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PHARMACEUTICAL INDUSTRY DEVELOPMENT IN DEVELOPING COUNTRIES AND THE CONCEPT OF TOTAL QUALITY CONTROL*

Prepared by the

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Division of Industrial Operations

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TABLES

1.0 GENERAL

Benjamin Disraeli, the noted British Statesman, said" "The Health of the people is really the foundation upon which all happiness and all their powers as the state, depend". However, one quarter of the people on this earth have no access to any health care whatsoever. High morbidity and mortality rates exist among the rural population that constitutes the majority of the worlds' population. Millions of people continue to suffer from symptoms which can be alleviated, die from diseases which can be treated and develop diseases which can be prevented entirely. Despite the staggering statistics of mortality and disease in the Third World, health matters have low priority in developing countries as can be seen from Table 1. In general, developed countries spend 5-8 percent of GNP on helath care, out of which the expenditure on pharmaceuticals accounts for 10-20 percent. In contrast, the expenditure on health care in many developing countries is below 2 percent of the GNP which up to 40 percent represents expenditure on pharmaceuticals.

Since health is a basic human need and pharmaceutical products directly affect the health of a nation, they have a greater social relevance than the products of almost any other industry. The pharmaceutical products, therefore, constitute an essential element in health care system. In view of this availability of pharmaceuticals assumes considerable significance. At this juncture, it may be appropriate to look at the per capita drug consumption figures for different countries which are indicated in Table 2. Pharmaceutical sales per capita figures are given in Table 3. These figures show a clear demarcation between the developed and developing countries as far as per capita drug consumption is concerned. While the per capita consumption of drugs in developed countries ranged from US$ 13 to 52, the corresponding figures for developing countries ranged from US$ 0.8 to 18. This is inspite of the fact that many developing countries spend over 40 percent of their health budget on drugs.

1.1 WORLD CONSUMPTION OF PHARMACEUTICALS

During 1983, the developing countries with 74 percent of the worlds' population had only 20 percent share of the global consumption of pharmaceuticals (Table 4). In fact 75-80 percent of the population in developing countries has practically no access to modern drugs. Apparently the consumption in developing countries remained static during 1980-1983, while the world

consumption increased. The pharmaceutical consumption as a percent of GNP is shown in Table 5.

1.2 WORLD TRADE IN PHARMACEUTICALS

During 1983, developing countries imported pharmaceuticals valued at US$ 3.619 million (Table 6) or about 27 percent of total world imports. During the same year the value of exports of pharmaceuticals by developing countries amounted to US$ 925 million or about 7 percent of total world exports (Table 7). This clearly highlights the dependance of developing countries on imports.

1.3 OVERVIEW OF THE PHARMACEUTICAL INDUSTRY IN DEVELOPING COUNTRIES

Based on the level of the development of the pharmaceutical industry, developing countries can be classified into five different stages of vertical integration (table 8). The countries in the first stage rely entirely on imports of pharmaceuticals in dosage form, since they have no pharmaceutical production activity. Those in the second and third stage of development import bulk drugs (pharmaceutical chemicals) and produce pharmaceuticals in dosage form. They have no facilities to produce pharmaceutical chemicals. The countries in the fourth and fifth stages have the highest degree of vertical integration. Besides producing pharmaceuticals in dosage form they manufacture a fairly broad range of pharmaceutical chemicals from intermediates and raw materials. China, India, Mexico, Brazil, Argentina and Egypt are in the fifth stage. These countries are also characterized by local research and development to some extent. It is observed from Table 8 that amongst developing countries the pharmaceutical industry is most developed in Latin America, less developed in Asia and the Middle East and least developed in Africa.

1.4 WORLD PRODUCTION OF PHARMACEUTICALS

During 1983, the share of developing countries in world production of pharmaceuticals amounted to about 18 percent valued at US$ 16.42 billion (Table 9). Out of this, the share of Asia was 10.6 percent, valued at US$ 10.03 billion.

1.5 WORLD PHARMACEUTICAL MARKET

The world pharmaceutical market in respect of some developing countries is indicated in Table 10 while the regional market shares for pharmaceuticals sales are shown in Table 11. The market share of developing countries is 20.1 percent. The largest 15 country markets in 1982 are given in Table 12. It is interesting to note that five developing countries find place in the above list. Special mention has to be made at this juncture of the spectacular progress made by the Indian Pharmaceutical industry during the past two decades. At present there are over 4000 units of varying sizes producing pharmaceuitcal formulations and several units manufacturing bulk drugs. The present production covers a wide range of bulk drugs including antibiotics, steroids, vitamines, synthetics, phytochemicals and biologicals in addition to the entire range of pharmaceutical formulations required by the medical profession. Apart from being self-sufficient with respect to formulations, the country also exports a wide range of pharmaceuticals. Hindustan Antibiotics Ltd. has to be complimented for its pioneering role in initiating and developing the basic manufacture of antibiotics in India.

2.0 STRATEGY FOR THE DEVELOPMENT OF PHARMACEUTICAL INDUSTRY IN DEVELOPING COUNTRIES

From the foregoing, it is obvious that the development of pharmaceutical industry has considerable relevance to the situation in developing countries specially in the Asian Region. The latter should, therefore formulate policies and implement programmes that ensure an adequate supply of good quality pharmaceuticals to their population at prices, which they can afford. The integrated development of this industry in this region would create vital and strategic health related industries having direct impact on the socio-economic development. Such a development can be achieved through a concerted action in different areas as described below briefly.

2.1 SPECIAL CONSIDERATIONS

It is but natural that the economic viability of the pharmaceutical industry in developing countries is looked upon like any other industry or for that matter like the pharmaceutical industry in the advanced industrialized countries. The pharmaceutical industry in the latter countries is characterised by large market,

elaborate research and development complex, availability of highly skilled technicians and scientists, existence of a strong chemical and machine fabricating industries, an active and competent state regulatory apparatus to ensure the quality and safety of the pharmaceuticals produced etc... Since most of the developing countries are characterised by the absence of these very factors, one is tempted to conclude that the pharmaceutical industry in developing countries is unlikely to be economically viable. Finally, it is argued that pharmaceuticals are available on the international market at competitive prices and it is, therefore, apparently more economical to import rather than take up local production. However there are other more compelling factors, which have to be taken into account in this context and these include social benefits, self-reliance, cost-effectiveness of pharmaceuticals in the overall health-care costs, employment opportunities, manpower development, export possibilities, utilization of natural resources and local raw materials, economizing on foreign exchange through reducing imports and development of ancillary industries etc...

In the light of above it is obvious that there are several special considerations, which are relevant and favour the development of pharmaceutical industry in developing countries.

2.2 PRODUCTION OF PHARMACEUTICALS IN DOSAGE FORM

The technology involved in the production of pharmaceuticals in dosage form is relatively simple and is well diffused specially in the Asian Region. This type of industry is also characterised by licencing arrangements, foreign subsidiaries and joint ventures. In view of this, it is appropriate to expand the capacities of pharmaceutical dosage form production. The second UNIDO consultation on the Pharmaceutical Industry held in 1983 concluded that where a country decided to establish or expand manufacturing of formulation capacity of specific products, it was appropriate for UNIDO to make available advice and assistance in the selection and acquisition of technologies, preparation of feasibility studies, obtaining of investment finance and, more generally, establishment of manufacturing capacity including the training of manpower [1]. To promote industrialization in the pharmaceutical sector, UNIDO has prepared a series of Technical profiles offering guidance to developing countries in the establishment of units for production of pharmaceutical dosage forms [2].

1. Second Consulation on the Pharmaceutical Industry, UNIDO/ID/311, 1983
2. Technical profiles for production of pharmaceutical dosage forms, UNIDO/ID/WG. 393/4, 1983

The UNIDO Directory of sources of supply assists developing countries in locating suitable sources of supply for the pharmaceutical Industry [3].

2.3 MANUFACTURE OF PHARMACEUTICAL CHEMICALS

The technology in the case of manufacture of pharmaceutical chemicals or bulk drugs is rather sophisticated and is held by a limited number of Technology holders. This is one of the reasons why only a few developing countries have been able to make some headway in this area. The availability, pricing and transfer of Technology for the bulk drugs formed one of the major issues of both the UNIDO consultations on the pharmaceutical industry held in 1980 and 1983 respectively [4].

The first consultation recommanded that mutually acceptable transfers of Technology should be facilitated through UNIDO providing reference information relevant to the transfer of Technology, including technical aspects, such as level of production, magnitude of investments, inputs, infrastructure etc... which could be significant and to individual developing countries in bilateral negotiations for transfer of technology.

The second consultation recommended that in respect of offers of technology for the production of bulk drugs and intermediates, UNIDO should in cooperation with technology holders prepare feasibility studies at the request by interested countries.

2.3.1 PHARMACEUTICALS BASED ON FERMENTATION

The "wonder drug" penicillin developed during World War II led to the discovery of several life saving antibiotics. It was in 1953 that the first batch of Penicillin was produced at Hindustan Antibiotics Ltd. The antibiotics group constitutes the most important therapeutic group amongst drugs consumed in many of the developing countries and accounts for about 25 percent of drug consumption. Except for a few, most of the developing countries entirely depend on imports of antibiotics in bulk as well as formulations to meet their demand. The recent advances in biotechnology and genetic engineering have opened up new avenues for the production of pharmaceutical products, vaccines etc...

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3. Directory of sources of supply of 26 essential drugs, their chemical intermediates and some raw materials, UNIDO/ID/WG/ 393/2, 1983.

4. First consultation on the Pharmaceutical Industry, UNIDO/ID/259, 1980. Second Consultation, Ibid.

In view of this, it is appropriate that the developing countries particularly those in groups 3 and 4, which possess the requisite base, infrastructure and market take up and expand the manufacture of pharmaceutical chemicals based on fermentation. Considerable progress has already been achieved in this area in the Asian Region in China, India and the Republic of Korea.

2.3.2 PHARMACEUTICAL CHEMICALS BASED ON CHEMICAL SYNTHESIS - MULTI-PURPOSE PLANT

In the Asian region, considerable progress has been achieved in this area in China, India and the Republic of Korea. However in these countries as well as others in the region, analysis of the market reveals that several drugs are consumed in quantities not large enough to render the establishment of a separate production unit for each drug economically viable. In such case the establishment of a multi-purpose plant is recommended for the production of a group of synthetic drugs. Such a plant will facilitate the transfer of technology and the manufacture of a number of products sequentially or to some extent simultaneously using single/double series equipment. Further, in such a plant sophisticated automation is generally not required. A plant of this type will also involve relatively lower investment and is versatile enough to take care of new products for which the technology might be under development. In other words, flexibility is built into the design of the multi-purpose plant to cope with the varying and ever changing demands of the pharmaceutical market. The design also facilitates an increase in the capacity of the plant through marginal investment. Such a plant will also facilitate adaptation and development of technology, based on which single line production units could be established depending on their viability. Multi-purpose plant of this type has already been established under the auspices of UNIDO/UNDP in Cuba and another plant is being established in Iran [5].

2.3.3 PHARMACEUTICALS BASED ON MEDICINAL PLANTS

The Asian region is very rich in plant resources, which can be exploited for industrial purposes. Considerable progress has been made in this area in China and India and traditional medicine and pharmaceuticals derived from medicinal plants constitute a significant element in health care in these countries particularly in rural areas. Similarly in other countries cultivation on a scientific basis of medicinal plants could be undertaken. Applied research and development work should also be carried out to produce important drugs from medicinal plants for internal consumption. Pharmaceuticals can be produced in the

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5. Multi-purpose plant for production of UNIDO essential drugs based on raw materials and intermediates. UNIDO/WG. 393/18.

existing processing and manufacturing units or in multi purpose plants newly established to extract active ingredients from local flora. The developing countries instead of exporting medicinal plants could process them for domestic use or for export at greatly enhanced values. The second consultation on the Pharmaceutical Industry has given a mandate to UNIDO to intensify its programme in the area of medicinal plants [6].

2.4 PRODUCTION OF BIOLOGICALS

The production of biologicals for the enhancement of preventive measures in the Asian Region assumes significance considering the efforts being made in this region towards Health Care. A sound base exists and great advances have been made in this area in countries in the region such as China and India. Existing facilities could be expanded to augment production as well as widen the range. New facilities could be established to meet the ever increasing demand. UNIDO has launched a programme on Industrial Production of Biologicals (IPB) and an Advisory Panel on Preventive medicine has been established with high level representatives from both industry and government to guide the above programme. The Second Consultation on the Pharmaceutical Industry has given a mandate to UNIDO to undertake a wide ranging programme in the area of biologicals [7].

2.5 The strengthening of the capabilities of National Institutions in the area of Research and Development particularly in the field of biotechnology and genetic engineering and development of technology are essential for the growth and development of Pharmaceutical Industry in the Region in keeping with the developments world wide.

3.0 ANCILLARY INDUSTRIES

The pharmaceutical industry in many of the developing countries is limited by the lack of local industry for the production of miscellaneous items such as glass and plastic containers and other packaging materials. The integrated development of the pharmaceutical industry should, therefore, include the establishment of ancillary industries to meet the requirements on a regional basis, where feasible. Ms. Hindustan Antibiotics Ltd has to be congratulated for having

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6. Second Consultation on Pharmaceutical Industry, Ibid

7. Second consultation on Pharmaceutical Industry, Ibid

provided facilities for the establishment of ancillary industries right at the start of its operations.

4.0 TECHNICAL CO-OPERATION AMONGST DEVELOPING COUNTRIES (TCDC)

In view of the scphisticated technology involved in the production of pharmaceutical chemicals and the limited number of sources available for the acquisition of such technology, TCDC assumes significance. Fortunately, some of the countries in the Asian Region such as China, India and the Republic of Korea are relatively more "advanced" than others in the technological field and they would be in a position to assist sister developing countries. The multi purpose plant mentioned earlier has been established in Cuba with the technical know-how from India. Similar possibilities exist within the region. The present training programme is another good example of TCDC.

5.0 CONCEPT OF TOTAL QUALITY CONTROL

Having considered the relevance of the development of Pharmaceutical Industry to the situation in developing countries specially in the Asian region and the strategy for such a development, it has to be ensured that total quality control which is of paramount importance is made an integral part of this industry.

According to the Federal Food, Drug, and Cosmetic Act of the U.S.A., "a drug or device shall be deemed to be adulterated, if it is a drug and the methods used in, or the facilities or controls used for its manufacture, processing, packing or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets che requirements of this Act as to safety and has the identity and strength, meets the quality and purity characteristics, which it purports or is represented to possess". Thus, total control of quality is the organized effort within an active establishment to design, produce, maintain and assure the specific quality in each unit or drug distributed.

The concept of toal quality control is of great relevance particularly at this juncture when developing countries are endeavouring to augment the supply of pharmaceuticals through local production. WHO has been devoting considerable attention to this aspcet and has been emphasizing the need for the institution

of a national drug registration system embodied within a legislative framework, that, inter alia, contains provisions to assure the quality of all registered products [8]. The code of good practices in the manufacture and quality control of drugs promulgated by WHO and the WHO certification scheme on the quality of pharmaceutical products moving in international commerce are of fundamental importance in this area. Some of the developed countries have formulated their own good manufacturing practices for pharmaceuticals (GMP) and several publications are available on this subject [9].

5.1 PROBLEMS AND PROSPECTS

A review of the status of quality control and assurance in Pharmaceutical Industry in developed as well as developing countries brings to surface reassuring as well as discomforting features. In highly developed countries a great deal of administrative and technical effort is directed to ensuring that the patients receive effective drugs. However, in developing countries, there, is considerable variation ranging from full fledged controls, GMP and enforcement to meagre and inadequate controls. While pharmaceuticals produced in some of the developing countries are comparable in every respect to the best available in the world, the same thing cannot be said about many produced in some other countries and units. The fact that illicitly manufactured drugs, which may be substandard or even spurious, may enter the distribution chain complicates the situation further.

Full implementation of the measures outlined above requires both extensive laboratory facilities and a well staffed inspectorate. In many of the developing countries, resources are not available to provide for investment on this scale. Although the WHO "certification Scheme" offers some safeguard insofar as imported products are concerned, it has no relevance to locally manufactured products. Further, it does not provide safeguard that an initially acceptable product will not deteriorate owing to improper storage; nor does it apply when a product is imported from a trading company located outside the country of original manufacture.

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8. WHO official records No. 226, 1975 (Revised as PHARM/82.4)
WHO Expert Committee on Specifications for Pharmaceutical Preparations, Technical Report Series 704, 1984; no. 645, 1980, no. 681, 1982.
WHO Technical Report series no. 685, 1983
The International Pharmacopoeia 3rd ed. vol I, 1979, col II, 1981.

9. Good Manufacturing Practices for Pharmaceuticals, A plan for total quality control, S.H. Willig, M.M. Tuckerman and W.S. Hitchings IV, 1982.

This is the reason why WHO recommended that every country regardless of its stage of development, should consider the need for investment in an independent national drug quality control laboratory.

The absence of extensive laboratory facilities required, qualified technicians and a well staffed inspectorate in several developing countries is often creating an unfavourable situation which is hampering the growth and development of this industry. Such a situation fails to instil the necessary confidence amongst the medical profession and the public in general to accept pharmaceuticals produced under such circumstances. Without assurance that these drugs meet acceptable standards of efficacy and safety, the efficiency of any health service is compromised. This is aggravated by the high pressure promotion carried out by certain quarters in overemphasizing the quality control aspect to an extent that the developing countries in several cases are scared to take up local production. In the result, these countries resort to imports sometimes from sources not too reliable and often products are priced beyond the reach of many. It will be appreciated that there is no need to overdo this in such a manner. Further quality control must be enforced in the case of imported pharmaceuticals with the same rigidity as in the case of local production. In practice, however, local production is often singled out for this purpose and hardly any control is exercised on imported pharmaceuticals, as can be seen from the information provided by the participants. This in its turn works to the detriment of local industry. In view of this, it is necessary to enforce quality control measures in the case of imported pharmaceuticals as well as local production with the same rigidity.

The developing countries are often eager to procure sophisticated equipment for quality control. The absence of such equipment is stated to handicap their functioning, as is evident from practically all the answers received from the participants to the above programme. The availability of complex automated equipment accelerates but does not necessarily raise the standard of analytical work. Further, such equipment performs reliably only when it is expertly maintained and highly purified and expensive reagents are used in its operation.

6.0 CONCLUSION

In the foregoing, an effort has been made to make the issue of pharmaceutical industry with special reference to quality control and assurance

transparent.

It is gratifying to note that this industry registered phenomenal growth in some developing countries, which instituted full f ledged controls, GMP and enforcement. Unfortunately, the same thing cannot be said about some other countries. Now, it is for the Governments of developing countries to decide upon the course of action, which they would like to take in order to find a lasting solution to the problem of non-availability of pharmaceuticals to meet the requirements of their health care programmes. It is realised that no country can ever be truly independent in this sector. However, it is feasible to attain a large measure of self-sufficiency through local production, making the concept of total quality control an integral part of the industry.

In view of this, it is essential to create an increased awareness of the importance of quality control and assurance at each level and segment of this industry and this is the purpose of the above training programme.

Table 1. National expenditure on health as % of GNP

Country category	Total as % GNP
Low income	
India	1.0
Ethiopia	0.8
Kenya	1.7
Middle income	
Philippines	0.5
Iran	0.6
Brazil	0.5
Centrally planned economies	
Hungary	3.0
USSR	3.5
Industrialized	
Italy	8.0
W. Germany	8.0
U.S.A.	7.9

Source: Pharmaceuticals for Developing Countries, National Academy of Sciences, 1979.

TABLE 2

Per Capita Drug Comsumption of Selected Countries

(dollars of the period)

	Year	Per capita drug consumption (in US$)	Population (in millions)
Developing Countries			
Algeria	1976	8.2	16.23
Afghanistan	1976	1.2	14.00
Argentina	1975	18.0	25.38
Bangladesh	1976	0.9	80.40
Brazil	1976	12.0	109.96
Chad	1977	0.8	4.2
China	1975		822.8
Egypt	1977	5.5	38.08
Ethiopia	1978	0.8	2.86
Guinea	1977	1.7	5.7
India	1977	1.6	620.44
Indonesia	1976	1.8	135.19
Iran	1977	14	34.3
Korea, Rep of	1977	14	35.96
Libyan Arab Jamahriya	1975	9.9	2.44
Malaysia	1977	2.5	12.65
Mexico	1976	11.6	62.05
Nigeria	1977	2.75	77.05
Pakistan	1976	1.3	71.30
Peru	1975	9.6	15.38
Sudan	1977	5.6	15.8
Thailand	1976	5.75	42.96
Tanzania	1976	1.3	15.1
Turkey	1975	4.1	40.1
Developed Countries			
Austria	1975	26	7.5
Belgium	1975	42	9.8
Canada	1976	28	23.18
Denmark	1976	28	5.07

TABLE 2 (continued)

Country	Year	Per capita drug consumption (in US$)	Population (in millions)
Developed Countries (Cont.)			
Finland	1976	36	4.73
France	1976	50	52.92
FR Germany	1976	52	62.00
Greece	1976	24	9.13
Ireland	1976	13	3.16
Italy	1976	34	56.19
Japan	1976	41	112.77
Netherlands	1976	26	13.77
Norway	1976	24	4.03
Spain	1976	36	35.70
Sweden	1975	36	8.22
Switzerland	1975	35	6.41
U.K	1976	18	56.07
U.S.A	1976	33	215.12
Centrally Planned			
Czechoslovakia	1975	27	14.80
Hungary	1975	28	10.54
Poland	1975	14	34.02
USSR	1975	9	254.39

Source: Population data from World Bank Atlas 1977
UNIDO case studies on developing countries and ACDIMA: "Arab Pharmaceutical Consumption and Industries".

Table 3 Pharmaceutical sales per capita (in US dollar) constant

Region	1975	1976	1977	1978	1979	1980	1981	1982	1983
North America	33.39	42.64	45.57	52.53	57.35	63.47	69.79	77.80	86.17
Europe North	36.67	39.40	42.08	55.09	63.96	73.17	66.78	65.01	68.27
Europe South	29.01	31.33	29.80	34.35	39.46	41.52	36.08	33.42	30.72
Europe East	14.32	16.94	19.50	23.13	24.73	25.95	24.42	22.70	23.56
Japan	32.27	35.47	43.28	65.28	70.01	82.20	97.75	101.31	125.78
Other industrialized	16.40	15.87	15.91	16.99	19.88	22.78	24.17	22.90	24.03
Total industrialized countries	33.02	37.60	40.51	51.30	57.50	65.00	66.46	68.55	75.81
Latin America	10.14	11.42	11.36	13.37	16.53	18.16	16.94	14.79	12.62
North Africa	4.49	4.87	5.38	6.57	7.35	8.60	8.78	10.38	12.69
Tropical Africa	1.93	2.14	2.31	2.47	2.67	2.87	3.21	3.06	3.12
West Asia	6.81	6.77	8.01	8.43	9.08	10.71	12.23	11.50	12.84
South Asia	0.73	0.83	0.93	1.14	1.22	1.39	1.37	1.44	1.49
East Asia	4.93	5.24	6.99	7.89	8.59	8.82	9.57	10.51	11.43
South-East Asia	1.72	1.76	1.92	2.14	2.30	2.85	3.32	3.66	3.24
Other Asia	2.67	2.96	2.96	3.49	4.04	4.33	4.08	3.92	3.96
Total developing countries	3.40	3.72	4.04	4.66	5.33	5.88	5.97	5.73	5.63
WORLD	9.93	11.20	11.94	14.51	16.11	17.85	17.84	17.71	18.88

SOURCE: UNIDO, 1985 (under Publication)

Table 4 World pharmaceutical consumption 1975-1983 by geographic regions (million $US)

Region	1975	1976	1977	1978	1979	1980	1981	1982	1983
North America	8,000	10,300	11,100	12,900	14,400	16,200	18,000	20,200	22,600
Europe North	10,600	11,400	12,200	16,000	18,600	21,300	19,500	19,000	20,000
Europe South	2,200	2,400	2,300	2,700	3,100	3,300	2,900	2,700	2,500
Europe East	5,200	6,200	7,200	8,600	9,300	9,800	9,300	8,700	9,100
Japan	3,600	4,000	4,900	7,500	8,100	9,600	11,500	12,000	15,000
Other industrialized	750	740	760	830	990	1,150	1,250	1,210	1,300
Total industrialized countries	30,350	35,040	38,460	48,530	54,490	61,350	62,450	63,810	70,500
Latin America	3,200	3,700	3,800	4,600	5,700	6,400	6,100	5,500	4,800
North Afirca	350	390	440	560	630	780	820	980	1,230
Tropical Africa	570	650	720	790	880	980	1,130	1,110	1,170
West Asia	900	920	1,100	1,200	1,330	1,630	1,920	1,860	2.140
South Asia	600	700	800	1,000	1,100	1,290	1,300	1,410	1,500
East Asia	700	760	1,030	1,190	1,330	1,400	1,550	1,730	1,920
South-East Asia	250	260	290	330	370	470	560	630	570
Other Asia	2,400	2,700	2,900	3,600	4,300	4,600	4,400	4,300	4,400
Total developing countries	8,970	10,080	11,090	13,270	15,640	17,550	17,780	17,520	17,730
World	39,320	45,120	49,540	61,800	70,130	78,900	80,230	81,330	88,230

SOURCE: UNIDO , 1985 (under publication)

Table 5 . Pharmaceutical consumption as a per cent of GNP, 1975-1983

Region	1975	1976	1977	1978	1979	1980	1981	1982	1983
North America	0.47	0.55	0.53	0.55	0.55	0.56	0.56	0.60	0.63
Europe North	0.70	0.68	0.65	0.70	0.68	0.73	0.61	0.62	0.71
Europe South	1.30	1.30	1.10	1.10	1.05	1.04	0.84	0.79	0.82
Europe East	0.56	0.60	0.59	0.63	0.62	0.64	0.59	0.54	0.55
Japan	0.70	0.70	0.66	0.85	0.80	0.91	0.97	1.01	1.25
Other industrialized	0.53	0.48	0.45	0.44	0.45	0.44	0.43	0.41	0.45
Total industrialized countries	0.62	0.64	0.61	0.67	0.66	0.69	0.64	0.67	0.75
Latin America	0.95	0.99	0.90	0.95	0.99	0.94	0.82	0.70	0.67
North Africa	0.74	0.70	0.67	0.69	0.64	0.69	0.66	0.75	0.94
Tropical Africa	0.73	0.76	0.70	0.65	0.56	0.60	0.64	0.63	0.71
West Asia	0.47	0.43	0.44	0.45	0.38	0.41	0.46	0.41	0.51
South Asia	0.54	0.59	0.60	0.65	0.61	0.63	0.55	0.57	0.61
East Asia	0.89	0.82	0.92	0.86	0.83	0.80	0.77	0.78	0.84
South-East Asia	0.55	0.51	0.47	0.49	0.46	0.48	0.48	0.49	0.45
Other Asia	0.78	0.82	0.73	1.46	1.54	1.55	1.34	1.30	1.33
Total developing countries	0.74	0.74	0.71	0.74	0.71	0.70	0.67	0.62	0.65
WORLD	0.64	0.66	0.63	0.70	0.68	0.71	0.66	0.66	0.72

SOURCE : UNIDO, 1985 (under publication)

Table 6 Import of pharmaceuticals, 1975-1983 (in million $US)

Region	1975	1976	1977	1978	1979	1980	1981	1982	1983
North America	455	526	622	994	1,078	1,216	1,349	1,390	1,682
Europe North	2,938	3,245	3,748	4,796	5,599	6,271	5,957	5,940	5,895
Europe South	490	522	530	633	716	755	770	679	522
Europe East	243	430	482	553	655	1,182	1,166	890	769
Japan	451	570	639	852	967	1,113	1,192	1,290	1,259
Other industrialized	245	241	240	295	335	393	389	399	272
Total industrialized countries	4,822	5,534	6,261	8,123	9,350	10,930	10,823	10,588	9.799
Latin America	689	681	768	889	978	1,229	1,244	1,113	707
North Africa	234	211	274	313	321	536	550	549	450
Tropical Africa	440	433	557	672	690	909	817	660	450
West Asia	593	580	751	853	950	1,221	1,342	1,316	853
South Asia	110	123	173	199	237	245	237	248	208
East Asia	379	423	540	617	716	806	804	838	784
South-East Asia	116	97	117	136	178	215	226	245	140
Other Asia	12	8	10	11	12	18	23	27	27
Total developing countries	2,573	2,556	3,190	3,690	4,082	5,179	5,243	4,996	3,619
WORLD	7,935	8,090	9,451	11,813	13,432	15,109	16,066	15,584	13,418

Source: Computed from UNSO Commodity Trade Statistics.

Table 7 Export of pharmaceuticals, 1975-1983 (in million $US)

Region	1975	1976	1977	1978	1979	1980	1981	1982	1983
North America	940	1,077	1,188	1,605	1,802	2,171	2,449	2,553	2,800
Europe North	4,831	5,156	6,007	7,573	8,740	10,190	9,751	9,730	8,870
Europe South	159	187	219	284	371	481	589	525	175
Europe East	185	378	435	477	534	891	849	596	52
Japan	128	147	184	224	267	298	333	303	343
Other industrialized	74	77	84	102	123	138	154	121	53
Total industrialized countries	6,317	7,022	8,117	10,265	11,837	14,169	14,125	13,828	12,293
Latin America	236	260	294	358	401	490	486	428	187
North Africa	12	11	18	20	21	21	18	25	11
Tropical Africa	56	46	49	67	65	78	45	45	11
West Asia	36	49	48	48	43	39	48	58	15
South Asia	57	64	84	89	110	144	60	58	41
East Asia	129	155	182	218	251	288	308	321	294
South-East Asia	31	21	20	24	28	34	36	37	23
Other Asia	125	143	189	227	288	403	386	407	343
Total developing countries	682	749	884	1,051	1,207	1,497	1,387	1,379	925
WORLD	6,999	7,771	9,001	11,316	11,044	15,666	15,512	15.207	13,218

Source: Computed from UNSO Commodity Trade Statistics.

TABLE 8

Levels of Development of the Pharmaceutical Industry in Third World Countries, 1979

Stage of Pharmaceutical Production	Africa	Latin America	Asia	Middle East
Group 1: Countries that have no manufacturing facilities and are therefore dependent upon imported pharmaceuticals in their finished form. In many of these countries there is insufficient trained personnel, limited public health services, and poor distribution channels.	Burundi Central African Republic Chad Lesotho Rwanda Sierra Leone Somalia Swaziland Togo Uganda Zambia	Honduras	Bhutan Mongolia	Yemen
Group 2: Countries that have started to repack formulated drugs and process bulk drugs into dosage forms.	Ivory Coast Kenya Madagascar Senegal Sudan Tanzania	Bolivia Costa Rica El Salvador Guatemala Haiti Trinidad & Tobago	Afghanistan Burma Malaysia Nepal Sri Lanka Vietnam	Jordan
Group 3: Countries that process a broad range of bulk drugs into dosage forms and manufacture some simple drugs from intermediates.	Algeria Ghana Morocco Nigeria Tunisia	Colombia Ecuador Peru	Bangladesh Indonesia Philippines Singapore Thailand	Iran Iraq Syria
Group 4: Countries that produce a broad range of bulk drugs, from intermediates and manufacture some intermediates using locally produced chemicals.		Chile Venezuela	Pakistan Republic of Korea Turkey	
Group 5: Countries that manufacture most of the intermediates required for the pharmaceutical industry and undertake local research on the development of products and manufacturing processes.	Egypt	Argentina Brazil Mexico	India	

Sources: United Nations Industrial Development Organization, 1978; revised and amended in IMS world Publication Ltd, 1979.

Table 9 Apparent production (million $US) (value of gross output)

Region	1975	1976	1977	1978	1979	1980	1981	1982	1983
North America	8,767	11,177	12,052	14,127	15,792	17,909	19,936	22,225	24,761
Europe North	13,844	14,804	16,183	20,983	24,317	28,104	26,034	25,522	25,687
Europe South	2,212	2,430	2,360	2,794	3,256	3,555	3,258	3,021	2,518
Europe East	5,142	6,148	7,153	8,524	9,179	9,509	8,983	8,406	8,983
Japan	3,493	3,851	4,752	7,281	7,864	9,319	11,213	11,632	10,688
Other industrialized	697	692	719	779	939	1,084	1,202	1,124	1,212
Total industrialized countries	34,155	39,102	43,219	54,488	61,347	69,480	70,626	71,930	77,849
Latin America	3,147	3,674	3,771	4,585	5,690	6,374	6,064	5,461	4,690
North Africa	175	232	239	330	394	372	398	566	881
Tropical Africa	274	350	323	319	393	331	521	627	821
West Asia	580	621	697	736	803	936	1,163	1,128	1,643
South Asia	591	690	780	970	1,068	1,287	1,218	1,319	1,416
East Asia	602	661	888	1,038	1,151	1,204	1,376	1,548	1,744
South-East Asia	211	223	240	272	291	375	460	520	509
Other Asia	2,513	2,835	3,079	3,816	4,576	4,985	4,763	4,680	4,716
Total developing countries	2,093	9,286	10,017	12,066	14,366	15,864	15,963	15,849	16,420
WORLD	42,248	48,388	53,236	66,554	75,713	85,344	86,589	87,779	94,269

Source: UNIDO, 1985 (under publication)

Table 10. World pharmaceutical market 1975 - 1983 country data (million US$)

Region/country	1975	1976	1977	1978	1979	1980	1981	1982	1983
North Africa									
Algeria	...	115	133	155	185	220	230	275	314
Egypt	...	140	160	241	243	321	368	451	671
Morocco	...	84	89	106	132	157	134	151	143
Tunisia	...	...	...	...	...	42	50	61	54
Libya	...	...	...	30	33	36	39	41	44
Tropical Africa									
Ghana	...	26	28	31	27	41	70	91	136
Kenya	...	...	...	40	47	52	50	47	45
Nigeria	...	270	295	318	370	430	516	481	493
Tanzania	...	28	31	47	51	59	69	71	79
Others	...	300	330	350	380	400	430	420	420
West Asia									
Iran	...	...	...	...		608	580	550	545
Saudi Arabia	...	61	90	140	170	229	319	376	497
Sudan	...	...	...	...	...	64	56	29	18
Syrian Arab Rep.	...	...	...	82	94	117	159	164	194
Turkey	...	252	277	361	370	390	536	431	554
South Asia									
Bangladesh						117	128	118	123
India	...	(508)	(570)	759	805	940	900	1,015	1,070
Nepal	...	...	...			7	8	9	9
Pakistan	...	99	119	143	172	212	256	260	287
Sri Lanka	...	11	13	9	10	11	11	12	12

Source: UNIDO, 1985 (under publication)

Table 11. Regional market shares for pharmaceutical sales 1975,1980 and 1983 (percentage)

Region	1975	1980	1983
North America	20.3	20.5	25.6
Europe North	27.0	27.0	22.7
Europe South	5.6	4.2	2.8
Europe East	13.2	12.4	10.3
Japan	9.2	12.2	17.0
Other industrialized	1.9	1.5	1.5
Total industrialized countries	77.2	77.8	79.9
Latin America	8.1	8.1	5.4
North Africa	0.9	1.0	1.4
Tropical Africa	1.4	1.2	1.3
West Asia	2.3	2.1	2.4
South Asia	1.5	1.6	1.7
East Asia	1.8	1.8	2.2
South-East Asia	0.6	0.6	0.6
Other Asia	6.1	5.8	5.0
Total developing countries	22.7	22.2	20.1
WORLD	100.0	100.0	100.0

Source: UNIDO, 1985 (under publication)

Table 12. **The largest 15 country markets 1982**

Country	$US million	Percentage of world market
United States of America	18,590	22.9
Japan	12,040	14.8
USSR	5,780	7.1
West Germany	5,530	6.8
France	4,340	5.3
People's Republic of China	4,110	5.1
Italy	3,140	3.8
United Kingdom	2,860	3.5
Spain	1,650	2.0
Brazil	1,650	2.0
Canada	1,350	1.7
German Democratic Republic	1,170	1.4
Argentina	1,060	1.3
India	1,015	1.2
Republic of Korea	972	1.2

Source: UNIDO database