COMMISSION
OF THE
EUROPEAN COMMUNITIES

XI/117/76-E
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Directorate-General
for Internal Market

PHARMACEUTICAL COMMITTEE

Legislation on the prices of proprietary drugs

GERMANY

1. Manufacturers are free to fix the price of proprietary medicinal products. Most of them apply the compulsory prices, namely the wholesale price which the pharmacist himself must pay. In other cases, manufacturers recommend a sales price which is usually applied.

2. Pharmacists, on the other hand, do not enjoy such freedom. They must conform to the provisions of the "German pharmaceutical Tariff" (Deutsche Arzneitaxe). This tariff is contained in a decree issued by the Ministry of Finance, as laid down by Article 37 of the law on drugs (Arzneimittelgesetz, 16 May 1961 - BGBl. 1 page 533). It is empowered to fix prices and price margins for the sale of drugs and to enact provisions determining prices in pharmacies. In doing this the Ministry must take account of the interest of consumers and of pharmacists as public institutions and suppliers of drugs.

The provisions regarding price formation concern medecines prepared by the pharmacist.

The pharmacist's margin for proprietary drugs varies according to the wholesale price. The present margin was fixed by the decree of 6 June 1968 (BAnz. no. 107). To the wholesale price applied on a normal market must be added,

a 70 % increase up to 2.40 DM	(gross profit 42.6 %)
a 68 % increase from 2.63 to 7.60 DM	(gross profit 40.5 %)
a 63 % increase from 8.21 to 14.28 DM	(gross profit 38.7 %)
a 53 % increase from 17 to 24.75 DM	(gross profit 34.6 %)
a 47 % increase from 26.80 to 38 DM	(gross profit 32 %)
a 42 % increase from 42.53 to 57 DM	(gross profit 29.6 %)
a 35 % increase over 68.40 DM	(gross profit 25.9 %)

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3. However, a draft law currently before the Bundestag provides for a reduction of 3.4 % in the dispensing pharmacist's margins and for a maximum wholesaler's margin.

   On the other hand, the discounts granted by the dispensing pharmacists to the sickness insurance funds will decrease from 7 to 5 %.

4. Finally, in order to ensure better market transparency, an independent committee must be set up. It will publish information notes on all the important medicines (composition, efficacy, side-effects, price) which will be distributed to the sickness-insurance funds and to the doctors affiliated thereto.

5. BASF, Bayer, Boehringer Mannheim and Hoechst have given notice of their intention of avoiding price increases in 1976 for large-turnover medicines, without, however, committing themselves to "freezing" the prices.
   The Pharmaceutical Industry Association (Bundesverband der Pharmazeutischen Industrie) has, in addition, recommended its members to reduce expenditure on samples, scientific information and advertising.

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BELGIUM

The law of 9 July 1975 (Moniteur belge of 30 July 1975) empowers the Minister for Economic Affairs to fix maximum prices for proprietary drugs and other medicines, maximum wholesale and retail margins and ceilings on the discounts granted by dispensing pharmacists. The Minister must consult the Price Commission.

I. The Price Commission

The royal decree of 8 August 1975 lays down the membership and the duties of this Commission (Moniteur belge of 19 August 1975). It is composed of equal numbers of representatives of the consumers and of representatives of the producers, the importers and the distributors. It also includes representatives of the ministries concerned. Its general task is to give its opinion on all questions relating to the prices of proprietary drugs, to keep track of the situation regarding the prices of proprietary drugs and to make suggestions concerning the price policy to be adopted, and to give opinions on the criteria to be taken into consideration where special decisions on prices are concerned.

In addition, it expresses opinions whenever maximum sales prices are fixed, whenever the levels of the margins are fixed and whenever the discounts granted by the dispensing pharmacists are regulated.

II. Criteria for fixing prices

These criteria were laid down by the royal decree of 11 December 1975 (Moniteur belge of 16 December 1975).

(a) When making his decision, the Minister must take into account one or more of the following general criteria:

1. trend of sales on the Belgian market and of the corresponding turnover;

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2. trend of expenditure by the sickness insurance funds;

3. impact of prices on consumers;

4. costs of the factors of production, of importation or of distribution;

5. level of advertising, of medical information expenses and sales expenses;

6. level of wholesale and retail margins;

7. incidence of V.A.T. rates;

8. research and investment;

9. effect on the profitability and the placing on an industrial basis of all the undertakings in the sector;

10. health interests of the public.

(b) The Minister must also take into consideration one or more of the following specific criteria, which must first have been examined by the Price Commission:

1. components of the ex-works or importer's price (starting materials and packaging, salaries, wages and social security contributions in respect of production and marketing, royalties, expenses for analysis and inspection, for research and development, general expenses, advertising, medical information, other sales expenses, profit);

2. effect of wholesale and retail margins;

3. incidence of V.A.T.;

4. balance sheets;

5. the number of units contained in each package and the strength per unit;

6. investment and numbers employed;

7. market and competition conditions and effect on export;

8. comparison with the current prices for identical or comparable products in other countries with a similar standard of living;

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9. comparison with the current prices in Belgium for medicines that are intercomparable from the therapeutic standpoint;

10. health interest, including the therapeutic value of the medicine, socio-economic, technical and scientific interest for society.

III. Application of the law

(a) The law on the system for pricing proprietary drugs seems to be of an experimental nature. It is to be applied only until 31 December 1977. Thereafter, failing any new ruling, the general law on prices will apply (law of 30 July 1971).

(b) The ministerial order of 10 February 1976 (Moniteur belge of 12 February 1976) laid down the application procedures.

1. The prices shall not exceed those that were current on 11 August 1975 or have been fixed since then.

2. Requests for fixing or raising prices must include information enabling an opinion to be given on the criteria set out in Section II above. Where no reply is received from the administration within a period of two months following the request for fixing the price, this shall be deemed to signify approval.

3. The wholesaler's margin shall not exceed 13.1 % of his selling price, not of V.A.T. (or BF 73 per package).

The pharmacists margin shall not exceed 31 % of his selling price, not of V.A.T. (or BF 250 per package).

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DENMARK

Pursuant to Article 30 of the law on pharmacies (Law No 248 of 2 July 1962), the selling price of medicines to consumers is fixed in a tariff laid down by royal decree. This tariff comprises the price of proprietary drugs and other medicines which cannot be sold at a lower or higher price (fixed prices).

The system for fixing the prices of medicines must be examined against the background of the strict control exercised by the Danish authorities, particularly with regard to the geographical distribution of dispensaries (334 pharmacies in 1974). It is by means of the tariff that the average net income of the dispensing pharmacists is fixed. The decisive factor that influences any change in the selling price of medicines is the estimate of the possibility of the net income of these pharmacists reaching the level fixed in advance by the Minister for the Interior (this level is at present equivalent to the annual salary of the head physician in a public hospital).

1. The tariff

The provisions of the tariff that concern the fixing of the price of proprietary drugs (selling price to the public) are as follows:

(a) In the case of proprietary drugs for which the pharmacist's purchasing price is Dkr 20 or less, this price is increased by 40 % + Dkr 0.70 or by 70 % of the pharmacist's purchasing price, whichever is the less.

In the case of proprietary for which the pharmacist's purchasing price exceeds Dkr 20, this price is increased by Dkr 8.70 + 30 % of the amount in excess of Dkr 20.

In the case of certain products (e.g. insulin), the pharmacist's purchasing price can only be increased by 10 %.

(b) An addition of 2) % is made to the amounts thus obtained.

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(c) The selling price to the consumer is obtained by adding certain supplementary costs that may arise in respect of ethical medicines or of certain special services (supply at night, for example).

The amount of these supplementary costs is fixed by the tariff, which also contains provisions relating to the discounts granted to hospitals, to public establishments, etc.

2. The dispensing pharmacist's purchasing price (Apoteksindkøbspris - A.I.P.)

The dispensing pharmacist's purchasing price (i.e. the producer's or importer's selling price) is registered but is not subject to approval by the public health authorities. However, Article 23 of Law No 327 of 26 June 1975 on medicines provides that the Danish Monopolies Commission (Monopoltilsynet) shall supervise the prices calculated by manufacturers, importers or wholesalers of pharmaceutical products in accordance with its terms of reference.

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FRANCE

I. System applicable to proprietary drugs which are not advertised publicly

The system is governed by the decree of 5 April 1968 (No 25.202: B.O.S.P. 9 April 1968) and amendments thereto.

1. Determination of maximum production price

Manufacturers fix the maximum production sales price, free of tax, by adding together the following components:

A. Industrial prime costs

(a) Cost of ingredients and packaging

This is obtained from the average purchase price during the two months prior to the month of manufacture, together with control costs duly motivated, actual losses in manufacturing, and approach costs duly motivated. The maximum percentage of such losses is fixed by the decree.

(b) Cost of direct labour

This covers wages or salaries paid to staff directly employed in the manufacture and packaging of products, and social costs relating thereto.

(c) Manufacturing and control costs

These cover: - wages or salaries and social costs paid to staff not working on the production side (cadres, supervision, checking, maintenance and handling excluding management, commercial and administrative departments)

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- materials consumed (coal, fuel, cleaning products, water, gas, electricity)
- rent and insurance of industrial premises
- amortization of materials and industrial premises

B. Financial, administrative and commercial costs

(a) Commercial costs

These are costs incurred for the sale of products, the sales force labour, packaging, mailing and advertising.

(b) Administrative costs

These relate to staff not coming under the preceding categories, rents, rental charges and insurance of administrative buildings, etc.

(c) Financial charges

These are the costs of capital used (interest, premiums, etc.)

C. Other costs

(a) Royalties, trade marks or licences

They are limited to 5 % of the sale price of products.

(b) Research costs

The real amount of this expenditure will be allowed for provided it is recoded in a special account.

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(c) Remuneration of own funds

This is calculated by applying 5 % interest, net of company tax, on own funds given in the most recent public balance-sheet.

D. Production sale price

This is obtained by adding together these different factors to which the manufacturer adds a profit margin which he himself fixes. In this way products whose industrial prime costs are low are not penalized.

2. Determination of prices at other stages

A. Wholesale price

This is the purchase price paid by the wholesaler, i.e. the production sale price plus VAT.

B. Pharmacist's price

This is the purchase price paid by the pharmacist. It is obtained by applying to the preceding price a maximum gross brand rate fixed at 10.70 % (Order No 25.795 of 24 July 1970 - B.O.S.P. 26 July 1970).

C. Price to the public

This is obtained by applying a maximum gross brand rate fixed at 33.44 % (Order of 24 July 1970) to the pharmacist's price.

D. Schedules of price variants

Manufacturers and wholesalers are free to fix scales of price variants to take account of the size of orders. These schedules must be lodged with the competent authorities and they alone are applicable.

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3. Notification and acceptance of prices

The maximum sales prices to the public proposed by the manufacturers must be notified to:

- The Directorate-General for Prices and Internal Trade
- The Ministry of Scientific and Industrial Development
- The Ministry of Public Health

at least thirty days before the date on which it is proposed to implement them.

The Directorate-General for Prices and Internal Trade may object to them.

Any subsequent price alteration is subject to the same obligations. However, the time-limit of thirty days is reduced to eight days where prices are lowered.

II. System for proprietary drugs reimbursed by Social Security

When a manufacturer applies to have his product included on the list of drugs reimbursable by Social Security, his application must be accompanied by a price slip in accordance with the provisions mentioned heretofor.

If such product is accepted for inclusion on the list, then it is this price which must be charged by the manufacturer. If the price proposed by the manufacturer is not accepted, the Ministry fixes the price on the basis of proposals from a commission of representatives of the sickness insurance funds and pharmaceutical industry associations.

By Order No 76-14/P (B.O.S.P. of 7 February 1976), the maximum selling prices of 230 medicines that are refundable to socially insured persons were reduced by 1 - 5 %. This reduction applies mainly to expensive medicines (antibiotics, tranquilizers, etc.).

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On the other hand, firms which in 1974 sold products whose producer price was not greater than FF 4 can increase prices by 13.3 to 60 %.

III. System for medicinal products advertised publicly

Those products must comply with the price programming scheme, in accordance with an Order dated 14 March 1972.

(i) Undertakings employing 20 persons or more:
Freedom to fix production prices if agreements have been concluded with the Directorate-General for Prices and Internal Trade either by the professional organizations or by the undertakings themselves. These agreements lay down a programme for price developments for a given period by reference to an average national indicator. But price increases may not exceed the limits fixed by the agreements.

(ii) Undertakings employing less than 20 persons:
Freedom to fix prices.

IV. System for imported proprietary drugs

No measures appear to have been taken in this regard.

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A report, which is still confidential, on the possibility of modifying the present system of price fixing, was recently forwarded to the Minister for Public Health by the "Guinard" working party.

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ITALY

Pursuant to Article 125 of the Act consolidating the Health Laws, approved by Royal Decree No 1265 of 27 July 1934 and subsequently amended, branded pharmaceuticals must be sold to the public at the price shown on the label.

I. Institutional framework

A. The Ministry for Health

The price of new medicines is fixed by the Ministry for Health when it authorizes the marketing of the product.

B. The Inter-ministerial Price Committee (I.P.C.)

The revision of the price of proprietary drugs already on the market falls within the competence of the I.P.C. Set up by Decree-Law No 347 of 19 October 1944, this committee is presided over by the President of the Council of Ministers and is composed of ten ministers(namely those for Finance, Treasury, Agriculture and Forestry, Transport, Industry and Commerce, Public Works, Labour and Social Security, Foreign Trade, Budget, State-subsidized industries) and three experts.

The Committee is assisted by an advisory body, the Central Price Commission, which conducts enquiries and makes proposals to it. The Commission consists of representatives of the Ministries, employers, workers, consumers and representatives of the regional Governments of Sicily and Sardinia.

This structure also exists at provincial level: in each province there is a Provincial Price Commission and a Provincial Advisory Commission.

C. The Inter-ministerial Economic Planning Committee (I.E.P.C.)

Set up by Law No 48 of 27 February 1967, this committee is presided over by the President of the Council of Ministers and includes many ministers. Subject to exercise of the powers conferred on the Council

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of Ministers it establishes, in particular, the guidelines for national economic policy.

On 27 July 1971 it issued a first directive fixing the prices of medicines (distributed by the press service of the Ministry for the Budget and Planning) and on 2 May 1975 a second directive (Gazetta Ufficiale No 143 of 3 June 1975).

II. The new method of price fixing

(a) The aims of the I.E.P.C.

The aims of the Interministerial Committee are seen from the recitals of the first directive to be as follows:

(i) To improve knowledge of "elementary" production costs;
(ii) To revise prices in the light of these costs, at the same time improving production in this sector;
(iii) To reduce marketing costs;
(iv) To reduce the number of branded pharmaceuticals and packagings;
(v) To encourage scientific research;
(vi) To extend this method, at a second stage, to veterinary products.

(b) Criteria laid down by the directives

(1) as regards the industrial cost:

This is arrived at by adding together the cost of the starting materials, the packaging and the value added. "The value added is determined primarily by reference to the labour cost plus an amount calculated by applying parameters resulting from the study of the function of the firm's cost which the I.E.P.C. has undertaken to establish. This function will be determined on the basis of a sample survey with the exclusion of certain factors relating to non-applicable features of the firm (size, technological level, quality of products)."

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(2) Commercial cost:

The aim is to reduce existing advertising costs to one third.

Advertising of popular branded pharmaceuticals will continue to be supervized by the Ministry of Health.

Hence, the present costs incurred in sending free samples, brochures, journals and any other advertising material will only be recognized to the extent of four-fifths.

These figures will be reduced in the course of subsequent price revisions.

(3) as regards scientific research and development:

An increase of 4 % of the turnover will be intended for research and development. However, an additional percentage (which must not exceed 10 % of the turnover on each proprietary drug) can be accorded to firms that are able to show that their research expenditure exceeds the 4 % mentioned above.

Royalties are considered as price components under the same conditions as research expenditure. However, they shall not exceed 7 % of the turnover on each proprietary drug.

(4) as regards imported products:

The directives also apply to imported products. For the cost evaluation of starting material that is original in its composition and has not yet been used on the national market, standard analysis criteria for industrial costs will be used. Firms will be required to submit an outline of the production process so as to enable this industrial cost to be evaluated.

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(c) Other provisions of the directive

(a) A general price catalogue of proprietary drugs (Prontuario generale dei prezzi) was to be published during the first half of 1973, but the publication date was subsequently postponed to 20 November 1975 and has not been adhered to.

It will include (i) the prices revised,

(ii) an assessment of certain items (technical and scientific information, samples) for the purposes of determining the prices of new medicinal products,

(iii) procedures for subsequent price alterations.

(b) However, regulation (provedimento) No 13/1975 (G.U. of 3 June 1975) allowed an increase of 12 % in the prices of proprietary drugs.

(c) Manufacturers' discounts to social security organizations will be abolished with effect from the entry into force of the new prices.

(d) The authorization to place drugs on the market will be suspended or withdrawn if the necessary factors for the revision of prices are not supplied. Draft laws will be introduced to increase the registration tax on branded pharmaceuticals and to ensure that the number of authorizations to place such products on the market corresponds to their actual use.

III. Current practice

The practice followed hitherto will be continued until the new method is applied.

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A. National products

The Ministry for Health fixes the price when the product is placed on the market.

The selling price to the public is calculated on the basis of the industrial cost of the product, to which are added the overheads and distribution costs and the wholesalers' and pharmacists' margins by application of predetermined coefficients and of parameters that vary in inverse proportion to the industrial cost.

B. Imported products

When applying for registration, an importer must furnish proof of the price applied in the country of origin by means of a document drawn up by the authorities in that country and stamped by the Italian consular authorities.

Three cases may occur:

1. Original branded pharmaceutical

If the branded pharmaceutical is original in its composition, i.e. if it is totally dissimilar to any other national branded product, the sales price is calculated on the basis of the price to the public in the country of origin, plus customs and transport costs.

2. Similar branded pharmaceutical identical to a national branded product

These are foreign branded pharmaceuticals which have the same composition as a national branded product. For these, the price is fixed at the same level as that of the national product.

3. Similar branded pharmaceutical not identical to a national branded product

Foreign and national branded pharmaceuticals do not have the same composition but there is an affinity in their composition and their therapeutic effects.

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Products are examined individually in order to determine whether it is possible to apply the price of the national product or if an increase should be allowed instead to take into account the value of the additional substances (which are not such as substantially to alter the characteristics of the branded product being compared).

C. Price of drugs reimbursed by sickness insurance funds

Since Law No 692 of 4 August 1965, it has been compulsory to give a discount to social security organizations on the public price of drugs consumed by persons covered by social security.

Decree-Law No 745 of 27 October 1970 fixed the discount on the selling price to the pbulic at 25 %, 18 % to be borne by the manufacturers, 1 % by the wholesalers and 6 % by the pharmacists.

This discount will be abolished when the new method of price fixing is applied.

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LUXEMBOURG

The main provisions regarding the price of branded pharmaceuticals are contained in the Regulation of the Grand Duchy of 28 July 1962.

I. System for national branded pharmaceuticals

These are products manufactured and packaged in the Grand Duchy which do not have any original equivalent in a foreign country.

1. Production price

The maximum production sales price to the wholesaler is established by adding together the following items:

(a) Production costs which consist of:

(i) The cost price of raw materials
(ii) Cost price of packaging materials
(iii) Wages and salaries and social costs relating to staff working on production
(iv) Cost price of electricity, gas, fuel and water
(v) General industrial costs, industrial amortization, amortization of research and control instruments, maintenance and repair costs, rental on industrial buildings, insurance, taxes
(vi) Wages and salaries and social charges relating to staff engaged in research, control and scientific information, plus the costs of running the laboratories.

(b) Other costs and benefits

These may not exceed a flat-rate amount equal to the following percentages of the total amount of production costs listed under point (a) above

120 % if the cost price of the raw materials used is less than 3 F
90 % if the price is between 3 and 10 F
60 % if the price is 10 F or more.

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Where the Ministry of Economic Affairs so authorizes, these percentages may be increased to 140 %, 110 % and 80 % respectively for a period of five years commencing from the date when the branded pharmaceutical is put up for sale if this has new therapeutic properties and is the result of research carried out entirely in the Grand Duchy.

2. Wholesale price

The wholesaler's margin, which must be approved by the Ministry of Economic Affairs, is at present fixed at 12.5 % of the pharmacist's purchase price.

3. Sales price to the public

This is the pharmacist's purchase price increased by 50 %.

II. System for branded pharmaceuticals originating in or coming from Belgium

The Regulations of the Grand Duchy of 29 March 1977 (Mémorial A No 21 of 9 April 1971) and of 10 July 1973 (Mémorial A 43 of 28 July 1973) are applicable in this regard.

Profit margins on products originating in or coming from Belgium are fixed as follows:

15.21 % of the wholesaler's pruchase price (13.20 % of his sales price)
46.70 % of the pharmacist's purchase price (31.83 % of his sales price)

However, public prices (including 2 % VAT), may not be more than 97.5 % of the public prices (including VAT) operative in Belgium.

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III. System for other branded pharmaceuticals

Where no customs duties are charged on branded products imported, the sales price in Luxembourg may not be more than 10 % in excess of the sales price in the country of origin.

Where duty is charged, this price may not be over 19 % in excess of the sales price in the country of origin in the case of drugs imported in bulk or over 14 % in excess for products imported fully packed.

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NETHERLANDS

At present no legal provisions exist regarding the prices of branded pharmaceuticals. Manufacturers are therefore responsible for fixing prices.

However, agreements under private law govern the relationship between the various categories in this sector. Thus, an agreement on trade in drugs (Handelsconventie) between manufacturers, importers and wholesale distributors fixes the maximum price margins, save in retail trade.

Similarly, a retain trade agreement (Pharmacon) governs relations between pharmacists.

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UNITED KINGDOM

1. General

In British terminology medicines fall into two classes, ethical and non-ethical. Ethical medicines are not advertised to the public, and physicians do not usually prescribe non-ethical medicines. Some ethical medicines can only be made available by pharmacists on prescription, but others may be sold over the counter without prescription. Non-ethical medicines are advertised for sale direct to the public.

Physicians are free to prescribe what medicines they think best for the benefit of their patients, and pharmacists are bound to dispense in accordance with the prescription presented to them. Pharmacists buy pharmaceuticals through wholesalers usually, but sometimes direct from manufacturers. Pharmacists are reimbursed by the Health Departments in the case of National Health Service (NHS) prescriptions (about 97 per cent of the total number), and by the patient in the case of private prescriptions.

2. Control of manufacturers' prices

Prices are controlled under the arrangements of the Voluntary Price Regulation Scheme (VPRS), whose terms are negotiated between the Health Departments and the Association of the British Pharmaceutical Industry. The scheme applies to all companies supplying medicines prescribed under the NHS. The major companies are asked to provide annual financial returns giving the breakdown of sales, costs and capital attributable to their business in NHS medicines, supported by and reconciled with the published accounts for their whole business (smaller companies are partly or wholly exempt from this requirement).

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The Department then assesses the profitability of each company's sales to the NHS in relation to the capital allocated to that part of the business, taking account of research, investment and any other special features of the company. If the Department considers that profitability is too high, negotiations are opened with the company with a view to securing price reductions. The Department's practice is to request an overall price reduction which the company is free to distribute among its products as it thinks fit, and not to ask for reductions on individual products.

Companies are free to increase prices of their minor products as they think necessary without reference to the Department, but they are asked to justify increases of major products. Companies may argue that the profitability as shown by their annual financial returns is too low. If the Department agrees, an overall increase will be settled, which again the company is free to distribute among its products as with price reductions.

These arrangements for regulating prices cover the total sales of medicines to the NHS, that is both specialty and generic medicines, whether prescribed by general practitioners or in hospitals. They are essentially appropriate to the bulk of the business that is the prescribing of specialities by general practitioners, and there are variations in the arrangements for generic prescriptions and hospital purchasing.

3. Generic prescriptions

The price reimbursed to the pharmacist for generic medicines (that is prescribed by their non-proprietary name) and preparations dispensed on National Health Service prescriptions is basically the net price for the appropriate quantity chargeable by the manufacturer or wholesaler. As, however, the majority of generic medicines and preparations are produced by a number of different manufacturers it is not possible to establish common prices payable by all pharmacists and because of this average reimbursement prices for these medicines are calculated by

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means of a weighting formula. This formula takes into account the shares in the total market of four firms who together provide 70 to 80 % of the trade in standard medicines and of supplies to pharmacists. Prices are subject to monthly revision and are the subject of consultation with the Central NHS (Chemist Contractors) Committee, the retail pharmacists' national representatives, before introduction.

The price reimbursed for any medicine which although generically prescribed, is only available in proprietary form is that of the lowest priced proprietary medicine which is generally available to all pharmacists.

4. Hospital purchases

Many medicinal products used in National Health Service hospitals are bought direct by hospital authorities under contracts placed by Regional Hospital Boards.

Items for which a regional contract cannot be justified either on grounds of quantity or price advantage are bought under local arrangements. Central contracts placed by the Department of Health and Social Security are only arranged where there are substantial price advantages or to ensure quality control. These contracts are very limited in number.

Although the negotiations under the VPRS relate only to the cost of medicinal products prescribed by general practitioners agreed price changes eventually reflect in prices charged to hospital authorities. It is also common for manufacturers to offer hospital supplies at prices considerably lower than those charged to the chemist for supplies under the General Practitioner Services.

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Accounts are met by individual hospital authorities from funds allocated by the Exchequer.

5. Statutory powers

Section 5 (i) of the Emergency Laws (re-Enactments and Repeals) Act 1964 empowers the Secretary of State by order to provide for controlling maximum prices to be charged for any medical supplies required for the purpose of the National Health Service Acts. No such order has so far been made. Prices of medicines provided outside the National Health Service are not subject to statutory controls.

6. Reimbursement of pharmacists under the NHS

The cost of materials used by a pharmacist in dispensing NHS prescriptions is calculated in accordance with the provisions of the Drug Tariff (using the word "drug" in the sense of medicines). The Tariff is prepared on behalf of the Secretary of State for Social Services in accordance with Regulation 26 of the NHS (General Medical and Pharmaceutical Services) Regulations 1966. In addition to detailing the calculation of payments for medicines, appliances and reagents, it specifies the grade or quality of medicines to be supplied. Payment is also made for the cost of containers; this allowance is paid on every prescription dispensed and is an average of the actual cost of containers used, as ascertained by regular container cost enquiries. A professional fee is also paid.

As in the case of generic products, the prices for all other medicines and appliances are reviewed monthly to take account of any price changes by manufacturers and such changes are similarly the subject of consultation with the Central NHS (Chemist Contractors) Committee, before introduction.

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7. Prices of private prescriptions

There is no mandatory method of pricing private prescriptions but pharmacists normally use that recommended by the Pharmaceutical Society of Great Britain. Under this method the pharmacist charges the cost price of the preparation and any container, plus 25 % as establishment charge and a fee of 30 p or, where it is greater, the retail price of proprietary preparations dispensed in their original packs. An extra fee of 12-1/2 p is charged for dispensing medicines controlled by the Dangerous Drugs Act 1965 and of 50 p for an urgent prescription dispensed outside normal hours.

8. Prices of over the counter sales

Preparations available for counter sale without a prescription are normally sold at retail price, or wholesale price plus 50 %.

COMMISSION
OF THE
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XI/117 /76-E

PHARMACEUTICAL COMMITTEE

Supplement to document XI/117/76 :

Legislation on the prices of proprietary drugs

Ireland

1. General

Medicines in Ireland are classed as ethical, which may be promoted to the medical profession but not otherwise advertised, and non-ethical which are promoted direct to the consumer through media advertising. Ethical medicines include those which may only be dispensed on a doctor's prescription and some which are sold by pharmacists over the counter without prescription. Non-ethicals do not require a prescription.

2. Source

Pharmacists obtain their supplies from manufacturers or from wholesalers. All new medicines must be authorised, on the advice of the National Drugs Advisory Board, but there is no restriction on the number of medicines marketed in the country.

3. Price Control

There is limited price control. Some medicines are imported in a manufactured state and since their prices are fixed outside the jurisdiction they are not subject to control. The basic ingredients of others are imported for final processing and in this situation while the price of the raw materials is not subject to control, increases in prices attributable to the processing undertaken in this country must be notified to the Prices Commission.

4. Price of drugs to the patient

Under the General Medical Service scheme some 37.5 % of the population are entitled to obtain medicines free of charge. These are dispensed by the retail pharmacists virtually all of whom participate in the scheme. For medicines dispensed in this way the pharmacist is currently re-imbursed by the State, the ingredient cost of the item (or trade price) plus 38p fee plus 6p towards container and other costs.

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The remaining 62.5% of the population must obtain their medicines from pharmacies at retail prices. These are not laid down by statute but in practice are normally calculated as trade price of the preparation plus 50%, for over the counter sales. Where the preparation is prescribed by a doctor an additional dispensing fee of 50p is added. In the majority of cases part of the cost of prescribed medicines can be recovered by the patient from health boards where the cost in respect of a month exceeds £ 5.00.

5. Price of medicines to Hospitals

Medicines purchased by hospitals or health boards attract discounts agreed with the association representing the manufacturers. The discount prices vary according to the quantities ordered, varying from trade price less 15% to trade price less 5%. Individual hospitals can sometimes negotiate more favourable terms.