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TECHNICAL ASSISTANCE TO THE PHARMACEUTICAL PRODUCTION UNIT OF THE SOCIAL SECURITY

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VENEZUELA

(R) Venezuela:

Technical report: Address given by a representative of the UNIDO Secretariat to the [illegible] National Pharmaceutical Industry in Latin America*

Prepared for the Government of Venezuela
by the United Nations Industrial Development Organization,
acting as executing agency for the United Nations Development Programme

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Many important topics have been presented and discussed by distinguished colleagues at this forum, such as the policies and requirements of the Public Health Sector, the pharmaceutical trade in Latin America, the technological research and the conditions for foreign investment in the transfer of technology. Others, such as the Social Security and the patents in the pharmaceutical industry will follow.

Before broaching the subject, I will make a brief overview of the pharmaceutical sector with regard to the consumption of drugs, to the pharmaceutical manufacture and to the trade in the Latin American countries, as well as to some aspects of the policies elaborated and implemented in this field.

1) THE PHARMACEUTICAL SECTOR

How did the Latin American pharmaceutical production, consumption and trade perform in the world context and vis-à-vis of other regions in the periods 1975-1980 and after that? While for pragmatic reasons we will discuss the Latin American region as a whole, subregions and countries may have different economic structures, be at different levels of their pharmaceutical industry's development, have sometimes special bilateral relations with neighbouring or other countries, and finally, have different interests, as far as oil prices, for instance are concerned.

1.1 Pharmaceutical Production

In 1983, the total value of the gross world output of pharmaceutical products was of US$ 94,269 billion, of which 77,849 billion were produced by the industrialized countries and US$ 16,420 billion by the developing countries, or 17.4% of the world production and 21% of the one of the industrial countries.

In the same year, Latin America had an output of US$ 3,890 billion representing 23.7% of the total output of the developing countries and slightly below 5% of the world drug production.

The industrial development of the pharmaceutical sector in Latin America from 1975 to 1980 showed a compounded annual growth of 15.16% reaching a figure of US$ 6,376 billion. For the same period of time, the total industrialized countries showed an annual growth figure of 13.27%, the developing countries of 69.94% and the world of 15.1%. The trend has drastically changed after 1980 with an annual compounded growth figure of the industrialized countries and 3.86% followed by a zero growth for the developing countries and 3.37% for the world. For the same period of time, the Latin American countries have demonstrated a strong negative growth with an output similar to the 1978 level of US$ 4,485 billion, or only 73.6% of the 1980 production. Table no. 1 illustrates these figures.

1.2 Pharmaceutical Consumption

The pharmaceutical consumption trend shows similar patterns at a

slightly lower level with a significant drop in the consumption of Latin America from 1980 - 1983 with a negative annual growth of 9.14% compared to a figure of 4.74% for the total industrialized countries and 3.80% for the world. Table 2 illustrates the above-mentioned data. One should note that, for instance, in 1982 Brazil was the 10th largest pharmaceutical market in the world and that Argentina was on the 13th place with a 2% and 1.3 % of the world market, respectively.

To avoid the fact that US$ consumption trends might be distorted by the inflation and the changes in the US$ exchange rates, the pharmaceutical sales per capita in constant US dollars are shown on Table 3. The strong annual decline of the sales in the Latin American region by more than 11% is clear and is negatively affecting the total results of the developing countries and the world as a whole. Another indication of the pharmaceutical consumption, as a percent of the GNP could be illustrated on Table 4. There, a somewhat similar trend could be observed as far as the Latin American region is concerned, i.e. a sizable drop in consumption in the period 1980 - 1983. One point is, however, important to mention, that even in the period 1975 - 1980, the region has shown a mild reduction of the consumption on a background of an increased one in the total industrialized countries and the world, of slightly over 2%.

The regional market share for pharmaceutical sales of Latin America in the years 1975, 1980 and 1983 has been of 8.1%, 8.1% and 5.4%, helping the decrease of the total developing countries' share to 20.1% according to the figures presented in Table 5.

1.3 Pharmaceutical Trade

With an annual import decline of 16.83% in the period 1980 - 1983, as against a 12.27% annual growth for the years 1975 - 1980, as well as an annual drop of exports of 27.45% versus a 15.73% growth for the same periods, Latin America's weak performance in the pharmaceutical trade after 1980 is obvious. Except for North America, all other regions have also shown a negative growth both in drug imports and exports for the period 1980 - 1983. More details are to be found on Tables 6 and 7.

The drastic change in the production, consumption and trade patterns of the pharmaceuticals in the Latin American region after 1980 is not an isolated phenomenon, but a part of general downtrend in the economies characterized in the recent years by a recession, by inflationary tendencies, by a heavy debt burden exacerbated by declining oil prices, etc. Maybe the words of Mr. Ortiz Mena, President of the Interamerican Development Bank could illustrate the situation: "The recession has eaten away a considerable portion of the progress achieved by the development efforts of the Latin American countries over the span of a generation. Even more serious is the fact that the continuation of the recession has been narrowing the prospects for the region's future progress". The contraction of both their internal and external demand, as well as the decline in capital investment and in the effective utilization of produciton capacity, were the chief reasons for the downturn in the region's productive potential.

2. THE DRUG POLICIES

In a constantly changing world of values and priorities, especially

in many developing countries with economies so very vulnerable to commodity price fluctuations, with often alternating periods of abundance and penury, what could the authorities undertake to alleviate the situation? For instance, in periods of reduced intensity of commodity consumption and soft commodity prices, governments have no other choice but to take swift actions to remedy the situation, being well aware that some of the measures might have long-lasting, maybe undesirable effects. It is, therefore, understandable that some regulatory policies implemented in the pharmaceutical sector have solved the immediate problems but were not an everlasting panacea for all ills, and that frequent shifts of policies and administrative procedures were often inevitable, depending on the situation.

Many governments have tried to stimulate their pharmaceutical sectors at all the levels of activity - the formulation and packaging, the manufacture of pharmaceutical chemicals by chemical synthesis, fermentation, extraction of active substances from vegetal or animal origin, etc., in order to increase the country's output of pharmaceuticals, to minimize the drug imports and finally to reach eventually a balance between the imports and the exports. It is well understood by all, however, that government policies were not meant to create a completely independant, isolated local pharmaceutical industry, which does not exist anywhere in the world today.

In their attempt to stimulate the pharmaceutical sector, some authorities, for instance, reduced their regulatory price intervention, which was followed by substantial increases in capital investments and in production capacity, with greatly improved drug supplies. A key factor of the production capacity growth was that the domestic enterprises grew

in tandem with the international ones. By the end of 1980, the national companies had both expanded production facilities and increased their total market share.

Sometimes, heavy administrative burdens of applying for and justifying price reliefs in more lucrative drug categories, appear to have pressured both of the smaller domestic companies into less stringently controlled, but also less profitable categories.

In practically all the measures seeking to regulate the pharmaceutical industry, it was also sought to encourage local production of raw materials and to increase the degree of vertical integration of the industry in some countries. This is the main subject for which we are invited here to make a contribution.

3. THE BASIC PHARMACEUTICAL INDUSTRY

The pharmaceutical industry in the Latin American region is at different levels of development, with a minority of countries manufacturing most of the intermediates required for the pharmaceutical industry and undertaking local research on the development of products and manufacturing, with others producing a range of pharmaceutical chemicals out of intermediates and manufacturing some of them using locally produced chemicals, etc. But, by and large the pharmaceutical industries of Latin America are not research and development oriented and are concentrating on the formulation and packaging of pharmaceutical chemicals and/or of semi-finished bulk pharmaceuticals (see Table 8).

Why did Latin America, a region with such resources, capabilities and potential did not develop a basic pharmaceutical manufacture, as it should have? Are investment funds the main driving force behind a down-stream integration of the pharmaceutical industry and the manufacture of intermediates and of pharmaceutical chemicals? What are the other factors which could influence the success of developing such industries?

The main factors with specific relevance to the basic pharmaceutical industry are:

- The technology (from intermediates and raw materials);
- The research and development;
- The price readjustment of intermediates and bulk-products;
- The auxilliary industries.

3.1 The technology

The manufacture of pharmaceutical chemicals in Latin America is based on imported technology, mainly from intermediates, produced usually by chemical synthesis. The difficulties in obtaining pertinent technology is perhaps the largest single constraint to the development of a viable domestic basic pharmaceutical manufacture. Even if such technologies are available, the transfer prices of imported intermediates are fluctuating in accordance to world prices, often out of proportion to the prices of pharmaceutical chemicals, leaving the domestic manufacturers in the dark as far as cost and price control of their end-products are concerned. When this coincides with the existing inflation, the cash position of the manufacturers worsens and the entire picture of the pharmaceutical industry becomes very negative. The technology from raw

materials is scarcer and if available as in some cases of antibiotic fermentation, for instance, the processes are out-dated, the manufacturing yields are low and the pace of obsolence very rapid. Sometimes, the costs of the end-products by adopting such technologies are even higher than by using intermediates.

The best technologies are usually developed and held by the private sector to secure the largest possible competitive edge of their products, price- and quality-wise, and it is understandable that such technologies are protected by the owners and that there is no way to expect them to be transferred compulsorily or free of charge.

Obviously, industries based on the above-mentioned premises, have not many chances for success and if the governments do not recognize these facts in time and do not act swiftly to help the domestic manufacturers to the price readjustments of intermediates, for instance, which will be described later, the existance of this industry is in real danger. This should be seen on a short or long-term basis. The first one concerns a close look to the price readjustment itself and the second one is meant to ensure the creation and development of locally owned technology to overcome the above-mentioned problem.

On this subject UNIDO has embarked on various studies presented to the first and second consultations, highlightened by the references in the attached bibliography.

As you are aware, for example, an in-depth study of nine of the 20 essential drugs which we identified as essential for establishing local manufacture revealed that while the developing countries consti-

tute large markets for all these drugs, there was very limited ownership of technology to produce them. In these cases there was virtually no possibility for transfer of technology for the manufacture of pharmaceutical chemicals from raw materials (see Annex A).

Here, it might be also opportune to mention, as another example, our investigation of the technology status and complexity of the know-how.

- In view of the dynamic development, facts must be evaluated in relation to the ideal concept of "most cost effective and efficient currently available technology to be transferred, given the conditions in the recipient country".
- A new developed technology may cost more (licence fee, royalties, etc. and the process involved could still have starting problems and bottle-necks. A technology in use for a long time will be more tested and should be certainly free of initial start-up troubles. This process may even cost less. Obsolete processes are not to be considered, bu the possibility of a technology becoming obsolete must be judged.
- The availability of alternative processes or steps thereof should be realistic and must be carefully studied. It will allow to make a feasibility study more transparent and could broaden the knowledge of the licensee, placing him in a better negotiating position.
- In technologies with a number of process steps, the feasibility "buy versus make" should be carefully checked. It is quite possible that a whole process starting with basic raw materials and auxiliaries is costlier than the realization of only part of it, starting with intermediates, or vice versa.
- The complexity of processes varies widely and is particularly significant for the production of pharmaceutical chemicals. In

a complete manufacturing process of a corticoid, for instance, up to 40 steps are involved when starting with basic raw materials, whereas for acetylsalicylic acid only 3 - 4 steps are required.

- Similar complexity applies to the know-how.

In addition it should also be mentioned that the imported technologies have their limitations for the exports; to overcome this obstacle and ensure a more viable industry, local technology should be developed.

Finally, following the recommendations at the second consultation, we have revised and updated the Directory of Sources of Supply of Pharmaceutical Chemicals, their intermediates and some raw materials included in the UNIDO list, and have distributed it in the beginning of 1985, in order to assist governments and manufacturers for the development of their price policies and to facilitate their procurement.

Although some directories of chemical producers already exist, this is the first attempt to compile a directory of suppliers of pharmaceutical chemicals and some of their intermediaries from both developed and developing countries. Its annual updating and progressive enlargement is undertaken to eventually cover the full WHO model list of essential drugs.

Including the subject discussed we have also prepared a document on "items that could be included in contractual arrangements for the setting up of the turn-key plants for the manufacture of pharmaceutical chemicals or intermediates", included in our UNIDO illustrative lists and for the production of formulations, which could also assist the governments and industries.

3.2 Research and Development

The precarious situation of the domestic industry employing technology mainly from intermediates and rarely from raw materials, brings us to the role of the research and development and its short and long term importance for the development of the basic pharmaceutical industry. The magnitude of the problems in time and investments being clear to everybody, this will not be the subject of this discussion.

The only solid base on which to build a viable basic pharmaceutical industry in Latin America, based on locally created and developed technology, are the research and development activities. Only then can the country by a master of its destiny in the pharmaceutical industry, and as the owner of technologies could decide on the best economic approach to be adopted, be it in the productivity, the prices, the market share, etc.

The research and development is separated into two groups of activities - the basic research and the applied research, with two distinctive roles to be attributed as far as reaching short or long term objectives is concerned.

The applied research as a short-term objective should concentrate on maintaining and improving, as far as possible, the already imported technologies and could be given in the hands of Government institutes to undertake research activities in accordance with the needs of the in-

dustry.

The basic research, to be directed towards long-term objectives, should look into the replacement of the imported technologies by its own, created and developed ones. In this case, the major role will belong to the universities in accordance with government spelled social and economic priorities. One day, the basic and applied R & D should join together, interact and present the full service of R & D, as in the case of the developed countries. This will be the best chance for the development of a viable basic pharmaceutical industry in Latin America.

With expenses, complexity and difficulty of the pharmaceutical R & D increasing steeply in the last 15 years, it is understandable that national pharmaceutical producers have little chance to indulge in long-term basic research and development and that even if they were inclined to do so, the financial institutions would be reluctant to back it as a "bankable proposition" - first of all, there would be no guarantee for success, and even if a new molecule would be born, until the final product comes eventually out of the pipeline, its price would be too high and the return on investment too low and too slow.

The only body, which could take care of R & D activities in the countries is the government, which should recognize the vital role of the basic pharmaceutical industry from a social, economic and even political point of view. The governments could commit themselves, release the necessary funds, insure the adequate infrastructure, and provide the necessary administrative and legal environment for these activities. This could be considered as a long-term government pre-invest-

ment policy in the pharmaceutical field in Latin America.

3.3 The Price Readjustment

As we have briefly mentioned when broaching the subject of technology, world prices of intermediates vary considerably and there seem to be no recipes to adequate them to the prices of the end-products. In other words, there is no pricing mechanism for intermediates and pharmaceutical chemicals. Often, prices of intermediates are equal or higher than the end-product, penalizing the domestic manufacturers by making them uncompetitive, reducing their profit margins and creating cash-flow problems. In the majority of cases, regulatory prices of intermediates do not follow the world price fluctuations and are not adjusted to the prevailing inflationary trends. Furthermore, if and when price readjustments are adopted, they are often late when compared to the inflation levels. All this creates an unhealthy environment resulting in a feeling of insecurity and lost confidence, adversely affecting further investments in this sector.

The governments' intervention in implementing appropriate measures in rapid and adequate price readjustments to alleviate the situation will be valuable.

3.4 The Auxiliary Industries

To create and install a viable pharmaceutical industry, many related industries should be established and properly developed. A failure to do so would mean unnecessary importation of various products, which would

dilute the efforts and would diminish the local control over the manufacturing costs. This fact seems not to be very transparent to some authorities, who are sometimes unaware of the industries involved, of the products in question, of their relation to the pharmaceutical manufacture, etc.

It is therefore essential for the governments to analyse in detail the exact situation in order to visualize all necessary parallel measures to ensure the success of the pharmaceutical industry, not as an isolated activity, but as a part of a global industrial development plan.

4. WHAT TO DO?

When analyzing various aspects pertinent to the four main factors relevant to the basic pharmaceutical manufacture, its complexity and magnitude are very apparent. In the majority of cases, the build-up of pharmaceutical facilities in Latin America was undertaken in accordance with the needs prevailing at that time, considering in parallel the development of all relevant parameters needed to assure its viability as a whole. However, due to economic and social reasons, this did not materialize as projected.

4.1 When visualizing a global approach for the establishment of a basic pharmaceutical industry, we believe that the governments could play a key role as catalyst to promote investment by taking the following short and long-term measures:

4.1.1 Short-Term

To consider all necessary measures and take adequate action in eliminating obstacles and facilitating the operation of the existing industries

regarding the four main relevant factors, especially in the field of rapid and effective price readjustments of intermediates and in the applied research and development of maintaining and upgrading existing imported technologies.

4.1.2. Long-Term

To create a national capacity for technology through the development of basic research and to formulate and implement a coherent, rational pre-investment policy, starting with the elaboration of a Master Plan for the development of a national pharmaceutical industry. This plan could begin with a study identifying and analysing all relevant parameters necessary for the creation and development of this industry in an integrated manner. The Master Plan could include a detailed plan of action, emphasizing the formulation of long-term industrialization plans and strategies, adapted to each country in the light of its social and economic structures, taking into account the potential raw materials, human resources and market sizes of such countries, with the object of achieving the highest degree of interaction between the pharmaceutical industry and the other sectors of the economy. It could also emphasize the achievement of the highest degree of efficiency, manpower development programmes and professional training, stimulation of applied scientific research, technological adaptation and innovation, industrial information and standardization and the elaboration of programmes and policies of research and development adapted to the individual requirements and priorities of developing countries.

More specifically, the Master Plan should contain concrete proposals for the implantation of new manufacturing capacities with the rele-

vant investments such as multipurpose plants for chemical synthesis*, a time-table for implementation, relevant production programmes, etc.

The Master Plan for the development of an integrated pharmaceutical industry in each country should be incorporated in the respective national pharmaceutical policy and will have also an impact on the acquisition, storage, pricing, distribution and utilization of pharmaceutical products. It should also be integrated into the countries' National Industrial Development Plans.

The further steps after the approval of the Master Plan as government policy, potential investors could be invited to participate in the implementation of the various projects and activities of the plan.

With our extensive experience in the pharmaceutical field, illustrated in Annex C, and our recent experience in the elaboration of a Master Plan for the development of an integrated pharmaceutical industry in a country by the year 2000, we feel that UNIDO could be a good partner for the development and the implementation of such a plan, if and whenever the governments think it appropriate.

All these subjects, including the Master Plan, will be presented and discussed at the Third Consultation in Madrid in 1987. It would be a good opportunity for the representatives of the Latin American governments and the pharmaceutical industry to participate in the deliberations of this consultation meeting.

* An innovative UNIDO approach for the manufacture of 10 - 15 basic pharmaceutical chemicals of limited capacity and with low investment. The "Multipurpose Plant" is a new option for D.C. for entering in the basic pharmaceutical industry. (see ID/WG/292/18)

Finally, we would like to re-emphasize the major role of governments in each and every phase of the creation and further development of the pharmaceutical industry and to convey our conviction that instead of applying adjustment management techniques, a firm commitment on the part of the government in a concrete long-term pre-investment policy, as a service to the industry and to the nation, will be essential. A properly planned and developed pharmaceutical industry will definitely exert a strong economic and social impact on the countries.

Table 1 Apparent production 1975 - 1983 (value of gross output)

(million US $)

Region	1975	1976	1977	1978	1979	1980	Compounded Annual Growth (%)	1981	1982	1983	Compounded Annual Growth (%)
North America	8,767	11,177	12,052	14,127	15,792	17,909	15.36	19,936	22,225	24,761	11.40
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	14.20	3,258	3,021	2,518	-3.33
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	14,688	
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	15.26	70,626	71,930	77,849	3.86
Latin America	3,147	3,674	3,771	4,585	5,690	6,374	15.16	6,064	5,461	4,690	-8.21
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	13.89	1,218	1,319	1,416	11.79
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 industrialized countries	2,093	9,286	10,017	12,066	14,366	15,864	49.94	15,963	15,849	16,420	1.15
WORLD	42,248	48,388	53,236	66.554	75,713	85,344	15.10	86,589	87,779	94,269	3.37

Source : UNIDO, basic data 1986

Table 2 Pharmaceutical consumption 1975 - 1983

(million $ US)

Region	1975	1976	1977	1978	1979	1980	Compounded Annual Growth (%)	1981	1982	1983	Compounded Annual Growth (%)
North America	8,000	10,300	11,100	12,900	14,400	16,200	15.16	18,000	20,200	22,600	11.74
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	13.83	2,900	2,700	2,500	-2.98
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	15.11	62,450	63,810	70,500	4.74
Latin America	3,200	3,700	3,800	4,600	5,700	6,400	14.87	6,100	5,500	4,800	-9,14
North Africa	350	390	440	560	630	780		820	980	1,230	
Tropical Africa	570	650	720	790	880	980		1,130	1,110	1,170	
East 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	14.35	1,300	1,410	1,500	8.57
West 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	14.37	17,780	17,520	17,730	- 0.3
World	39,320	45,120	49,540	61,800	70,130	78,900	14.95	80,230	81,330	88,230	3.80

Source : UNIDO, basic data 1986

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

Region	1975	1976	1977	1978	1979	1980	Compounded Annual Growth (%)	1981	1982	1983	Compounded Annual Growth (%)
North America	33.39	42.64	45.57	52.53	57.35	63.47	13.71	69.79	77.80	86.17	10.73
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	11.94	36.08	33.42	30.72	-4.49
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	14.51	66.46	68,55	75.81	5.26
Latin America	10.14	11.42	11.36	13.37	16.53	18.16	12.36	16.94	14.79	12.62	-11.42
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	10.87	1.37	1.44	1.49	6.85
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	11.58	5.97	5.73	5.63	-1.44
World	9.93	11.20	11.94	14.51	16.11	17.85	12.44	17.84	17.71	18.88	1.89

Source : UNIDO, basic data 1986

ble 4 Pharmaceutical consumption as per cent of GNP, 1975 - 1983

gion	1975	9176	1977	1978	1979	1980	Compounded Annual Growth (%)	1981	1982	1983	Compounded Annual Growth (%)
rth America	0.47	0.55	0.53	0.55	0.55	0.56	3.57	0.56	0.60	0.63	4.00
rope North	0.70	0.68	0.65	0.70	0.68	0.73		0.61	0.62	0.71	
rope South	1.30	1.30	1.10	1.10	1.05	1.04		0.84	0.79	0.82	
rope East	0.56	0.60	0.59	0.63	0.62	0.64		0.59	0.54	0.55	
pan	0.70	0.70	0.66	0.85	0.80	0.91		0.97	1.01	1.25	
her 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	2.16	0.64	0.67	0.75	2.82
tin America	0.95	0.99	0.90	0.95	0.99	0.94	-0.21	0.82	0.70	0.67	-10.67
rth Africa	0.74	0.70	0.67	0.69	0.64	0.69		0.66	0.75	0.94	
opical Africa	0.73	0.76	0.70	0.65	0.56	0.60		0.64	0.63	0.71	
st Asia	0.47	0.43	0.44	0.45	0.38	0.41		0.46	0.41	0.51	
uth Asia	0.54	0.59	0.60	0.65	0.61	0.63		0.55	0.57	0.61	
st Asia	0.89	0.82	0.92	0.86	0.83	0.80		0.77	0.78	0.84	
uth-East Asia	0.55	0.51	0.47	0.49	0.46	0.48		0.48	0.49	0.45	
her 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	-1.11	0.67	0.62	0.65	-2.44
World	0.64	0.66	0.63	0.70	0.68	0.71	2.10	0.66	0.66	0.72	0.47

IDO, basic data, 1986

Table 5 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, basic data, 1986

Table 6 Import of pharmaceuticals, 1975 - 1983

(million US $)

Region	1975	1976	1977	1978	1979	1980	Compounded Annual Growth (%)	1981	1982	1983	Compounded Annual Growth (%)
North America	455	526	622	994	1,078	1,216	21.73	1,349	1,390	1,682	11.42
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	17.46	770	679	522	-7.08
Europe East	243	430	482	553	655	1,182		1,166	890	169	
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	17.78	10,823	10,588	9,799	-3.58
Latin America	689	681	768	889	978	1,229	12.27	1,244	1,113	707	-16.83
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	27.57	237	248	208	-7.24
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	15.02	5,243	4,996	3,619	-11.26
World	7,935	8,090	9,451	11,813	13,432	15,109	13.75	16,066	15,584	13,418	-3.88

Source : Computed from UNSO Commodity Trade Statistics.

Table 7 Export of pharmaceuticals, 1975 - 1983

(million US $)

Region	1975	1976	1977	1978	1979	1980	Compounded Annual Growth (%)	1981	1982	1983	Compounded Annual Growth (%)
North Africa	940	1,077	1,188	1,605	1,802	2,171	18.22	2,449	2,553	2,800	8.85
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	17,44	589	525	175	-7.68
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	17.53	14,125	13,828	12,293	-4.62
Latin America	236	260	294	358	401	490	15.73	486	428	187	-27.46
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	-9.61
South Asia	57	64	84	89	110	144	14.82	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	17.02	1,387	1,379	925	-14.83
World	6,999	7,771	9,001	11,316	11,044	15,666	17.49	15,512	15,207	13,218	-5.51

Source : Computed from UNSO Commodity Trade Statistics.

Table 8 **Production level of 25 essential drugs in developing countries**

DRUGS	COUNTRIES									
	Latin America									
	Argentina	Brazil	Colombia	Mexico	Peru	Uruguay	Venezuela			
Acetylsalicylic acid	4	3	2	4	1	1	1			
Ampicillin	4	4	1	4	3	1	1			
Bephenium	2	2	-	1	1	1	1			
Blood fractioning	-	-	-	4	-	-	-			
Chloroquine phosphate	2	1	-	1	1	1	1			
Dapsone	2	1	-	1	1	1	1			
Diethylcarbamazine	2	1	-	1	1	1	1			
Ethambutol	2	2	-	4	1	1	2			
Ethinylestradiol	-	-	-	4	-	-	-			
Erythromycin	-	-	1	4	1	-	1			
Furosemide	-	2	-	-	-	-	-			
Isoniazid	2	1	1	1	1	1	1			
Methyldopa	-	-	1	-	1	-	1			
Paracetamol	2	2	-	2	1	1	1			
Penicillin Benzyl-Piperazine	4	4	1	4	1	1	1			
Primaquine	2	1	-	1	1	1	1			
Reserpine	2	1	-	1	1	1	1			
Streptomycin	4	4	1	1	1	1	1			
Sulphadimidine	2	1	-	1	1	1	1			
Tetracycline	4	4	1	4	1	1	1			
Tolbutamide	2	2	1	2	1	1	1			
Vitamin A	-	-	-	1	-	-	-			
Vitamin B_{12}	-	-	-	2	-	-	-			
Vitamin C	-	-	1	1	1	-	1			
x	x	x	-	x	-	-	x			

Explanation of table :

1. Formulated locally
2. Manufactured from late intermediates
3. Manufactured from early intermediates
4. Manufactured from local raw materials
x. Research and development availability

Blank : Data not available
Source : Country studies

ANNEX A

Illustrative UNIDO List of 26 Essential Drugs

A. ANALGESICS

1. Acetylsalicylic acid *
2. Paracetamol

B. ANTI-INFECTIVE DRUGS

Anthelmintic drugs

3. Mebendazole
4. Piperazine

Antibacterial drugs

5. Ampicillin *
6. Benzylpenicillin
7. Erythromycin
8. Sulfadimidine *
9. Tetracycline *

Antifilarial drugs

10. Diethylcarbamazine *

Antileprosy drugs

11. Dapsone *

Antimalarial drugs

12. Chloroquine *
13. Primaquine

Antituberculosis drugs

14. Ethambutol *
15. Isoniazid *
16. Streptomycin

C. BLOOD PRODUCTS

17. Plasma fractions

D. CARDIOVASCULAR DRUGS

Antihypertensive drugs

18. Hydralazine
19. Propranolol
20. Reserpine

E. DIURETICS

21. Furosemide

F. DRUGS AFFECTING THE BLOOD

22. Hydroxocobalamine

G. HORMONES

Antidiabetic agents

23. Insulin

Oral contraceptives

24. Ethinylestradiol/Levonorgestrel

H. VITAMINS

25. Ascorbic acid
26. Retinol

Note : This list was prepared by UNIDO in consultation with WHO. The classification and nomenclature was updated according to WHO's "The Use of Essential Drugs", Technical Report Series No. 685.

* Selected 9 priority drugs for which sources of supply are limited (report: UNIDO/PC. 33)

Annex B

Illustrative List of UNIDO Publications on Contractual Arrangements in Pharmaceutical Industry

ID/WG. 393/1/Rev. 2	Items which could be incorporated in contractual arrangements for the transfer of technology for the manufacture of those bulk drugs/intermediates included in UNIDO's illustrative list.
ID/WG.393/2/Rev.1	Directory of sources of supply of pharmaceutical chemicals, their intermediates and some raw materials included in the UNIDO list.
ID/WG.393/3/Rev.2	Items which could be included in licensing arrangements for the transfer of technology for the formulation of pharmaceutical dosage forms.
ID/WG.393/4/Rev.2	Items which could be included in contractual arrangements for the setting up of a plant for the production of bulk drugs (or intermediates) included in UNIDO illustrative list.
ID/WG.393/14/Rev.1	Technical profiles for production of pharmaceutical dosage forms.
ID/WG.393/17	Relevant topics to be taken into account in the preparation phase of technology transfer arrangements for the production of pharmaceuticals.
ID/WG.393/18	Multipurpose plant for Production of Unido Essential Drugs Based on Raw Materials and Intermediates.

Annex C

Illustrative List of On-going Projects of Pharmaceutical Industries, Chemical Industries, Department of Industrial Operations, 1985 - 1986 (US $ 250,000 or above)

UC/ALG/85/062	Establishment of a Development Plan for the Pharmaceutical Industry
DP/BRA/82/809	Transfer of technology through the pharmaceuticals chemical multi-purpose pilot plant
US/BKF/81/057	Assistance a la production de produits pharmaceutiques a partir de plantes medicinales selectionnees
UC/CUB/78/093	Establishment of a multi-purpose plant in Cuba (multi-fund to UD/CUB/79/093 and DP/CUB/79/004; UD/CUB/84/225 also refers)
DP/CUB/79/004	Multi-purpose plant (Phase II) (multi-fund to UC/UD/78/093)
DP/CUB/81/013	Centre for the development of the pharmaceutical industry
RP/GUI/85/602	Establishment of a pilot demonstration plant for production of oral rehydration salts (ORS) and intravenous fluids (IDDA)
DP/GUI/78/008	Rehabilitation and establishment of a local pharmaceutical plant (Phase II of SI/GUI/79/803) (multi-fund to DC/GUI/78/008)
DP/IRA/83/014	Establishment of a pharmaceutical chemicals multipurpose pilot plant
DP/MAG/84/017	Assistance au centre national de recherches pharmaceutiques pour la fabrication de produits pharmaceutiques a partir de plantes medicinales
DP/MON/82/002	Assistance to the experimental centre of applied enzymology and microbiology in production of sterile enzyme products
DP/MON/82/004	Programme "BIOMED" (Associated Agency: WHO)
DP/MON/84/001	Demonstration of modern technology for drug packaging
DP/MOZ/83/004	Preparatory Assistance for the establishment of a pilot plant for pharmaceuticals

DU/NEP/78/009	Primary health support services programme
DP/NEP/80/003	Strengthening the Roya l Drugs Research Laboratory (Associated (Associated Agency: WHO)
DP/NEP/80/044	Processing of medicinal plants cultivated and collated in Nepal
DP/NIC/83/004	Development of the pharmaceuticals industry
DP/RLA/83/003	Programa Regional de Biotecnologia para America Latina y el Caribe
DP/RWA/80/003	Production de medicaments a base de plantes medicinales
DP/THA/82/006	Assistance in the production of pharmaceuticals from the Thai traditional pharmacopoeia
DP/TUR/83/003	Production of pharmaceutical materials from medicinal plants
DP/URT/81/026	Assistance for the production of plant derived pharmaceuticals
DP/VIE/80/032	Pilot production of medicines using indigenous raw materials