



OCCASION

This publication has been made available to the public on the occasion of the 50th anniversary of the United Nations Industrial Development Organisation.



DISCLAIMER

This document has been produced without formal United Nations editing. The designations employed and the presentation of the material in this document do not imply the expression of any opinion whatsoever on the part of the Secretariat of the United Nations Industrial Development Organization (UNIDO) concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries, or its economic system or degree of development. Designations such as "developed", "industrialized" and "developing" are intended for statistical convenience and do not necessarily express a judgment about the stage reached by a particular country or area in the development process. Mention of firm names or commercial products does not constitute an endorsement by UNIDO.

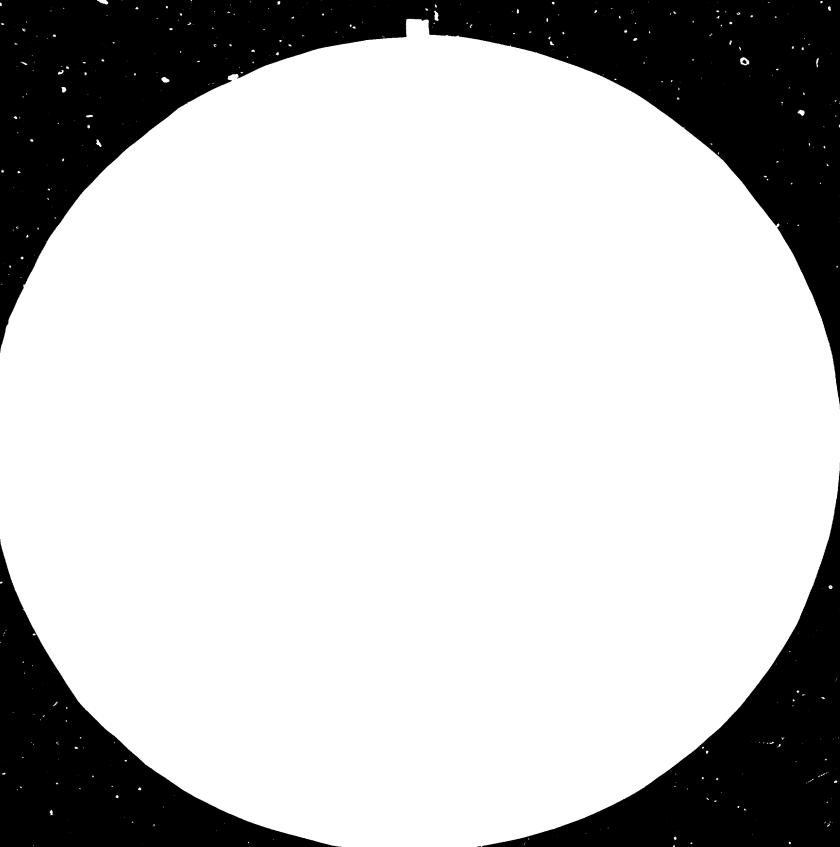
FAIR USE POLICY

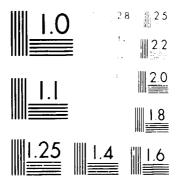
Any part of this publication may be quoted and referenced for educational and research purposes without additional permission from UNIDO. However, those who make use of quoting and referencing this publication are requested to follow the Fair Use Policy of giving due credit to UNIDO.

CONTACT

Please contact <u>publications@unido.org</u> for further information concerning UNIDO publications.

For more information about UNIDO, please visit us at www.unido.org







12915



Distr. LIMITED ID/WC.393/15 11 October 1983 ENGLISH

Organisation des Nations Unies pour le développement industriel

Second Consultation on the Pharmaceutical Industry

Budapest, Hungary, 21-25 November 1983

THE NEED FOR DRUG POLICIES

prepared by the UNIDO Secretariat

^{*} This document has been reproduced without formal editing



		Page
INT	RODUCTION	1
Α.	ELEMENTS OF DRUG POLICIES IN SELECTED COUNTRIES	3
	l. India	3
	2. <u>Nexico</u>	7
	3. <u>Sweden</u>	9
	4. United Kingdom	12
В.	IMPACT OF PRICE CONTROL	15
С.	SOME CONCLUSIONS	20

THE NEED FOR DRUG POLICIES

INTRODUCTION

A number of countries have established drug policies. One important aim of a drug policy is to provide maximum safety and efficacy when drugs are used. This objective is interrelated with pharmacological, toxicological, clinical and other scientific considerations; it is also related to storage conditions, safe transportation lines and the reliability of distribution systems.

However, the most fundamental policy problem is how to ensure the availability of drugs, and in particular essential drugs to the population. This involves economic, financial, technological, organizational and other aspects.

In developing countries considering the limited financial resources available, it seems to be of paramount importance to establish drug policies that ensure an optimum utilization of finance and manpower. Experience from countries with developed drug policies could assist other countries in the establishing of such policies.

In order to initiate a process of exchange of information a few case-studies are presented here. Economic elements of drug policies and especially price control systems have been highlighted in the studies concerning four selected countries: United Kingdom, Sweden, India, Mexico. The United Kingdom has a long experience of a nationwide system operating under free market conditions where the Government is the major and almost exclusive purchaser of drugs and where the main supplier is the private pharmaceutical industry. The price control system is not covered by statutory regulations, but based on a voluntary arrangement of understanding between the Department of Health and Social Security (DHSS) and the pharmaceutical industry. The main principle of this price control system is that the DHSS has access to financial information on pharmaceutical companies in order to control that drug prices are reasonable and fair and that the profits of the drug companies are not unacceptably high. It is assumed that if company profitability is controlled at an acceptable level, the prices of individual drugs will also be reasonable.

In Sweden a most comprehensive drug policy has been applied for more than ten years, characterized by a government involvement in production, wholesales and retail distribution and dissemination of producer-independent information, and, including price control.

Among developing countries, both India and Mexico have acquired experience in price control of drugs and in the promotion of pharmaceutical production within the countries. Essential drugs have been made available and, during a relatively short period of time, a pharmaceutical industry has been built up, based to a certain degree on domestic research and development.

The history of the development of drug policies in the four countries demonstrate first of all a strong awareness of the problem. One lesson which has been learned is that the first prerequisite for establishing drug policies is co-ordination of main interests involved. Not one ministry but several have to contribute and to co-operate. The involvement of non-governmental sources seems also to have been important.

This paper deals essentially with price control systems as parts of drug policies. It should be kept in mind, however, that in the pharmaceutical field, price control should not necessarily aim at promoting cheap drugs and opposing expensive ones. The overall aim must be to take into account all possibilities to make available appropriate drugs at reasonable costs. This includes the promotion of costeffective production and stimulation of research and development.

A. ELEMENTS OF DRUG POLICIES IN SELECTED COUNTRIES

i. India

History

The development of a drug policy in India goes back to general policies for regulation of retail prices of essential goods such as cloth, food grains, sugar and petroleum products. The motivation for this legislation has been the public concern with ensuring availability of common consumer goods to the common man in situations of shortages due to increase in demand outpacing the increase in production.

The early specific actions regarding the pharmaceutical sector occurred in 1962 when it became compulsory for the manufacturer and the pharmacist to publish and display prices of medicines prominently, and, in 1963, when drug prices were frozen. Later, the instrument of drug price control has been gradually developed, refined and transformed to a tool for remoulding and channeling drug production into a new pattern. The aim has been to bring down prices of essential drugs, to curb excessive profits, to promote research and development, and to diversify the range of pharmaceuticals.

Present Practice

The current price control system was established by the Drug Prices Control Order, promulgated in 1979. The prices of both bulk drugs and formulations are controlled according to this legislation. (However, some 15-20% of the total turnover is exempted from detailed price control). The basic work is done by the Bureau of Industrial Costs and Prices, an expert body of the Government which receives and collects data from the manufacturers. After examination of the data, the Bureau presents its reports and recommendations to the Development Commissioner Drugs, who scrutinizes them and notifies the prices in the Official Gazette after approval by the Minister for Chemicals and Fertilizers in

each case. The work of the Bureau is overseen by the Drug Prices Review Committee, with representation of the Development Commissioner Drugs, the Drug Controller, the Ministry of Health and Family Welfare, and the Economic Adviser in the Ministry of Industrial Development.

Drugs included

At present there are more than 300 bulk drugs included in the list of price controlled drugs. Out of these bulk drugs, about 200 are produced in the country.

In respect of bulk drugs for which there are no notified prices the manufacturers are required within 14 days of the commencement of production to furnish the details relating to cost. Based on this given data the Government fixes a provisional price, normally for a period of six months. After this period the manufacturer has to give available information based on the actual cost and actual working experience. After scrutiny of all information and a detailed study of technical aspects and other parameters, the final price is fixed and published by the Government.

New bulk drugs which are not produced elsewhere in the world are exempted from price control for a period of five years from the date of commencement of production. This rule has been established with a view to providing encouragement to the manufacturers to introduce new drugs produced through original research and development efforts in the country.

Import of only those finished and packed pharma euticals is permitted which are not produced in the country. Most of the medicines imported in the finished and packed form are essential and life saving medicines.

The import of finished and packed medicines, bulk drugs and intermediates is regulated under the Imports and Export Policy, issued by the Government. Restrictions have been imposed, varying from

absolute ban, and limited permissible imports to imports under Open General Licenses. Such restrictions take into consideration the indigenous production, capacity installed etc.

The Government is the biggest single buyer and distributor of drugs. It outs and distributes through its various departments and agencies, such as Central Government Health Services, Employees' State Medical Services, Defence and Railway Medical Services, etc. Drugs are also required in large quantities for National Programmes for eradication of epidemics or other diseases such as malaria, tuberculosis, leprosy, control of blindness and sexually transmitted diseases. In 1979-80, 25 million people were covered by these programmes. The target set for the 1980-85 Plan period is a coverage of 35 million people.

The hospitals under the Government of India (as distinct from the States) receive medicines from the "Government Medical Stores", run by the Ministry of Health and Family Welfare. Those stores invite tenders, before concluding rate-contracts for a full year's supply - as a rule at the lowest rates. State Governments make purchases separately through tenders for lots or annual rate contracts.

Price control systems as parts of a national drug policy have been in operation in India for twenty years. Recently steps have been taken to develop a more comprehensive drug policy. The following facts may be mentioned.

Institutional Set-up

In April 1983, a Development Council for Drugs and Pharmaceuticals Industry was established. The Council comprises 25 members, including represent tives of the Ministry of Chemicals and Fertilizers, the Ministry of Health, the Parliament, and scientific, professional and trade experts in the pharmaceutical field. Chairman is the Minister of Chemicals and Fertilizers.

The functions of the Council are:

- (1) Recommending targets for production, co-ordinating production programmes and reviewing progress from time to time.
- (2) Suggesting norms of efficiency with a view to eliminating waste, obtaining maximum production, improving quality and reducing costs.
- (3) Recommending measures for securing the fuller utilisation of the installed capacity and for improving the working of the industry, particularly of less efficient units.
- (4) Promoting arrangements for better marketing and helping in the devising of a system of distribution and sale of the produce of the industry which would be satisfactory to the consumer.
- (5) Promoting standardisation of products.
- (6) Assisting in the distribution of controlled materials and promoting arrangements for obtaining materials for the industry.
- (7) Promoting or undertaking inquiry as to materials and equipment and as to methods of production, management and labour utilisation, including the discovery and development of new materials, equipment and methods and of improvements in those already in use, the assessment of the advantages of different alternatives and the conduct of experimental establishments and of tests on a commercial scale.
- (8) Promoting the training of persons engaged or proposing engagement in the industry and their education in technical or artistic subjects relevant thereto.
- (9) Promoting the retraining in alternative occupations of personnel engaged in or retrenched from the industry.
- (10) Promoting or undertaking scientific and industrial research, research into matters affecting Industrial Psychology and research into matters relating to production and to the consumption or use of goods and services supplied by the industry.
- (11) Promoting improvements and standardisation of accounting and costing methods and practice.
- (12) Promoting or undertaking the collection and formulation of statistics.
- (13) Investigating possibilities of decentralising stages and process of production with a view to encouraging the growth of allied small scale and cottage industries.

- (14) Promoting the adoption of measures for increasing the productivity of labour, including measures for securing safer and better working conditions and the provision and improvement of amenities and incentives for workers.
- (15) Advising on any matters relating to the industry (other than remuneration and conditions of employment) as to which the Central Government may request the Development Council to advise and undertaking inquiries for the purpose of enabling the Development Council so to advise, and
- (16) Undertaking arrangements for making available to the industry information obtained and for advising on matters with which the Development Council are concerned in the exercise of any of their functions.

2. Mexico

History

In Mexico the established drug policy has been developed out of general economic policies aimed at controlling imports and protecting the citizens from undue price increases on food, cloth and other essential products.

Price control of pharmaceuticals goes back to 1947. In that year a system of warning regarding prices of finished drugs was introduced, followed in 1951 by a more firm price control system covering all finished products. A more comprehensive policy has been introduced later on. One landmark is 1976 when also active ingredients became part of the price control. Another one is 1977 when a National Commission on Prices was created and instructed to include in its work reviewing of the prices of all finished products and active ingredients in the pharmaceutical sector.

Industry and Trade

A pharmaceutical industry was established in Mexico by 1940. It now comprises 316 companies, including both domestic and transnational firms. Some companies produce just active ingredients, others produce only finished drugs and a few of them make both ingredients and finished drugs. The existing companies have a capacity sufficient to satisfy the actual demand and demand forecasts up to 1988.

Mexico is a net-importer of active ingredients. However, it should be noted that it exported 20% of the total production of such products in 1981. The aim is not to be self-supporting as there are many active ingredients with only a small consumption but to increase both the number and the quantities of active ingredients produced in order to reach an auto-supply between 30 to 65% of the total value of all used ingredients. The hope is that the importation value of the rest should be at least covered by the export of others. As far as finished drugs are concerned, Mexico is almost self-supporting with an import 1981 of only MXP 511 millions, which corresponds to 1,6% of the total national consumption. From the viewpoint of balance of trade, there is a slight surplus.

Drugs included

A Basic List of Drugs has been established. The List comprises 444 formulations, including 635 different presentations. Governmental institutions should limit their acquisitions of finished drugs to those enumerated in the Basic List.

Price Control

Within the price control system three sets of detailed rules have been established, each applying to one of the following kinds of drugs:

- (i) finished drugs paid by the consumer;
- (ii) finished drugs paid by the government;
- (iii) active ingredients.

Before a finished drug is put on the market, and every time when the manufacturer wants to increase the price of the product, he has to present an application with comprehensive economic information to the competent authority. This information should include general data regarding the company, general data on the product and similar products, information about production, commercialization and taxes, raw material used, direct labour costs, other costs for manufacture, sales and administration.

Institutional Set-up

The competent authority scrucinizes the data and if the different components of the information are approved as reasonable and in accordance with established rules they serve as a basis for fixing – dependent on the circumstances – one or more of the following prices:

The manufacturer's price; the distributor's price; the retailer's price; price to be charged when selling to the government.

It should be underlined, however, that about 70% of the governmental acquisitions are made by consolidated tenders. In 1981 the savings through tender acquisition amounted to 15%, calculated on the maximum prices.

In order to promote local production of active ingredients the system for setting maximum prices of such ingredients is more flexible than those referred to before.

The special Mexican policy to promote domestic industry comes through particularly as far as establishing maximum prices of active ingredients is concerned. If production of an active ingredient takes place in Mexico, a maximum price is given which is competitive compared to the price of the same product if imported. Changes in the prices are being calculated with the help of information on the actual price of imported intermediates, and changes in direct labour costs and consumer prices.

3. Sweden

Institutional Set-up and Control Procedures

Price control on pharmaceuticals is an integral part of the comprehensive governmental drug policy in Sweden. The institutional framework to support the policy includes the following:

- The National Board of Health and Social Welfare has the decisive influence on what kind of drugs are used in Sweden;
- One of the leading manufacturing drug companies, Kabi-Vitrum, is owned by the Government;
- All Swedish pharmacies are run by the government-dominated National Corporation of Swedish Pharmacies;
- Wholesales in pharmaceuticals are to 70% controlled by the Corporation;
- Drug prices are controlled by the Government through the Corporation;
- Producer-independent information on arugs is collected and disseminated by the Board and the Corporation.

About 98 per cent of all prescribed pharmaceuticals are finished drugs - so-called pharmaceutical specialities. About 2500 specialities are available on the Swedish market.

Before a pharmaceutical speciality can be sold in Sweden, it must be approved (registered) by the National Board of Health and Welfare. For registration, it is required that the speciality meets certain medical and pharmaceutical criteria and that it is reasonably priced. A price agreed by negotiation between the Corporation of Swedish Pharmacies and the applying manufacturing company is deemed to be reasonable provided that there are no special reasons to the contrary. If agreement cannot be attained, the drug company can take the case further to the National Board of Health and Welfare for a decision. As regards the prices of already registered specialities, these can be changed by negotiation between the Corporation and the drug company involved.

It follows that the policy in Sweden is aiming at the lowest possible price on drugs compatible with a high degree of pharmaceutical service. To achieve this goal arrangements have been made to control the cosc levels at the manufacturer, in wholesaling and in retailing. However, the control of drug prices is not an end in itself. As stated in the Agreement between the Swedish Government and the National Corporation of Swedish Pharmacies on the Activities of the Corporation, the prevailing goal is a cost-effective pharmaceut.cal service to people, doctors and hospitals.

Although a negotiation on the original price is different from that one dealing with a demand for a price change, there are a number of parameters which are more or less the same. These include:

- the therapeutic importance of the speciality and its effects on other treatment and medical care costs;
- the price of equivalent preparations in Sweden;
- the price of the same preparation in other countries;
- product calculation (raw material, manufacturing costs, package costs, etc.);
- sales volume.

The normal situation when a new drug is presented for approval in Sweden is that it has already been introduced elsewhere. If so, the prices in other countries are taken into account. Moreover, the therapeutic importance of the speciality and its possible effects on other treatment and medical care cost are discussed. On the basis of such material it usually has been possible to reach agreement on a price which the Corporation has considered reasonable. When agreement is reached on the price of a new drug it is often understood that the price is based on an assumption of a certain sales volume and that new negotiations should be initiated if that volume is exceeded.

In the discussion on individual price changes within the calculated total space for changes, the five main parameters come into operation. The most important one in this situation is normally the comparison with prices in other countries but also changes in sales volume is a matter of great importance. An objective of the Corporation is that the price should not be higher than the medium price by international comparison.

A slight change of the procedure took place in 1978 when the Government issued a decree introducing a general obligation to make advance notification of the price increases on goods and services to the National Price and Cartel Office. From then on,

the Office has carried out negotiations with the Swedish drug companies on the framework for price increases that can be approved in the light of general cost trends and other factors. Subsequently, the Corporation has negotiated with the individual companies about the distribution of the price increases among different preparations.

Information

Finally a couple of examples of the dissemination of producerindependent drug information may be mentioned.

The National Board of Health and Welfare has published a number of booklets on important drugs with evaluations based on reviews of the international scientific literature. The National Corporation of Swedish Pharmacies publishes every second year a comprehensive handbook with advice and information about the proper use of all pharmaceuticals available on the Swedish market. These publications are published and distributed free of charge to all doctors, hospitals and pharmacies in the country.

United Kingdom

History

For more than thirty years a most comprehensive health insurance scheme has been in operation in the United Kingdom. The scheme is compulsory and covers every citizen independent of income. A drug benefit is part of the scheme: prescription drugs, whether distributed to the patient in hospitals or acquired by the patient from pharmacies, are substantially financed by the Department of Health and Social Security. The DHSS total expenditure on drugs is now approximately GBP 1000 millions per year.

Industry

The United Kingdom is a net exporter of pharmaceuticals.

The companies supplying prescribed drugs to the DHSS cover a wide range of pharmaceutical activities from the more complex ones, which undertake bulk drug synthesis from substantially basic raw materials, through formulation and packaging and including local research and development facilities; to companies wholely dependent upon the importation of prescribed drugs in finished pack form.

Control Procedures

The DHSS control scheme covers some 170-180 pharmaceutical manufacturers and suppliers. However, companies with sales of drugs prescribed under DHSS of less than G3P 200 000 per annum are generally excluded from control; although such companies may be included in the price control scheme in special circumstances. The United Kingdom price control system is not covered by statutory regulations, but is based on a voluntary arrangement of understanding between the DHSS and the pharmaceutical industry.

Control is exercised over the annual profit of individual pharmaceutical companies either in relation to their level of capital investment, or in relation to annual sales value. Control is not ordinarily applied to the prices of individual products. However, where a single product has an annual sale in excess of GBP 300 000 (or 10% of a company's total sales) to the DHSS, the Department may exercise control over any suggested increase in the selling price of that product.

Although pharmaceutical companies are generally free to fix or amend individual product prices, control over company profitability should ensure that the DHSS annual expenditure on drugs is maintained within reasonable limits and at the same time, that the national pharmaceutical industry remains financially viable.

There is no fixed formula for determining what constitutes or does not constitute an acceptable level of profitability.

since circumstances vary considerably from one pharmaceutical company to another. At one extreme a company may be supplying products to the DHSS which are imported wholly in finished packed form. In such cases, control criteria will be concerned with the relationship between annual net profit and annual sales. Alternatively a company may supply products from a fully integrated chain of local manufacturing operations, including bulk drug synthesis, formulation and packaging. Under such circumstances profit levels can best be assessed in relationship to invested capital. Other situations may lie between these two extremes.

As a general guide the profitability of United Kingdom industry as a whole is taken into account. At the present time and broadly speaking, a 20% return on invested capital or a 10% profit on sales seems to be acceptable. However, the final decision on whether or not a company's level of profit is acceptable depends upon judgement, taking into account all related factors.

In the event that a company's profit level is found to be excessive the DHSS may require prices to be reduced in the current trading year to the point where profits are brought into line; or in some circumstances, repayment to the Department of excess profits which were generated in the preceeding year.

Generally speaking the DHSS does not attempt to negotiate or fix the selling prices of individual drugs. Consequently the prices of identical or equivalent formulations may vary from company to company. The DHSS does, however, provide all medical practitioners (who are responsible for prescriping drugs purchased by the DHSS) with comprehensive information on the cost of drug therapy for all major areas of medical treatment. In his choice of prescriptions, therefore, the practitioner is expected to take into account both the cost of the individual formulations and their therapeutic efficiency.

One of the objectives in building up the control system has been to establish an effective control of prices and profits with the minimum level of bureaucracy and at the lowest operating cost to the Government. It should, therefore, be mentioned that the group responsible for regulating pharmaceutical profits and prices under the scheme has a total staff of only ten departmental personnel. However, the major part of this group is made up of highly experienced people capable of conducting effective analysis of company financial statements and of applying sound judgement in assessing the acceptability or otherwise of company profitability.

Outlook

Recently it has been stated that the Price Control Scheme in its present form does not go far enough to reduce government expenditure on drug purchases. A report is due to be issued shortly. It is understood that the main recommendation to be contained in the report will be that pharmacists should dispense generic drugs where ever they are available at lower prices than the alternative branded preparations. It is estimated that this modification to the scheme would reduce annual expenditure on drug purchases by GBP 200 millions; or by 20% of government purchases.

B. IMPACT OF PRICE CONTROL

Attempts have been made to study to what extent price control has influenced drug prices in the four selected countries, and whether price control may have had an impact - positive or negative - on the activities of pharmaceutical industry.

Obviously it is not possible to estimate quantitatively the savings - or losses - which may have occurred as a result of the introduction of a price control scheme, since there is no way of forecasting precisely how drug prices would have evolved in the absence of such a scheme. However, several indications suggest that the different types of price control which operate in the selected countries have actively contributed to keeping drug prices at a reasonable level.

Price Index Comparisons

In India, Mexico and Sweden special drug price indexes have been developed and compared to price indexes in general. Comparisons in all the three countries show that drug price indexes exhibit more steadiness than indexes for prices in general. The following details may be mentioned.

The whole price index for drugs in India grew from 100 in 1970/71 to 151.6 in 1982/82. During the same period the index for all commodities taken together increased from 100 to 280.4.

In Mexico the general price index was growing 5.9 times during the period 1975-82, while the prices of finished drugs to the consumers increased only 2.71 times. In other words the drug prices to the consumers increased 46% compared to costs in general. As far as drug prices regarding governmental supply are concerned, they increased only 22% measured in the same way. The same impression remains if the drug costs are compared to wages. In 1982 a worker had to work half the time as in 1976 in order to buy the same drug. An observation of special interest is that as of 1977 when the National Commission of Prices was created there has been a remarkable slow-down in the increase of drug prices.

Also in Sweden comparisons between the general price index and drug price indexes show that drug prices have increased much slower than prices in general. In the period 1972-82 the general price index increased from 100 to 240 and the drug price index from 100 to 170. In a random sample of 20 drugs only two had a price increase higher than consumer prices in general during a period of 10 years. Of the remaining 18 drugs 8 had increased less than half of the percentage in which the consumer price index had increased.

Another indication of the impact of a price control system could be found through a comparison of drug prices in different countries. Such comparisons have been made between drug prices in Mexico and Sweden on one hand and a number of countries on the other. The Mexican prices were compared to drug prices in Central America, the Dominican Republic, Columbia, Brazil, Uruguay, Argentina, Canada, the United States, France and Italy. The lowest prices were in Mexico, followed by Brazil and Columbia.

The Swedish prices were compared with prices in 1: other European countries. In this study the outcome is that prices were lower in 5 countries (Norway, United Kingdom, Finland, France, and Italy). The prices were higher in 6 countries (Denmark, Belgium, the Netherlands, Switzerland, the Federal Republic of Germany, and Austria).

By and large, drug prices in the <u>United Kingdom</u> have been considered to be low. This is also confirmed by the Swedish study.

The price control system in the United Kingdom is explicitly designed to keeping the profitability of industry at an acceptable level. There is no evidence that this has hampered the development of British pharmaceutical industry. The United Kingdom pharmaceutical industry, and in particular the manufacturing sector, has remained comparatively prosperous over the last two decades, in spite of the imposition of profit controls. In particular:

- (i) Capital investment in expanded manufacturing operations, and in research and development facilities, has continued unabated.
- (ii) American and West European multinational pharmaceutical companies have established, or where they were already established have expanded, their manufacturing, research and development operations in the United Kingdom.
- (iii) Both national and foreign multinational pharmaceutical companies have developed substantial export markets, using the United Kingdom as a manufacturing base.

In <u>Sweden</u>, the current price control system has been in operation for more than a decade. Detailed studies have been made and published regarding the activities of Swedish pharmaceutical

industry during that time. So far, there is no evidence that the price control has had any adverse effects on the development of this particular industry.

Both in India and in Mexico incentives for the development of domestic industry have been built into the price control system:

As far as Mexico is concerned it has already been mentioned that an important industrial production of pharmaceuticals takes place in the country. From 1940 when industrial production started some 310 pharmaceutical companies have been established. The total sales of these companies in 1981 was MXP 40 775 millions distributed between MXP 33 490 millions on finished products and MXP 7 225 millions on bulk drugs. About 43 000 people are employed in the pharmaceutical industry. A comparison of figures concerning return on investments and net income on sales in 1977 and 1981 shows a positive development. The return on investments had increased from 17% to 20%; and the net income on sales had grown from 6% to 8%.

Figures from <u>India</u> covering the period 1978-1981 show a certain increase of the value of produced drugs, both formulations and bulk drugs. However, the most interesting thing is that a redistribution has taken place in favour of the public sector and the small scale sector. The foreign sector shows a slight decrease. Details are given in the following table.

Value of Indian Production of Bulk-Drugs & Formulations
Changes in Sectoral Shares

(USD millions)

Sector	1978-7	1979-80	1980-81 ^x)		
Bulk drugs					
1. Public sector	49	59	63		
2. Foreign sector	56	53	53		
Indian organise private sector	d 75	90	98		
4. Small scale sec	tor 20	24	26		
Total: bulk drugs	200	226	240		
Formulations					
1. Public sector	60	72	80		
 Foreign sector Indian organise private sector 	a 800	778	790		
4. Small scale sec	tor 190	300	330		
Total: formulation	<u>s</u> 1050	1150	1200		

x) estimated

Source: Ministry of Chemicals & Fertilizers

A complementary tool to reduce the drug costs is the use of organized tenders.

In India and Mexico, two countries with detailed price control on each drug, the tender system has been used in connection with big purchases for the government. The experience in both countries is that considerable savings have been made.

Still another method is authorization to dispense general drugs instead of branded preparations. Estimates in the United Kingdom suggest that remarkable savings could be gained this way.

C. SOME CONCLUSIONS

- 1. A comparison of Price Control Systems as part of National Drug Policies in India, Mexico, Sweden and the United Kingdom show that the systems follow different approaches. There are a number of similarities between the Indian and the Mexican systems with principall, price control on each single product. In the United Kingdom the emphasis is on the control of company profitability; in Sweden the control is performed through a negotiating process, being one element of a comprehensive pharmaceutical system under governmental control.
- 2. Drug policies, including price control systems in the studied countries have contributed to lowering the price level of pharmaceuticals.
- 3. The experience reflected in the case studies verify the importance of establishing National Drug Policies.
- 4. It seems likely that features of different existing systems can serve as guidance when building up National Drug Policies in Developing Countries. However, it seems unlikely that one pattern of Drug Policy can be universally suitable for all countries, taking into account varying national conditions regarding raw materials, manpower, research potential, etc.
- 5. Based on analysis and experience of existing drug policies, guidelines with provisions for their flexible application could be elaborated to assist Developing Countries in establishing National Drug Policies. The Second Consultation on Pharmaceutical Industry may wish to recommend that such guidelines be developed.

