differences as they

specifically affect the manufacture and selling of pharmaceuticals (Prognos Study) has revealed that, when the Federal Republic of Germany – with a wage and salary index of 100 – is taken as a basis of comparison, the corresponding figures are 86 for France, 79 for Italy, and 47 for Great Britain. Such differences in national costs are bound to be reflected in differing prices where the system of price calculation is based on costs. So long as costs continue to differ so widely within the European Community, prices, too, would continue to differ in each of the EC countries even if it were possible to introduce a uniform ‘European’ system of price calculation.

It must thus be concluded that neither with a competitive pricing system nor with a system of price calculation based on costs would it be feasible at present to achieve uniform ‘European’ prices for pharmaceuticals.

This being the case, there might be a temptation to try and bring about such uniform prices by imposing free trade in pharmaceuticals within the European Community. In this event, countries in which prices have been allowed to evolve in accordance with the laws of supply and demand would be flooded with pharmaceutical products emanating from countries in which the State practises extreme intervention. Admittedly, the results might well be uniformity of ‘European’ prices for pharmaceuticals. But these prices would mean the end of the present structure of the European research-based pharmaceutical industry. The research-based pharmaceutical companies operating in countries with drastic price controls are currently trading at a loss. Although the turnover they achieve at the unrealistically low prices imposed upon them is still adequate to meet their direct costs, it is no longer fully sufficient to cover their consolidated (ie national and international) general expenses, including especially their research and development costs.

‘Free trade’ not a viable solution

Under normal circumstances, international trade should result in changes both in the structure and in the geographical location of industries, ie changes designed to exploit comparative cost benefits on an international plane. In other words, the existence of differing cost situations sets adaptational processes in motion which lead to an internationally optimal division of labour – provided, however, that free competition prevails. Where free markets and regulated markets exist side by side, free trade has the effect of causing distortions in the international division of labour, with the result that resources become misdirected. Viewed from the international standpoint, parallel imports* of (patented) pharmaceutical preparations,

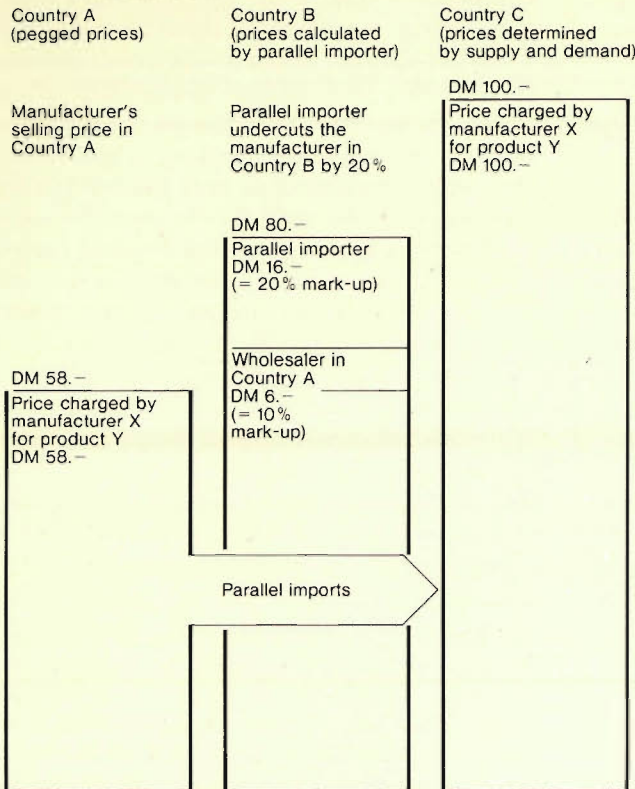
such as are now taking place in Europe, represent a form of misallocation; they have an adverse effect upon markets organised on the basis of free competition and, in the long run, they thus damage the economies of these markets. While it is true that parallel imports may result in short-term savings, they involve no economically rational arbitrage, but merely thrive on aberrations that have developed in a European Community whose economic harmonisation is at present paralysed. Thus they are harmful for the overall economy. No blame, however, attaches to those resorting to these parallel imports; as individual entrepreneurs they are acting in a perfectly sensible manner. The guilty parties are the institutions of the European Community which allow certain EC countries to be exposed to this form of damage affecting not only individual members of their business communities but also their economies as a whole.

The parallel importer is not a David fighting a Goliath. Admittedly, the war he is waging with the manufacturer who originally produced the pharmaceutical preparation in question is an unequal one, but the inequality stems from the fact that the manufacturer has no means of defence, whether economic or legal. Indicated in Figure 21 – once again in the simplified form of a model – is the ‘incentive threshold’ for trade in parallel imports. This threshold is attained when a product sells at the equivalent of DM 58 in one country as compared with DM 100 in another – assuming that the parallel importer is able to undercut the original manufacturer’s price in Country B by 20 per cent, that he allows himself a 20 per cent mark-up, and that the wholesaler’s mark-up in Country A is 10 per cent.

What is repeatedly forgotten by those advocating international free trade in pharmaceutical specialties is that these products represent a combination of commodities plus services. It is only possible, however, to trade internationally in the commodity itself, whereas the services that should go with it have to be ‘consumed’ in the country in which they are ‘produced’: services are neither internationally marketable nor can they be placed in storage until such time as they are needed. Assuming for the sake of argument that – as shown in Figure 22 – roughly 37 per cent of the overall costs are accounted for by specifically national services, then at least this much of the pharmaceutical specialty would not be internationally marketable. The following example

*‘Parallel’ importing is the practice of relatively small-scale entrepreneurs buying supplies in ‘low price’ markets and then exporting these to compete on price alone with the original innovator’s higher priced goods which are already available in ‘more expensive’ markets.

21 The 'importation of State-pegged prices' by parallel importers. An example illustrating how international competition may become distorted



If the price in one EC country is approximately 70% higher than in the other country, parallel imports become a paying proposition

may serve to illustrate this point: A pharmaceutical company in Great Britain provides specific services for the British market, the costs of which are largely determined by the specific wage and salary levels in that country. Included in the price of the British product are not only the costs entailed in manufacturing the commodity itself but also the costs involved in providing specific services for the British market. If the product in question is now exported to the Federal Republic of Germany, the German importer will be importing service components which may be quite different in the German market and, owing to the higher German wage and salary levels, also much more expensive. So long as it remains impossible to import, together with the product, British doctors and medical representatives earning British salaries, such parallel imports are bound to distort international competition. It is obvious to anyone that a holiday spent in the Federal Republic of Germany cannot be made cheaper by importing Italian hotel beds (=commodities) into the country; a German holiday would only become cheaper if the services required were to be made available at a price comparable with the price in Italy. Since, however, the commodity and the services are inextricably interlinked in the case of a pharmaceutical specialty, the research-based pharmaceutical industry is faced with considerably greater problems than other service-providing branches of the economy.

22 Pharmaceuticals – a combination of services plus 'commodity'

Overall costs (in DM)	Incl. wages and salaries	Incl. costs of materials
Production and quality control 30.-	20.-	10.-
Research and development 15.-	10.-	5.-
Scientific information 15.-	12.-	3.-
Promotion 5.-	2.50	2.50
Marketing 7.-	3.50	3.50
Administration 7.-	5.-	2.-
Other costs 6.-	3.-	3.-
Profit before tax 15.-		
	$\Sigma = 56.-$	$\Sigma = 29.-$
	Of which 1/3 for manufacturing the "commodity" = 19%	Of which 2/3 for specific national services = 37%

Future prospects and conclusions

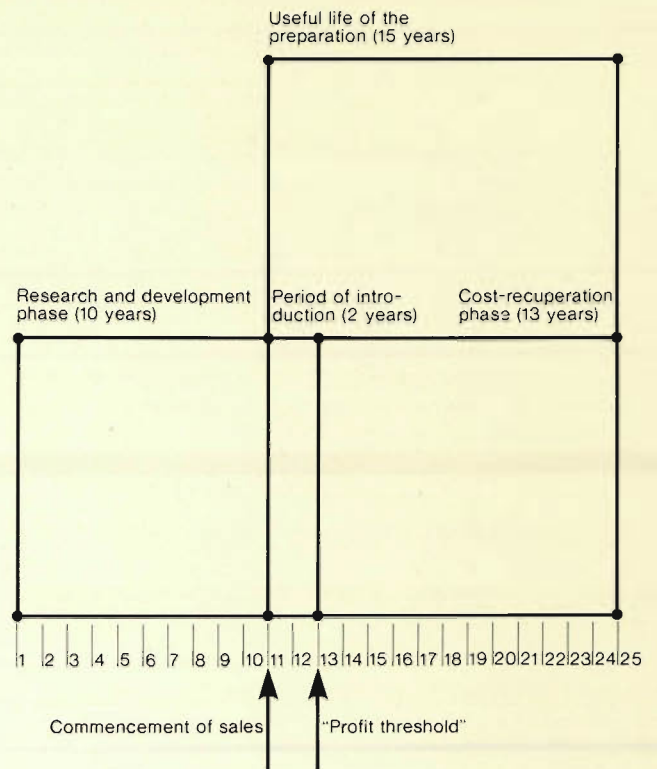
Economic consequences apparent only at a later stage

By forcing countries to throw open their frontiers to 'free trade' and by imposing drastic price controls, it might well be possible on a short-term basis to reduce the prices of medicines and thus to cut the costs of health care. Such a policy, however, would further diminish the pharmaceutical industry's earning power in markets operating a system of free competition and would increase the political pressure exerted on prices in these markets. Since in the regulated markets conditions have already reached the lower limits of what is still tolerable, savings on a general plane would also have to be effected in major cost categories. Economies made at the expense of research and development would only begin to produce visible repercussions after a time-lag of at least 10–20 years (cf Figure 23), always provided that research projects already started could be completed. But it must be borne in mind that cheeseparing operations affecting research and development are virtually impossible to reverse at short notice, because the 'human capital' invested in research cannot be 'liquidated' and then built up again regardless of the time factor. Economies of this type would eventually also cause health care costs in general to rise more steeply, because hardly any further cost-reducing therapeutic alternatives would be appearing on the scene.

In the health services – only a fraction of whose costs is accounted for by the pharmaceutical industry – economically rational savings can be achieved only by undertaking global reforms. Not until every participant in the health care market is provided with the economic incentives to make efficient use of the resources available to him will it be possible to effect savings. In the long run, coercion and regimentation have never led to economically rational patterns of behaviour – nor, for that matter, have appeals, exhortations, and voluntary restraints.

It will be recalled that in the case of prices for agricultural products the European Community has been trying to achieve a collective solution in the face of market forces. From recent publications it is apparent that in the agricultural field the Community is now confronted with the problem of coping with large surpluses while at the same time having to pay its farmers high subsidies. At present, prices for agricultural products in the Federal Republic of Germany are 15 per cent above the average European level and 40 per cent higher than in Great Britain. A European pharmaceutical market modelled along the lines of the existing agricultural market would thus hardly be a solution to be recommended.

23 The research and development phase in relation to marketing



No supranational authority with which to negotiate

Until such time as the research-based pharmaceutical industry succeeds in finding within the European Community a competent supranational authority able and willing to concern itself with the industry's international activities, there is every reason to suppose that selective national price interventions (exemplifying the 'beggar my neighbour' policy), arbitrary regulations, and other measures confined to individual national markets will continue eating away at the industry's earnings to such an extent that in certain countries it will hardly be worthwhile to remain in business. While it is true that initially only the research-based pharmaceutical enterprises suffer from the lack of an industrial policy within the European Community, in the long run it is society as a whole which must suffer.

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