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ASSESSMENT OF
THE PHARMACEUTICAL INDUSTRY IN DEVELOPING COUNTRIES,
ITS POTENTIAL, AND THE NATIONAL
AND INTERNATIONAL ACTION REQUIRED
TO PROMOTE ITS DEVELOPMENT */

by the UNIDO Secretariat

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I. INTRODUCTION INCLUDING SUMMARY OF PREVIOUS UNIDO ACTIVITIES

1. UNIDO's activities in the pharmaceutical industry have in the past emphasized the provision of technical assistance, the organization of meetings and training and the promotion of co-operation among developing countries. However it has become evident that there is also a need for UNIDO to propose to developing countries for their consideration suitable policies to guide the development of this complex industry.

Technical assistance

2. UNIDO technical assistance has been provided to developing countries on the establishment and expansion, pharmaceutical production facilities, their operation and quality control. 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 made valuable contribution to the development of local production of drugs in these countries.

Meetings

3. The initial activities of UNIDO were guided by the Expert Working Group Meeting on the Establishment of Pharmaceutical Industries in Developing Countries, held at Budapest in 1969. The stage of development reached by the pharmaceutical industry in developing countries was discussed and it was suggested that five different levels of technological development could be distinguished. Table 1 groups developing countries according to the suggested classification.^{1/} A number of other meetings and seminars on pharmaceutical production have been organized in the following nine years. At a UNIDO meeting in Budapest in 1975, 25 participants from developing countries prepared a list of essential drugs. At a UNIDO meeting in Lucknow, India in 1977, the production of drugs from medicinal plants was considered.

^{1/} Table 1 is included in Chapter II.

Training

4. The importance of training has been given special attention by UNIDO. For example, every year since 1974, UNIDO in collaboration with the Belgian pharmaceutical industry has organized a training course on pharmaceutical technology at the University of Ghent. Over 100 technologists from developing countries have attended this training course.

Co-operation among developing countries

5. UNIDO has encouraged developing countries at different stages of development to co-operate in the field of technology transfer and to learn from one another's achievements and experience. For example, Indian experts have visited Latin America to identify areas of co-operation and technical assistance; Indian experts have visited Algeria to set up a programme of technical co-operation between the two countries; Nepalese experts have visited Burma to explore the possibilities of technical co-operation.

Policy on the development of the pharmaceutical industry

6. The establishment of a pharmaceutical industry is not a simple task since this industry is based on sophisticated techniques and substantial investment. To help the developing countries establish this industry, UNIDO has elaborated a range of policies that need to be considered by developing countries such as a drug policy, a production policy, basic principles for transfer of technology, strategy on replacement of chemical raw materials by natural raw materials such as medicinal plant extracts. Papers and publications on the different subjects mentioned above have been prepared by UNIDO.^{2/}

^{2/} See Chapter III - "New Policies on Pharmaceuticals" in The Growth of the Pharmaceutical Industry in developing countries - Problems and Prospects 1978. ID/204

Basic principles for the transfer of technology for the establishment of a pharmaceutical industry in developing countries. (UNIDO/IOD.76)

Draft strategy paper on UNIDO pharmaceutical activities. Prepared for UNIDO/WHO Meeting, 11-12 November 1976. (Unpublished)

Raw materials and local production of contraceptives in developing countries: Global. Report prepared for the United Nations Fund of Population Activities. 23 July 1975. (UNIDO/ITD.346)

Report on Technical Consultation Meeting on Production of Drugs from Medicinal Plants in Developing Countries. (ID/WG.271/5)

Production Policy and its role in the development of Pharmaceutical Industries in Developing Countries. (UNIDO/ID/CIS)

Consultations between developing and developed countries

7. The Second General Conference of UNIDO at Lima, Peru in March 1975 declared that in view of the low share of developing countries in total world industrial production, their share should be increased to the maximum possible extent and as far as possible to at least 25 per cent of the total world industrial production by the year 2000.

8. To help achieve this goal UNIDO was asked to organize a system of continuing consultations between developed and developing countries at the sectoral, global, inter-regional and regional levels. ^{3/}

9. In 1977, first consultation meetings were convened by UNIDO on the fertilizer, iron and steel, leather and leather products and vegetable oils and fats industries. Preparations were also begun for consultations on other industrial sectors including the pharmaceutical industry.

10. The First Panel Meeting of Industrial Experts on the Pharmaceutical Industry was convened in Vienna in June 1977 as an initial step in making preparations for the consultations on the industry. At the meeting, 16 topics were discussed and the following six topics were subsequently selected for further examination by UNIDO: ^{4/}

- the preparation of a national list of essential drugs;
- the availability and price of intermediates;
- the transfer of technology;
- the establishment of regional pharmaceutical centres;
- co-operation with developed countries;
- international co-operation involving UNIDO.

11. The First Panel Meeting showed the importance of establishing appropriate policies to guide the development of the pharmaceutical industry in developing countries. Later in 1977 the World Health Organization published guidelines for the preparation of a national list of drugs. ^{5/}

^{3/} "Report of the Second General Conference of the United Nations Industrial Development Organization" (ID/CONF.3/31), chap. IV, "The Lima Declaration and Plan of Action on Industrial Development and Co-operation".

^{4/} The Report of the Meeting is available as document UNIDO/Ex. 24.

^{5/} The Selection of Essential Drugs Report of a WHO Expert Committee Technical Report Series 615, Geneva 1977

12. The Second Panel Meeting of Industrial Experts on the Pharmaceutical Industry which was convened in Vienna in February 1978 therefore concentrated its discussion on specific aspects of policy relating to the production of drugs, namely:

- criteria for the selection of drugs for local formulation;
- criteria for selecting drugs suitable for basic manufacture;
- terms and conditions for the transfer of technology on the basis of guidelines suggested by UNIDO.

In order to facilitate discussion of these issues in concrete terms, UNIDO proposed that the meeting consider an illustrative list of 12 drugs included in the WHO list of essential drugs. The Panel modified and added new drugs to this list.^{6/}

the purpose of the inter-regional meeting

13. Based on the discussion and recommendations of the two Panel Meetings, the following agenda has been chosen:

- The selection of drugs for local formulation
- The selection of drugs suitable for basic manufacture
- The scope for using multi-purpose plants
- The 20 drugs selected by UNIDO for illustrative purposes
- Guidelines for negotiating terms and conditions for the transfer of technology
- Co-operation among developing countries in the Pharmaceutical Industry.

14. UNIDO decided to convene the inter-regional meeting in order to:
(a) produce a clear assessment of the stage reached in the development of the pharmaceutical industry in developing countries, the problems and the future prospects and, (b) determine which priority issues (whether included in the agenda of the meeting or not) should be recommended for consideration at the First Consultation Meeting on the Pharmaceutical Industry.

^{6/} See Report of the Meeting ID/WO.267/4.

The purpose and scope of the paper

15. This paper provides information in Part II on the present situation in the pharmaceutical industry in developing and developed countries. The information presented is based on contributions to the UNIDO World-wide study of this industry, reports of missions to developing countries undertaken for the UNAPEC/UNIDO/UNCTAD/WHO joint project^{7/} and a study of "The development of the pharmaceutical industry in six Latin American Countries".^{8/}

16. The paper, in Part III, reviews the major problems developing countries are encountering in the development of their pharmaceutical industries. Part IV considers the relation of these problems to the issues so far considered by UNIDO at the two Panel Meetings. Part V suggests action that might be taken by Governments, international organizations and transnational corporations to promote a faster development of the pharmaceutical industry in developing countries.

17. On the basis of this paper and other documents, participants are expected to identify and clearly define the priority issues that could be considered at the First Consultation Meeting.

^{7/} UNIDO participated in the Meeting of the Group of Experts on Pharmaceuticals at Georgetown, Guyana, in July 1976, which prepared the Action Programme subsequently adopted by the Fifth Conference of Heads of State of Government Non-Aligned Nations held at Colombo, Sri Lanka, in 1976. A joint Task Force of UNIDO, UNCTAD, WHO and UNAPEC was established in 1977 to implement the resolution of the Non-Aligned Countries and to guide implementation of the above-mentioned project financed by UNDP.

^{8/} prepared by Emilio Meneses, Consultant to UNIDO.

II. SOME INFORMATION THAT ILLUSTRATES THE PRESENT SITUATION OF THE PHARMACEUTICAL INDUSTRY IN DEVELOPING AND DEVELOPED COUNTRIES

18. The pharmaceutical industry is unevenly developed in different parts of the world; beside the highly concentrated and developed pharmaceutical companies of the industrialized world, there are countries - mostly the less developed ones - where no manufacturing facility has been established. This chapter presents some information to illustrate this situation.

Table 1 presents a preliminary assessment of the stage reached by the industry in developing countries. The classification of countries into one of five groups as a tentative one that was made by UNIDO for the Second Panel Meeting.

Table 2 shows that the world pharmaceutical industry's output has grown rapidly in the past decades.

Table 3 provides a geographical breakdown of the world pharmaceutical production in 1976.

Table 4 shows that the developing countries share of world production in this industry was about 12 per cent in 1975, a low share compared to their share of world population.

Table 5 shows that seven industrialized countries account for 70-75 per cent of the total world drug production and estimates the value of production in selected developing and developed countries.

Table 6 compares the level of per capita production of drugs in selected developing and developed countries.

19. These tables show that the industry is most developed in Latin America and certain Asian countries. The production of the African region is low. In some developing countries, where the pharmaceutical production was started a few decades ago, production of active ingredients has been developed. The progress made by Argentina, Brazil, Egypt, India, Mexico and the Republic of Korea may be noted. In all of those countries, the value of drug production already exceeds US\$100 million.

Table 7 summarizes production level of about 40 essential drugs in selected countries in Africa, Asia and Latin America. Five levels of production are considered: 1. Imported in finished form 2. Formulated

locally, 3. Manufactured from late intermediates, 4. Manufactured from early intermediates, 5. Manufactured from local raw materials.

Table 8 provides, by way of example, the large number of different drug formulations produced in India in 1972. This matter was discussed by the First Panel of Experts.

Table 9 provides data on the participation of national and foreign-owned companies in the industry in selected developing countries.

Table 10 provides information on the level of per capita consumption in regions of the world.

Table 11 provides information on per capita consumption of drugs in a number of developed countries and developing countries.

20. These tables show (a) the very low consumption of drugs in developing countries and (b) that only a few developing countries can so far produce themselves the active ingredients of drugs. Detailed comparison of output levels is difficult; because of differences in the price level prevailing in different countries, the statistical data should be interpreted cautiously.

Table 1

STAGE OF DEVELOPMENT OF THE PHARMACEUTICAL INDUSTRY
IN VARIOUS DEVELOPING COUNTRIES

Group 1: Countries which have no manufacturing facilities and therefore are dependant 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. Examples of countries in this group are:

AFRICA: Burundi, Chad, Lesotho, Rwanda, Sierra Leone, Somalia, Swaziland, Togo, Central African Republic;

LATIN AMERICA: Honduras, Trinidad;

ASIA: Bhutan, Mongolia;

ASIA, MIDDLE EAST: Jordan, Democratic Republic of Yemen.

Group 2: Countries which have started to repack formulated drugs and process bulk drugs into dosage forms. Examples of countries that have made a beginning as manufacturers are:

AFRICA: Madagascar, Sudan, Tanzania, Uganda, Zambia;

LATIN AMERICA: Haiti, El Salvador, Guatemala;

ASIA: Afghanistan, Burma, Malaysia, Nepal, Sri Lanka, Vietnam.

Group 3: Countries which manufacture a broad range of bulk drugs into dosage forms and manufacture some simple bulk drugs from intermediates. Examples of countries in this group are:

AFRICA: Algeria, Ghana, Morocco;

LATIN AMERICA: Colombia, Ecuador, Peru;

ASIA & MIDDLE EAST: Iran, Iraq.

Group 4: Countries which produce a broad range of bulk drugs from intermediates and who manufacture some intermediates using locally produced chemicals. Examples of countries in this group are:

AFRICA: Egypt, Tunisia;

LATIN AMERICA: Argentina;

ASIA: Pakistan, Turkey.

Group 5: Countries who manufacture most of the intermediates required for the pharmaceutical industry and undertake local research on the development of products and manufacturing processes.

Countries in this group are:

LATIN AMERICA: Brazil and Mexico;

ASIA: India.

Source: The steps involved in establishing a pharmaceutical industry in developing countries. ID/WG.267/3 page 3.

Table 2

World production of pharmaceuticals

<u>Year</u>	<u>Production in billion US\$</u> (based on the value of US\$ in 1977)
1950	2.7
1960	7.9
1970	18.6
1975	37.5
1976	42.3
1977	47.7

Source: Scrip No. 324 1978 page 14

Table 3

Geographical Breakdown of World Drug Production in 1976

<u>Region</u>	<u>Percentage of</u> <u>world</u> <u>production</u>
Western Europe	29.97
North America	19.71
East Asia ^{1/}	17.86
Eastern Europe	16.02
South America	6.99
Central and Southern Asia	3.49
Africa	2.67
Middle East	2.05
Oceania	1.09

^{1/} Including China and Japan

Source: Scrip No. 283 1977.

Table 4

BREAKDOWN OF WORLD DRUG PRODUCTION BY COUNTRY GROUPS IN 1975

<u>Country groups</u>	<u>Percentage of world production</u>
Developed countries	68.03
Developing countries	12.00
Centrally planned economies ^{1/}	19.97

^{1/} exc. live China

Source: Scrip No. 283 .1977.

Table 5

DRUG PRODUCTION IN VARIOUS COUNTRIES
(in million US dollars) (dollar of the period)

Developing countries	Centrally Planned Countries			Developed countries					
	1973	1975	1977	1972	1975	1977			
Afghanistan	—	—	5.2	Czechoslovakia	413	Austria	102	162	239
Algeria	51	—	—	German Dem. Rep.	870	Belgium	289	447	—
Argentina	371	450	534	Hungary	780	Canada	518	642	—
Bangladesh	13	27	—	Poland	417	Denmark	131	188	—
Brazil	761	1,120	1,281	USSR	2,305	Finland	54	—	—
Chile	135	—	—			France	2,186	2,934	—
Colombia	—	—	—			Germany Fed. Rep.	3,256	4,480	6,023
Egypt	120	162	154			Italy	1,450	2,221	—
Ethiopia	—	3.8	—			Japan	5,050	6,086	10,500
India	422	—	900			Netherlands	429	522	—
Indonesia	38	44	1,344			Spain	1,180	1,556	—
Iran	43	—	110			Sweden	187	287	—
Iraq	14	21	—			Switzerland	650	1,310	—
Korea Rep. of	151	—	517			United Kingdom	1,107	1,488	1,680
Malaysia	—	94	596			U.S.A.	6,016	10,500	—
Mexico	237	524	624						
Morocco	21	—	—			World total	26,000	37,500	—
Nigeria	8	—	33						
Pakistan	65	—	83						
Peru	84	—	128						
Philippines	93	—	—						
Sri Lanka	—	5	—						
Sudan	—	4	8						
Thailand	—	—	85						
Tunisia	—	7	9						
Turkey	—	240	—						
Uruguay	30	38	46						
Venezuela	124	—	171						

Sources: OECD statistics, UNIDO, "The growth of the pharmaceutical industry in developing countries U.N. New York, 1978".

ACDIMA: "Arab Pharmaceutical Consumption and Industries" Report 1976

Table 6

Per capita pharmaceutical production
in various countries

<u>Developing Countries</u>	<u>US dollars</u>	<u>Year</u>
Afghanistan	0.4	1977
Algeria	23.4	1973
Argentina	17.5	1975
Bangladesh	0.34	1975
Brazil	10.5	1975
Chile	13.5	1973
Egypt	9.1	1975
India	1.6	1977
Indonesia	0.34	1975
Iran	1.4	1973
Iraq	1.4	1973
Korea, Republic of	14.4	1977
Malaysia	7.6	1975
Mexico	8.7	1975
Morocco	1.3	1973
Nigeria	0.12	1973
Pakistan	1.2	1977
Peru	6	1973
Philippines	2.76	1973
Sri Lanka	0.4	1975
Sudan	0.5	1977
Thailand	3.	1973
Turkey	6.	1975
Venezuela	11.	1973

Table 6 continued

<u>Centrally planned Countries</u>	<u>US dollars</u>	<u>Year</u>
Czechoslovakia	27.9	1975
German Democratic Republic	51.7	1975
Hungary	60.	1975
Poland	13.8	1975
USSR	9.1	1975
<u>Developed countries</u>		
Austria	21.6	1975
Belgium	74.5	1975
Canada	28.1	1975
Denmark	37.6	1975
Finland	11.4	1975
France	55.3	1975
Germany, Federal Republic	72.5	1975
Italy	39.8	1975
Japan	54.8	1975
The Netherlands	38.3	1975
Spain	44.0	1975
Sweden	35.0	1975
Switzerland	204.6	1975
United Kingdom	26.6	1975
U. S. A.	49.2	1975

Source: Country Studies
CEOD statistics

Table 8

Analysis of Products of Indian-owned Pharmaceutical Industry (1972)

Products (Group-wise)		No. of formulations in the market	
1	Vitamins - Multivitamins	308	} 1 134
	Vit. B complex	406	
	Vit. B ₁₂	126	
	Others	294	
2	Tonics, nutrients or deficiency drugs		685
3	Tranquilizers and sedatives		376
4	Expectorants, cough syrups, decongestants		340
5	Analgesics and antipyretics		296
6	Antibiotics: Penicillin and salts	99	} 527
	Chloramphenicol	155	
	Streptomycin	82	
	Tetracycline	115	
	Neomycin	28	
	Others	48	
7	Anti-infectious: Sulphas	320	} 1 069
	Anti-TB drugs	223	
	Antidysentery	185	
	Antimalarial	133	
	Anthelmintics	66	
	Antifilarials	48	
	Antileprosy	20	
	Antifungal	19	
	Antiseptic	54	
8	Steroids and hormones		354
9	Anti-histamines		151
10	Antiacids		113
11	Anaesthetics (local and general)		88
12	Laxatives and purgatives		69
13	Anti-inflammatory drugs		75
14	Alkaloids		445
15	Galenicals (Crude drug extracts)		55
16	Inorganic elements and compounds (excluding iron preparations)		146
17	Sera and vaccines		49
18	Enzymes		104
19	Household remedies (dexture, gripe water, etc)		180
	Others		1 144
	Total		7 399

Source: TD/B/C.6/20 Case studies in the transfer of technology. The pharmaceutical industry in India. UN 1977

Table 9

Participation of national companies
in domestic market

<u>Country</u>	<u>Participation of</u>		<u>Year</u>
	<u>National companies</u>	<u>Foreign-owned companies</u>	
	<u>Per cent</u>		
USA	84	16	1975
Egypt	79	21	1976
Japan	76.6	23.4	1975
India	75	25	1977
Morocco	75	25	1976
German Fed. Republic	70.3	29.7	1975
Italy	55.5	44.5	1975
France	55	45	1977
Sweden	50	50	1976
Chile ^{1/}	48	52	1977
Pakistan	41	59	1977
Argentina ^{2/}	40	60	1977
Iran ^{1/}	40	60	1977
United Kingdom	36.3	63.7	1975
Algeria	35	65	1976
Philippines	35	65	1975
Uruguay ^{2/}	31	69	1977
Venezuela ^{2/}	30	70	1977
Iraq	30	70	1976
Tunisia	25	75	1976
Peru	21	79	1977
Brazil ^{2/}	21	79	1977
Mexico	20	80	1977

Table 9 continued

<u>Country</u>	<u>Participation of</u>		<u>Year</u>
	<u>National companies</u>	<u>Foreign-owned companies</u>	
	<u>Per cent</u>		
Jordan	20	80	1975
Canada	15.3	84.7	1975
Syria	15	85	1976
Sudan	15	85	1976
Colombia ^{2/}	12	88	1977
Ku wait	10	90	1976
Libya	7	93	1976

Source: Berry G. James: The future of the multinational pharmaceutical industry to 1990. Associated Business Programmes London. 1976 page 35; and Country studies

1/ Scrip No. 324 page 22

2/ Scrip No. 318 page 17

Table 10

PER CAPITA DRUG CONSUMPTION IN 1976

BY REGIONS

IN US\$
(dollar of the period)

<u>Region</u>	<u>US\$</u>	<u>World population Percent</u>
Western Europe	37.3	12
North America	35.2	18
Asia ^{1/}	6.2	44
Eastern Europe	17.0	13
South America	13.1	10
Africa	2.9	12
Oceania	30.6	1

^{1/} Including Japan

Source: Duncan Reekie; Scrip No. 310 1978 page 21

Table 11

PER CAPITA DRUG CONSUMPTION OF SELECTED COUNTRIES

(dollars of the period)

<u>Country</u>	<u>Year</u>	<u>per capita drug consump tion in \$</u>	<u>Population in millions</u>
<u>Developing Countries</u>			
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

Table 11 continued

<u>Country</u>	<u>Year</u>	<u>per capita drug consump tion in \$</u>	<u>Population in millions</u>
<u>Developed:</u>			
Austria	1975	26	7.5
Belgium	1975	42	9.8
Canada	1976	28	23.18
Denmark	1976	28	5.07
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
<u>Centrally Planned:</u>			
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 ACDINAs "Arab
 Pharmaceutical Consumption and Industries".

PART III SOME MAJOR PROBLEMS DEVELOPING COUNTRIES ARE ENCOUNTERING
IN THE DEVELOPMENT OF THEIR PHARMACEUTICAL INDUSTRY

21. The developing countries are at various stages of development of the pharmaceutical industry, ranging from simple formulation and packaging based on imported active ingredients to chemical synthesis based on local raw materials. The problems being encountered by them will naturally depend on the particular stage of their pharmaceutical industry. The immediate need, however, is to increase the production significantly keeping the costs within the reach of the majority of the population and ensure equitable distribution. No matter at which stage of development a given developing country is, the composition of the products shall also be adjusted to meet the most pressing needs of the people. In brief, an integrated development of the entire system of procurement, production and distribution of pharmaceuticals at the national level is called for. The major problems are discussed below:

GENERAL
ASPECTS

(a) List of essential drugs.

22. The shortage of foreign currency is experienced in many developing countries, consequently, the drug import cannot be increased to cover local requirements. There are several ways which can assist in saving foreign currency concerning the expenses of drug import: first of all it is necessary to concentrate the drug import on those drugs which are of vital importance. The WHO issued in 1977 ^{1/} a list of essential drugs to orient both health authorities and physicians, suggesting to prescribe and import only these essential drugs if possible. In this way the great variety of drugs on the market can be reduced and a considerable amount of foreign currency may be saved. Studying the imports in various developing countries, it has been found ^{2/} that in some developing countries the number of imported drugs amounted to 8,000-12,000, which appears highly exaggerated. The number of medicines belonging to each therapeutic group ought to be revised and sensibly reduced.

^{1/} The selection of essential drugs WHO, Geneva 1977 Technical Report Series 615.

^{2/} PALCOZ: Pharmaceutical Study UNIDO 1977.

23. Table 12 indicates in which country the health authorities have accepted a national list for this purpose. It is advisable to revise above lists yearly, correct them according to local requirements and keep them up-to-date.

(b) Central procurement system

24. Another way which may assist the foreign currency saving is the establishment of a national central procurement system. There are also developed countries (e.g. Sweden), where this type of procurement has already been efficiently working. One of the advantages of this facility is that by buying centrally, the quantity of each purchased drug can be increased, consequently, lower prices obtained. If the number of drugs in each therapeutic group might be reduced, the import volume of the single system could be augmented. For smaller countries a regional procurement system could act as a central organisation and could coordinate the purchase of pharmaceuticals. Table 13 indicates those developing countries where the central procurement system has already been established.

(c) International tenders

25. International tenders have been proven to assist in purchasing low-priced drugs with good results. Favourable experiences have been gained in this way in Sri Lanka; the State Pharmaceutical Corporation achieved savings ranging from 14.7 per cent to 90 per cent in imports between 1972 and 1974. Generally, purchasing good quality generics may help in saving foreign currencies. The quality control of the purchased generic ought to be organized.

(d) Purchase of raw materials

26. Not infrequently, the purchase of raw material or intermediates represent a major problem for local industry. Intermediates for the last few steps of the syntheses are hardly available, bulk drug for formulation procedures are

expensive. According to Pakistan experiences, imported intermediates are frequently purchased only at a price almost equivalent to that of the finished products. To quote examples: when isonicotinhydrazine powder could be purchased at Rs. 19-20 pro kg, isonicotinic acid was available only at Rs. 18 pro kg, making local production uneconomical. Similar incidences: the cost of salicylic acid was almost the same as that of imported aspirin powder. Considering above experiences, one may come to the conclusion that the purchase of low priced intermediates and bulk drugs for a longer period could be improved only by the aid of long-term commercial agreements.

(e) Proportion of import and export

27. The unfavourable proportion of export and import should be regarded as a major problem in developing countries. Concerning this question Tables 14 and 15 give details based on UN statistics. As a comparison, the proportion of import and local production in developing countries are illustrated in Table 16. By establishing domestic production, the trade deficit may be advantageously reduced.

(f) Investment

28. The investment in local industry may represent a major problem in developing countries. As a start, the list of the drugs intended to be produced, ought to be determined by a government committee; the factors which have to be taken into account are detailed in a UNIDO report^{1/} issued in 1978. The statistics on imported drugs may assist in the choice when selecting drugs for local production. Evidently, those drugs which are among the first 20 drugs imported in highest volume and value have to be chosen for this purpose.

29. It is advisable that local investment ought to be carried out stepwise; not more than 10-20 drugs should be selected for formulation, and not more than 5-10 drugs for local manufacture. After having obtained good economic results the enlargement of local manufacture may be continued.

^{1/} Report on Second Panel Meeting of Industrial Experts on the Pharmaceutical Industry UNIDO. ID/WG.267/4 page 5.

30. When investing in the pharmaceutical industry the UNIDO classification ^{2/} ought to be taken into consideration. All those countries which have sufficient experiences with formulation may start bulk production; those countries which belong to Group I or Group II should start only formulation activities. The pharmaceutical industry needs relatively less capital than the traditional heavy industry.

31. According to some calculations, the investment costs concerning formulation may generally be recovered within 5 years. Based on rough calculations the value of the yearly sale may be 100-200 per cent higher than that of the investment cost.

II. Medical aspects.

32. Regarding the drug distribution, the medical infrastructure is of great importance as medicines are normally not chosen by the consumers (the patient), but by a mediator (the physician). It is this latter who decides which drug should be used; the increase of drug consumption depends to a great extent on the number of physicians. The number of population versus one physician is indicated in Table 17 reflecting the situation in various developing countries. The same applies to the pharmacy network, which assists in the drug distribution; the lack of pharmacies may hinder the expansion of drug production.

33. The proper drug policy adopted by the governments may help in solving problems concerning the medical care.

^{2/} see Table 1.

II Problems
related to
production

34. Based on the choice of essential drugs selected for local production, the problems encountered can be dealt with based on the actual level of production prevailing in the concerned developing country, as follows:

(a) Formulation and packing; (i) Technology

35. A country wishing to take up local production with simple formulations and packaging based on imported bulk materials has to acquire technology. The technology for formulation is relatively more simple and could be acquired from many of the developing countries such as India, Brazil, Argentina, Mexico, Egypt, Algeria, Pakistan, etc. The technology from developing countries could perhaps be more easily adapted to the other developing countries in view of the similarity of the environment and infrastructure available. Although more sophisticated technology may be available from some developed countries, very often it calls for a much higher investment and skill to operate the equipment and imported components to maintain them, apart from being less labour-intensive, whereas the labour in the developing country may be plentiful.

(ii) Utilization of existing capacities

36. It is observed that the existing production capacities are not being fully utilized in most of the developing countries. The utilization very often ranges from 30 to 50 per cent based on a recent UNIDO survey in some of the Arab countries. By rationalization of the existing facilities, renovation and innovation particularly in the field of maintenance of equipment, working more shifts and by the introduction of the latest technology, it would be possible to boost production by fully utilizing the existing production facilities with much less investment in a relatively shorter period than by the establishment of new facilities for production.

37. In Sri Lanka, the capacity utilization in the case of tablets in 1972 was 40 per cent while that in respect of capsules was hardly 15 per cent. A large quantity of pharmaceutical products in dosage form had to be imported to meet the local requirements. The introduction of an extra shift would have augmented the production by about 30 per cent with nearly the same production facilities.

(b) Chemical synthesis based on intermediates

38. As production expands from the formulation of imported bulk chemicals to the manufacture of the chemicals themselves, a number of constraints appear:

(i) scale: economies of scale take place in the production of bulk chemicals and antibiotics so that developing countries can only take up economical production provided they have large markets, if they are assured of exports to other countries, or if they have a cooperative arrangement with the other developing countries. Of course, certain countries like India, restrict the imports to the quantity required after taking the local production into account and they pool the prices of imported and local products to give benefit to the consumer despite price protection given to the local manufacturer.

39. (ii) skills: pharmaceutical manufacture, quality control, formulation, packaging and storage constitute skill intensive operations. The sophisticated technology involved in synthetic chemical production and antibiotic fermentation, call for a large supply of trained manpower. Only countries with established fine chemicals industry and relevant forms of university training can envisage this stage of pharmaceutical development.

40. (iii) technology: this refers to acquisition of new technology. The most common problem encountered by developing countries is perhaps the transfer of technology. Fortunately, many developing countries have already developed considerable technological capability and experience for the production of a range of bulk chemicals. Many units in developing countries have successfully adapted imported technology to their specific needs and environments while some have even improved upon the productivity of imported technologies. As noted in a UNIDO study, India, Mexico and Brasil 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 in a position to assist less industrialized countries in setting up and expanding their pharmaceutical industry offering certain advantages such as:

- terms offered particularly by public-sector enterprises are extremely competitive;
- there are practically no restrictive conditions;
- equity participation by the contractor is usually kept to a minimum enabling the recipient countries to establish an independent industry;
- the recipient in developing countries can sell the products under generic names;
- the technology may be better adapted to the conditions of developing countries in terms of scale, skills, capital intensity, formulation and packaging;
- the developing country selling the technology can earn foreign exchange.

41. (iv) quality control: a common problem faced by developing countries is lack of adequate quality control by some domestic enterprises. The Committee on Drugs and Pharmaceutical Industry set up by the Government of India in its report in 1975 noted a widespread incidence of substandard and "spurious" drugs, particularly in areas in which the high prices charged by transnational corporations created an extremely favourable situation for unscrupulous or inefficient manufacturers. In Pakistan, an attempt to abolish brand names in order to break the hold of transnational corporations failed as poor quality drugs flooded the market; the market share of the transnational corporations rose, prices did not decline and the scheme had to be substantially modified.

Quality control requires a high degree of skill, sophisticated equipment, strict adherence to good manufacturing practice. However, the cost of adequate quality control is far from prohibitive and is well within the reach of even small firms in developing countries. It requires concerted government effort to enforce good manufacturing practices and to constantly monitor production. With the strictest of checks and the most sophisticated drugs, small firms can maintain quality just as well as large ones.

42. (c) Chemical synthesis based on raw materials: All the problems encountered in the case of chemical synthesis based on intermediates would also be applicable in this case too apart from the fact that chemical synthesis from raw materials requires even more complicated technology, higher investment and broader infrastructure. In most of the developing countries where a number of products is to be manufactured in small volume, the multipurpose plant concept can be utilized.

(i) Utilization of capacity

43. As indicated in the case of formulation units the capacities in the developing countries where bulk drug production facilities exist, are under utilized. A recent UNIDO survey of Arab countries revealed that the antibiotic fermentation capacity at El Nasr Co. Egypt and State Drug Industries, Iraq is grossly underutilized. By rationalization and the introduction of new technology such as the high yielding strains of antibiotic producing microbes, it would be feasible to fully utilize the capacities at both the plants to manufacture Tetracycline to meet the entire demand of the Arab countries within a short period and with relatively less investment. Similarly twenty chemicals and drugs can be produced within a short period in the idle equipment of El Nasr Co. Egypt, which is utilized at present to the extent of 20 percent.

(ii) Availability of raw materials:

44. With the rapid development of petrochemical industry particularly in the oil producing countries, many of the raw materials required for chemical synthesis and antibiotic fermentation would become available. These countries can exchange raw materials for bulk chemicals produced in the other developing countries.

45. (d) Production of pharmaceuticals products from medicinal plants: Most of the developing countries have rich flora of medicinal herbs and plants growing wild. If scientific methods of cultivation and collection are organized the medicinal plants can be a valuable source of raw materials for local pharmaceutical industry and for export in the form of crude extracts or finished products. In this case too the capacity utilization in the case of existing production units is less. For example there is an idle capacity of about 80 percent at State Drug Industries, in Iraq. And efforts should be made to fully utilize the capacity.

46. (e) Ancillary industries: The absence of local industry for the production of miscellaneous items required by the pharmaceutical industry such as glass and plastic containers and other packing materials is limiting the pharmaceutical production in many of the developing countries. The integrated development of pharmaceutical industry shall also include the establishment of such ancillary industries to meet local or regional requirements.

47. (f) Infrastructure: The problems encountered by developing countries very often relate to inadequate infrastructure such as utilities, transport and storage facilities which are common to any other industry, although the pharmaceutical industry has certain special requirements. For example, many developing countries are plagued by frequent interruptions in the power supply and this can cause serious losses in the case of operations involving sterile techniques and fermentation of antibiotics. Similarly the pharmaceutical products need refrigerated transport and storage facilities to preserve the shelf life of products. In a similar manner the water used in the pharmaceutical industry has to be treated in a special manner and has to conform to certain standards of purity.

48. (g) Obsolescence: Very often the technology in the developing countries is obsolete resulting in higher costs of production or poor quality. Where obsolescence is taken care of in the transfer of technology by the insertion of a clause for the introduction of innovations over a period of time, it is not a serious problem. However, in the absence of such provisions, it is necessary for the developing country to establish facilities for process development on a continuous basis to ensure that the process adopted is efficient.

49. In a similar manner it is necessary to update the equipment to remove obsolescence.

Table 12

National list of drugs

AFRICA

<u>Country</u>	<u>Manufacture</u>	<u>Import</u>
Algeria		Contains 2,500 pharmaceutical products. Revised every 2 years.
Angola		
Chad		Contains 146 drugs (53 types of tablets, 51 types of injections, 3 types of capsules and 39 miscellaneous drugs.
Egypt	List as envisaged by WHO under consideration. There is a list confined to the Ministry of Health units.	Index of specialities sold contains 2,500 drugs, printed twice a year.
Ethiopia		List covers 18 therapeutic groups and 57 sub-groups.
Guinea		WHO model list of essential drugs adopted.
Ghana		
Morocco		
Nigeria		
Rwanda		
Sudan		
United Republic of Tanzania		List under preparation with the help of WHO.
Tunisia		
Upper Volta		
Zambia		

Table 12 continued

ASIA

<u>Country</u>	<u>Manufacture</u>	<u>Import</u>
Afghanistan		
Bangladesh		
Burma		
India	Contains 116 drugs (43 types of tablets, 39 types of injections and 34 miscellaneous drugs)	
Indonesia		
Iraq		
Korea, Republic of		
Malaysia		
Nepal		
Pakistan		
Philippines		
Sri Lanka		
Thailand		
Yemen Arab Republic		
Yemen Democratic Rep.		

Source: country studies

Notes: Data not available

TABLE 13

Central Procurement

AFRICA

Country

Algeria	Public Sector Pharmacie Central Algérienne imports and distributes
Angola	
Chad	Public sector Pharmacie Nationale d'Approvisionnement Monopolizes imports and distribution
Egypt	Government El Gournhouria and Egyptian Pharmaceutical Trading Co. procure and distribute. 500 drugs allowed to be imported. Import by individual importers controlled by central procurement committee.
Ethiopia	State owned Pharmaceutical and Medical Supplies Corporation imports and distributes. Individual importers also import.
Ghana	
Guinea	State owned Pharmaguinee monopolizes import and distribution
Morocco	
Nigeria	
Rwanda	Office Pharmaceutique du Rwanda is the main agency for import and distribution. Three private pharmacies also import.
Sudan	
Tanzania	No central procurement agency. Central medical stores and national pharmaceutical company import and distribute to government and private sector respectively.
Tunisia	
Uganda	Government Uganda Pharmaceuticals Ltd imports for public and private sectors.
Upper Volta	
Zambia	Ministry of Health, Industrial Development corporation trading and chemicals and Ministry of Trade and Industry are designated import agencies.

Table 13 continued

ASIA

Country

Afghanistan

Bangladesh

Burma

India

Public Sector
State Trading Corporation imports and distributes.

Indonesia

Iraq

Korea, Republic of

Malaysia

Nepal

Pakistan

Philippines

Sri Lanka

Thailand

Yemen Arab Republic

Yemen Democratic Rep.

Sources: country studies

Blanks: Data not available.

Pharmaceutical export and import in developing countries from 1972 to 1975

(in million dollars) (dollar of the period)

COUNTRY	E X P O R T					I M P O R T					
	1972	1973	1974	1975	1977	1972	1973	1974	1975	1976	1977
Algeria						42.5	68.4				
Argentina	14.5	19.1	24.9	32.5	35.7	36.9	40.5	64.1			
Bolivia						5.1					
Brazil				46	60						
Chile						19.9	20.8	20.8			
Colombia	5.2	7.4	8.4			21.5	25.3	26.7			
Ecuador	2.0	3.7				17.3	20.9				
Egypt						12.7	11.9	14.0			
Fiji						1.1	1.5				
India	11.5	16.7	26.4		65.8	28.8	32.2	40.0		45.5	
Iran						68.7	95.0	139.7			
Iraq						25.0	18.7				
Korea Rep. of					50						
Mexico	3	15	50	60	120						
Morocco						14.0	15.9	60.5			
Algeria						48.4	59.9	16.1			
Pakistan						13.1	12.3	73.9			
Peru								24.1			
Philippines								34			
Puerto Rico			1.5			22.8	22.5	41.4			
Sri Lanka								6.1			
Tunisia				26		13.7	15.8	21.4		29.1	
Turkey						20.9	33.9	24.3			
Uruguay						2.7	9.8	12.1			
Venezuela						35.2	30.1	36.2			
Yugoslavia	31.6	39.1	54.0			38.2	51.6	60.5			
Zaire			26.								
Zambia		62.9				8.6	8.2	28.8			

Sources: Yearbook of International Trade Statistics, 1975 United Nations, New York 1976.
 OECD: "Trade by Commodity".

Table 15.

Pharmaceutical export and import in developed countries from 1972 to 1975.

C O U N T R Y	(in million dollars) (dollar of the period)									
	E X P O R T					I M P O R T				
	1972	1973	1974	1975	1977	1972	1973	1974	1975	1977
Australia	28.2	43.9	43.5	43		73.6	96.5	137.5	122	
Austria	25.8	34.6	46.7	59.3	103	70.4	90.6	115	133.5	208
Belgium & Luxembourg	150	200	282.8	313.7	64	194	250	330	348	242
Canada	78.5	110.6	55	58		102	119	162	180	
Denmark			124	141		51.5	69.8	92.5	94.6	
Finland			7	11		45.8	55.3	69.8	78.8	
France	308.3	439.3	502.1	635.1	932	194.3	273.9	309.2	341.6	661
Germany Fed. Rep.	628.9	855.4	1035.9	1060.3	1,968	230	355.5	432.7	532	1,062
Ireland	29.7	55.7	85.0	93.5		37.8	45.6	59.7	64.3	
Israel	7.3	8.5	10.6			17.5	22.1	26.6		
Italy	221.8	261.7	335.3	378.9		177.7	287.5	309.5	340	612
Japan			137	124	180	260.9	360.5	455.7	440	
Netherlands	220.2	267	299.9	332		149.8	202.2	231	246	
Norway			10	11		34.4	50.3	64.4	73.1	
Portugal	14.5	20.3	25.4	17.0		44.4	59.7	70.8	72.5	
Spain	20.3	26.1	48.7	40.9		105.4	149.5	174.8	204.8	
Sweden	52.6	67.5	86.9	115		104.8	127.9	153.8	190	
Switzerland	429.2	588.2	749.1	839.2		101.5	127.7	159.3	170.7	
United Kingdom	451.4	542.2	706.4	825.9	1,051	109	163.8	216	215	400
USA	480.3	629.9	876.4					214	237	

Source: Yearbook of International Trade Statistics, 1975 United Nations, New York 1976.
OECD: "Trade by Commodities".

Table 16

PROPORTION OF IMPORT AND LOCAL PRODUCTION
VERSUS TOTAL CONSUMPTION IN
VARIOUS DEVELOPING COUNTRIES
(dollars of the period)

	<u>Import</u> %	<u>Local pro- duction</u> %	<u>Value of import</u> US\$ millions	<u>Value of local production</u> US\$ millions
<u>AFRICA</u>				
Algeria	81.5	18.5 (1976)		
Angola				
Chad	100		1.9 (1978)	
Egypt	20	80 (1976)		346 (1975)
Ethiopia	83.7	16.3 (1977)	19.7	3.85 (1974)
Ghana	70	30 (1976)		
Guinea	84	16 (1976)	8.4	1.6
Morocco	73	23 (1978)		18 (1972)
Nigeria	91	9 (1977)	193 (1977)	19 (1977)
Rwanda			0.55 (1973)	
Sudan	90	10 (1977)		8.6 (1977)
Tanzania	95	5	24 (1977)	
Tunisia	80	20	35 (1977)	9 (1977)
Upper Volta				
Zambia			11.25 (1975)	

Table 16 continued

PROPORTION OF IMPORT AND LOCAL PRODUCTION
VERSUS TOTAL CONSUMPTION IN
VARIOUS DEVELOPING COUNTRIES
(dollars of the period)

	<u>Import</u> %	<u>Local pro- duction</u> %	<u>Value of import</u> US\$ millions	<u>Value of local production</u> US\$ millions
ASIA				
Afghanistan	61.6	38.4	8.5 (1977)	5.3 (1977)
Bangladesh				
Burma				
India	5.6	94.4	58.7 (1977)	980 (1977)
Indonesia	90			
Iraq				
Korea, Republic of				
Malaysia	75	25 (1976)		
Nepal	84	16 (1976)	2.5 (1976)	0.5 (1976)
Pakistan				
Philippines				
Sri Lanka			5.7 (1973)	
Thailand	65	35 (1977)	157 (1977)	85 (1977)
Yemen Arab Republic				
Yemen Democratic Republic				

Table 16 continued

PROPORTION OF IMPORT AND LOCAL PRODUCTION
VERSUS TOTAL CONSUMPTION IN
VARIOUS DEVELOPING COUNTRIES

	<u>Import</u> %	<u>Local pro- duction</u> %	<u>Value of import</u> US\$ millions	<u>Value of local production</u> US\$ millions
<u>LATIN AMERICA</u>				
Argentina	22	78	149 (1976)	560 (1976)
Brazil				
Colombia				
Cuba				
Mexico				
Paraguay				
Uruguay				
Venezuela				

Source: Case studies on pharmaceutical industry in developing countries,
prepared by UNEDC 1978.

Table 17

Number of physicians and pharmacists
in various countries

	<u>Number of physicians</u> <u>in the country</u>	<u>Population</u> <u>per physician</u>	<u>Number of pharma-</u> <u>cists in country</u>
<u>Africa</u>			
Algeria	1,698 (1969)	8,200	265
Botswana	63 (1974)	10,500	7
Burundi	74 (1973)	48,700	13
Cape Verde	22 (1977)	13,600	8
Central African Republic	59 (1973)	27,100	1
Chad	101 (1977)	39,600	5
Egypt	7,495 (1974)	5,200	2,627
Ethiopia	530 (1977)	56,600	95
Ghana	856 (1974)	11,200	444
Guinea	350 (1972)	14,300	32
Lesotho	50 (1974)	20,400	5
Madagascar	687 (1973)		97
Morocco	1,223 (1974)	13,800	364
Nigeria	109 (1974)	41,100	7
Rwanda	77 (1974)	53,500	3
Sierra Leone	149 (1970)	17,100	7
Somalia	193 (1973)	15,500	21
Swasiland	54 (1974)	8,900	8
Sudan	1,400 (1974)	12,300	312
Tanganyika	494 (1973)	27,500	34
Togo	100 (1973)	21,200	22
Tunisia	1,004 (1971)	5,200	163
Uganda	540 (1974)	20,700	28
United Republic of Tanzania	727 (1977)	22,000	
Upper Volta	99 (1974)	59,500	15
Tanganyika	494 (1973)	27,500	34
Zambia	527 (1971)	8,170	81
Zanzibar	43 (1967)	8,140	3

Table 17 continued

	<u>Number of physicians in the country</u>	<u>Number of population per physician</u>	<u>Number of pharma- cists in country</u>
<u>Asia</u>			
Afghanistan	701 (1973)	26,091	37
Bangladesh	7,663 (")	9,345	
Burma	4,280 (")	6,906	54
India	138,000 (")	4,162	66,000
Indonesia	7,027 (1974)	18,863	1,664
Iraq	4,545 (")	2,369	
Korea, Republic of			3,640
Malaysia	1,556 (")	7,647	55
Nepal	338 (")		
Pakistan	17,194 (")	4,086	996
Philippines	14,000 (1970)	2,632	
Sri Lanka	3,251 (1972)	4,007	455
Thailand	4,662 (1973)	8,980	1,616
Yemen Arab Rep.	245 (1974)	26,449	20
Yemen Dem. Rep	42 (1968)	32,380	2

Table 17 continued

	<u>Number of physicians in the country</u>	<u>Retail drug stores</u>
<u>Latin America</u>		
Argentina	55,000 (1977)	7,300
Brasil	72,700 (1977)	17,400
Colombia	13,200 (")	6,000
Chile	7,400 (")	1,060
Ecuador	5,000 (")	1,100
Mexico	35,000 (")	8,750
Peru	11,000 (")	1,500
Uruguay	5,000 (")	700
Venezuela	12,500 (")	1,725

Source: Barral: *Economie de la Santé*, Dunod edition, Paris 1977, page 149.
and Case Studies on pharmaceutical industry in developing
countries, prepared by UNIDO 1978.

World Health Statistics, Annual, WHO, 1977
Vol I, II and III.

IV. RELATION OF THESE PROBLEMS TO THE ISSUES PROPOSED FOR CONSULTATIONS
BETWEEN DEVELOPING AND DEVELOPED COUNTRIES

50. The purpose of this chapter is to examine whether the major problems of developing countries confirm that the issues proposed by the two Panel Meetings are the correct ones for discussion at the Consultation Meeting.

51. The problems which the developing countries encounter may be identified as follows:

- (a) No existence on national drug list.
- (b) Purchase of too many drugs with a brand name.
- (c) Absence of control of procurement procedure.
- (d) No existence of good quality control, legislation or registration system.
- (e) Their production policy is not well developed.
- (f) As a result of this, the local production in many countries does not develop according to the domestic requirements.
- (g) The valorization and utilization of natural resources has not been given enough attention and has not been integrated in the production of drugs.
- (h) The development of an integrated pharmaceutical industry in developing countries excluding India, Mexico and Argentina has not been considered.
- (i) The countries who have started an integrated pharmaceutical industry such as India, Mexico and Argentina, due to the high price of intermediates, produce products whose prices are higher than those on the international market.
- (j) Due to the non-appropriateness of the lay out, the equipment and machines according to the capacities and technology to be used, the production programme and the cost of the drugs is higher than foreseen.
- (k) Insufficient attention has been given to the development of this industry in most developing countries.

- (l) The production of most essential drugs, through chemical synthesis, for diseases which are most prevalent in developing countries, has been hampered due to the difficulty in obtaining the appropriate technology.
- (m) Absence of infrastructure and trained personnel.
- (n) Absence or no policy for supporting chemical or packaging industries in developing countries.
- (o) The absence of available research and development centres which may be difficult and costly to establish at national level. However, at regional level, such centres are also not available.
- (p) Co-operation with international organizations, such as UNIDO, is limited. Some projects are already established in different regions. However, a more close co-operation would be more effective.
- (q) Co-operation between developing countries in this field is also not very effective and does not really exist in the field of formulation and packaging, utilization of medicinal plants, where many developing countries are in an advanced position and could assist other developing countries.

52. the course of the First Panel Meeting 16 issues were discussed and 6 of them selected for further examination. These issues were as follows:

- the preparation of a national list of essential drugs;
- the availability and price of intermediates;
- the transfer of technology;
- the establishment of regional pharmaceutical centres;
- co-operation with developed countries;
- international co-operation involving UNIDO.

53. The Second Panel Meeting discussed mainly the following three issues:

- Criteria for the selection of drugs for local formulation;
- Criteria for the selection of drugs suitable for basic manufacture;
- Terms and conditions for the transfer of technology based on guidelines suggested by UNIDO.

54. The Inter-Regional Meeting is expected to consider the problems encountered by developing countries listed in paragraph 51 above and consider whether the solution depends on:

- (a) national action and/or
- (b) greater co-operation among developing countries; and/or
- (c) greater co-operation between developed and developing countries at the government and industry level.

Only the last group of solutions (item (c)) warrant discussion at a consultation meeting which provides a forum for consultations between developing and developed countries at which representatives of Government as well as representatives of industry, labour and consumer groups are invited to attend.

55. The Inter-Regional Meeting is also expected to take into account the related work of other international organisations such as WHO and the responsibility of UNIDO for promoting the industrial development of developing countries. This means that problems such as the preparation of a national list of drugs (which is a medical matter) should only be considered in the context of facilitating development of local pharmaceutical production.

56. Finally, the selection by UNIDO of 20 drugs for illustrative purposes needs to be considered. There is a need to consider whether this list contains a sufficient number of drugs that developing countries want to manufacture themselves to provide a basis for discussion at the Consultation Meeting. Or should the list be modified and/or broadened?

**Part V: ACTION BY GOVERNMENTS, INTERNATIONAL ORGANIZATIONS AND
TRANSNATIONAL CORPORATIONS TO PROMOTE FASTER DEVELOPMENT
OF THE PHARMACEUTICAL INDUSTRY IN DEVELOPING COUNTRIES**

57. From the foregoing it is obvious that the immediate need is for an integrated development of the entire system of procurement, production and distribution of pharmaceuticals at the national level to meet the requirements of preventive and curative health care.

58. The prerequisites for the establishment of a viable pharmaceutical industry are:

formulation of a national health policy, provision of appropriate medical services, preparation of specific lists of drugs to meet local health needs, procurement policies, enactment of suitable drug legislation including the registration of drugs, setting up quality control facilities, drug production and equitable distribution and training of personnel.

59. All these have to be accomplished within the constraints of limited financial resources and infrastructure available. This also calls for concerted action on the part of Governments, International organizations as well as Transnational corporations as described below:

(1) Actions to be taken by governments

60. The actions to be taken by governments of developing countries on various matters are described below:

- (a) Preparation of national list of drugs
- (b) Production policies and criteria
- (c) Central procurement
- (d) Valorisation of raw materials
- (e) Development of production of drugs

- (f) Utilisation of existing capacities
- (g) Ancillary industries
- (h) Infrastructure
- (i) Industrial training
- (j) Transfer of technology
- (k) Policies and legislation
- (l) Regional pharmaceutical centres
- (m) Technical co-operation amongst developing countries.

The actions to be taken under each of the above categories are enumerated below:

(a) Preparation of national list of drugs:

61. Each country should prepare a specific list of drugs to meet local health needs and this constitutes an important part of national health policy. Such a list offers the advantage of reducing the number of pharmaceutical products which are to be purchased or produced to meet priority requirements. Guidelines for the preparation of a National list of drugs and National Formulary are given in UNIDO report.^{1/}

(b) Production policies and criteria

62. Having finalised the national list of essential drugs, an analysis can be made as to how best to make them available. Some drugs may be selected for local production from the stage from which such manufacture can be undertaken based on the capabilities of the local pharmaceutical industry and the infrastructure available. The criteria which have to be fulfilled for selecting drugs and active ingredients for production in developing countries are described in UNIDO report.^{2/}

^{1/} Guidelines for the Preparation of a National list of Drugs and National Formulary
UNIDO ID/WG.267/1, 1978

^{2/} Report - Second Panel meeting of Industrial Experts on the Pharmaceutical Industry.
UNIDO ID/WG.267/4/Rev.1 1978

63. The criteria for local manufacture should be techno-economic ones such as adequate demand to render the production unit viable, the availability of raw materials or intermediates, the availability of technology and its degree of complexity, savings in foreign exchange, the investment required and the existing capacities within the country. The criteria should not be too restrictive and if the drug was required by the country in sufficient volume to warrant local manufacture, this would be enough justification.

(c) Central procurement

64. Every country should establish centralized procurement agencies where feasible for the procurement of active ingredients for the formulation and packaging units as well as intermediates and raw materials required by the pharmaceutical industry. The experience of some developing countries in this regard has amply demonstrated that materials meeting the quality standards specified can be procured at competitive prices through such centralized agencies resulting in considerable savings in valuable foreign currency. Even after taking up local production, it may be necessary to import some essential drugs in dosage form to meet the requirement of health-care. It will be beneficial to canalize such imports also through central procurement agencies and derive the advantages mentioned above.

(d) Valorisation of raw materials

65. Most of the developing countries possess abundant resources of raw materials such as agricultural products, rich flora of medicinal herbs and plants, essential oil bearing plants and slaughter-house by-products which are required by the pharmaceutical industry. However, it is necessary to survey and evaluate these raw materials both with respect to quantity as well as quality to assess their suitability for use in the industry. The governments can utilize pharmaceutical centres for this purpose. A mobile

unit on the pattern of one organized by UNIDO-Roumanian centre surveying different countries in Africa and Asia could be very useful for the evaluation of medicinal plants.

(a) Development of production of drugs

66. Several developing countries had already established pharmaceutical industries and in these countries a substantial proportion of the medical needs is covered by pharmaceutical products formulated locally. This clearly shows that such an industry can be established in countries which are currently meeting their requirements of pharmaceuticals solely through imports. However, a number of factors has to be considered for successful implementation of a manufacturing programme and these are described in UNIDO report.^{3/}

67. Based on the requirements of developing countries and the infrastructure available, broadly two different levels of production can be considered as follows:

- (i) Processing of bulk drugs into dosage forms
- (ii) Production of bulk drugs starting from intermediates/raw materials

Besides, the following pharmaceutical products can be considered for local production:

- (iii) Pharmaceuticals from medicinal plants
- (iv) Biological products from slaughter-house by-products
- (v) Production of vaccine and Sera

68. The actions to be taken by governments under each of the above are described below briefly:

^{3/} Report - Second Panel meeting of Industrial Experts on the Pharmaceutical Industry.

(i) Processing of bulk drugs into dosage forms:

69. Simple formulation and packaging based on imported bulk drugs might be taken up as a first step in the establishment of indigenous pharmaceutical industry. This would require less complicated technology, which is available in many developing countries. Apart from saving considerable foreign exchange in terms of the cost of imported pharmaceutical products, this would serve as the basis for the creation of an infrastructure for a more developed pharmaceutical industry. The manufacturing activities in a typical formulation unit may include tablets, capsules, liquids, injectables, infusions, ointments, powders and granules.

70. The formulation of essential drugs identified by WHO expert committee ^{4/} can be taken up to meet the immediate requirements of preventive and curative health care.

(ii) Production of bulk drugs starting from intermediates/raw materials:

71. Based on the size of the market and the infrastructure available, a multipurpose plant or industrial scale production based on imported intermediates could be established. In most of the developing countries where a number of products is to be manufactured in small volume, the multipurpose plant can be utilised. Based on the similarities of processes and operations involved, a number of simple bulk drugs can be grouped for production in a multipurpose plant based on late intermediates. The major groups under synthetic drugs are sulpha drugs which can be produced using the same type of equipment and starting from intermediates similar chemically. The other synthetic drugs belonging to different therapeutic groups have different chemical configurations and hence involve different methods of manufacture. By varying the composition of intermediates and optimizing the conditions of reaction, a number of synthetic drugs can be produced.

^{4/} Report of a WHO expert committee, Technical Report Series 615, 1977.

72. Depending on the status of chemical industry in the country, the manufacture of synthetic drugs from basic raw materials might be taken up. The chemical industry provides the raw materials, which are the major cost items in the total cost of production of the drug. Secondly the synthetic drug manufacture involves different chemical reactions/unit processes. The country should have adequate mastery over these unit processes for successful production through synthesis. Where chemical industry has developed, the equipments necessary for carrying out unit processes involved in the production of synthetic drugs would also be available. In other words, an integrated development of chemical industry to produce basic chemicals and intermediates required for the manufacture of synthetic drugs is necessary.

73. Antibiotics belong to some of the most important therapeutic groups having widespread coverage in developing countries. The manufacture, therefore, of antibiotics might be taken up and this involves fermentation technology using special types of microbial cultures in most of the cases. The major raw materials required by the antibiotic industry are mainly agricultural products which are available in most of the developing countries. The other raw materials such as solvents, intermediates and auxiliary materials could be easily imported. The production involves submerged fermentation followed by chemical purification and the latter is analogous to other chemical processes.

(iii) Pharmaceuticals from medicinal plants

74. Most of the developing countries have rich flora of medicinal herbs and plants and essential oil bearing plants growing wild in many cases. The indigenous or traditional medicine which is still widespread in many of the developing countries especially in rural areas depends on the medicinal herbs. The medicinal plants can serve as a valuable source of raw material for local

pharmaceutical industry as well as for export either in the form of crude extracts or finished products. In view of this, developing countries can organize scientific methods of cultivation and collection of medicinal herbs and plants. As a first step, each country may prepare an essential/national drug list based on the flora and the needs of the population. The essential drug list drawn up by UNIDO in 1978^{5/} on the basis of therapeutic groups can be taken as a model for the preparation of such lists for each country. A versatile but simple multipurpose plant can be established for the extraction of medicinal plants or active principles. Scientific cultivation of medicinal herbs and plants such as dioscorea tubers, solanum, lemon grass, Rauwolfia vomitoria, Ipecac, digitalis, scilla and senna is recommended.

(iv) Biological products from slaughter-house by-products

75. The slaughter-house by-products serve as raw material for the production of important biological products such as insulin, heparin, pancreatin, adrenalin and other hormones, pepsin and other enzymes, plasma and albumin and catgut. While a large number of animals are slaughtered in many developing countries, the slaughter-house by-products are not utilized properly in many cases. In view of this it is necessary that developing countries modernise abattoirs, provide deep freezing and refrigerated transport facilities to make available proper raw materials for the processing units. Primary extraction centres can be set up in the immediate vicinity of slaughter-houses.

(v) Production of vaccines and Sera

76. Vaccines, Sera, anti-toxins and toxoids necessary for prophylaxis and treatment can be produced with simple equipment. It is, therefore, recommended that developing countries take measures to set up/expand public health

^{5/} Technical consultation meeting on Production of drugs from medicinal plants in developing countries. Lucknow, India, March 1978.

laboratories for the production of vaccines against cholera, smallpox, anti-tetanus serum and toxoid and antirabic vaccine and triple antigen and oral polio vaccine.

Drugs selected for basic production

77. As it would not be feasible to consider all the drugs for taking up production, UNIDO selected about 26 drugs as shown in Annex I for illustrative purposes in order to be specific and to facilitate formulation of a concrete plan for implementation. Drugs recommended by the Second Panel of Industrial Experts on the Pharmaceutical Industry for local production are given in Annex II. The selection of the above drugs is in conformity with the criteria laid down for production of drugs in developing countries. Further these drugs cover therapeutic groups of utmost importance based on disease patterns obtained in developing countries. However, it is desirable to ascertain the views of developing countries whether these drugs would meet the priority health requirements in their respective countries.

The technologies for these drugs are available with the transnational corporations and it is necessary to explore the ways and means as to how the developing countries can have access to the same. The technologies for these drugs are also available in some of the developing countries and technical co-operation amongst developing countries may facilitate technology transfer.

78. It is recognised that the manufacture of the above drugs no doubt covers practically the entire gamut of pharmaceutical industry entailing a large investment, involving often complex technologies. Further, the infrastructure and trained manpower available within the developing country might serve as constraints. Yet the fact remains that these drugs are essential for the health programmes. In view of this it may be desirable to draw up a phased programme for establishing facilities for manufacture. For example, a multipurpose plant can be installed for the manufacture of some of the synthetic drugs involved.

Similarly a fermentation complex can be established for the production of antibiotics. A simple versatile multipurpose plant can also be established for the extraction of medicinal plants. Pooling of production capacities on a regional basis and distribution of products within the region may offer definite advantages in undertaking the production of all the above drugs simultaneously.

79. Industrial profiles indicating the process, raw materials required, investment involved for a unit of economical size, the sources of technology, cost of production and return on investment for some of the drugs are given in UNIDO report. ^{6/}

80. The availability and prices of intermediates may pose serious problems as indicated earlier. Shopping around and a long-term arrangement with the suppliers may provide a solution to this problem to a certain extent. The possibility of establishing manufacturing facilities for these intermediates on a regional basis to cater to the demands of the entire region might be considered as a long-term solution. This is possible in some of the developing countries where the chemical industry has made some headway.

(f) Utilization of existing capacities

81. Developing countries should endeavour to fully utilize existing capacities by rationalization, renovation and innovation particularly in the field of maintenance of equipment, working more shifts and by the introduction of the latest appropriate technology. This can be achieved with much less investment in a relatively shorter period than by the establishment of altogether new facilities for production.

(g) Ancillary industries

82. Developing countries should establish ancillary industries such as glass and plastic containers other packing materials, chemical industry and

^{6/} Reports on drugs from the National Drug list which because of their essentiality could be produced in the developing countries.

engineering industry to meet the requirements of pharmaceutical industry within the country or on a regional basis. The integrated development of pharmaceutical industry should include the establishment of ancillary industries.

(h) Infrastructure

83. It is important that the governments of developing countries take parallel action on the provision of adequate infrastructure including utilities, communication network, transport, storage facilities, Research and Development and Engineering institutions both educational and consultancy with particular reference to the special requirements of pharmaceutical industry such as refrigerated transport and storage, uninterrupted power supply, water and effluent disposal facilities.

(i) Industrial training

84. It is highly necessary that the governments of developing countries take measures to establish/strengthen facilities for the training of personnel required by the pharmaceutical industry. As a long-term measure, educational institutions in the fields of chemical engineering, chemistry, pharmacy, microbiology, industrial fermentation, management techniques etc. will have to be set up if necessary with the assistance of international experts. In the interim nationals can be trained abroad in reputed institutions and factories. Some developing countries are fairly well developed in this area and can co-operate with other developing countries in extending training facilities to their nationals. One of the important functions of regional pharmaceutical centres is to provide training in different fields such as manufacture, quality control and engineering design.

(j) Transfer of Technology

85. The transfer of technology is by far the biggest single constraint on the development of domestic production. Whereas the production of pharmaceutical products in dosage form requires less complicated technology, the manufacture of bulk drugs in many cases calls for a relatively sophisticated technology. The methods available for transfer of technology are described in UNIDO report.^{1/} Above all the technology proposed to be transferred must be appropriate and should be adapted to suit local conditions. Where different technologies are available for the manufacture of the same drug a careful evaluation has to be carried out to identify the most appropriate technology. Technical co-operation amongst developing countries is one of the best ways for transferring appropriate technology.

86. UNIDO would like to invite discussion on the transfer of technology relating to the following drugs:

<u>Therapeutic group</u>	<u>Drug</u>
Analgesics	Aspirin
Anti-infectious agents	Sulphacetamide Sulphadiazine Sulphadimidine Ampicillin Tetracycline
Malaria	Chloroquine Primaquine
Antituberculous agents	Isoniazide Streptomycin Ethambutol

87. These drugs have been selected on the basis of their covering therapeutic groups of considerable importance and their widespread use in developing countries. Based on the experience of the participants in the field of

^{1/} Report - Second Panel meeting of Industrial Experts on the Pharmaceutical Industry.

technology transfer in respect of above drugs. it would be possible to formulate a policy for transfer of technology for the benefit of developing countries.

(k) Policies and legislation

88. Concurrent with the actions mentioned above, it is desirable that the governments formulate policies and enact legislation where necessary, to develop pharmaceutical industries in their countries as mentioned below in brief:

- (i) Laying down of clear-cut strategies with specific targets based on commitment to encourage the growth and development of pharmaceutical industries.
- (ii) Formulation of health policies to extend the use of appropriate pharmaceutical products to the majority of the population particularly in rural areas to derive full benefit from the newly established industry.
- (iii) Framing uniform policies in respect of imports and exports of drugs, registration, national formulary and pharmacopoea within the region.
- (iv) Taking steps to regulate prices of raw materials etc. required by the industry within the region.
- (v) Taking measures to develop the chemical industry, auxiliary industry and the infrastructure necessary for the same to ensure rapid and sustained growth of an integrated pharmaceutical industry.

(l) Regional pharmaceutical centres

89. Most of the developing countries do not have access to up-to-date information on technology, process development, valorisation of raw materials and industrial design. It is necessary to establish a pharmaceutical centre to provide these services. As it may not be feasible to establish such centres in each country, it is proposed that a regional pharmaceutical centre be established. Such a centre will be provided with all the facilities to perform different tasks mentioned above in addition to training of staff and carrying out techno-economic and feasibility studies. The pilot plant

of the centre can be used to evaluate the technology, test raw materials in the process and to produce small quantities of pharmaceutical products for testing the market. It is also useful for demonstration purposes and for the training of staff. It will facilitate industrial planning. In brief the regional pharmaceutical centre will furnish valuable data on the basis of which a sound industrial policy can be formulated.

(m) Technical co-operation amongst developing countries

90. Fortunately some of the developing countries are relatively more 'advanced' than others in the technological field and they would be in a position to assist sister developing countries in this field. Similarly there are other spheres such as technical training, valorization of raw materials, supply of basic chemicals and intermediates, pooling of production capacities and exchange of pharmaceutical products, establishment of regional pharmaceutical centres in which technical co-operation amongst developing countries will go a long way in developing pharmaceutical industry.

Major issues for discussion

91. In the light of the above, UNIDO would like to focus attention on the following issues:

- (1) Selection of drugs for formulation
- (2) The selection of drugs suitable for basic manufacture
- (3) Guidelines for negotiating terms and conditions for the transfer of technology
- (4) Co-operation among developing countries on the Pharmaceutical Industry.

II Action to be taken by international organisations

92. International organisations such as UNIDO have a vital role in assisting developing countries in the task of developing an integrated pharmaceutical

industry. It is necessary that UNIDO takes action on various issues discussed above in order to supplement the efforts of developing countries in achieving rapid growth of pharmaceutical industries. UNIDO is often called upon to take a leading role in initiating action in certain spheres as given below:

- (a) Establishment of pharmaceutical centres for carrying out various activities required for the development of pharmaceutical industries.
- (b) Creating pilot plant facilities for the purpose of demonstration and training and updating existing technology, for introducing new technology and scaling up.
- (c) Carrying out feasibility studies.
- (d) Assisting in the transfer of appropriate technology.
- (e) Industrial planning to develop integrated pharmaceutical industries.
- (f) UNIDO in co-operation with WHO, UNCTAD and other international organizations can assist developing countries in the field of quality control, registration, central procurement etc.

III Action to be taken by trans-national corporations

93. Transnational corporations can make a significant contribution towards the development of pharmaceutical industries in developing countries. They can render assistance on the following lines:

- (a) Transfer of appropriate technology on reasonable terms. This constitutes one of the crucial factors in the development of pharmaceutical industries.
- (b) Reviewing and developing processes which are more appropriate for small scale production.
- (c) Making available intermediates at reasonable prices to facilitate production of drugs at costs within the reach of the majority of people.
- (d) Reviewing their Research and Development programmes to pay more attention to the disease patterns prevailing in developing countries.
- (e) Extending training facilities to key personnel from developing countries in different facets of pharmaceutical industry.

Drugs selected by UNIDO for illustrative purposes

Analgesics

Aspirin

Antiinfective drugs

Anthelmintic drugs

Bephenium

Antibacterial drugs

Ampicillin

Benzyl penicillin

Phenoxymethyl penicillin

Sulphacetamide

Sulphadiazine

Sulphadimidine

Tetracycline

Antifilarial drugs

Diethyl carbanasine

Antileprotic drugs

Dapsone

Clofazimine

Antiprotozoal drugs

Amoebicides

Metronidazole

Antimalarials

Chloroquine

Primaquine

Antituberculosis drugs

Ethambutol
Isoniasid
Streptomycin
Tolbutamide

Cardiovascular drugs

Antihypertensive drugs

Reserpine
Cardiac glycosides
Digitalis glycosides

Hormones

Insulin

Other drugs of vegetable origin

Sennosides

Other drugs of animal origin

Pepsin
Catgut

Disinfectants

Chlorine
Parachlorone[†] xylene

Drugs recommended by Second Panel of Industrial Experts
on the Pharmaceutical Industry for local production ^{8/}

Analgesics

Acetyl salicylic acid

Anti infective drugs

Antibacterial drugs

Ampicillin

Benzyl penicillin

Phenoxy methyl penicillin

Tetracycline

Antimalarials

Chloroquine

Primaquine

Antituberculosis drugs

Ethambutol

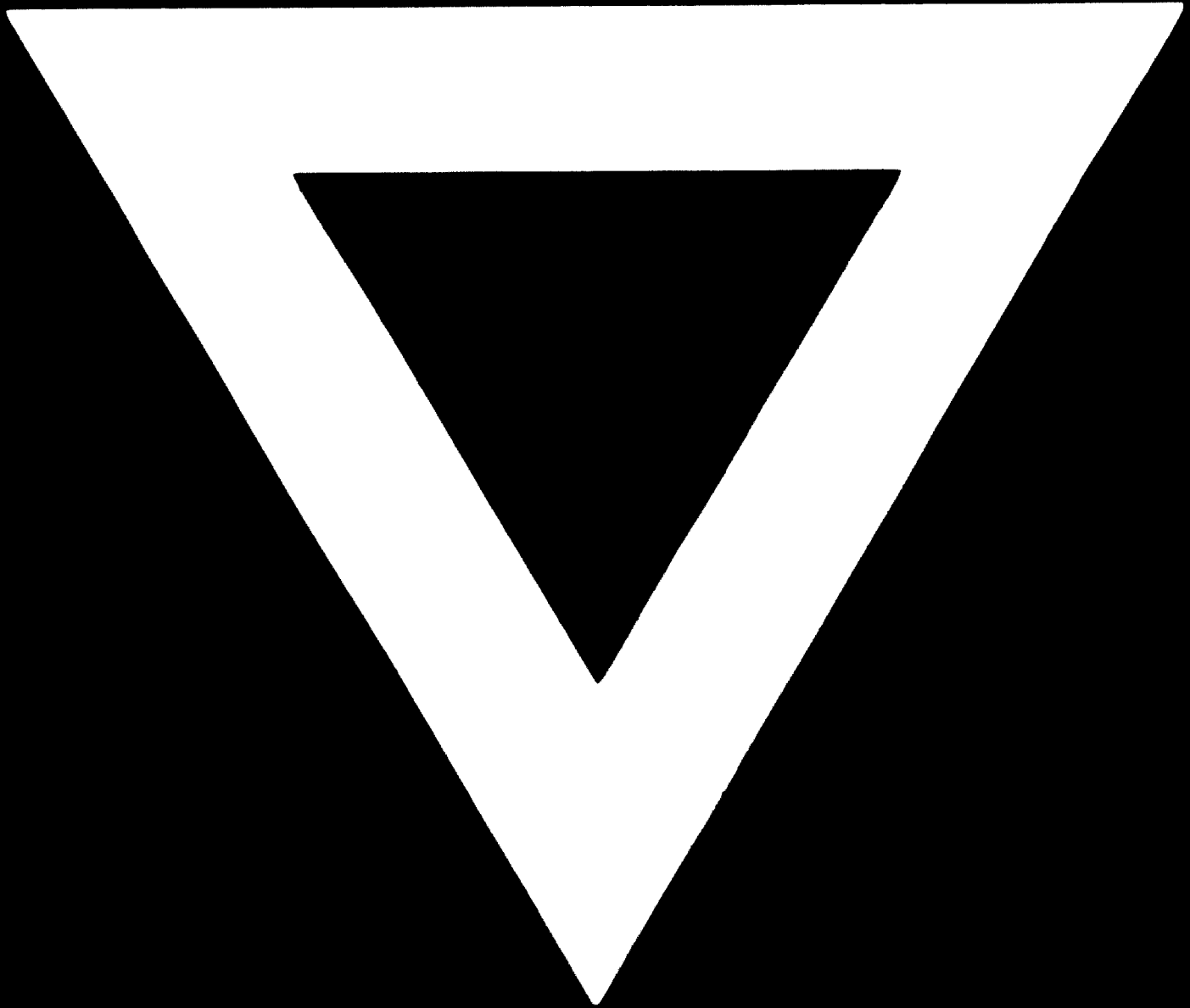
Isoniazid

Streptomycin

Additions to the list should be made to include immunologicals, sulpha drugs, disinfectants and antiseptics for medical practice and household use.

^{8/} Report on Second Panel meeting of Industrial Experts on the Pharmaceutical Industry UNIDO ID/WO/267/4/Rev.1 1978.

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