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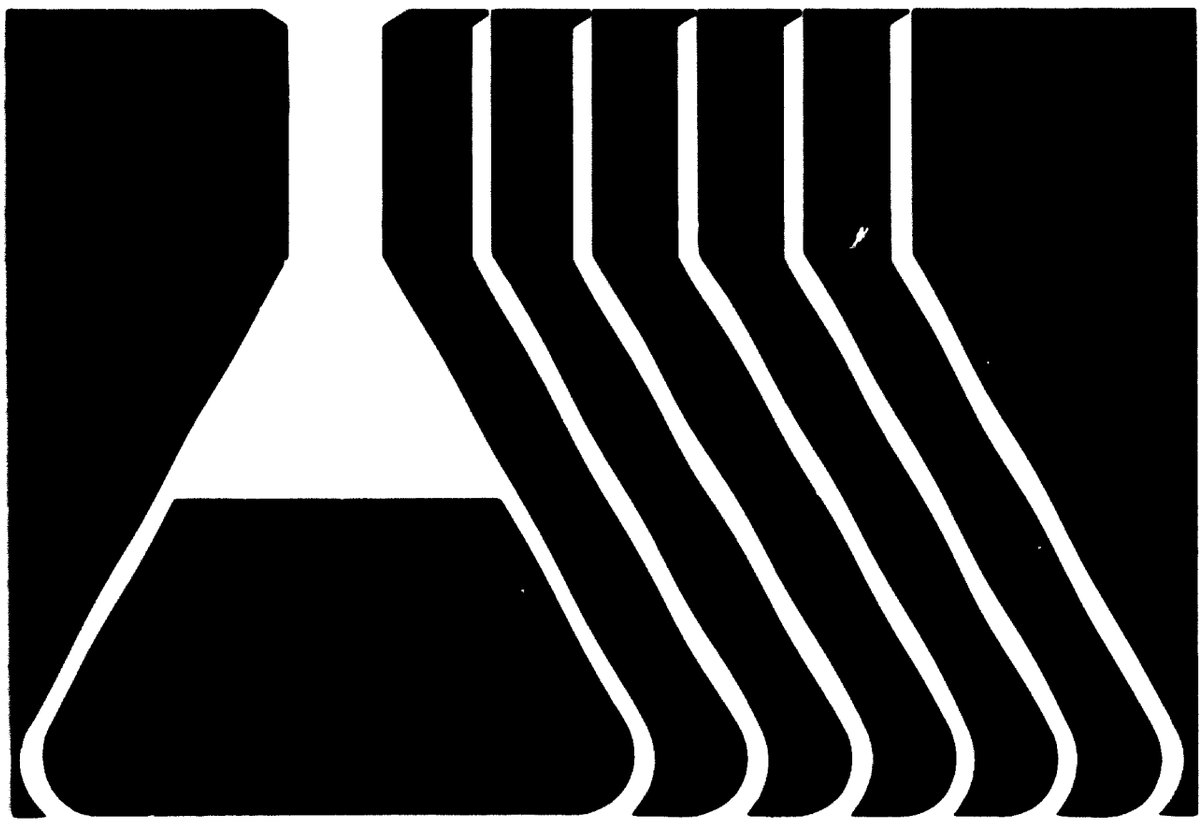
THE GROWTH OF THE PHARMACEUTICAL INDUSTRY IN DEVELOPING COUNTRIES: PROBLEMS AND PROSPECTS



UNITED NATIONS

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UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION
Vienna

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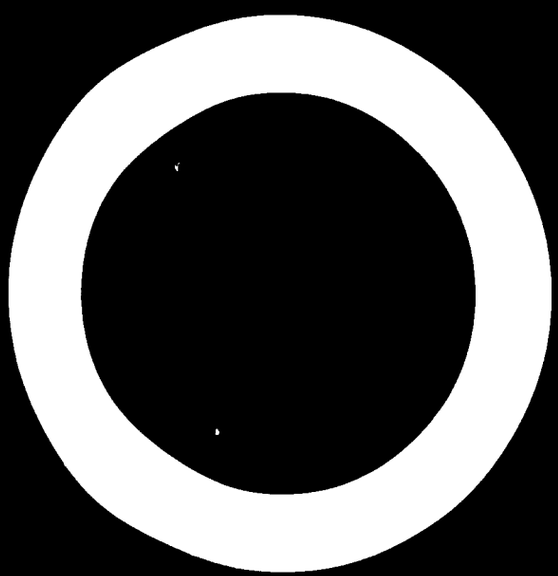

Preface

This study was prepared by Sanjaya Lall of the Oxford University Institute of Economics and Statistics, as consultant for the United Nations Industrial Development Organization (UNIDO). Except for chapter IV, which was prepared jointly by the consultant and the Chemical Industries Section of UNIDO, the views expressed are those of the consultant and do not necessarily reflect the opinions of the secretariat of UNIDO.

EXPLANATORY NOTES

References to dollars ($) are to United States dollars, unless otherwise stated.

The term "billion" signifies a thousand million.

The following forms have been used in tables:

Three dots (. . .) indicate that data are not available or are not separately reported

A dash (–) indicates that the amount is nil or negligible

A blank indicates that the item is not applicable

R and D refers to research and development

The following abbreviations of organizations are used in this publication:

COPPTEC	Co-operative Pharmaceutical Production and Technology Centre
CSIR	Council of Scientific and Industrial Research (India)
FDA	Food and Drug Administration (United States of America)
SPC	State Pharmaceuticals Corporation (Sri Lanka)

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Introduction

The difficulties that developing countries encounter in the development of pharmaceuticals are far more complex and widespread than those associated with the growth of most other industries. They range from the strictly technological problems common to most industries of obtaining know-how held by companies in developed countries and of fostering indigenous innovation to the economic difficulties of reducing the costs of buying technology and products in highly imperfect and oligopolistic markets, the medical difficulties of ensuring rational and effective therapeutic practice, the social difficulties of providing for the basic health needs of large numbers of poor people, the legal difficulties of defining property rights, contracts and obligations in the context of the international operations of private firms, and the political difficulties of countering abuses in the present system, with its entrenched interests, by careful and well-directed policies.

Consequently the task of pharmaceutical development is formidable. A UNIDO strategy to promote it must have two aims. Firstly, the interlinking complex of difficulties must be tackled on as broad a front as possible. To concentrate on one aspect such as how to promote the transfer of know-how and to neglect others may not help to resolve the general problems of developing countries in providing adequate medicines to their populations. While there are no easy solutions, a long-term strategy must be firmly directed towards comprehensive reform and planning at the national level. Secondly, since it is unlikely that most developing countries can muster enough financial, technological or manpower resources on their own to undertake a full policy for pharmaceuticals, the strategy must be based on co-operation between developed and developing countries and among developing countries themselves at regional and interregional levels, backed by appropriate support from international organizations.

The pharmaceutical industry is a crucial industry for developing countries for a variety of reasons.

Health care

The pharmaceutical industry provides products that are essential to the immediate welfare of the population and that cannot be replaced by other products. The industry is vital to the provision of health care and to the long-term improvement of standards of living. Judged on the basis of any set of criteria, moreover, the need for drugs in developing areas is far greater than their present supply.

Economic benefits

While the needs of health care could be met simply by importing all the necessary drugs from the developed countries, the pharmaceutical industry also

offers substantial tangible economic benefits if local production is undertaken. Even setting up simple formulation and packaging facilities can save developing countries up to 40 per cent in foreign exchange, and as great economies of scale are unnecessary, this potential can be exploited by countries with fairly small markets. A UNIDO strategy paper estimates that the minimum market for formulation and packaging plants is 3 million consumers; the paper mentions 14 countries that could proceed with such investments at once.[1] It also names 15 countries that are too small to set up independent facilities, but that could set up an indigenous industry on a co-operative basis.

Catalytic effect on industrial development

The pharmaceutical industry offers, besides savings in foreign exchange and its amenability to small-scale production, other important attractions to developing countries starting to industrialize. Firstly, machinery for the formulation and packaging of pharmaceuticals can be designed for a variety of end-products, thus giving the industry a commercial and economic advantage over other forms of modern industry. Secondly, the technology for establishing the preliminary stages of pharmaceutical production is well known and fairly well diffused. Thus, it can be purchased relatively easily from other developing countries, sometimes in a form adapted to the needs of unindustrialized economies. Thirdly, the rigorous need for control, testing, uniformity and other skills inherent in modern pharmaceutical production has important and beneficial external effects on developing economies. It enables the establishment of testing laboratories and preliminary screening facilities, the institution of relevant training in educational institutions, and a diffusion of technology related to chemicals, all of which are essential to continued progress in industrialization. Fourthly, a number of indigenous plants and some animal extracts have medicinal properties and can be used in modern pharmaceutical production.[2] The technology for the use of many of these natural products is already known; that for a number of others is in the process of initial screening, research and development.

For countries that already possess formulation and packaging facilities, the broadening and deepening of the industry locally is a more difficult task. The technology is more complex, especially when the manufacture of bulk chemicals is envisaged, and it is sometimes very new and under the tight control of the innovators in the industry. There may be substantial economies of scale, calling for large internal markets or for exports. These very factors can, however, contribute to industrial development if tackled with proper care and planning. The development of the indigenous manufacture of chemicals in bulk can substantially reduce the cost of obtaining such products. Much of the technology for the bulk production of essential drugs is already possessed by the more advanced developing countries and can be transferred to others on a basis that is both more economical and better adapted to the needs of less-industrialized countries.

The technological requirements of developing pharmaceutical industries at this level are greater than in the initial stages. Highly developed chemical and pharmacological skills, sophisticated process know-how, formulation and packaging

[1] UNIDO, "Draft strategy paper on UNIDO pharmaceutical activities", 10 November 1976.

[2] For a brief description see *ibid.*, pp. 10-12.

research and extensive quality-control facilities are all an intrinsic part of this industry's natural development. Further, some research and development of new drugs may also be undertaken once productive units have reached a certain minimum size, although it should be noted that a successful programme of research may be extremely costly and risky and thus beyond the reach of individual enterprises in developing countries.

Social benefits

Besides the benefits to the industrialization process that the development of pharmaceuticals may bring, there are quite distinct social benefits that an indigenously based production programme may offer. A relatively independent drug industry may give the developing countries more freedom to form health-care policies that are relevant to their peculiar needs than would otherwise be the case. A pattern of pharmaceutical production that reproduces the experience of the developed countries has certain built-in costs. These costs may be minimized with locally based production facilities governed by an overall health policy.

The pharmaceutical industry is, in sum, one of the most promising areas for industrialization in developing countries. It is also one in which socio-economic considerations call for a carefully planned strategy rather than the free play of market forces.

The potential for this industry has been recognized by the developing countries. It is one of the industries selected under the provisions of the Lima Declaration and Plan of Action on Industrial Development and Co-operation[3] for the negotiation of the relocation of productive facilities from the developed to the developing world. Hence, by the end of this century, 25 per cent of total world production of pharmaceuticals should come from the third world. Member Governments of UNIDO are expected to hold consultation meetings in 1978 to decide on the issues for negotiation, to form working groups and to devise a strategy for implementing the Lima Declaration.

Other international efforts are being made to design and implement a broad strategy relating to pharmaceuticals. The World Health Organization (WHO), the United Nations Council on Trade and Development (UNCTAD) and UNIDO have recently formed a Joint Task Force to implement, under the auspices of the United Nations Action Programme on Economic Co-operation (UNAPEC), a resolution passed by the Summit Meeting of Non-Aligned Countries at Colombo, Sri Lanka, in August 1976, and later by the Group of 77 in Mexico.

In chapter I of the present study the structure of production and trade for the pharmaceuticals industry is given for 1973, the last year for which data were available. Chapter II deals with the problems that developing countries face in achieving a rational and desirable form of growth for their indigenous pharmaceutical industries. In chapter III mention is made of some of the new directions in policy that have become evident in both developed and developing countries, as well as in the international organizations concerned. The activities of UNIDO in the field of pharmaceuticals are described in chapter IV and plans are discussed for its future strategy.

[3] ID/Conf.3/31, chap. IV.

I. Production and trade in pharmaceutical products

Data on the production of pharmaceutical products are not readily available for a large number of countries outside the Organisation for Economic Co-operation and Development (OECD) (and within the OECD for Switzerland, a leading pharmaceutical producer). Data on trade in pharmaceutical products are easier to obtain, but even so it is impossible without laborious and detailed work to obtain a breakdown of different therapeutic categories and of drugs in different stages of manufacture. The description here draws on an earlier work[4] and is therefore incomplete and based on conjecture. Still it represents the most comprehensive survey of the field and may be useful as a guide until an exhaustive study being prepared by UNIDO is completed. For the most part only market economies are considered; data are mainly for 1973, the latest year for which production and trade statistics were widely available. The year 1974 is the base year for the review of production of the transnational corporations.

Production

Table 1 gives data on the estimated production and consumption of pharmaceuticals in 1973 by three groups of countries, using values expressed in millions of current United States dollars. Detailed figures are provided in table 7, annex I, which shows production, exports, imports, consumption and trade balance for 17 developed countries, 4 southern European countries and 27 developing countries. Many of the production figures are estimates based on data for earlier years; thus, existing figures are extrapolated using rates of growth in keeping with recent performance of the industry in the country in question. Sources and details of the calculation are given in notes to table 7, annex I.

TABLE 1. ESTIMATED PRODUCTION AND CONSUMPTION OF PHARMACEUTICALS, 1973

	Production		*Consumption*[a]	
Country group	*Million dollars*	*Percentage*	*Million dollars*	*Percentage*
Developed market economies	24 919	84.3	23 372	80.8
Southern European countries	1 534	5.2	1 798	6.2
Developing countries	3 113	10.5	3 767	13.0
Total	29 566	100.0	28 937	100.0

[a]Defined as production plus imports minus exports.

[4] S. Lall in co-operation with the UNCTAD secretariat, *Major Issues in Transfer of Technology to Developing Countries: A Case Study of the Pharmaceutical Industry*, TD/B/C.6/4 (Geneva, 8 October 1975).

It seems safe to assume that the 48 countries included in the calculation account for most of the drug producers of any significance in the world. Of the total estimated production of about $30,000 million, the developed world accounts for nearly 85 per cent, the southern European countries for 5 per cent and the whole developing world for slightly over 10 per cent.

An earlier calculation for 1971 indicated that the total world production of about $21,000 million was divided between the three groups 86 per cent, 4 per cent and 10 per cent respectively[5] in a very similar fashion. In the course of these two years, the developed world lost a slight amount of its share and the developing world slightly improved its share; the southern European countries showed more significant improvement, registering a 1 percentage point gain. In terms of annual rates of growth, world output rose (at current prices) by 19 per cent, output of the developed countries by 18 per cent, output of the southern European countries by 31 per cent and output of the developing countries by 22 per cent in this period. While care should be taken not to put too much reliance on the precise figures for both years, and while individual country performances show important differences, the broad magnitudes are indicative and significant:

(a) In real terms, world pharmaceutical output seems to be growing at about 10 per cent per annum (this may have to be corrected when specific estimates for changes in drug prices are found);

(b) Output in the developed world is growing somewhat more slowly than elsewhere. Southern European countries and some developing countries (viz. Brazil, Indonesia and Iran) are showing nominal rates of growth of over 20 per cent per annum;

(c) Given the present distribution of world output and relatively small differences in performance between the developed and developing countries, if recent trends continue, it is highly unlikely that the 25 per cent relocation of production called for in the Lima Declaration will be achieved. If the southern European countries are counted in the developed world and if it is assumed that this group continues to grow at 10 per cent per annum while the developing world grows at 15 per cent per annum, which is an optimistic assumption, in 20 years the latter would account for only 17 per cent of a total world output of some $160,000 million. The developing world would have to grow at about twice the rate of the developed world over the entire period to achieve a 25 per cent share by the end of the century.

Among the developing and southern European countries, Brazil, India, Mexico, Spain and Yugoslavia account for $2,854 million or 61 per cent of the total output of the two groups together. The other countries producing pharmaceuticals in significant amounts (over $100 million per annum) are Argentina, Chile, Colombia, Egypt, Portugal, the Republic of Korea, Thailand, Turkey and Venezuela. These are the countries which (with the possible exception of the Republic of Korea, Thailand and Venezuela) have also achieved some degree of backward integration in production and which are able to manufacture domestically some, or many, bulk chemicals. Of the non-European countries, those best equipped to provide technology to other developing countries are Argentina, Brazil, Egypt, India, Mexico and Turkey.

[5] *Ibid.*, table 1.

Trade

Figures for exports and imports of pharmaceutical products in 1973 are given after production figures in table 7, annex I (pharmaceutical products being defined as SITC item 541, "Medicinal products"). The information is summarized in table 2, which gives a breakdown of exports and imports by the three groups of countries for 1968 and 1973.

Total exports of the developed market economies grew by 144 per cent in the five years 1968-1973, or at an annual compound rate of growth of 20 per cent. In the two-year period 1971-1973, for which production estimates have also been made,[6] total exports grew by 24.5 per cent per annum, or at a rate that was considerably faster than that for total output (19 per cent). The share of developed countries in exports remained overwhelmingly large, although it declined slightly from 93 per cent to 92 per cent in 1968-1973. Both the southern European and the developing countries increased their shares of total exports, registering annual growth rates of 29 per cent and 23 per cent respectively. In the two-year period, 1971-1973, the growth rates of exports of the three groups separately were: (A) 24.5 per cent, (B) 24.5 per cent and (C) 22.1 per cent. Although the growth in exports of these groups was surprisingly similar, when it is compared with the growth of output it is evident that exports increased proportionately at the fastest rate for the developed countries and at the slowest rate for the southern European countries.

In 1973, developed market economies exported 17.2 per cent of their production, southern European countries 3.6 per cent and developing countries 11.1 per cent. The figure for the export performance of the developing countries must, however, be treated with some caution. International trade statistics give data for "medicinal products" as a whole and include natural substances (mainly plants) used for medical purposes. These materials comprise a large part of the exports of developing areas. To determine the manufactured pharmaceuticals exported by the industry in developing areas, such raw material exports would have to be separated out; the result would be that exports as a proportion of output for the poor countries would be much lower.

Only seven developing countries in 1973 exported over $10 million worth of pharmaceutical products (broadly defined). They were Argentina, Bahamas, Hong Kong, India, Mexico, Singapore and Yugoslavia. If the entrepôt trade centres and tax havens are excluded (Bahamas, Hong Kong and Singapore), only four had exports of any significance. Of the southern European countries, Portugal and Spain were major exporters, both having recorded impressive increases in recent years.

As may be expected, developing countries are much larger importers than they are exporters. In 1973, their deficit in pharmaceutical trade reached $1,300 million, an 87 per cent increase over 1968. As a percentage of world production, developing countries imported 51.8 per cent in 1973, compared with 11.7 per cent for developed countries and 20.7 per cent for southern European countries. The largest importer was Brazil (10.8 per cent of world output); it was also the largest producer among the developing countries although a relatively minor exporter. Iran was close behind—a minor producer exporting practically nothing. Among the major producers, Mexico imported 25.3 per cent of its output, Argentina 24.7 per cent (production figures are based on guesswork), India 6.9 per cent and Yugoslavia 20.5 per cent. Most of these countries, in contrast to the less industrialized

[6] *Ibid.*

TABLE 2. WORLD TRADE IN PHARMACEUTICAL PRODUCTS, 1968 AND 1973

Country group	Exports				Imports				Balance	
	1968		1973		1968		1973		1968	1973
	Million dollars	Percentage	Million dollars	Percentage	Million dollars	Percentage	Million dollars	Percentage	Million dollars	Million dollars
(A) Developed market economies	1 784.1	92.9	4 282.2	91.4	1 097.7	54.6	2 910.2	60.1	686.4	1 372.0
(B) Southern European countries	15.5	0.8	55.8	1.2	113.7	5.7	318.0	6.6	- 98.2	- 262.2
(C) Developing countries[a]	120.7	6.3	344.6	7.4	797.7	39.7	1 613.6	33.3	- 677.0	- 1 269.0
Total	1 920.3	100.0	4 682 6	100.0	2 009.1	100.0	4 841 8	100.0	- 88.8	- 15° 2

Source: United Nations, *Yearbook of International Trade Statistics*, various issues.

[a] Including Yugoslavia.

developing countries, imported mainly bulk chemicals for further processing and formulation, and many of them had ambitious programmes to set up domestic fine chemical industries to reduce import dependence. India had advanced the most in establishing import-substitution industries; the country is now able to produce a broad range of the bulk chemicals required in pharmaceutical manufacture.[7] Mexico ranks second. Among the southern European countries, Spain is the most advanced in the production of bulk drugs.

Transnational corporations in world pharmaceutical production and innovation

In an earlier study it was estimated that the leading 61 firms in the industry, all with transnational operations, in 1970 accounted for just under 60 per cent of total production of pharmaceuticals of the world market economies.[8] To obtain an idea of the level of concentration in a more recent year, sales data have been collected on 34 of the leading transnational drug corporations; and, using the 1970 ratio of pharmaceuticals to total sales (for lack of better estimates), their pharmaceutical sales have been calculated as a percentage of estimated world sales for 1974. The firm-by-firm data are given in table 8, annex I; estimates of various concentration ratios on a world-wide scale are given for 1970 and 1974 in table 3.

TABLE 3. WORLD-WIDE CONCENTRATION OF PHARMACEUTICAL PRODUCTION, 1970 AND 1974

	1970		1974	
Sales	*Million dollars*	*Percentage*	*Million dollars*	*Percentage*
Total sales[a] of developed market economies	18 633	100	34 001	100
Sales of leading 10 firms	4 987	27	9 498	28
Sales of leading 20 firms	7 748	42	14 561	43
Sales of leading 30 firms[b]	9 249	50	17 682	52

[a] Estimated from 1971 and 1973 figures assuming 12 per cent growth in 1970-1971 and 15 per cent growth in 1973-1974.

[b] Only firms for which data are available for 1974 were chosen for 1970.

The figures for world-wide production are based on incomplete data and some guesswork, so that the estimates of firm concentration cannot be precise. However, in view of the similarity of the concentration ratios for the two years and their stability,[9] the magnitudes indicated should be substantially reliable. Some 30

[7] For a detailed discussion, see the Hathi Committee, *Report of the Committee on Drugs and Pharmaceutical Industry* (New Delhi, Ministry of Petroleum and Chemicals, 1975).

[8] S. Lall and UNCTAD, *op. cit.*, pp. 16-17.

[9] Interestingly enough, recent data for trends in this industry in the United States and United Kingdom show that concentration at the 20-firm level declined somewhat in the 1960s and rose slightly (by 2 percentage points in both countries, to about 75 per cent of sales, by 1973) between 1970-1973. This trend accords with the slight increase in concentration shown by our data. See H. G. Grabowski and J. M. Vernon, "Structural effects of regulation of innovation in the ethical drug industry", in Masson and Qualls, eds., *Essays on Industrial Organisation in Honor of Joe S. Bain* (Cambridge, Mass., Ballinger, 1976).

transnational corporations thus account for half of the total output of drugs in the developed market economies, and some 60 for about 60 per cent. The share of such corporations varies from country to country, depending on government policy (for instance, Egypt has strictly limited foreign participation) and the strength of the local drug industry (Argentina seems to have a particularly strong indigenous private sector), but on the whole it may safely be assumed that the 100 odd firms from developed market economy countries that invest in developing countries control 70 to 90 per cent of sales in the third world, several thousand firms serve the remainder. While the degree of concentration shows that the drug industry is not monopolistic in the conventional sense, the data tend to conceal the real extent of market or monopolistic power exercised by the leading firms. The pharmaceutical market is heterogeneous, and there are a large number of submarkets that are economically distinct from one another. Within each of these markets the degree of concentration is very much higher and exhibits the normal features of modern oligopoly much more clearly.[10] The exact nature of competition differs from one submarket to another, depending on such characteristics as the state of technology, the dominance of patented products, the importance of brand names, and, sometimes, government policy. However, the pharmaceutical industry can in general be described as strongly oligopolistic, with the leading firms possessing substantial market power.[11]

Because of the increasing cost of maintaining large R and D programmes and the increasing difficulty of introducing new drugs on the markets of safety-conscious developed countries (especially the United States), innovation has shown a tendency to become concentrated to a much greater extent than sales in recent years.[12] This has also caused large drug companies to give priority to commercially more promising fields of research (cancer, cardio-vascular and psychotropic drugs), and to diversify away from pharmaceutical products. Some United States firms have stepped up R and D investments in cheaper (and more lax) areas of Europe; others are spending more on marketing activity to compensate for the decline in innovation.

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[10] See S. Lall and UNCTAD, *op. cit.*, pp. 14-16, and D. Reekie, *The Economics of the Pharmaceutical Industry* (London, Macmillan, 1975), chap. 2, on the United Kingdom case.

[11] See S. Lall, "The international pharmaceutical industry and less-developed countries, with special reference to India", *Oxford Bulletin of Economics and Statistics*, August 1974, and S. Lall and UNCTAD, *op. cit.* See also M. Silverman and P. R. Lee, *Pills, Profits and Politics* (Berkeley, University of California Press, 1974).

[12] See Grabowski and Vernon, *op. cit.*, for a valuable and interesting discussion. They quote L. H. Sarrett as estimating that the cost of developing a new chemical entity rose tenfold during 1962-1972, to $11.5 million in the latter year, in Merck Laboratories. Also see Reekie, *op. cit.*, chap. 4; B. Cohen, J. Katz and W. T. Beck, *Innovation and Foreign Investment Behaviour of the United States Pharmaceutical Industry*, Working Paper No. 101 (New York, National Bureau of Economic Research, August 1975) (mimeo); and J. Schnee and E. Caglarcan, "The changing pharmaceutical Research and Development environment", *Business Economics*, May 1976. Grabowski and Vernon show that the top four innovating firms in the United States increased their share of the new products from 46 per cent in 1957-1961 to 61 per cent in 1966-1971.

II. Problems of pharmaceutical production and provision in developing countries

In the UNCTAD study several reasons were advanced to explain why the normal, currently evolving pattern of drug production and provision in developing countries was unlikely to provide cheap and effective drugs to meet the basic needs of the poor. The arguments are reviewed briefly below as they affect the three main stages by which drugs are provided to the consumer: imports, production and marketing.

Imports

Countries producing few or no drugs must import finished pharmaceuticals as the only source of supply. Those that have domestic formulation and packaging facilities must import the pharmaceutical chemicals involved. Those with a fine chemicals industry and some degree of backward integration need import only those chemicals, intermediates and finished drugs not produced within the country.[13]

On the basis of the premises that resources available (in this instance, in foreign exchange) for the purchase of pharmaceuticals are strictly limited in poor countries and that the socio-economic objective of each Government should be to maximize the amount of good-quality drugs that it can obtain for the resources available, in a free market, as typified by the uncontrolled economies of poor importing countries, imports of finished drugs will be heavily dominated by the brand-named, well-promoted drugs of the transnational corporations. Several brands of the same drug will be imported and sold. The final cost of providing the medicines will be far higher than if the country scouted the world market for the most economical suppliers–as a rational consumer in economic theory should–and purchased from whoever gave the best terms.

An examination of price differences within the markets of developed countries–dramatically illustrated by a recent United States study of antibiotics[14]–would lead to the assumption that a developing country could benefit greatly from shopping around. The evidence provided by Sri Lanka, which in 1973 instituted a national system of world-wide tenders for pharmaceutical imports, strongly supports this assumption. Table 4 gives illustrative figures for imports of 10 pharmaceutical products in 1974. The c.i.f. cost of actual imports by the State Pharmaceuticals Corporation (SPC) is compared with what the same quantities would have cost if

[13] An early list of developing countries at various stages of production is given in United Nations Industrial Development Organization, "The pharmaceutical industries in the Second Development Decade" (ID/WG.37/2), 1969.

[14] P. A. Brooke, *Resistant Prices: A Study of Competitive Strains in the Antibiotic Markets* (New York, Council of Economic Priorities, 1975). Because of the importance of antibiotics, some findings are reproduced in annex II, tables 9 and 10, showing the price differences that persist between identical products (after patent expiry) and illustrating how highly priced products continue to dominate the market even when cheap substitutes are available.

TABLE 4. IMPORTS OF SELECTED PHARMACEUTICALS BY THE STATE PHARMACEUTICALS CORPORATION (SPC) OF SRI LANKA, 1974: COMPARISON OF ACTUAL COST WITH COST OF TRADITIONAL SUPPLIER

(Dollars)

Drug		*Traditional supplier*	*Cost*	*New supplier*	*Cost*	*Savings*	*Savings as percentage of original cost*
1.	Benzyl penicillin	Hoechst	45 999	Sarabhai	33 166	12 833	27.9
2.	Chloramphenicol Inj.	Carlo Erba	926	Ranbaxy	555	371	40.1
3.	Methyldopa	Merck, Sharp and Dohme	15 208	Medimpex	10 866	4 342	28.6
4.	Nalidixic acid	Sterling	9 072	Medimpex	6 871	2 201	24.3
5.	Nitrofurantoin	Smith, Kline and French	7 611	Unique	1 485	6 126	80.5
6.	Phenylbutazone	Ciba-Geigy	30 088	Ranbaxy	1 710	28 378	94.3
7.	Benzhexol	Cyanamid	5 433	Aktielskabet	1 503	3 930	72.3
8.	Belladonna a phenobarbitone	Sandoz	23 126	Wockhardt	1 997	21 129	91.4
9.	Chlorpromazine	M and B	16 179	Unique	1 521	14 658	90.6
10.	Diazepam	Roche	19 583	Ranbaxy	790	18 793	96.0
	Total		173 225		60 464	112 761	65.1

Source: S. Bibile, *The State Pharmaceuticals Corporation of Sri Lanka*, Colombo, 1976.

they had been purchased from the traditional supplier. The value of the latter is given in prices actually quoted by the firm named for the appropriate quantity in that period.

The extent of savings possible from a rationalization of the purchasing system varies from drug to drug, depending on its age, technology and the existence of small producers. The main problems in undertaking such procedures arise from requirements of quality and bio-equivalence.[15] The SPC made thorough tests on both counts. Several low-price bids were rejected on grounds of quality[16] and exhaustive tests and reviews of the literature were undertaken to determine the bio-equivalence of more expensive products.

In particular, the findings of the United States Food and Drug Administration (FDA) on its drug interchangeability tests were studied closely. Despite the heavy emphasis placed on this factor by the industry in its defense of brand-named products and high prices, bio-equivalence was found to be a real problem for only 24 drugs. For such drugs the SPC continued to buy products from transnational corporations until such time as interchangeability could be fully established. The problem of quality control recurs more seriously in domestic production and it will be touched on later in this study.

The strongest objections raised by the transnational corporations to buying economically from generic or non-patent-observing suppliers are related to the high cost of R and D borne by the innovating firms.[17] There are basically three distinct arguments:

(a) Every country, rich or poor, ought to contribute towards the profits and expenses of innovating firms for R and D in the form of higher prices of the drugs they use;

(b) If some countries, for example the developing countries, bought drugs from other sources, the inducement for transnational corporations to engage in R and D would become less and the countries would suffer in the long run from the introduction of fewer innovations;

(c) Even if the rate of innovation did not fall, these countries would not have access to the innovations once they were outside the ambit of the transnational corporations. These are genuine objections, although they are not convincing arguments for the laissez-faire approach that the industry would like to uphold. Since they are at the heart of the whole question of reform, they are considered at length in the following section.

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[15] On the United States, see Brooke, *op. cit.*, and the study by the Office of Technology Assessment, *Drug Bioequivalence* (Washington, D.C., 1974).

[16] Some bids, as those from Italian firms (the best-known sellers of cheap drugs), were not considered because there was no independent assessment of the manufacturing practices of the suppliers.

[17] As Joseph Stetler, President of the United States Pharmaceutical Manufacturers' Association (PMA), says in his critique of the study by S. Lall and UNCTAD, "What is at issue (in Dr. Lall's report) is whether developing countries are willing to succumb to the allure of short-term savings, to refuse to contribute to the search for new drugs, to relegate themselves permanently to a second-class status in pharmaceutical development, and to condemn their inhabitants to inferior-quality, limited and obsolete pharmaceutical care", *SCRIP*, 13 December 1975, p. 2. For a review of the issues, see also M. Muller, "Drug companies and the third world", *New Scientist*, *29 April 1976*.

The moral argument that every country ought to pay for R and D, usually implicit in the arguments of the transnational corporations, makes little economic sense. Surely a poor country ought to act rationally in world markets and buy from the cheapest source.

The argument about the effect on R and D is more serious. If reform of the present system really reduced the flow of innovations relevant to the health care of developing countries, and if this reduction were not compensated for by increased innovation elsewhere, they would clearly be worse off in the long run. A system would then have to be evolved whereby transnational corporations would be compensated sufficiently for research so that they would maintain the effort required. This may not, however, imply that the existing structure of import, production and distribution need be kept intact. Since this structure has several other costs besides simply those of supporting R and D, ideally countries should try to arrive at some arrangement by which they could cut down on other costs but continue to contribute to the R and D of transnational corporations according to their incomes, their therapeutic needs and the specific cost of the R and D undertaken.[18] There is an important distinction to be made here. Drugs which are innovated primarily to satisfy the demand of rich markets (for treatment of psychotropic or cardio-vascular diseases or cancer), and for which the developing world represents a small proportion of total sales, are not going to suffer from lack of incentive for innovation if poor countries buy elsewhere. Research which on the other hand is aimed primarily at developing countries would suffer, and in this case a co-operative strategy is needed which meets the needs of both parties.[19]

Policy measures will be discussed later in this study. The point to be made here is that a mere preservation of the *status quo* and trust in the free market provides a very costly solution for developing countries. More rational solutions should be possible.

The argument that new drugs may become unavailable in a system in which the purchase of pharmaceuticals is centralized has less force. This danger would be serious only as far as genuine therapeutic advances (rather than duplicates and combinations) are concerned which cannot be imported from the transnational corporations by a central buying agency, and which would not be copied fairly quickly by non-patent-observing producers. There is no evidence, however, from the experience of Sri Lanka that transnational corporations would refuse to sell drugs to countries that have set up a central purchasing agency (as long as they have an effective monopoly, of course, they may charge very high prices). Furthermore, in

[18] For a scheme in which Governments, universities and firms could collaborate in R and D on tropical diseases proposed by W. Ormerod, see *SCRIP*, 10 January 1976. The French Government has worked out a scheme to fix prices to encourage the development of low-priced drugs. According to *Business Europe*, this is "a highly technical formula . . . based on a *'barème forfaitaire'*, which while including the cost of raw materials, production and R and D would favour new products with prices that could be costed out at less than the average for drugs in each particular generic category", 25 June 1976, p. 204. Such a scheme has obvious relevance for developing countries wishing to arrive at specific arrangements for financing innovation leading to cheaper drugs.

[19] The needs of developing countries for innovation are twofold: firstly, to get cheaper, more economical processes of making existing products and, secondly, to find new products, new formulations and new forms of treatment for diseases which are not being satisfactorily treated by existing drugs. Transnational corporations provide both process and product innovation, but their contribution to the latter (mostly basic research) is the most significant.

most recent cases such monopolies have been broken fairly soon (say, in three to five years), for example by firms in India, Italy and Eastern Europe where cheap alternatives to transnational corporations have become available, usually at adequate levels of quality and reliability. In general, therefore, the objections of the transnational corporations to the rationalized import of finished drugs have little immediate validity; they do, however, have long-term implications for the flow of innovation which need careful consideration.

The figures for Sri Lanka given above illustrate the extent of savings available from shopping around for finished pharmaceuticals. A similar situation obtains, naturally, for the import of intermediate chemicals. High prices and monopoly rents which arise from technological and marketing power can be realized just as easily for the sale of bulk chemicals as for finished medicines. Two cases should be distinguished:

(a) When the sale is by a foreign firm to an *unrelated buyer*, the problem for the buyer is one of paying high prices for lack of market information or for the technological monopoly enjoyed by the seller;

(b) When the sale is from a foreign parent to an affiliate, the problem is also one of *transfer pricing.*[20]

Transfer pricing in the drug industry is an extremely complex matter and merits more discussion than can be given it here. In essence, it reflects the technological rent of the parent firm plus the global tax minimization strategy pursued by the transnational corporation as a whole. Attempts to justify high transfer prices purely as an "R and D contribution" ignore the element of tax planning a strategy that is well recognized in the business literature and often admitted by the transnational corporations themselves.[21]

Table 5 presents some data on the savings achieved by the SPC of Sri Lanka on the import of some bulk chemicals for the few formulation plants that are in operation there. It should be noted that most of the SPC suppliers are large transnational corporations. There is thus little ground for suspecting poor quality or unreliability, fears commonly raised by critics of reform of the existing market structure.

For three intermediates (items 1, 8 and 9) in table 5, the seller reduced his price drastically after intervention by the SPC, reductions which may be seen as benefits to Sri Lanka resulting from better market knowledge and bargaining. For item 1, Hoechst's large reduction still left a price much higher than that of the Polish firm, Polfa. The SPC ultimately switched over entirely to the latter, saving on the large premium charged by Hoechst for its reputation.

Four items (3, 4, 10 and 11) may be considered as subject to transfer pricing (Pfizer and Glaxo being local formulators). On these items, the substantial saving to Sri Lanka can be seen as arising from better information as well as from counteracting the tax-avoidance practices of the firms concerned.

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[20] See S. Lall, "Transfer pricing by multinational manufacturing firms", *Oxford Bulletin of Economics and Statistics*, August 1973, and C. V. Vaitsos, *Intercountry Income Distribution and Transnational Enterprises* (Oxford, Clarendon Press, 1974).

[21] The best known example is Roche in the United Kingdom, which publicly stated that transfer prices were assigned according to tax considerations. See the Monopolies Commission, *Chlordiazepoxide and Diazepam* (London, H. M. Stationery Office, 1973).

TABLE 5. IMPORTS OF INTERMEDIATE CHEMICALS BY THE PRIVATE SECTOR, 1972, AND BY THE STATE PHARMACEUTICALS CORPORATION (SPC) OF SRI LANKA, 1973: COMPARISON OF COSTS PER KILOGRAM AND SAVINGS BY THE SPC

(Dollars)

Intermediate chemical	*Private sector, 1972*		*SPC, 1973*		*Savings as percentage original cost*
	Supplier	*c.i.f. cost per kilogram*	*Supplier*	*c.i.f. cost per kilogram*	
1. Tolbutamide	Hoechst	40.62	Hoechst-Polfa	19.24	52.6
				2.52	93.8
2. Paracetamol	Sterling	3.24	Rhône Poulenc	2.76	14.8
3. Chlorpropamide	Pfizer	126.21	Pliva	9.46	92.5
4. Aspirin	Glaxo	1.16	Polfa	0.99	14.7
5. Magnesium hydroxide	Sterling	5.18	Nichiman	0,61	88.2
6. Prednisolone	Organon	632.68	Roussell	321.77	49.1
7. Chloramphenicol	Boehringer	25.24	Lepetit	15.46	38.7
8. Cloxacillin	Beecham	606.47	Beecham	135.96	77.6
9. Ampicillin	Beecham	569.90	Beecham	95.11	83.3
10. Tetracycline	Pfizer	98.87	Hoechst	19.72	80.1
11. Chlorpheniramine	Glaxo	411.00	Halewood	52.53	87.3

Source: S. Bibile, *The State Pharmaceutical Corporation of Sri Lanka*, Colombo, 1976, table 4.

Domestic production

For countries that already have production facilities based on imported intermediates or domestically produced chemicals, the problems in fostering the expansion of industry and proving adequate drugs are complex and difficult. They fall under two headings, which are considered briefly below.

Number of drugs

Most developing countries with production facilities (with transnational corporation subsidiaries playing an important, even preponderant, role in investment and production) follow the oligopolistic pattern of competition of the developed countries. They produce a proliferation of brand-named drugs,[22] often ending up with several thousands of variations of a basic number of 700 to 1,000 drugs which are actually used. The extent of proliferation is only partly revealed by the number of preparations put on the market. There are relatively few brands for drugs which are very new (and so patented) or very specialized (and so having a small market). On the other hand, for drugs which have large markets and for which competition has developed, there are large numbers of brands, and constant attempts are made to introduce slight variations or combinations.

[22] Not only the transnational corporations indulge in this sort of competition, however. Given the structure of the industry, private local producers are just as prone to enthusiastic product differentiation and promotion. In the case of Argentina, see D. Chudnovsky, *Dependencia Tecnológica y Estructura Industrial: El Caso Argentino* (Buenos Aires, Latin American Faculty of *Social Sciences*, 1976). On the practice in Brazil and Mexico, see R. J. Ledogar, *Hungry for Profits* (New York, IDOC/North America, 1975).

Three actions may be taken to rationalize brand-named drugs on the market:

(a) Firstly, the elimination of "imitative" drugs for which adequate therapies already exist on the market;

(b) Secondly, the elimination of "ineffective" drugs, along the lines of the United States FDA and the Swedish drug control authority. This would get rid of a large number of irrational combinations and drugs of unproven efficacy, for both ethical and over-the-counter drugs;

(c) Thirdly, the elimination of drugs for which the toxic effects are unacceptably high and the use of which needs to be more severely limited than is actually the case.[23]

A country wanting to keep the therapeutic benefits provided by the existing array of drugs could do it with some 500 to 600 pharmaceuticals. This is roughly the number of drugs used by the most advanced hospitals in the developed countries and corresponds with the number that Sri Lanka has found necessary to meet its needs. (Poor nations may well decide to do with a smaller number.)

To return to the case for rationalization: if several brands were available on the market, at prices corresponding to a competitive optimum, with full consumer information enabling rational choice and prescription and no unnecessary expenditure on promotion, there would be little justification for rationalization. What actually happens, however, is that brand-named products of large firms are backed by heavy advertising and promotion (the cost of which is reflected in their price); information on their use is generously mixed with persuasion; and there are few effective alternative sources of objective information on these products. Thus, brands that become dominant are able to obtain prices far higher than those for truly competitive brands, even long after the period of patent protection has expired; and the final costs to the consumer in terms of high prices and interference with rational choice are far greater than they need be. There is certainly competition in drug markets, but its oligopolistic nature introduces elements that are undesirable, especially for poor countries with pressing health needs and extremely scarce resources.

As noted in a recent strategy paper of UNIDO, the developing countries cannot afford the luxury of unplanned production of many different drugs for preventing one and the same disease. Depending on the public health needs, disease patterns and techno-economics of production of particular drugs in the respective countries, UNIDO is recommending that each country should draw up a priority list of essential drugs which are most commonly required. The idea of a priority or rationalized drug list has gained wide acceptance. India has already prepared a basic drug list and the Central de Medicamentos (CEME) in Brazil is operating on the basis of one;[24] both the Indian and the Brazilian lists contain 100 odd medicines.

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[23] Ledogar, *op. cit.*, found several drugs which had toxic effects and which were unacceptable in the United States being sold and promoted (without adequate warning) in Latin America, e.g. chlormadinone acetate, "Raudixin", long-acting sulfonamides, dipyrone and dithiazanine iodide. A later, more comprehensive, study by M. Silverman, *The Drugging of the Americas* (Berkeley, University of California Press, 1976) provides a disturbing compendium of facts about such practices by United States transnational corporations and their harmful effects on consumers in countries where self-medication is common.

[24] See R. J. Ledogar, *op. cit.*, and P. B. Evans, "Foreign investment and industrial transformation", *Journal of Development Economics*, No. 3, 1976.

Production problems

The production of pharmaceuticals in developing countries has tremendous potential. As noted in the introduction to this study, formulation and packaging facilities can be economical with quite small markets, and the types of skill created render substantial external benefits. However, as production grows more complex and expands from the formulation of imported bulk chemicals to the manufacture of the chemicals themselves, a number of constraints appear.

Scale. Economies of scale occur in the production of bulk chemicals and antibiotics, so that developing countries can only undertake economical production if they have large markets, if they are assured of exports to developed countries, or if they enter a co-operative arrangement with other developing countries.

Skills. Pharmaceutical production, quality control, formulation, packaging and storage are skill-intensive operations. The most complex tasks of synthetic chemical production and antibiotic fermentation require advanced technology and a large supply of trained manpower. Only countries with established fine chemicals industries and relevant forms of university training can contemplate this form of pharmaceutical development.

Technology. The transfer of technology is perhaps the largest single constraint on the development of domestic production. Many developing countries, however, have already developed considerable technological capability and experience, not only for accomplishing the simpler formulation and packaging stages but also for producing a range of bulk chemicals. Many units in developing countries have successfully adapted imported technology to their specific needs and environments: some have improved upon the productivity of imported processes.

There is, of course, still an important segment of production technology which is new, patented and under the control of large transnational corporations. This technology has to be transferred to countries where the production of the relevant chemicals is likely to be economical. The transfer can take place in one or more of three ways: through direct investment of the transnational corporations, through licensing by the transnational corporations of local units, and through copying foreign technology by local units. The choice of the mode of transfer would vary from one case to another, depending on the preferences of the transnational corporations, the secret nature of the technology, the strictness of patent laws, the capabilities of the recipient and the speed with which the transfer is desired.

As pharmaceutical technology by its nature relies heavily on R-and-D-based product innovation, it is extremely unlikely that any country, developed or developing, could achieve anything resembling technological self-sufficiency. The large innovative firms have such enormous technological productivity, and the economies of scale at this level are so great, that they will continue to lead the industry in several fields of therapy. Two factors would mitigate the extent of continuous dependence on foreign technology, however: firstly, the slowing down of the process of innovation in general and, secondly, the reduced need of developing countries if they adopt a rationalized drug list. None the less, and allowing for expanding R and D efforts in the developing world, there would remain a substantial and important role for transnational corporations to play.

The process of transferring technology from transnational corporations to developing countries raises many issues related to the general issue of technology transfer. These have been well aired in the literature and in governmental and international circles; they need only be pointed out here:

Restrictive business practices, such as export restrictions, import tying, price control

Control over R and D by the subsidiary, and the horizontal transfer of technology to other local enterprises

Royalties and technical fees

Transfer-pricing

Adaptation of technology to local needs

One issue needs careful consideration: the patent system. The role of patents is of particular significance to the pharmaceutical industry, and its importance is growing with the increasing duration and cost of producing innovations as well as the growth of potential imitators in various industrializing countries. While there is extensive and continuing debate about the costs and benefits of the patent system in this industry within the developed world, the belief is growing in the developing countries that the patent system in its traditional form may not work to their best interests. Most of the innovations that are patented are not designed primarily for the markets of developing countries. Thus, the rate of innovation would not be affected if these countries did not grant patents. Most patents, which are owned predominantly by the transnational corporations, are not used for production in developing countries. Thus, they serve to block the import of cheaper drugs from non-patent-observing sources, and they prevent domestic firms from imitating the patented product (where the more restrictive product patents are granted) or the process (where the less restrictive process patents are granted).[25]

Measured against these very real costs, the following benefits are offered by the patent system. Firstly, it creates a favourable ambience for foreign investment. Secondly, it protects domestic innovation. Thirdly, it fosters foreign innovation in drugs which have their main markets in developing countries. Fourthly, it facilitates the licensing of domestic firms. Not all these benefits are equally significant. As regards the first, firms invest heavily in Brazil and Italy which have abolished pharmaceutical patents of all sorts. The second and third are real benefits, and they may warrant retaining the patent system in some form. The last is not a substantial benefit since licensing could be based on the real technological advantages offered by the licensor and not simply on his possession of the patent right.

In countries with very little industry, a case may be made for weakening the patent system considerably in order to receive the benefits of cheap drug imports. In countries with a developing pharmaceutical industry, a case exists for keeping the system with a number of safeguards so that its potentially restrictive effects on domestic development are minimized. In countries engaged in major R and D, the case is clear for a fairly strong patent system, but this is unlikely to be relevant to the developing world for some time to come. The exact form of patent protection offered to foreign firms should be determined by the form of technological

[25] See UNCTAD, *The Role of the Patent System in the Transfer of Technology to Developing Countries*, TD/B/AC.11/19, 1974, for a critique of the system, and D. Reekie, *op. cit.*, chap. 6, for a defense.

agreement reached with them, and this depends on the right rate of return from developing countries for R and D done by the transnational corporations. If, for instance, it is determined that developing countries should pay little (or on a preferential scale) for innovations designed primarily for developed countries (rich man's drugs), the patent protection offered for such products would be weak. Concomitantly, for innovations developed primarily for developing markets (poor man's drugs), patent protection would be stronger, guaranteeing a fair return for the innovator. The patent system, in other words, could become subsidiary to a separate process of determining technological returns; that is, it would not act as an automatic monopoly granted in a free market.

The safeguards that should be attached to the patent system should have the main aim of promoting the flow of technology to enterprises in developing countries. Patents, even on poor man's drugs, should not be left unused if domestic production were feasible. Thus, provisions for compulsory licensing normally part of most patent legislation but not applied very often should be strengthened and used where necessary. Governments may even consider granting free licences of right to prospective domestic producers when the technology has not been developed primarily for developing countries.

The internal problems that normally arise from the use of patents molecule manipulation, misdirected R and D, excessive profits should be counteracted by the institution of the rationalized drug list, the operation of a national buying system and direct negotiations on prices (with domestic firms).

The other issues concerned with transfer of technology fall within the scope of a country's general policy on foreign investment regulation and control. The monitoring of royalty payments and other intra-firm transfers, the registration and control of restrictive clauses, the precise terms agreed upon after a process of study and bargaining, are all an intrinsic and vital part of minimizing the costs of technology purchased abroad.

An emerging aspect of technology transfer, which will assume great significance in the future, is an important part of the strategy proposed here. It concerns the transfer of pharmaceutical technology between developing countries. As noted in a UNIDO study, India, Mexico and Brazil have acquired a remarkable amount of technology, representing 60 per cent of the technology required for the production of bulk chemicals in the list of essential pharmaceuticals. These countries are able to assist less industrialized countries in setting up and expanding their pharmaceutical industries, offering some advantages over the traditional process of transferring technology through transnational corporations, such as:

(a) The terms they offer are extremely competitive. This is especially true of public-sector enterprises, which can set up complete plants in other developing countries on a cost-plus-commission basis;

(b) Practically no restrictive conditions are attached;

(c) Equity participation by the seller of technology is usually kept to a minimum, enabling recipient countries to build up an independent industry;

(d) Since enterprises in developing countries have little stake in brand names, the recipient can use the technology to sell the products under generic names. (However, as indigenous enterprises grow, they also tend to invest money and effort into developing brand-named products);

(e) The technology may be better adapted to the conditions of developing countries in terms of scale, skills, capital intensity, formulation and packaging;

(f) The developing country selling the technology can earn foreign exchange that would otherwise have gone to a developed country.

The proposal for intra-developing country transfer of technology has received the explicit support of the developing world and has already been incorporated into the operations of UNIDO. There is every reason to strengthen this line of action.

Quality control. An important obstacle to the development of indigenous pharmaceutical industries, as well as to a reform of the present structure, lies in the lack of adequate quality control by some domestic enterprises. The Hathi Committee[26] commented extensively on the need to exercise better control over the production processes of small firms in India. It noted a widespread incidence of substandard and "spurious" drugs, especially in areas in which the high prices charged by transnational corporations created an extremely profitable umbrella for unscrupulous or inefficient manufacturers. In Pakistan, similarly, an attempt to break the hold of transnational corporations and to promote indigenous producers by abolishing brand names floundered on this problem. Poor-quality drugs flooded the market; the market share of transnational corporations rose rather than fell; prices did not decline; and the scheme had to be substantially modified. The transnational corporations charge high prices, but they enjoy a justifiable reputation for quality control--an argument they invariably advance against any reform that would reduce their role in developing countries.

It is obvious that no attempt at change can proceed without tackling this problem. It is not an easy problem, by any means. Quality control requires a high degree of skill, sophisticated equipment, strict adherence to good manufacturing practice and very close official supervision. However, the following points should be noted:

(a) A large number of indigenous firms in developing countries have impeccable records in this context, including small as well as large firms;

(b) The cost of adequate quality control is far from prohibitive and certainly within the reach of even small firms in developing countries. What is really needed is a concerted government effort to enforce good manufacturing practices and to constantly monitor production. There is little doubt that even with all the expense involved, drugs would be far cheaper than under the present system;

(c) The experience of developed countries indicates that, with the strictest of checks and the most sophisticated of medicines, small firms can maintain quality just as well as large ones.

Use of indigenous medicines and raw materials. The bulk of the population in many developing countries uses traditional, indigenous medicines, which have not been fully explored or appreciated in modern, science-based therapy. In recent years, however, there has been growing realization that local botanical products have a tremendous potential for use as raw material in industrial pharmaceutical production. Local production can therefore exploit this potential fruitfully by developing technologies for the extraction, purification, formulation and packaging of these materials. For several herbs and plant extracts there is also a large export market.

[26] See Hathi Committee, *op. cit.*

India has explored these possibilities the most extensively. It has set up a Central Drug Research Institute at Lucknow, with advanced facilities for screening and testing medical plants. UNIDO has been collecting data on available medicinal plants for a number of years and is now promoting international co-operation among developing countries to promote the industrial use of such plants.

The following are examples of plant extracts of pharmaceutical use:

1. Vinca rosea for the anti-cancer alkaloids, vincristin and vinblastin
2. Lemon grass for carotenoids for the preparation of vitamins
3. Pyrethrum, as a source for mosquitocides
4. *(a)* Dioscorea species, e.g. dioscorea deltoidea, dioscorea floribunda and dioscorea composita
   (b) Solanum kashianum

   } As source of intermediates for the synthesis of therapeutically active steroids including anti-fertility steroids
5. Cinchona for quinine and quinidine
6. Poppy for opium alkaloids, e.g. morphine, codeine and noscapine
7. Ergot of rye (claviceps purpurea) for ergot alkaloids, ergotamines, ergotmetrine etc.
8. Digitalis species—Digitalis lanata and Digitalis purpurea for cardiao glycosides, e.g. digoxin, digitalin etc.
9. Ipecac for the production of emetine
10. Duboisia and atropa species (atropa belladonna and atropa acuminate) for atropine and hyoscine
11. Nux vomica for strychnine and brucine
12. Rauwolfia for hypertensive and CNS active total alkaloids and reserpine

In view of the largely unexplored but promising potential for plant utilization, local industry could certainly base its development in part on medicinal plants.

Certain animal organs also have well-established industrial uses. Most of these organs are wasted in developing countries, but their extracts have large domestic and export markets for the production of insulin, heparin and haemoglobin. If the relatively simple technology for their collection and extraction could be transferred to developing countries, more complex industries based on their purification and formulation could be started economically.

Marketing and distribution

The marketing, pricing, advertising and distribution of pharmaceuticals involve separate problems of their own. The handling of such operations by large drug companies has aroused great concern among the developed countries, and several policies are being considered or implemented to reform the existing system. Concern is also becoming manifest among developing countries. Some countries have examined and have tried to tackle the problems comprehensively; some have attacked certain aspects and neglected others; and some have let the free-market mechanism take its course. A major reconsideration of policies is now in order, in the direction, not of haphazard controls or of a return to *laissez faire*, but of a carefully

planned, gradual but comprehensive reform drawing fully on the experience of the developed countries.

The precise details of such reform will vary from country to country, depending on their administrative resources, the extent of local production, the bargaining strength of the transnational corporations, the attitudes of the medical profession, the general system of health care and the prospects of co-operative action with other countries and agencies. Before the sorts of reform needed are discussed here, however, the problems under the present system are first considered.

Prices

Most countries now have some system of price control for pharmaceuticals. Most of such controls are designed, however, to hold prices down rather than to rationalize the entire system of internal pricing, thus leading to great anomalies in the price structure. Some manufacturers are placed in grave financial difficulties because the price of output is held down in the face of rising costs of raw materials and production. Other producers are able to maintain price levels much higher than would be warranted by comparison with the price of equivalent products made by others. Some producers are, therefore, genuinely placed in jeopardy; others are able to earn (and perhaps conceal) very high profits.

The ideal system of pricing would be one that secured identical prices for identical products (i.e. disregarding brand names), that guaranteed a fair rate of profit, that did not penalize efficient producers or protect inefficient ones, and that gave adequate rewards for risky R and D expenditures. To achieve such ideal prices would pose several difficulties:

(a) It is difficult to work out the right price for individual products when there are large fixed costs spread over a number of products. It is also difficult to work out relative prices between products that are backed by heavy R and D and identical products that are imitations;

(b) It is even more difficult if a number of very successful products have to subsidize less successful ones, and if they have to finance R and D for various projects which may fail;

(c) The right reward for risk is difficult to calculate when the extent of risk is essentially incalculable. In developing countries, it also involves the problem, discussed above, of distinguishing between rich man's and poor man's drugs;

(d) There is a related problem of rewarding R and D devoted to producing minor or unnecessary innovations, since some amount of such R and D is therapeutically valuable while most of it is not;

(e) When costs of production of transnational corporations are distorted by the use of transfer-pricing on imported inputs, it becomes very difficult to make a meaningful comparison of their costs with those of other firms;

(f) Prices decided upon by individual Governments are becoming increasingly linked to one another. Many authorities now look at prices in home countries of the transnational corporations, or in other countries, when deciding on their own prices. This makes for a reproduction of the same price structure in different countries, without any particular rationale. It also makes it difficult for developing countries to assign lower prices, say, to innovations developed primarily for rich markets, if this

leads the rich countries in turn to lower their prices (and, thus, the returns to research) in line with developing countries.

In essence, drug pricing and control involve three general issues: securing information on the true costs of manufacture, R and D, profits and other costs, as distributed between the subsidiary in the country concerned and the rest of the company; allocation of fixed and overhead costs on an equitable basis between different products over time; and bargaining and negotiation over the fair sharing of these costs between different countries, and in particular between main (rich) and peripheral (poor) markets. *The objective of developing countries should be to set the lowest possible prices for the desired number of drugs consistent with the encouragement of production and relevant research.* This objective cannot be achieved with a free market which allows too many drugs to be sold, with enormous price variations on identical products (and so a large rent accruing to more heavily promoted, brand-named or patent-protected products), profits often in excess of a reasonable return, wasteful promotional spending and a confusion of proper information flows to prescribers. The market, left to itself, exerts a regulation of some sort; as most countries have realized, the regulation is imperfect and costly. Official regulation entails a different set of problems, but most Governments in developed as well as developing countries have felt it imperative.

Basically, two alternative systems exist for regulating the price of drugs. One would be to negotiate and set prices for products on the basis of certain criteria, but to leave promotion, marketing etc. to the companies; this is the system used in most countries at present. The other would be for the central official agency to buy all the drugs from the companies (internally as well as on world markets), again at prices negotiated on the basis of certain criteria. So far as price control *per se* is concerned, there is not much choice between the two. However, if there is a central agency to purchase drugs and bulk chemicals on world markets, and if there is also an agency to distribute and market drugs (as recommended below), there is a strong case for combining them with the price-regulating agency to form a central purchasing and marketing body. By the same logic, a case exists for combining several national bodies into a joint inter-country co-operative venture.

Different Governments have evolved different systems for pharmaceutical pricing. The United Kingdom has a Voluntary Price Regulation Scheme which seeks to control the overall profitability of drug firms. Several European countries regulate the prices of individual products on the basis of novelty and therapeutic benefit. The United States FDA is starting its programme for paying the cost of the cheapest generic equivalent. India has a complex system of calculating costs and prices. All these systems need to be studied and evaluated by Governments or some advisory body in order to evolve the best possible combination.

Brand and generic names

The great bulk of prescription drugs, and an even greater bulk of over-the-counter drugs, is sold in free markets under brand names. In general, the larger manufacturers sell their products under brand (or trade) names; small manufacturers generally sell by generic names. The distinction is not always hard and fast. Some large firms, while selling most of their newer and more profitable products under brand names, sometimes sell well-established, competitive lines under generic names. A few small firms sell their specialities under brand names. Given the amount

of promotion required to capitalize on a brand name, however, and the rewards that accrue from successful promotion, it is natural that the large firms dominate the brand-name market.[27]

The main social benefits and costs of using brand names as opposed to generic names in the pharmaceutical industry are as follows:

(a) Immediate benefits are that, by identifying the origin of a particular product in a generic class, brand names (i) provide a guarantee of quality, or a recourse to the manufacturer in cases of lapses of quality, and (ii) reduce the search costs to prescribers by enabling them to identify reliable sources of supply of the appropriate quality as well as to learn about new forms of treatment more easily;

(b) Costs are: (i) that brand names create an undesirable amount of monopoly or market power (and so raise social cost in terms both of high profits and of high marketing expenditures), which may be redundant in the initial stages when there are no competitors (without patent protection, this technological monopoly may be short-lived), but may be activated by promotion and stretch out over fairly long periods after substitute competition begins; (ii) that they are not necessary to ensure quality if competitors observe good manufacturing practice and are kept under strict official surveillance; (iii) that they are required to ensure proper bio-availability in only a relatively few cases; and (iv) that they are not the best means of conveying scientific information about drugs because of the element of promotion, the profusion of brand names and the occasional marketing of ineffective drugs.

Even if it were granted that brand-named drugs enjoy a market power distinct from that generated by quality and innovation, it may be argued that the profits yielded (and therefore the social cost) are necessary in order to sustain the rate of innovation and its commercialization. This may be termed the long-term innovational benefit of having brand names. As has been noted already in this study, there is an element of truth in this claim, but there is also some obfuscation. A strong case can be made, especially for developing countries, that the social cost of sustaining this method of obtaining drugs - new and old together - is far higher than necessary. And, indeed, the figures show that it can be reduced. Thus, *it is vital to separate the innovation process as far as possible from the rest of the process of providing drugs to poor countries,* to ensure its adequate but economical continuation and to minimize the cost of the rest.

A strong argument may be made for a change from brand to generic names. However, it must be stressed that this changeover is a slow, complex and delicate task. It must not be done suddenly by administrative fiat without adequate preparation. The main factors to bear in mind are:

(a) That quality and bio-equivalence must be carefully controlled as discussed previously;

(b) That there will be resistance from the medical profession. The large drug companies have over the years developed a close, almost symbiotic, relationship with the prescribers of their products, and the profession has become heavily dependent on the firms for information. Any move to replace brand by generic names and to reduce the number of drugs is, therefore, bound to meet with the disapproval of a large part of the profession. In developing countries, the resistance is likely to be

[27] For a good recent discussion of marketing, advertising and brand-naming in the pharmaceutical industry, see S. Slatter, *Competition and Marketing Strategies in the Pharmaceutical Industry* (London, Croom Helm, 1977).

stronger since the promotional efforts of the companies are relatively more effective, the faith in foreign brands is stronger, the habit of brand-name prescribing is more widespread, the danger of poor-quality generic drugs is more real, and the countervailing efforts of consumer and official organizations are relatively weaker. Any policy of reform must, in consequence, be based on rigorous quality control and scientific tests of drug interchangeability, which are used extensively and over a long period, with data on price reductions, to inform and educate doctors before the changeover is implemented.[28] Such is the hold of brand names, and the power of the continuous and expensive promotion that supports them, that some measure of competitive re-education is necessary. Furthermore, the changeover itself should be gradual, starting with a few drugs.[29] To quote from the case of Sri Lanka:

> "Changing over from brand to generic names requires the publishing of cross-reference lists of brand and generic names because manufacturers' promotion has left the doctors unaware of generic names. The changeover in names was easiest with long-established drugs, and the Corporation instructs suppliers to use generic names in labelling . . . . For some drugs the changeover has been gradual. The brand name is permitted as an interim measure, but in [print] half the size of [that for] the generic name";[30]

(c) That the change-over must be accompanied by a strict control of advertising and promotion. Otherwise, large firms may simply switch from advertising brand names to advertising generic drugs made by them, stressing the superior quality and performance of their products and thus retaining some of the market power formerly carried by brand names. No amount of vetting the content of advertising can eliminate the advantage of well-established brand names, especially if medical detail men continue to promote their firms' products by (unrecorded) personal contact. These big firms may continue to dominate the market and charge a premium for their products, unless the price control system ensures equivalent prices for equivalent products, and the Government's encouragement of small domestic enterprises may require that the re-education of doctors include promoting the products of small firms (in terms of good quality and reliability). If the State takes over the whole information function, this task would become easier, but the take-over may raise problems of its own which have to be evaluated and tackled;

(d) The process of re-education must extend to the consumers also. While this is obvious in the case of over-the-counter drugs,[31] it also applies to prescription medicines.

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[28] The failure to do this accounts for the virtual collapse of the Pakistani programme to abolish brand names.

[29] In India, the Hathi Committee recommended starting with 18 drugs.

[30] S. Bibile, *The State Pharmaceutical Corporation of Sri Lanka*, Colombo, 1976, p. 3. For a discussion of the problems faced by Sri Lanka in implementing its reform programme, see S. Lall and S. Bibile, "The political economy of controlling transnationals. The pharmaceutical industry in Sri Lanka 1972-76", *World Development*, July 1977.

[31] In this context, it is interesting to note that the United States authorities are now starting to evaluate 200,000 to 500,000 over-the-counter medicinal items sold in the United States (based only on some 1,000 active ingredients) for safety, efficacy and correct labelling. It is likely that a large proportion of these drugs will be removed for lack of proof of efficacy, and many exaggerated claims will be modified. Some well-known mouth washes and expectorants have already been affected. Of a sample of 420 over-the-counter drugs studied, 75 per cent were found ineffective after preliminary study. See T. D. Rucker, "Economic aspects of drug over-use", *Medical Annals of the District of Columbia*, December 1973.

Many consumers, especially the élite of developing countries, pick up a smattering of knowledge about brand-named drugs and their main uses. They are perhaps even more susceptible to the attractions of international brand names and are likely to resist a change-over to generic names despite the considerable saving in cost. The implications for policy are obvious.

In sum, then, there are genuine and significant savings to be achieved by the replacement of brand by generic names in drugs. But these savings can be achieved only with stringent official quality control and the re-education of prescribers and consumers.

Promotion, information and labelling

The pharmaceutical industry spends heavily on marketing its products. It is one of the most advertising-intensive industries in the non-socialist world, spending about 15 to 25 per cent of its turnover on such activities as journal advertising, direct-mail advertising, representatives, gifts, samples, hospitality, sponsorships and so on, all with the aim of impressing particular brands on the consciousness of doctors and of creating good will. Table 6 gives the result of a recent survey of promotional costs in several countries.

TABLE 6. PROMOTIONAL EXPENDITURE AS A PERCENTAGE OF SALES IN SELECTED COUNTRIES

United States	22
Federal Republic of Germany	22
Italy	22
Belgium	21
Canada	21
Sweden	18
India	18
France	17
Turkey	16
Indonesia	16
United Kingdom	15

Source: S. Slatter, *Competition and Marketing Strategies in the Pharmaceutical Industry* (London, Croom Helm, 1977), p. 102.

So much has been written about the effects of this promotion system (see references in the UNCTAD study, as well as in Silverman, Ledogar, Klass and Rucker) that it is unnecessary to repeat the details here. It is generally agreed that it is an effective means of providing information on new drugs to doctors. Indeed, it is probably too effective, and many people obviously feel that it is too expensive. Its social costs are not simply limited to the vast expenditures involved, which all consumers, rich or poor, have to bear, but also include: the suppression of small competitors who charge much less for products of equal quality; the selling of ineffective drugs; confusion in the information provided to doctors, in many cases leading to improper or excessive prescribing; and the creation of medium to long-term monopolies. Alternative means of providing information to doctors, in

conjunction with or instead of the promotional efforts of the firms themselves, can be conceived which do the same job at much lower cost and with fewer undesirable effects.[32] Such efforts, still at a rudimentary stage, are being undertaken in several developed countries. Developing countries may seriously consider more rapid and widespread reforms.

It should be noted, however, that the replacement of the existing system by an alternative state-controlled one would be far from easy. Doctors are used to the powerful and expensive, but effective, methods evolved over decades of experience by the drug companies. A new system should get the message across equally effectively but at less cost. This may involve sending detail men and giving samples; it will certainly entail some measures to placate doctors who will resent the loss of gifts, hospitality and literature that are now provided so lavishly by the drug companies. It is reasonable to expect that in the final analysis the dissemination of information could be achieved much more economically than under the present system, and, indeed, the industry itself has cut such expenditures recently under pressure from several Governments. A strong political direction and a gradual, well-conceived plan are indispensable to a reform of the information system.[33]

The labelling of drugs, including all information given at the time of sale, is a matter of growing concern in developing areas. Research by Ledogar and by Silverman in Latin America has shown that a number of potentially dangerous drugs have been and are being sold without adequate warnings in developing countries, or after they had been withdrawn from the markets of the developed countries. The great variety of labelling and warnings undertaken by the same company in different areas[34] indicates a readiness to take advantage of lack of information or laxity on the part of host Governments. Yet, relatively simple and inexpensive systems of collecting and exchanging information between countries would resolve much of the problem. There is clearly scope for international action, as revealed by WHO efforts in this field. These efforts need to be extended and strengthened.

The health-care system

Much of the problem with the present system of health care in the developing countries is that as a whole it is misconceived and inadequate.[35] Much greater emphasis should be placed on preventive rather than curative measures; the system needs to be reoriented more to meet the demands of the rural masses and less to cater to the urban elites; and it needs a much simpler and more widespread network for delivery. The structure of pharmaceutical production and distribution reinforces a basically inequitable structure of health care and delivery. As Segall notes,

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[32] See the very interesting paper by T. D. Rucker, "Drug information for prescribers and dispensers: Towards a model system", *Medical Care*, February 1976, in which the author argues for a national drug education foundation in the United States to provide information cheaply to doctors.

[33] See S. Lall and S. Bibile, *op. cit.*

[34] See, for instance, the International Organization of Consumers Unions, *Clioquinol*, London, 1975, and the Research Institute for Consumer Affairs, *Chloramphenicol*, London, 1971.

[35] See the Haslemere Group, *Who Needs the Drug Companies?*, London, 1976, and M. Segall, "Pharmaceuticals and health planning in developing countries", Communication No. 119, Institute of Development Studies, 1975.

> " . . . it is well known that in many countries the rural health services are very deficient and possibly 80 per cent of the rural populations have little or no organized health care. Health services are disproportionately provided for the minority urban populations, and are heavily biased towards expensive curative care, often in large sophisticated hospitals. . . . The need is to find a policy that will provide the necessary drugs for the whole population in the context of rational health service."[36]

While a discussion of the health-care system is not within the competence of this study, a reformed structure of pharmaceutical production will not have the desired effect on the population unless accompanied by a change in the system as a whole. The means of health delivery must be more evenly and equitably distributed together with the provision of essential drugs at low prices. The requirements in terms of rural health centres, paramedical staff and so on will vary from country to country, but the general lines of reform are presumably clear and known.

[36] M. Segall, *op. cit.*, p. 8.

III. New policies on pharmaceuticals

Most of the problems concerning the development of the industry in poor countries is discussed in the previous chapter, which indicates the broad lines for a strategy. The attempt is made here to draw the various threads together.

The need for new policies has been widely recognized; various Governments are implementing reforms with a greater or lesser degree of success. Moves are also being made in the international sphere. The recent Fifth Conference of Heads of State or Government of Non-Aligned Countries (Colombo, Sri Lanka, 1976) considered a proposal drawn up by a group of experts, and passed a resolution requesting action at national and international levels. The text of the resolution follows:

> *"The Conference,*
>
> *"Recalling* the Non-Aligned Action Programme for Economic Co-operation among developing countries adopted at the Conference of Foreign Ministers of Non-Aligned countries in Georgetown in August 1972, and approved at the Fourth Summit held in Algiers in September, 1973,
>
> *"Recalling* also the Economic Declaration of that Summit calling for the further strengthening of economic co-operation among developing countries,
>
> *"Noting* the inclusion of the production and distribution of medicine and medical susbtances in the Lima Programme for Mutual Assistance and solidarity as an additional area of co-operation among developing countries,
>
> *"Bearing in mind* the possibilities for joint action by developing countries, identified in the study commissioned by UNCTAD on major issues in the transfer of technology to the developing countries in the pharmaceutical industry,
>
> "1. *Endorses* the recommendations of the Group of Experts on Pharmaceuticals which met in Georgetown in July 1976 and which proposes among other things:
>
> *"(a)* The preparation of a list of priority pharmaceutical needs of each developing country and the formulation of a basic model list of such needs as a general guideline for action by the developing countries;
>
> *"(b)* The establishment of a national buying agency to undertake the purchase and supply of pharmaceuticals;
>
> *"(c)* That in the context of the revision of the industrial property systems, consideration be given to excluding pharmaceutical products from the grant of patent rights or alternatively the curtailment of the duration of patents for pharmaceuticals;
>
> *"(d)* The elimination, wherever possible, of brand names and the adoption of the generic names for pharmaceuticals; and provision of information only from official sources;

"*(e)* The establishment by each developing country of its own pharmaceutical industry as appropriate, beginning with formulation and packaging and building up to more complex production activities;

"*(f)* The creation of regional Co-operative Pharmaceutical Production and Technology Centres (COPPTECs), as proposed by UNCTAD and UNIDO, in order to draw up drug lists, to co-ordinate research and development, facilitate the transfer of technology, collect and disseminate information on pharmaceutical uses and prices and on the technological capabilities among member countries and also to co-ordinate the production and exchange of drugs between different member countries as well as between different regional centres;

"2. *Invites* the relevant international organizations such as UNCTAD, UNIDO, WHO and UNDP to assist in the achievement of the objectives outlined in operative paragraph 1 above with particular regard to the establishment of appropriate National Pharmaceutical Centres in developing countries and Regional Co-operative Pharmaceutical Production and Technology Centres (COPPTECs) among them.

"3. *Decides* further that the co-ordinator of the trade, transport and industry sector of the Non-Aligned Action Programme for Economic Co-operation among developing countries should take the necessary follow-up action to ensure early implementation of the provisions of this resolution."[37]

The idea of establishing COPPTECs, first proposed in the UNCTAD study,[38] was subsequently endorsed in Mexico by the Group of 77 in October 1976. In December 1976, three United Nations agencies, UNIDO, WHO and UNCTAD, held a consultation meeting with representatives of the industry. It was agreed to set up a joint task force of the three agencies, which would work with UNDP assistance and under the auspices of the Action Programme, to look into ways of implementing the above resolution.

The resolution contains, in a condensed form, the essence of new policies which developing countries might follow in reforming the present pharmaceutical industry and in guiding its future growth.

The priority drug list

The first step in any reform in the supplying of pharmaceuticals is to specify the number and types needed by each country. It has already been noted that the Government of India has drawn up a list of 117 essential medicines. The CEME in Brazil has a list of 108 drugs of which 52 are classified as essential. UNIDO has compiled a basic list of drugs for developing countries which must be adjusted according to each country's needs. The UNIDO list has been established, however, with the sole aim of limiting the production programmes of countries to their requirements for becoming self-sufficient in such drugs. WHO assistance in drawing

[37] "Resolution on co-operation among developing countries in the production, procurement and distribution of pharmaceuticals", Fifth Conference of Heads of State or Government of Non-Aligned Countries, Colombo, Sri Lanka, 1976, A/31/197 (Annex IV: Political and economic resolutions, NAC/CONF.5/S/RES.25).

[38] S. Lall and UNCTAD, *op. cit.*

up a much more scientific and medically accepted list of essential drugs would be welcome. WHO has already issued such a list,[39] and the WHO criteria will be considered in future UNIDO production programmes.

The methodology suggested by WHO corresponds to the one described in the paper by Malcolm Segall.[40] Such an approach, which could be called a rationalized rather than an essential drug list, allocates different priorities to different kinds of drugs, based on therapeutic need, efficacy and cost. All the drugs contained in the list would be provided within the country (and thus would be essential in a sense), but they should be grouped into three categories according to priority.

First-line drugs would be the main drugs needed by the primary health-care units of the country. These products would be relevant to the diseases of wide prevalence and would include pharmaceuticals needed for preventive care. Such drugs would number 50 to 60 and would meet 80 to 90 per cent of the total health needs of developing countries.

Second-line drugs would be available at district or regional hospitals and would be needed for cases that have not responded to first-line drugs or that are so severe that second-line drugs should be used immediately; they would also be needed for less prevalent conditions. This list may be longer than the first, but the quantities needed would be much less.

Finally, the *third-line* drugs would be available only for specialized tertiary care. What is usually meant by *basic* drugs refers to first-line drugs, while all the drugs taken together may be called the "rationalized list" of drugs.

The basic list is defined by the prevalence of illness, therapeutic effectiveness, available resources and cost. A drug that was in the second line may be transferred to the first line if it has proved more effective or cheaper than an existing first-line drug. The list does not correspond to the pattern of domestic production of drugs, since production is governed by different criteria (comparative advantage, skills, scale, technology etc.). However, many of the basic drugs are fairly standard and unpatented, and the technology for their production already exists in the developing world. They may well be produced, in successive stages, by many developing countries. The basic drugs must, however, be provided as cheaply as possible.

The drawing up of rationalized lists is primarily conceived as a national task. The international bodies would merely assist and advise. Each country has a direct responsibility for evaluating and adopting a list of essential drugs according to its own policy in the field of health. This work should be seen as a challenging occasion for planning a therapeutic system that would not be passively dependent on transfer of technology from developed countries. As a number of official agencies in the developed countries are also engaged in similar tasks of evaluating the effectiveness of drugs, ensuring their interchangeability, promoting the use of generic-named products and ruling out large numbers of unnecessary drugs, there is obviously a great deal to be gained from seeking their advice and drawing upon their experience. While the needs to assign priorities and to economize drastically do not exist in the developed countries, the need to rationalize generally does, and it is conceivable that concerted action among a wide representation of rich and poor countries on this issue would lead to a major reorientation of the industry.

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[39] WHO, *The Selection of Essential Drugs*, Technical Report Series No. 615 (Geneva, 1977).

[40] M. Segall, *op. cit.*

National drug-buying agency

The economic advantages of centralized buying of drugs and intermediate chemicals are obvious. They apply to local purchases as well as to imports. The benefits arise from the following factors: better market information (from world-wide shopping around); better product information (by picking the most economical of differentiated but therapeutically identical products); bargaining; and bulk purchase. Such advantages imply economies of scale, in that the larger the buying agency, the cheaper it would be to collect information (often through a process of direct quality control and bio-equivalence tests), the better it could bargain and the more it could buy in bulk. There is thus a strong case for combining several national buying agencies, especially in small countries, into regional or interregional agencies (such as COPPTECs). The responsibility for rationalizing the purchase of pharmaceuticals has been accepted by UNCTAD.

The main problem in establishing buying agencies concerns the arrangement to be reached with firms regarding the correct price or remuneration for new drugs. It is assumed that established drugs would be bought generically at the lowest prices. *A two-tier system, with developing countries paying relatively little for innovations developed primarily for the developed countries, and paying more for those developed primarily for developing countries, might be the fairest solution.*[41] According to strict economic logic, there is no reason why such countries should pay any premium for rich man's drugs since the flow of innovations would not be affected and alternative (and much cheaper) sources of supply exist, especially if patent laws are appropriately reframed. However, as it is unlikely that the transnational corporations would agree to provide the second category of poor man's drugs if nothing were paid for the first, some compromise would have to be reached. Such a compromise should include a commitment by the transnational corporations to do more research on tropical diseases, to provide economical alternatives to new drugs, and to provide standard drugs for which generic equivalences exist at prices not above those charged by small generic producers. In return, developing countries should agree to pay a negotiated premium for research-based innovations.

Several complex problems of cost allocation, risk and government intervention (by developed countries) are involved, which suggest that a lengthy process of negotiation, involving the Governments of developed and developing countries, the transnational corporations and possibly the United Nations Task Force, would be necessary. If no agreement were reached, however, it is likely that all parties would be worse off: the developing countries by buying cheap products and constricting the flow of valuable innovations; the developed countries by losing good will and by paying more for the innovations of interest to them; and the transnational corporations by alienating potentially large markets and fruitful areas for investment.

The quality control of drugs bought in world markets is not easy, even for the 500 to 700 drugs that a rationalized list would contain. The problem could be greatly eased if each exporting country established official quality-control centres, supported

[41] Such a two-tier system has been accepted in part by the industry, and several European firms have recently approached WHO with a proposal to sell a limited number of basic drugs at cost to the developing world. While the move is clearly a reaction to the recent concern expressed by developing countries in various forums (as described above), it shows a welcome attitude of co-operation and social responsibility on the part of the transnational corporations.

at the apex by an international agency such as WHO which would monitor all drugs sold between countries. In particular, small generic manufacturers in developed countries would find it worthwhile to establish jointly centres with universally accepted stamps of approval. There would still be a need to have quality-control facilities in the importing countries to deal with local manufacturers, with drugs of short shelf lives, locally formulated imports and so on, as well as to check on drugs from other developing countries that did not guarantee the quality of their exports.

Considerable work has already been done, especially in the United States, on drug interchangeability and bio-equivalence. If the results of this work could be made available to developing countries, the task of rationalizing imports could be made much simpler.

A number of operational problems would also have to be tackled by a central buying agency in taking over from private importers: proper inventory control to ensure that the right quantity of each drug is kept in stock; following up tenders, shipments and deliveries; storing large quantities of drugs; and collecting information on prices, quality and bio-availability. The careful planning of each step would be vital to the agency's success.

Local R and D

This is an issue that has not been touched on so far, mainly because so little effective R and D is actually conducted in developing countries. Technological development in this industry, as in many others, displays the classic symptoms of dependence in developing countries.[42] There is very little of it. What there is tends to be too academic or irrelevant. It is not meshed into the domestic productive structure. It suffers from the risk that its promising results will be picked up by subsidiaries of transnational corporations, transmitted abroad and commercialized by the parent companies. There is, therefore, a continuous state of dependence on expensive, often inappropriate, technology developed and controlled by foreign transnational corporations. Developing countries cannot develop the capacity to innovate. Often they do not even develop the capacity to assimilate imported technology.

In the drug industry, a distinction may be made between three types of technology: product technology (the discovery of new drugs, the most difficult, expensive and lengthy part of technological innovation in the industry); process technology (improvements or adaptations in production methods for given drugs); and formulation and packaging technology (innovations in dosage forms, packaging, storage and so on). As regards product innovation, the increasing cost of mounting successful research programmes and the increasing difficulty of finding important new drugs have been noted. This suggests that countries with limited investment and human resources should not devote much effort to fundamental product research, except insofar as pressing medicinal needs are not being met by the existing system. If they are not, there are two alternatives: to do the R and D in the countries concerned or to induce established centres (private or official) to do it in the developed countries. If all the costs and benefits are taken into account, a case may still be made for

[42] See C. Cooper, "Science policy and technological change in underdeveloped economies", *World Development*, March 1974.

undertaking a certain amount of product research in the developing countries. The case is strengthened if international or bilateral aid agencies can be persuaded to finance the infrastructure required; skilled manpower is plentiful in many developing countries. Given the economies of scale involved, moreover, it would seem most economical to undertake R and D on a co-operative or regional basis, under the aegis of a COPPTEC.

As regards process, formulation and packaging technologies, there are much stronger reasons for establishing R and D activities in developing economies. There is a great deal of evidence that local firms in countries like Argentina, India[43] and Mexico have developed improved process know-how independently of foreign assistance. They have adapted and improved upon imported technology, they have substituted local for foreign technology, and they are often able to supply more appropriate technology at much lower cost to other developing countries than the transnational corporations can provide. It is imperative that every country invest in some R and D efforts for the development of indigenous industry and for the absorption of imported technology. In addition to the need for quality control, there is a need for facilities to do process, formulation and packaging research, to set up pilot plants and to upgrade these into full-scale commercial plants.

Government policy must, therefore, provide resources and incentives for this sort of innovation, within plants and in laboratories and pilot plants.[44] An important area of research, which has been noted already, is that into locally available natural products with medicinal properties. Again, co-operative effort can be very rewarding; one such effort is already under way under UNIDO auspices at the Central Drug Research Institute at Lucknow, India.

Policy must also aim to stimulate the transfer of technology between developing countries. There are signs that this has already begun, in two ways: firstly, the amount of trade in pharmaceutical products between developing countries is growing faster than their trade with developed countries; secondly, pharmaceutical firms–public and private–and engineering consultancy firms from the more advanced developing countries are selling technology and know-how to other developing countries. UNIDO may undertake the responsibility for promoting inter-country transfer of technology.

Local production

The setting up of local formulation/packaging plants is economically feasible in most developing countries. The introduction of the production of bulk chemicals requires large markets, substantial capital, sophisticated technology and an established fine chemicals industry. These facts dictate the economics of establishing pharmaceutical industries.

The technology for simple activities is well-diffused and easily available within the developing world. The technology for producing bulk chemicals is available in part. The remainder has to be transferred, bought or copied from the transnational corporations where local production is feasible; the active ingredients must be bought

[43] See the papers submitted to the International Consultation Meeting on Transfer of Technology and Technical Know-how between Developing Countries in the Field of Pharmaceutical Industries, Lucknow, India, April-May 1976.

[44] This may necessitate the retention of patent protection.

where it is not. The role of direct investment by the transnational corporations will have to be determined by each developing country, depending on its general policy towards foreign investment, the capabilities of domestic enterprises and the response of the transnational corporations to the needs of the host country. If transnational corporations can be induced to accept the broad objectives of developing countries—and there are new and hopeful signs of this—an important role remains for them in a reformed structure of drug production and delivery. However, much greater emphasis should now be placed on developing local industry and local skills, and this should form the base of the strategy of UNIDO.

In economies of scale in production and the purchase of technology or active ingredients, there are advantages to be gained from co-operative action between developing countries. In the first case, developing countries can set up complementary industries, the more advanced among them specializing in the more complex tasks, and achieve economies of scale by supplying bulk chemicals to formulation plants elsewhere. While transnational corporations realize the benefits of such complementarities, several incidental costs must be borne by the host country. In the second case, co-operative action can economize on the costs of importing technology by more effective bargaining and by cutting out repetitive purchases, and on the costs of active ingredients, by bargaining and bulk purchase.

The regulation of imports of technology requires special policies and institutions, which shall not be discussed here since they are not germane to the main interest. UNIDO bears the primary responsibility for promoting domestic production in developing countries.

Marketing and information

The central drug-purchasing agency should bear the chief responsibility for marketing drugs, effecting the change from brand to generic names and providing information to doctors and consumers. For reasons given previously, the phasing and planning of this stage are absolutely crucial. There is an entrenched hostility to reforms of this sort, not just from the transnational corporations whose activities would be curtailed by them, but also from many doctors, consumers and people generally who believe in the free market.[45] Such hostility needs to be carefully countered and overcome.

Reform must be primarily a national task. Co-operative or international institutions can, however, provide support and information, and WHO has already started work in this direction.

Co-operative Pharmaceutical Production and Technology Centres. There are several good reasons for initiating some form of co-operative action in the developing world in the drug industry. It is not, however, clear whether such action should take place informally on an issue-by-issue basis, or whether it should be formalized in an institution like a COPPTEC. Obviously, all the changes have to be initiated at the national level, and international action would make sense only if the national changes that would make it worthwhile have already been set in motion. It would be futile to

[45] For accounts of how attempted pharmaceutical reforms have been subverted in Brazil, see P. B. Evans, *loc. cit.*, R. J. Ledogar, *op. cit.* For an account of the United Kingdom experience, see R. W. Lang, *The Politics of Drugs* (London, Saxon House, 1974), and for an analysis of Sri Lanka, see S. Lall and S. Bibile, *op. cit.*

set up COPPTECs before Governments are prepared for them. There are enough international bodies in existence to cope with the preliminary demands of reform, and there are hopeful signs that they are responding to these demands. Thus, there is little need to establish COPPTECs in the short run. If reforms are instituted, there will be a need for them in the long run.

COPPTECs are envisaged as part of long-term policy in the drug industry. Their economic benefits are plain enough; it is the political reality that demands caution in their introduction.

IV. The role of UNIDO

Activities of UNIDO in the field of pharmaceuticals

The Chemical Industries Section of UNIDO has been active in the pharmaceutical sector for a number of years. In 1969 it issued a report entitled "The pharmaceutical industries in the Second Development Decade", a paper prepared for an Expert Group Meeting on the Establishment of Pharmaceutical Industries in Developing Countries, held at Budapest. More recently it has initiated a programme of technical assistance, seminars, training, international co-operation and information activities. Support of such activities has grown from $94,600 in 1973 to $362,265 in 1976 and an estimated $700,000 in 1977. The figure estimated for 1978 is about $800,000 to $1,000,000.

Technical assistance

Technical assistance makes up the core of UNIDO work in the field of industrialization. Several activities are undertaken in the area of pharmaceuticals.

UNIDO provides experts to advise and assist developing countries in the establishment, expansion, improvement, maintenance and quality control of pharmaceutical production. In recent years, expert advisers have been assigned to the following countries: in Africa—Algeria, Burundi, Cape Verde, Central African Empire, Ghana, Lesotho, Rwanda, Uganda, United Republic of Tanzania and Zambia; in Asia—Burma, India, Iraq, Nepal, Sri Lanka and Thailand; in Latin America—Cuba, Guyana, Ecuador, Haiti and the countries of the Andean Pact. The experts have dealt with various production and quality control problems, and their contribution to developing local production has been valuable. As an example of this activity, the pharmaceutical factory of the Ghana Industrial Holding Corporation (GIHOC) was provided with three experts- a production engineer, a quality control adviser and a maintenance engineer in 1969. This factory had encountered several management and technical problems after its construction in 1966 and had been unable to reach an agreement with a transnational firm to take over production. Most of its installed capacity lay idle by 1969. The UNIDO experts, with the co-operation of local counterparts and the Government of Ghana, were able in phase I of the project to raise the production of injections from a designed capacity of 1 million to 6 million by 1974 and of tablets and capsules from 100 million to 645 million. The line of products rose from 14 to 57 items, and the factory became one of the most profitable operations of GIHOC. Phase II of the project, now under way, will institute further improvements and the expansion of production and quality-control facilities.

Several projects are being undertaken to set up pilot plants:

(a) In India, for the production of the anti-malarial drug chloroquine phosphate. The purchase of the advanced technology required for this plant is being directly negotiated by UNIDO with two firms in developed countries;

(b) In Afghanistan and Nepal, a mobile pilot plant will be sent in 1978 for the evaluation and analysis of medicinal plants;

(c) In Africa, a similar pilot plant for evaluating medicinal plants and herbs is planned for the Central African Empire, Rwanda and the United Republic of Tanzania. In Algeria, a mobile unit for the production of essential oils is in the process of being set up.

Feasibility studies are prepared for the establishment of pharmaceutical plants. Three major studies have been completed for establishing plants to serve several countries on a common basis. UNIDO and the Industrial Development Centre for Arab States (IDCAS) jointly carried out a study of the Arab pharmaceutical industry in 1972, the follow-up of which was the establishment of the Arab Company for Drug Industries and Medical Appliances (ACDIMA) by 14 Arab countries. UNIDO is now preparing a more detailed and comprehensive production plan to implement the recommendations of the original study; an important part of this plan is the preparation of industrial profiles for each group of drugs to be produced for the common Arab market. A detailed study of the pharmaceutical industry was carried out for the East African Common Market (EACM) (Kenya, Uganda, and the United Republic of Tanzania). The follow-up to this study has been the establishment of several pharmaceutical units at the national level in these countries. Finally, UNIDO has prepared industrial profiles for antibiotic production for the Andean Pact countries.

These initiatives to promote a joint effort by developing countries are promising for the co-operative development of the pharmaceutical industry and are fully in keeping with the express wishes of the Non-Aligned Countries and the Group of 77 as reviewed previously.

Feasibility studies have also been prepared for several individual countries in recent years, including Burundi, the Central African Empire, Ecuador, Iran, Rwanda, Sri Lanka, Thailand and Zambia.

Through the promotion of transfer of technology among developing countries UNIDO has sought to encourage countries at different stages of pharmaceutical development to exchange technology, personnel and experiences in order to minimize the costs of technology transfer, to provide the most appropriate technology and to enable developing countries to learn from one another's achievements and mistakes. Three such ventures have already been arranged:

(a) Indian experts have visited Latin America to identify areas of co-operation and technical assistance;

(b) Indian experts have visited Algeria to set up a programme of technical co-operation between the two countries;

(c) Nepalese experts have visited Burma to explore the possibilities of technical co-operation. Other co-operative ventures along these lines are envisaged in the future.

UNIDO has initiated several measures (in addition to the pilot plants mentioned above) to help developing countries to use medicinal plants and animal by-products for pharmaceutical production and to develop traditional medicine. Such measures include collecting data on medicinal plants and animal products, providing experts,

arranging seminars, meetings and training schemes, and collaborating with the Council of Scientific and Industrial Research (CSIR) of India for testing plants for other developing countries. It is envisaged that, by collecting and disseminating all available information, and by helping to discover the medicinal properties of natural substances, UNIDO will enable developing countries to undertake production and exports based on locally available resources and to develop local skills and expertise.

UNIDO is establishing a Pharmaceutical Centre in Africa in order to transfer technology to a group of countries for the production of simple drugs for local needs, such as intravenous fluid, vaccines and sera, extraction of herbs and animal by-products. This centre will be used as a demonstration unit in the first instance and in addition for training technicians, designing different production units for countries, and providing information concerning drugs and *ad hoc* technical assistance. Later, it will be expanded for research and development of drugs based on available raw materials, ascertaining the quality of processes in accordance with the requirements and better packaging and formulation methods for tropical conditions.

Finally, UNIDO provides help in the production of birth control devices. It has supplied Cuba with technical assistance in this area and is preparing a major study for Turkey. A study of world-wide contraceptive production has been completed for the United Nations Fund for Population Activities.

Meetings, seminars and training

UNIDO has sponsored a number of meetings of experts on pharmaceutical production, as well as a series of seminars and training courses for technologists from developing countries. These activities include:

(a) In 1969, an Expert Working Group Meeting on the Establishment of Pharmaceutical Industries in Developing Countries, held at Budapest;

(b) In 1971, a study tour on the production of contraceptives, Budapest, Western Europe and the United States, for 20 experts from developing countries;

(c) From 1974-1980, an annual training course on pharmaceutical technology, held at the University of Ghent, Belgium, with the co-operation of the Government of Belgium. Scientists and technologists from developing countries, who totalled about 100 in the first three years of the course, are given lectures and practical training, and participate in visits and discussions;

(d) In 1975, the International Consultation Meeting in the Field of Pharmaceutical Industries, Budapest, with 25 participants from the developing countries. A tentative list of essential drugs was prepared by this Meeting;

(e) In 1976, the International Consultation Meeting on Transfer of Technology and Technical Know-How between Developing Countries in the Field of Pharmaceutical Industries, India, held jointly with CSIR and the Ministry of Petroleum and Chemicals, with 35 delegates from India and 24 from other developing countries. This Meeting comprised lectures, country papers, discussions and study tours. The main result was a strengthening of the co-operative effort among developing countries in the production and technological development of pharmaceuticals and in the promotion of traditional medicines.

Inter-Secretariat Task Force

UNIDO participated in the meeting of the group of experts at Georgetown, Guyana, which prepared the Action Programme for the Fifth Conference of Heads of State or Government of Non-Aligned Nations held at Colombo, Sri Lanka, in 1976, and contributed to the establishment of production policies and programmes in the pharmaceutical industry by the non-aligned and other developing countries. The outcome of these initiatives was the establishment of the joint Task Force of UNIDO, UNCTAD, WHO and UNAPEC to implement the resolution of the Non-Aligned Countries mentioned previously.[46]

There was a marked change in the approach of UNIDO to pharmaceutical policy between 1969 and 1976. In the earlier period, the emphasis was almost exclusively on production and how to increase it. The international structure of the industry, the proliferation of drugs, the role of patents, all were noted but taken as given: production was to develop within this structure, according to established rules. Not surprisingly, subsequent programmes concentrated on the technical aspects of production establishing plants, improving facilities, training specialists and so on and ignored the broader ramifications. The effects of these programmes were undoubtedly beneficial to the recipient countries since they improved their productive capabilities. However, there was no effort to introduce reforms beyond the functioning of plants.

By 1976, however, the emphasis had changed. More recently UNIDO has been supporting many of the reforms noted in this study as a part of its activities. In particular, it has proposed a list of essential drugs and the use of generic names to accompany its programmes of technical assistance. It has not been a comprehensive programme of reform of the sort described here, but it has been a major step in this direction. A main element of the new strategy was the proposal for co-operative action among developing countries in the transfer of technology.

The change in approach, involving whether or not new industries are started according to the old rules, will make a great difference to the long-term outcome. The future strategy of UNIDO should therefore be based on efforts to extend the change and to encourage its adoption by Governments.

Plans for a future strategy for UNIDO

Technical assistance

The main thrust of UNIDO activity will continue to be in the field of technical assistance to developing countries, with the emphasis placed on locating the development of indigenous industry in the context of the general reforms discussed in this paper and endorsed by the developing countries. UNIDO may pay special attention to:

(a) The encouragement, development and use of multipurpose plants in order to open up new possibilities for developing countries to produce drugs based on local raw materials. This forms part of the strategy of UNIDO along with the essential task of identifying the specific groups of drugs suitable for production in multipurpose plants (not all drugs can be produced by such plants, and the design of the plant

[46] A/31/197.

limits the number of drugs that may be produced). A promotional and demonstration meeting on the use of multipurpose plants, planned for 1978, should be of special value for countries just starting pharmaceutical production and for those with small markets;

(b) A phased development of pharmaceutical industries in developing countries to be built on the basis of complementarity and comparative advantage. Countries at different stages of industrial advancement should be encouraged to co-operate in the exchange of equipment, intermediates, finished drugs and personnel. The practice of using experts, consultants and skills from developing countries along these lines could be extended;

(c) UNIDO has accepted the principle of promoting generic names in drug production and marketing. Developing countries should consider a general reform in this area. They should be aware, however, of the difficulties present in implementing such a reform and should study past experience in order to avoid past mistakes;

(d) UNIDO favours the concept of a national drug authority which would act as a central purchasing, distribution and price-fixing agency. In promoting this concept it seeks the co-operation of UNCTAD and WHO in assisting developing countries in procuring drugs on the world market, in ensuring quality, in negotiating prices, and in collaborating in these activities;

(e) UNIDO is expected to play a more significant part in transferring technology and promoting research and development in several ways: firstly, by acting as an intermediary or adviser in technology-transfer agreements between developing and developed countries; secondly, by directly channelling technology between developing countries; thirdly, by participating in the difficult and complex task of working out the best policy for promoting research in developed countries (on the part of transnational corporations and other research bodies) on therapies of importance to developing countries; fourthly, by providing experts and equipment for process and formulation research in developing countries; and, finally, by strengthening its on-going work of setting up pilot plants, utilizing natural products and providing other types of assistance to production.

UNIDO agreed, at the Consultation Meeting on Pharmaceuticals held at Lucknow in 1976, to act as an international information centre on pharmaceutical technology; in this respect, it acts as a clearing house for data on the technology market (buyers and sellers) and on products, to complement the activity that WHO may undertake relating to basic lists, labelling and adverse effects.

International consultations and the Inter-Secretariat Task Force

The Inter-Secretariat Task Force has prepared a programme for implementing the resolution on pharmaceuticals of the Non-Aligned Countries. Data on various aspects of pharmaceutical procurement, production, use and distribution will be gathered in several developing countries and in the international agencies, and a group of experts will visit a number of developing countries to gather information, to establish counterparts in Governments, to harmonize the programmes of different ministries in each Government, and to give any technical assistance that may be required. This mission is then expected to draw up feasibility studies for specific measures to be undertaken to implement the resolution.

A consultation meeting of developed and developing countries on the pharmaceutical industry, scheduled for 1978 to consider ways of relocating a part of the industry in developing countries in accordance with the Lima Declaration, could help to establish closer co-operation between the two groups of countries.

Seminars and training

The annual training course held at Ghent, Belgium, is to continue until 1980. UNIDO may consider sponsoring conferences and symposia to air the most important issues concerning the development of the pharmaceutical industry and to stimulate an awareness among developing countries of existing problems and constraints. Since an important step is to create the right climate of opinion for a reorientation of policy, such conferences are vital in bringing together experts from different areas and backgrounds (including the transnational corporations).

Annex I

DATA ON PHARMACEUTICAL PRODUCTION AND SALES

TABLE 7. PRODUCTION AND TRADE IN PHARMACEUTICAL PRODUCTS,[a] 1973

(Million dollars)

	(A) Output	*(B) Exports*	*(C) Imports*	*(D) Consumption[b] (A + C – B)*	*(E) Trade balance (B – C)*
Developed market economies					
Australia	367	44	97	420	53
Austria	102	35	91	158	– 56
Belgium/Luxembourg	289	201	250	338	– 49
Canada	497	48	119	568	– 71
Denmark	131	111	70	90	41
Finland	50	3	55	102	– 52
France	2 283	439	274	2 118	165
Germany, Federal Republic of	3 293	855	175	2 613	680
Italy	1 785[c]	262	288	1 811	– 26
Japan	5 050	100	361	5 311	– 261
Netherlands	429	267	202	364	65
Norway	32	7	50	75	– 43
South Africa	259	13	47	293	– 34
Sweden	187	68	128	247	– 60
Switzerland	671[d]	588	128	211	460
United Kingdom	1 108	542	164	730	378
United States	8 386	630	167	7 923	463
Subtotal	24 919	4 213	2 666	23 372	1 547
Southern European countries					
Greece	63[e]	8	75	130	– 67
Portugal	160[f]	20	60	200	– 40
Spain	1 180	26	150	1 304	– 124
Turkey[e]	131[e]	1	34	164	– 33
Subtotal	1 534	55	319	1 798	– 264
Developing countries and areas					
Algeria	51[g]	–	74	125	– 74
Argentina	162[h]	19	40	183	– 21
Bahamas	...	25	16	...	9
Bangladesh	13	–	11	24	– 11
Brazil	761[i]	9	82	834	– 73
Chile	135	–	25[l]	160	– 25
Colombia	114[j]	6[k]	24[k]	132	– 18
Ecuador	15	2[f]	11	24	– 9
Egypt	120	2	12	130	– 10
Ghana	3	–	11	14	– 11
Hong Kong	18	55	73	36	– 18
India	422	13[k]	29[l]	438	– 16
Indonesia	38	6	29	61	– 23
Iran	43[e]	–	79[e]	122	– 79
Iraq	14	–	19	33	19

TABLE 7 *(continued)*

	(A) Output	*(B) Exports*	*(C) Imports*	*(D) Consumption (A + C B)*	*(E) Trade balance (B C)*
Developing countries and areas (continued)					
Israel	44[l]	8	22	58	14
Mexico	237	45	60	252	15
Morocco	21[e]	1	16	36	15
Nigeria	8		41	49	41
Pakistan	65	1	12	76	11
Peru	84	1	31[m]	114	30
Philippines	93[e]	2[m]	27[m]	118	25
Republic of Korea	151	5	18	164	13
Singapore	...	34	35	...	1
Thailand	120[n]	2	47	165	45
Venezuela	124[d]		39[k]	163	39
Yugoslavia	254	39	52	267	13
Subtotal	3 113	275	935	3 767[o]	660
Total	29 566	4 543	3 920	28 937	623
Other developing countries	...	140	922	...	782
WORLD TOTAL	...	4 683	4 842	...	159

Sources: United Nations *Yearbook of Industrial Statistics, 1974 Edition* and *Market Trends and Prospects for Chemical Products*, 1973; Organisation for Economic Co-operation and Development (OECD), *The Chemical Industry 1973/1974*, and *Trade by Commodities* (Series C); Documentation d'Analyses Financières S.A. (DAFSA), *The Pharmaceutical Industry in Europe*, 1974; *Bulletin of Statistics*, Republic of South Africa, 1976; Hathi Committee, *Report of the Committee on Drugs and Pharmaceuticals*, Government of India, 1975; Economic Commission for Africa, *Pharmaceuticals in Africa*, 1976; papers presented at the UNIDO Consultation Meeting on Transfer of Technology and Technical Know-How between Developing Countries in the Field of Pharmaceutical Industries, Lucknow, India, April-May 1976; Banco de Mexico, *Informe Anual 1975*.

[a] Production data taken from the United Nations *Yearbook of Industrial Statistics* covers gross output under ISIC 3522, "Drugs and medicines". Trade data from the United Nations *Yearbook of International Trade Statistics* covers SITC 541 "Medicinal and pharmaceutical products". All conversions to dollars made at the International Monetary Fund (IMF) *International Financial Statistics* average market rate for the relevant year.

[b] Including finished as well as intermediate drugs whenever the latter are included in the production and trade figures.

[c] Calculated from 1974 figures, assuming 15 per cent growth over 1973.

[d] Projected from 1971 estimate at 15 per cent growth per annum.

[e] Projected from 1972 figures at 15 per cent growth per annum.

[f] This is the Organisation of Economic Co-operation and Development figure, which is much higher than the United Nations figure of 89 million.

[g] Rough estimate, projected from 1967 figures at 10 per cent growth per annum.

[h] Rough estimate, projected from 1966 figures at 10 per cent growth per annum.

[i] Projected from 1972 figure at 20 per cent growth per annum.

[j] Projected from 1972 figure at 5 per cent growth per annum.

[k] Projected from 1972 figures at 10 per cent growth per annum.

[l] Assumed constant at 1972 level.

[m] Projected from 1971 figures at 10 per cent growth per annum.

[n] Projected from 1970 figures at 10 per cent growth per annum.

[o] Total consumption figures do not match total production plus trade figures because of lack of production data for the Bahamas and Singapore.

TABLE 8. PHARMACEUTICAL SALES OF LEADING COMPANIES, 1974

Company	*Country*	*Pharmaceutical sales (million dollars)*	*Percentage of firm's sales*	*Percentage of total*	*Percentage change 1970-1974*
Roche	Switzerland	1 386.0	70	7.6	65.0
Merck	United States	1 196.6	90	6.6	78.6
Hoechst	Federal Republic of Germany	1 173.5	14	6.5	136.1
Ciba-Geigy	Switzerland	1 062.8	29	5.9	116.0
Bayer	Federal Republic of Germany	861.7	11	4.8	201.3
Sandoz	Switzerland	847.3	54	4.7	144.9
Lilly	United States	789.2	71	4.3	87.5
American Home Products	United States	757.9	37	4.2	58.2
Pfizer	United States	740.0	48	4.1	77.9
Upjohn	United States	683.4	86	3.8	99.8
Warner-Lambert	United States	611.5	32	3.4	49.9
Rhone-Poulenc	France	595.2	13	3.3	131.6
Sterling	United States	565.8	65	3.1	35.4
Abbott	United States	551.1	72	3.0	67.0
Boehringer Ingelheim	Federal Republic of Germany	506.2	70	2.8	139.9
Schering	Federal Republic of Germany	449.0	70	2.8	136.5
Schering-Plough	United States	443.4	63	2.4	73.9
Squibb	United States	442.0	44	2.4	42.6
Bristol Myers	United States	429.5	27	2.4	38.5
Glaxo	United Kingdom	419.1	69	2.3	60.6
Takeda	Japan	414.8	44	2.3	98.5
Searle	United States	385.2	62	2.1	208.2
Cyanamid	United States	373.8	21	2.1	53.8
Beecham	United Kingdom	348.5	34	1.9	164.0
Smith Kline	United States	321.2	62	1.8	49.4
Boehringer Mannheim	Federal Republic of Germany	319.5	100	1.8	168.5
Wellcome	United Kingdom	269.0	66	1.5	97.8
Akzo	Netherlands	257.5	6	1.4	112.8
Johnson and Johnson	United States	232.5	12	1.3	93.8
Astra	Sweden	198.8	72	1.1	125.9
Richardson Merrell	United States	172.9	30	1.0	47.8
ICI	United Kingdom	138.8	2	0.8	107.2
Smith and Nephew	United Kingdom	78.3	32	0.4	50.6
Carter-Wallace	United States	62.5	42	0.3	17.9
	Total	18 134.5	28.4	100	90.7

Sources: For United States firms, *Fortune*, May and June 1975; for Japanese firms, *Fortune*, August 1975; for European firms, *Vision*, October 1975 (note that *Vision* figures are somewhat higher for given firms than *Fortune* figures).

Note: Figures on pharmaceutical sales are not available separately for 1974; these percentages are based on 1970 data. Since pharmaceutical sales are not known, figures for 1970-1974 growth refer to the firm's total sales. Figures for 1970 are from Lall (1975).

Annex II

MARKET DATA ON ERYTHROMYCIN

TABLE 9. ERYTHROMYCIN SUPPLIERS IN THE UNITED STATES, 1973

(Major dosage form: 250 mg/100 tablets)

Supplier	*Brand*	*Price (dollars)*	*Code*
Sherry[a]		5.70	S r
Geneva		6.60	S r
Premo		7.10	S r
Abbott		7.17	B t
Arcum		7.25	B r
Approved Pharmaceuticals		7.45	S r
ICN		7.45	S r
Penhurst		7.50	B r
Squibb[a]	Ethril	7.66	S ts
Wyeth (AHP)[a]		7.73	S t
Pfizer[a]	Pfizer-E	7.82	S ts
McKesson	Kesso-mycin	7.83	B t
Ulmer		7.95	B r
Parke Davis[a]	Erypar	8.13	S ts
West-Ward		8.30	S r
Barry-Martin		8.35	B r
Columbia Medicine		8.45	S r
CMC		8.50	S r
Am. Quinine		8.65	S r
Zenith		8.69	S r
Lannett		8.80	S r
Towne-Paulsen		8.83	S r
First Texas		9.12	S r
Robins	Robimycin	9.56	B t
Mallinckrodt	QID-Mycin	9.68	S t
Smith Kline[a]	SK-Erythromycin	9.83	S ts
Lilly[b]	Ilotycin	9.87	B ts
Bell		9.95	B r
Purepac		9.95	B r
Bristol	Bristamycin	10.21	S ts
Robinson		10.87	S r
Upjohn[b]	E-Mycin	10.90	B ts
Phillips		11.00	S r
Cenci		12.50	S r
Abbott[b]	Erythrocin	12.96	S ts

Source: P. A. Brooke, *Resistant Prices: A Study of Competitive Strains in the Antibiotic Markets* (New York, Council of Economic Priorities, 1975, and Cambridge, Mass., Bellinger, 1976) table 2, chap. VI.

Note: Key "S" indicates erythromycin stearate; "B" indicates erythromycin base; "r" indicates the published wholesale price in the 1974 Red Book, and that sales were not significant; "t" indicates average transaction price to drug stores computed by *Chemical Engineering Progress* (CEP) from IMS data, and that average wholesale price is higher; "s" indicates significant sales.

[a] Manufactured for these firms by Milan Laboratories, United States.

[b] Sole domestic manufacturers of bulk erythromycin.

TABLE 10. UNITED STATES ERYTHROMYCIN MARKET DRUG STORE PURCHASES, 1973

		Major dosage form						
			Bottles of 100					
Supplier	*Brand*	*100 TP-W*	*ATP*	*DP*	*AWP*	*$ (thousands)*	*DS-Rx (thousands)*	*All forms DS-$*
Pfizer	Pfizer-E	7.39	7.82	9.75	11.58	881	99	1 293
Squibb	Ethril	7.66	7.66	9.95	11.83	830	267	830
Parke-Davis	Erypar	8.13	8.13	13.60	15.87	534	153	538
Bristol	Bristamycin	8.51	10.21	9.95	11.85	1 615	460	1 615
Robins	Robimycin	9.15	9.56	. . .[a]	10.00	767	250	767
Smith Kline	DK-Erythromycin	9.66	9.83	. . .[a]	10.15	645	78	645
Lilly	Ilotycin	9.87	9.87	. . .[a]	10.00	397	258	578
Upjohn	E-Mycin	10.90	10.90	13.35	16.02	5 545	2 113	5 545
Abbott	Erythrocin	11.96	12.96	14.99	17.39	11 779	10 076	23 216

Source: P. A. Brooke, *Resistant prices: A study of Competitive Strains in the Antibiotic Market* (New York, Council of Economic Priorities, 1975, and Cambridge, Mass., Ballinger, 1976), table 3, chap. VI.

Note: Percentage of new prescriptions written generically: 27 per cent; dollar volume of market: $38,974,000; percentage in sales of suppliers listed: 90 per cent; major dosage form 250 mg tablets—percentage of market 66 per cent.

Key:
- TP-W — Weighted transaction price per 100, all package size (IMS-1973)
- ATP — Average transaction price per bottle of 100 (IMS-1973)
- DP — Published price direct from supplier (Red Book-1974)
- AWP — Published average wholesale price (Red Book-1974)
- DS-Rx — Numbers of prescriptions for brand (NPA-1973, add 000)
- DS-$ — Supplier revenues (IMS-1973, add $000)
- $ — Total supplier revenues, major dosage form

[a] Supplier sells only through wholesalers.

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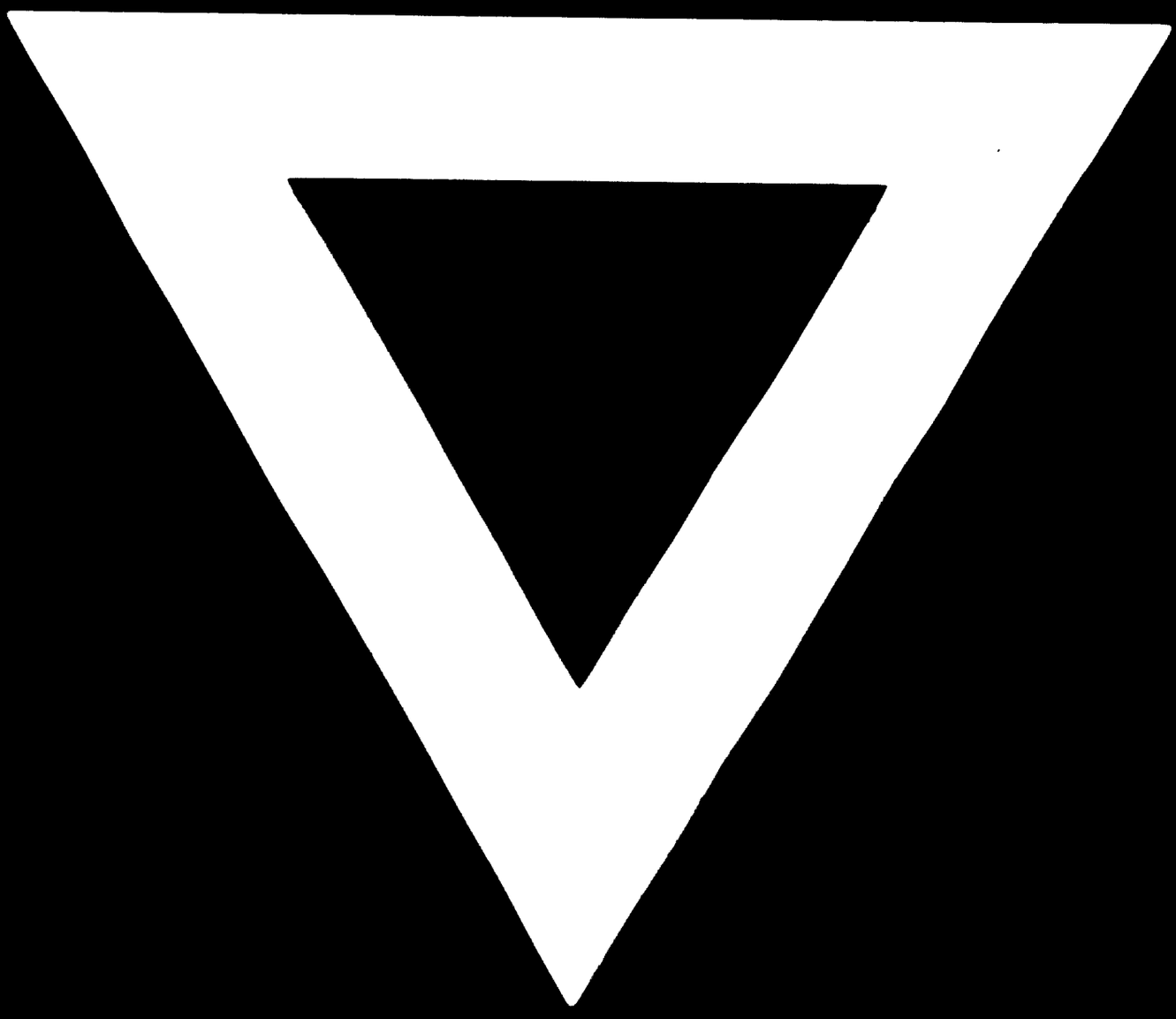

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