OCCASION

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

DISCLAIMER

FAIR USE POLICY

CONTACT

Please contact publications@unido.org for further information concerning UNIDO publications.

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

UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION
Vienna International Centre, P.O. Box 300, 1400 Vienna, Austria
Tel: (+43-1) 26026-0 · www.unido.org · unido@unido.org

08154

Distr.
LIMITED

UNIDO/ICIS.74
21 June 1978

ORIGINAL: ENGLISH

UNITED NATIONS INDUSTRIAL
DEVELOPMENT ORGANIZATION

SUMMARY OF THE DRAFT WORLD-WIDE STUDY OF THE PHARMACEUTICAL INDUSTRY*/

(Preliminary draft)

Prepared by the
International Centre for Industrial Studies

---

*/ This document has been reproduced without formal editing.

id.78-3828

TABLE OF CONTENTS

INTRODUCTION

The Lima Declaration and Plan of Action on Industrial Development and Co-operation (ID/Conf. 3/31, Chap. IV), which was adopted at the Second General Conference of UNIDO in March 1975, re-asserted that industry was a dynamic instrument essential to the rapid economic and social growth of the developing countries. In the Declaration, the General Conference called for the share of the developing countries in total world industrial production to reach 25 per cent by the year 2000.

The Lima Declaration and Plan of Action instructed UNIDO that :

> "in order to give concrete content to the process of industrialization in the developing countries, studies must be undertaken and specific measures formulated in different sectors of industry, special attention being given to priority sectors". (ID/Conf. 3/31. Chap.IV, para 67)

One of the selected priority sectors was the pharmaceutical industry. The results of this industry have a very important effect on mankind by curing illnesses, increasing life expectancy and there are also other factors which could contribute to all these factors, like better sanitation, housing, education, etc., that should be taken into account when dealing with the development of the pharmaceutical industry.

The Draft World-wide Study of the Pharmaceutical Industry, of which this is the first preliminary summary, is intended to serve as a basic document for the consultation system, as a policy making tool for national policy makers and as a help in developing technical assistance programmes and development strategies.

The Draft Study is an attempt to provide an overview of the present situation, to qualify the programmes in their complexity, to quantify the

future trends in their wide variety and the opportunities for and constraints upon the development of this sector.

This sector's development is closely connected with the medical and health system and the chemical industry in each country, illustrating the very complex nature of the related problems.

During the preparatory work it was realized that in many cases the available information was not complete and therefore it is essential to recognize that the presented situation may change. In view of the continuous and dynamic sectoral development, the revision and updating of the study is required, leading to additional research and expert meetings.

Production and trade figures expressed in US$ (or any other currency) under a system of flexible exchange rates must however be interpreted with special attention, realizing that these are intended for indicating trends and prospects as against actual figures.

The time which was available for the preparation of the draft study and this summary was very limited and this should be taken into account when we are dealing with the conclusions and forecasts for the future. It should be realized that no previous studies were available treating this subject from a global overview aspect.

It has also to be noted that the forecasts as we have tried to develop, were not existing previously and therefore further work has to be done on the improvement of the methodology of the forecasts, taking into account all important and possible variables from the demographic point of view to the medical, just as political, economic and social aspects.

The expansion of the pharmaceutical industry requires a commitment on the part of governments, so to encourage such developments. Government policy in the form of clear strategy is a basic necessity for the development of this sector.

I. PRESENT AND PAST SITUATION OF THE PHARMACEUTICAL INDUSTRY

Characteristics of the pharmaceutical industry.

The pharmaceutical industry which must serve so elevated goals as the safeguarding of human health and alleviation of the sufferings of mankind, is itself in reality a moderate-sized industry. Its production volume and value lag behind the output of the food industry, the textile and apparel industries or even that of the automobile industry, (see Table 1) - the pharmaceutical industry's production in 1975 was estimated at 37,5 billion dollars.

However, comparing the pharmaceutical industry to other industrial branches, we may state that there are certain characteristics of this industry which support its outstanding importance.

Table 1.

Production of various industrial branches

Industrial branch	Production value in billion $
Textile and apparel industry.....	168,7
Total chemical industry.....	146,7
Motor vehicles industry.....	94,1
Construction industry.....	377,2
Food processing industry.....	170,6

Source : UNIDO, ICIS (figures are from 1970)

One of the main features of the pharmaceutical industrial production is that the products meet vital requirements, e.g. the drugs used in surgery and those for lethal diseases, disregarding now the phenomenon that a considerable part of the drugs are consumed by habit.

Further characteristics of this branch of industries are based upon the fact that the consumption of its products are financed to a large extent by insurance policies, and further by public sources. The health care, the cost of pharmaceuticals are in a number of countries free, especially for the poorer strata of the society. Table 2 indicates that the developed countries spend 7 - 8 per cent of their gross national product on health care and that 15 - 20 per cent of this sum is used for pharmaceuticals. In relation to the developing countries this share amounts only to 2 per cent of the gross national product and to 40 - 50 per cent, regarding the expenditures for pharmaceuticals, owing, among other factors, to the lack of medical infrastructure. Whoever would dream of a similarly organized and free care of products in any other field of our everyday life. The involvement of the state as chief responsible for proper supply in the medical fields results in a focussed attention to that industrial branch.

Table 2.

National expenditures on health care and pharmaceuticals in some developed countries.

Country	GNP in billion $	Percentage of GNP spent on health care	Percentage of health care spent on pharmaceuticals	Expenditures of pharmaceuticals in billion $	Number of population in million	Expenditure per capita in $
France	279	7,8	20,7	4,5	52,5	85,7
Germany (F.R.)	420	8,0	20,2	6,8	62,0	109,6
Italy	150	8,0	23,3	2,8	55,4	50,5
Japan	438	5,5	33,2	8,0	109,6	72,9
Sweden	61	7,8	10,5	0,5	8,1	61,7
U.K.. .	195	5,5	16,8	1,8	55,9	32,2
U.S.A.	1397	7,9	12,2	13,5	211,9	63,7

Source : Stanford Research Institute : Pharm. ind. dynamics, page 5 , 1976

Analyzing further characteristics of the pharmaceutical industry, we have to draw attention to the following features : - great dynamism; the production of this industry may be quickly enlarged. This relatively new industry made a soaring rise during the past decades, from the discovery of sulphonamides in the thirties, through the elaboration of antibiotica, it made an unprecedented progress in our century.

- The investment costs are relatively quickly amortized; these costs are - with the exception of research investments - relatively low. Under the notion of pharmaceutical factory we may encounter large-scale industrial complexes employing a large number of workers and small laboratories with a few dozens of co-operators.
- The products may easily be transported and therefore the industry tends to concentration, which is also motivated by the high research cost and the compulsion to research, challenged by competition.

The conception of health, as it is elaborated by the WHO, covers a broad field of goals : "Health is a state of complete physical, mental and social well being and not merely the absence of disease or infirmity." To obtain only a fragment of this endeavour is a task, shared by the pharmaceutical industry. However, we want to emphasize here that the pharmaceutical industry alone is not able to solve all the health problems, - sanitary institutions, canalisation, education, nutrition, supply of clean water and public hygiene cannot be replaced by drug consumption.

The production of the pharmaceutical industry.

The world-production of pharmaceuticals has shown a rapid increase during the past decades. (See Table 3). The discoveries of this period and the increased consumption of drugs as a consequence of the postwar economic prosperity and expanded social care have contributed to this phenomenon and helped to raise the production from its 1950 level to the present one. The manifestly dynamic expansion of the industry supports the assumption that the upper limits of the pharmaceutical production are unrestricted, the growth of output is influenced alone by the absorption of the market and that this industry may react very sensitively and quickly to any appearance of new, financially stable consumption areas.

Tables 4 to 7 illustrate some data concerning the share of world-

production pointing out the leading role of developed countries in this field. Seven industrialized countries account for 70 - 75 per cent of world production. The developing countries, with their 10-12 **per cent** production-share lag behind the countries with centrally planned economies. Most important producers among the developing countries are those of Latin-America. The contribution of Asia and Africa, taking into account the number of their population, seems to be low.

Table 3.

World-production of pharmaceutials

Year	Production in billion $ (in current $)
1950	2,7
1960	7,9
1970	18,6
1975	37,5
1977	45,0

Source : Estimations, based on various publications.

Table 4

Production of pharmaceuticals

in billion $

and percentage of total

	1960	%	1965	%	1970	%	1975	%
World	7.905	100	13.667	00	19.500	100	37.500	100
Developed countries	6.250	79,06	10.623	77,72	13.966	73,50	25.510	68,03
North-America	3.320	42,00	4.660	34,09	5.246,5	27,61	7.468	19,91
Western Europe	2.360	29,85	4.418	32,33	5.346	28.14	11.596	30,93
Australia	75	0,95	125	0,92	210	1,10	370	0,99
Japan, Israel, South-Africa	495	6,26	1.420	10,38	3.163,5	16.65	6.076	16,20
Developing countries	665	8,40	1,204	8,81	1.935	10,18	4.500	12,00
Africa	15	0,18	78	0,57	263	1,39	486	1,29
Latin-America	380	4,80	640	4,68	942	4,95	2.360	6,30
Asia Middle-East	270	3,42	486	3,56	730	4,05	250	3,74
Asia Far-East							1.404	0,67
Centrally planned economies								
Europe	990	12,53	1,840	13,47	3.100	16,32	6.500	17,33
Asia (excl. China)	-	-	-	-	-	-	990	2,64

Source : See Table 3.

Table 5

Pharmaceuticals production of developed countries

in million $

Country	1960	1965	1970	1975	1976
U.S.A.	2.441,5	3.160,9	4.622	6.936,8	7.734,5
Austria	18	30	59	161,9	215
Belgium	57	98	207	356	395
Denmark	33	49	88	189,1	236,9
France	470	715	1.300	3.758,7	4.172,2
FRG	560	907	1.738	4.206	4.415
Italy	320	580	891	2.106	2.500
Netherlands	82	131	238	522	610
Spain	92	208	429	-	843,3
Sweden	42	66	119	320	431,4
Switzerland	160	238	500	1.310	1.460
U. K.	535	742	1.197	1.760	1.933
Japan	489	1.279	2.980	5.788	7.340

Source: see Table 3

Table 6.

Pharmaceutical Production of some Centrally Planned Countries

in million $ 1/

Country	1960	1965	1970	1975
Czechoslovakia	47	104	208,3	413,7
G D R	151	244	314,2	870,0
Hungary	103,4	293,8	546,4	1.058,6
Poland	74	147	301,8	470,7
USSR	482	697,7	1.066,1	2.305,3

Source : See Table 3

1/ calculation based on national currencies.

Table 7.

Pharmaceutical production of some developing countries

in million $

Country	1960	1965	1970	1975	1976
Afghanistan				41	
Argentina					450
Bangladesh			17	27	
Brazil	100	170	350	1120	
Chile			55	100	
India	147	216	333	635	770
Indonesia			9	44	
Iran		7	16	29	
Iraq			0,4	1,5	
Malaysia			25	94	
Mexico	105	207	378	524	
Pakistan	12,3	34	57	81	
Peru		30	47	74	
Philippines	24	30	50	70	
Sri Lanka			3,7	4,7	
Thailand	2	6	24	75	

Source: see Table 3.

Table 8

Population-Growth

in millions

(up till year 2000)

	1960	1965	1970	1975	1985	2000
Developed countries, total	653,8	694	731,9	774,78	810	1075
North-America	199	214	228	236,84	250	300
Western Europe	328	345	358	366,83	385	470
Australia and New-Zeeland	15,8	17,5	19,4	21,31		
Japan, Israel, South-Africa	111,3	118,4	126,5	139,79	175	305
Developing countries, total	1.323,73	1.537	1.764	1.969	2.455	2.950
Africa	232,2	284,13	323,9	375,91	395	420
Latin-America	212,1	246	283	324,09	405	600
Middle-East				144	185	260
Far-East	888,43	1.007,78	1.157,1	1.125	1.470	1.670
Centrally planned economies	974,57	1.098	1.142	1.236,28	1.377	1.645
Europe	311	331	347	361,33	390	425
Asia	663,57	727,22	795,94	874,95	987	1.220
W o r l d	2.959,21	3.289	3.637,9	3.970	4.642	5.670

Source : UN Statistics

The number of countries where highly developed pharmaceutical industries can be found is not more than fifteen, the number of those where the building up of pharmaceutical industry has been started totals to 60 - but in the remaining countries no industrial activity in the pharmaceutical field can be traced.

Of the developing countries, those countries with bulk production facilities (chemical synthesis or extraction of the active ingredients), include: Argentina, Brazil, Egypt, India, Indonesia, Mexico, Nigeria, Pakistan, Republic of Korea and Turkey. Some fifty countries (including some of the above mentioned ones) have formulation plants and about the same number merely imports finished pharmaceuticals. A very limited number of the developing countries have reached the stage where a fully developed pharmaceutical company can carry out researches and introduce new products.

The largest number of formulation plants in developing countries are in Latin-America, representing almost 50 per cent of the developing world. Next in importance is Asia, with about 25 per cent, followed by Africa and the Middle-East. On the other hand bulk production facilities are more numerous in the Far-East, followed by Latin-America and the Middle-East.

Structure of the industry

Presently there are more than 10,000 companies that consider themselves pharmaceutical manufacturers. Of these, not more than 2,000 to 3,000 can actually be considered as broadly competent pharmaceutical operators. Of these probably no more than 50 companies are supplying 60 per cent of the total world production, while the leading 25 account for more than 40 per cent and the first 14 companies for about 30 per cent, with a variation of their position among companies from one year to the other.

These levels of concentration do not appear to be unusual and exaggerated for a major high technology industry, however the further concentration is expected to increase only moderately in the coming decades.

The trend to concentration is characteristic to the pharmaceutical industry as the large-scale production is preferred by the economical manufacture, and the transportation of the products does not contraindicate the centralized production. Another motivation for the concentration of the industry lies in the fact that research and development absorb large amounts which may be covered only by considerable turnover and returns.

A trend to concentration may be observed also in the centrally planned economies, where in the course of industrial development huge broad-scale factories were built.

As the highly concentrated companies are fully capable to fulfill their task, namely to supply the market with their products, and as on the other hand their formation has been an economic necessity, we cannot assume that the process of industrial concentration and the establishment of multinational companies per se should be regarded as a harmful phenomenon. We may even presume that in the next decades the trend to concentrate the pharmaceutical industry will evolve also in developing countries.

The present market share of some important groups of pharmaceuticals could be indicated as follows: (taking into account that in individual countries variations could appear)

Major groups of drugs	Share in the world market in %
Antibiotics	13.0
Medicines for central nerves system	19.0
Analgesics and antipyretics	9.4
Cardiovasculars	8.7
Vitamins	5.8
Hormones	4.3
Antituberculotics	1.2
Antimalarial drugs	1-5 (depending on epidemics)
Antileprosy agents	0.4
Neoplasms and endocrine	11.0
Digestives and genito-urinary	11.0

Source: Consultants estimations.

One more important aspect belongs to the structure of the pharmaceutical industry - namely necessity of the existance of external infrastructure- as medical system, universities, educational backgrounds, distribution systems, pharmacies' network, etc.

Taking into consideration that some developing countries are determined to establish their own pharmaceutical industry, the following stages could be recommended parallel with the development of health policy, mother-and infant-care, health service, health insurance, etc:

1. Organization of drug control and medical examinations;
2. Packing activity/packaging of bulk medicines;
3. Gradual establishment of:
   - Tabletting/pills, capsules, dragées.
   - Galenics, ointments, powders, etc.
   - Preparation of infusion solutions.
   - Manufacturing of injections/vials.
4. Production of active ingredients by way of:
   - synthesis
   - fermentation
   - extraction
5. Research and development activities.

It should be noted, that the raise from one level to the other will be a qualitative step, with the establishment of the proper conditions.

Consumption of drugs.

Tables 9 to 11 illustrate indicatively the distribution of world drug consumption, - revealing an assymetry : the average per capita drug consumption in 1975 amounted in the developed countries to over $ 30, whilst that of the developing countries was under $5. The per capita consumption reflects the immense gap between the industrialized nations and the developing ones. It is beyond doubt that the per capita consumption of nearly half of the world's population has to be raised.

In the framework of this study we are not intending to determine the ideal level of the drug consumption, only assumptions may be expressed in this respect. Supposing that a part of the consumed pahrmaceutics in the industrialized countries may be regarded as not absolutely necessary, the ideal level might be between $ 20 to 25 per capita. A realistic target for the developing countries seems to be a minimum of $ 12 per capita drug-consumption, which should be considered a basis for the planning of total health expenditures. This level of consumption must cover all essential and basic pharmaceuticals, so to fulfil all fundamental health requirements in developing countries.

Studying the factors influencing drug consumption, we may arrive at the conclusion that these are different in the industrialized countries from those in the developing ones.

In developed countries the consumption of drugs in influenced first of all by the physicians. Every physician can prescribe to his patients the best pharmaceuticals according to his professional obligations, paying little or no regard to the prices and without considering who will come up for the expenses. The more physicians are practicing in a country the greater the drug consumption will be on the average.

There exists however a tendency developed and guided by health authorities to induce to more careful prescribing and choosing less expensive pharmaceuticals in industrialized countries.

In developing countries the factors influencing the drug consumption are far less simple. Here the consumption is determined not only by the number of physicians but also by the system of the drug distribution and above all the availability of money to cover the relevant expenses, together with the availability or lack of proper government policies.

The situation of the great majority of the population in developing countries, related to the low drug consumption are essential indicators as to the necessity of establishing local pharmaceutical industry. By extending medical care to broad masses in developing countries new market areas for local production of pharmaceuticals can be opened, which in turn will be a decisive factor for the rentability of local factories, not to mention the social and humanitarian factors towards a more healthy population.

The variety of pharmaceuticals

Before the Second World War the diversity of the known pharmaceuticals was not significant, the drugs offered by pharmacists were easily to be surveyed. The enormous increase of pharmaceuticals after the Second World War made such a survey more complicated. The marketed products amounted to 8,000 in the FRG to 6,000 in Switzerland in 1975; at that time a moderate variety of about 4,500 drugs was offered in France or 3,000 in U.K. and about 1,500 in Hungary.

Analyzing the consumption of the broad spectrum of drugs, we may, however, come to the conclusion that the first 500 of the most frequently prescribed pharmaceuticals accounted for 80 to 90 per cent of all the prescriptions. Furthermore the top 200 drugs accounted for more than 68 per cent of all prescriptions and the top 50 drugs represented 39 per cent of all prescriptions.

This experience has lead to the idea of setting up a list of the essential drugs, which could help developing countries and orient them in the great number of pharmaceuticals, taking into account the most frequent diseases in each country. Although this suggested minimum of essential drugs may be very helpful in supporting the distribution of drugs and in planning new facilities - it does not, however, make superfluous those drugs which are used for less frequent diseases or in special individual cases, recognizing that some of the not widely used drugs could be essential for individual cases.

Generic name.

The orientation difficulty due to the great variety of drugs raised the demand of disclosing the generic name of the pharmaceuticals on each package. It occurs, as a matter of fact, that the same type of drug prepared by several companies in different countries appear under different trademarks on the same market. The right to a trademark and its application is ensured and regulated by national legislation and international treaties. Without trespassing on rights it is obvious that the health authorities and those who are responsible for purchase and distribution of drugs keep a record and register the chemical and generic name of marketed pharmaceuticals.

In addition, in most countries the chemical composition of the drugs has to be indicated on the packages. It is advisable to inform the physicians about the variety of pharmaceuticals and thus about identical products, enabling them to make a proper selection, taking into consideration the prices of the drugs and the financial situation of the patients.

The question of the generic name and its indication on the package seems, however, of secondary importance compared to the necessity of increasing the drug consumption and establishing local pharmaceutical industry in the developing countries.

Trade

The value of pharmaceuticals imported and/or exported by various countries is summarized in Tables 12 to 14, revealing the unequal export activities of different countries. The current situation may be characterized by a high export level of developed countries and low level or lack of exports from developing countries. This fact is illustrated in Table 15 indicating the destination of pharmaceutical exports in 1973.

According to these data 52.8 per cent of the total exports of the major exporting countries was disposed of in Western European countries; all the other territories have a share of 2 - 13 per cent only. The value of exported pharmaceuticals disposed of in Africa, Asia and Latin-America amounted to 40 per cent of the total.

All these data point to the fact that a large new market area may be opened up in the developing countries. The key to a successful industry is namely a market of size. Unless production can reach a certain scale, the business will not be on a sound basis. Since most developing countries have too small domestic markets, they would be well advised to try to expand it locally by increasing medical and social care and to seek to strengthen regional economic integration movements by specializing in the production of specific goods.

Table 9. Consumption of pharmaceuticals in developed countries

Country	1960	1965	1970	1975	1976
Canada	9,47	14,15	18,52	25,41	28,38
USA	16,29	20,31	27,3	34,31	35,10
Austria	3,53	6,45	11,0	16,0	-
Belgium	9,86	13,49	16,0	48,50	-
Denmark	4,94	6,41	-	22,05	25,24
Finland	-	9,27	17,7	30,7	36,5
France	8,75	12,87	19,5	47,64	54,50
FRG	8,66	12,18	17,48	54,30	65,75
Greece	1,92	4,37	8,45	-	-
Ireland	-	-	6,32	8,94	9,90
Italy	6,27	11,07	18,31	26,10	31,72
Netherlands	4,50	9,46	15,86	22,93	27,25
Norway	3,61	5,36	22,0	26,33	28,57
Spain	3,19	7,08	9,56	30,54	35,80
Sweden	7,5	11.29	15,5	37,80	42,57
Switzerland	11,22	16,40	21,03	49,25	-
United Kingdom	7,96	11,08	16,66	19,50	26,65
Japan	5,27	13,46	24,5	47,85	48,64

Source : see Table 3

Table 10

Consumption of pharmaceuticals in some Centrally Planned Countries x/

(in $ per capita)

Country \ Year	1960	1965	1970	1975	1976
Czechoslovakia	7.19	10.82	14.53	27.89	28.8
Hungary	12.06	18.47	23.92	27.91	29.50
Poland	3.85	7.85	9.16	13.81	15.1
USSR	2.68	3.05	4.44	9.29	10.37

x/ estimations

Table 11

Consumption of pharmaceuticals in some developing countries

$ per capita

Country	1960	1965	1970	1975	1976
Algeria				5,1	
Afghanistan				0,2	
Argentina			4,7	9,5	
Brazil			2,8	10,2	
Egypt				4,7	
Ghana				4,4	
India	0,4		0,6	0,75	
Indonesia				1,25	
Iran					9
Jordan			1,3		
Qatar			11	13	
Kuwait				12	
Liberia				2	
Libyan Arab Jamahiriya				9,9	
Mexico			5,3		
Nigeria				1,2	
Yemen			0,6		
Oman				2,4	
Pakistan				2,2	
Peru			5,2	11,6	
Philippines					4,3
Saudi Arabia				4,7	
Sierra Leone				0,7	
Republic of Korea					11,5
Thailand				4,2	

Source: see Table 3

Africa		0,15	0,2	0,26
Latin America	2	2,5	2,5	10
Middle East			2,45	4,3

Source: see Table 3

Table 12.

Pharmaceutical export and import in developing countries from 1972 to 1975 /in million $/

Country	EXPORT				IMPORT			
	1972	1973	1974	1975	1972	1973	1974	1975
Algeria					42,5	68,4		
Argentina	14,5	19,1	24,9		36,9	40,5	64,1	
Bolivia					5,1			
Chile					19,9	20,8	2o,8	
Columbia	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		28,8	32,2	40,0	
Iran					68,7	95,0	139,7	
Iraq					25,0	18,7		
Lybia					19,8	23,8	29,3	
Morocco					14,0	15,9	16,1	
Nigeria					48,4	59,9	73,9	
Pakistan					13,1	12,3	24,1	
Philippines					22,8	22,5	41,4	
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
Sri Lanka							6,6	
Tunesia					13,7	15,8	21,4	29,1
Turkey					20,9	33,9	24,3	
Uruguay					2,7			
Venezuela					35,2	30,1	36,2	
Yugoslavia	31,6	39,1	54,0		38,2	51,6	60,5	
Zaire							28,8	
Zambia					8,6	8,2		

Source: Yearbook of International Trade Statistics, 1975 United Nations New York 1976

Table 13. Pharmaceutical export and import in developed countries from 1972 to 1975 /in million $/

Country	EXPORT				IMPORT			
	1972	1973	1974	1975	1972	1973	1974	1975
Australia	28,2	43,9	43,5		73,6	96,5	137,5	
Austria	25,8	34,6	46,7	59,3	70,4	90,6	115	133,5
Belg. Luxem.	150	200	282,8	313,7	194	250	330	348
Canada					102	119	162	180
Denmark	78,5	110,6	124	141	51,5	69,8	92,5	94,6
Finland					45,8	55,3	69,8	78,8
France	308,3	439,3	502,1	635,1	194,3	273,9	309,2	341,6
Germ. Fed. Rep.	628,9	855,4	1035,9	1060,3	230	355,5	432,7	532
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
Japan					260,9	360,5	455,7	44,2
Netherlands	202,2	267	299,9	332	149,8	202,2	231	246
Norway					34,4	5o,3	64,4	73,1
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	109	163,8	216	215
USA	480,3	629,9	805,9	876,4				

Table 14. Pharmaceutical export and import in centrally planned countries from 1972 to 1975

Country	EXPORT				IMPORT			
	1972	1973	1974	1975	1972	1973	1974	1975
Bulgaria	54,1	64,2	68,3		31,9	40,8	62,4	
Czechoslovakia	41,7	48,6	54,3		27,1	40,2	45,2	
Germ. Dem. Rep.	52,7	49,6	60,9		35,5	46,5	61,2	
Hungary	176	194	225	266	28	42,7	52,7	63,8
Poland	110	128	136		56,7	68	99,7	
Romania	12,7	14,7			16,1	16,8		
Soviet Union		68	92	112		332,3	313	411,5

Source: see Table 12.

Table 15

Destination of pharmaceutical exports of major producers in 1973 (in million $-s)

Exporting country	Exports to						
	Western Europe	Eastern Europe	Canada U.S.A.	Latin America	Africa	Middle East	Asia
France	169	6,9	31,9	21,9	178	21,7	31,5
F.R.G.	493	19	37	80	47,6	44,4	117
Italy	141	6,6	19	26	15	18	39
Netherlands	181	6,3	11,6	27	11	9,6	18
Switzerland	358	12,5	29	46	32	37	69
U.K.	250	6,5	37	34	78	42	63
U.S.A.	256	4	56	124	18	28	123
Total in %	52,8	1,76	5,4	10,2	10,8	5,8	13,1

Source: U.N. ECE, Annual Bulletin of Export of Chem. Prod. 1973
New York 1975

II. MAIN VARIABLES - INFLUENCING THE DEVELOPMENT OF THE PHARMACEUTICAL INDUSTRY

After having a brief overview of the pharmaceutical industry's present and past situation it seems essential to list and discuss briefly some of the main variables — having a very definite influence on the general development of the industry.

These variables are generally mentioned when the industry's development is discussed at different fora because of their importance - either assisting or hindering development. It was not the intention of this Summary to search a full and complete analysis in relation to variables, but to indicate their importance with some major problems. Some of the variables - legislation, technological problems - are not mentioned here, but are discussed and analyzed in the study.

Investment

The pharmaceutical industry needs relatively less capital than the traditional heavy industry, and this fact, along with the social and health importance of the drug supply, urge the governments to give preference to the investments in the pharmaceutical section. The establishment of pharmaceutical plants is encouraged by the fact that the total of the investment costs of newly established pharmaceutical plants is usually recovered within a relatively short time, under favourable circumstances, based on the experiences in developed countries.

Investment in the pharmaceutical branch could be taken on one hand as an industrial objective which should be resolved just on economic and technical grounds, and should not be mixed with other (humanitarian etc.) objectives. If the industry is not economically sound it will only make things worse, as its products will cost more and its establishment will be largely a waste of limited resources that could be better spent on other purposes. However, by the other hand many - social, health, standard of living, life expectancy, care system etc. - aspects should be taken into account as well, when planning investment in this field.

The investment may be carried out at various levels :

I. Establishing formulation units and plants.
II. Establishing active ingredient manufacturing plants.
III. Establishing of local research and development facilities.

Within the first level we can distinguish small formulation units and formulation plants. The former may be connected to pharmacies where pills, coated pills, ointments and suppositaria may be prepared on a small scale, however in a sufficient quantity to provide a district with the most required pharmaceuticals.

The formulation plant may consist of larger units for preparing pills, coated pills, ointments, suppositaria and injections. The active ingredients can be imported, if not manufactured locally. The formulation plant should provide a smaller country or more preferably should meet the requirements of several neighbouring countries.

Within the second level the available capital and expected market should be decisive. It has to be decided whether a broad-spectrum factory or a highly specialized plant should be established. As a first step it is advisable to invest in specialized factories : e.g. where extraction is carried out on a large scale or fermantation procedures are introduced, or chemical synthesis is performed. The output should preferably cover the consumption of more than one country.

The conditions and requirements for moving from one level to the other are complex ones and are involving, besides the technological factors many others, like legislation, quality control, training, transport, distribution, packaging infrastructure, etc.

In connection with the location of plants the following aspects should be taken into consideration :

it is necessary to ensure

- sufficient amount of water of proper quality,
- electric and thermal energy,
- appropriately qualified workers and experts with higher education/qualification.

The planning and establishment of the research and development facilities may be started when the lower level establishments are well functioning and proper experience on management and operations were collected.

The cost of invesments for formulation units may be given as example as follows:

Small formulation machinery unit, probably attached to a pharmacy: machinery for producing pills and coated pills with a capacity of 350,000 pills/8 hours costs from $ 25,000 to $ 40,000.

Formulation machinery with a capacity of

2,4 million of pills/8 hours	costs from $300,000 to 400,000
60 thousand injections/8 hours) and 25 thousand vials/8 hours)	costs from $650,000 to 750,000
64 housand unit of solutions/8 hours /50% thereof syrups/	costs from $500,000 to 600,000
24 thousand units of ointments/8 hours /500 kg/	costs $150,000 to 250,000
30 thousand of suppositoria/8 hours	costs from $300,000 to 400,000
a packaging machinery unit for all the above products	costs from $300,000 to 400,000
Quality control facilities and equipped laboratory for above production	costs from $250,000 to 350,000

Land requirement for above formulation plant: 10-20,000 sq.meters

Construction costs : about $ 25 millions

Minimum yearly production of above formulation plant may be estimated as follows:

500 million of pills and coated pills	/ year
13 million injection	/ year
5,5 million vials	/year
10 million solution and syrups	/year
5 million units of ointments	/year
12 million of suppositoria	/year

Patents

An estimated two thirds of all drugs currently used in the world is free of patent protection as the duration of the respective patents has already expired. Thus the production of these drugs is not hindered by any legal obstacle. A major part of the essential drugs belong to this category, thus from a legal point of view their production may be started at any time in the developing countries.

The production of the remainder one third of drugs may be carried out on the basis of licences. By this way the transfer of know-how

can be ensured most satisfactorily.

The number of patents granted in developing countries is considerably lower than that issued in developed countries. Only a few hundred patents are granted per country in developing countries per year, whereas more than thousand or even several thousands are issued in each of the industrialized countries. The same proportion applies to pharmaceutical patents. The lack of invention activity is mainly due to the moderate research in developing countries.

In developing countries 80 - 90 per cent of the patents are owned by non-residents whilst only 60 - 70 per cent thereof belong to foreigners in the developed countries. The high percentage of foreign owned patents is due to the fact that the total of patentable inventions all over the world always exceeds the number of local discoveries.

No fundamental change in the figures concerning patents in developing countries may be expected before the research activity will have been increased there.

Article 5 of the Paris Convention is providing legislative measures to prevent abuses which might result from the exclusive rights of a patent. A compulsory licence may be granted when the invention has not been worked locally. This measure was not frequently applied in the past.

It is necessary to emphasize that the expression "working of the patent" in Article 5 of the Paris Convention means local manufacture only, and not importation or sale. However important the legal assurance of the local working of patents, this measure alone is not sufficient to build up an industry.

Asessing all that has been analyzed the conclusion is that the patent system itself may not be responsible for the unequal growth of pharmaceutical industry in developing countries. Furthermore it may be asserted that the patent system and a reform thereof could neither liquidate the existing unequalities nor help to overcome the insufficiency of the infrastructure.

Due to the unequality of industrial strength in various countries, the tendency and evolution of patent systems in the next decades may differ in the developed countries from that in the developing ones. As the present system proved to be efficient in the developed countries and is essential for the highly organized pharmaceutical industry to ensure research for future inventions, it will be maintained and sponsored in all those countries where this industry attained a high level (e.g. West-European countries an U.S.A.), furthermore it will be accepted and taken over by those countries which reached this level by increasing their production and research (e.g. Japan).

In the countries where no notable pharmaceutical research and manufacture has flourished sofar, the patent system has played a role of minor importance and the privilages deriving thereof will probably to be exposed to temporary restrictions and limitations. Considering the consequences of the above mentioned limitations, attention should be given to two different tendencies which may be observed in certain developing countries where patent protection has been limited in the pharmaceutical domain:

a) there are countries where the restriction of patent rights has resulted in the reduction of investment activity financed by foreigners;

b) there are countries where the limitations of patent rights has not caused the decrease of foreign financed investment, but the investment and its fair returns are assured by commercial agreements offering trade monopoly to the investor. Thus the function and role of patent righs (as import regulator by means of exclusive rights) are conferred to and replaced by commercial agreements.

We consider it most likely that future development will show the latter mentioned trend. Whilst the tendency mentioned under paragraph a) would induce negative effects influencing disadvantageously the pharmaceutical industry the phenomenon illustrated in paragraph b) could ensure the balanced increase of local industry in developing countries. An example of this evolution is offered by Brasil, where no patent protection is granted to pharmaceutical applications at all, however the foreign financed investments have been increased recently based on trade agreements. The future trend in developing countries may very probably be characterized by the combination of the regulating function of patents with trade agreements.

Research and development

On examining the composition of the world pharmaceutical production it is to be found that 75% of the present production consists of medicines completely unknown to public use 40 years ago, so it can be observed how rapid the development has been. 50-55% of the total production is of synthetic, 10-15% of fermentic whilst about 5 % is of human and veterinary origin, respectively.

The pharmaceutical research and development requires considerable expenses and large amount of time. The large-scale pharmaceutical factories spend 15-20% of their total turnover on research and development. A compound from laboratory level requires a number of years and expenses until it will be available in the pharmacy.

The intense specialization becomes more and more characteristic to the prospects of pharmaceutical research. Scientists could attain outstanding results by specializing on individual spheres such as polypeptides, molecular biological researches, immunology, etc. The trend of development shows a further specialization in these fields.

The development of pharmaceutical research could be characterized by strong concentration of material and intellectual powers.

Outstanding results can only be attained by the intense concentration of scientific, technical and economic resources.

Distribution patterns and market segments

In the industrial countries the margins are much higher than in developing countries, particularly at the wholesale level, but this higher profit assures more intensive coverage and service. In the F.R.G. for example the price buildup - taking 100 as the ex-factory price - is 110 - 117 at the distribution/wholesaler level and 140 - 151 at the pharmacist level. In France the wholesaler adds 11.78, the pharmacist 56.26 and taxes represent 11.78, so that the customer pays 180.02; In the U.K. the wholesaler adds 17.65, the pharmacist 58.83 so that the customer pays 176.48; In Italy the wholesaler adds 10.05, the pharmacist 36.01 and taxes represent 8.86, so that the customer pays 156.94; Finally in Switzerland the wholesalers add between 14.29 and 21.21 and the pharmacist 44.45 to 49.14 so that the customer pays 158.74 to 220.35

Distribution in developing countries can be divided into two marketing sectors : the private and the public.

In the private sector promotion is handled by people visiting periodically retail clients like doctors and pharmacies. While in industrialized countries distributors/wholesalers have developed extensive coverage and are able to deliver to the most remote areas of a country, in many developing countries there is no adequate distribution structure to cover the entire market.

The distributor's markup varies greatly in the developing world, ranging from 5 to 15 per cent. In Latin America it tends to be closer to the 15 per cent level, while in countries like India it generally hovers around the lower end of the range. It should be noted that many developing countries regulate markups. At the retail level, markups are around 25 per cent.

Distribution in the public sector in most of the larger developing countries is different from patterns in the private sector. The marketing effort is relatively simple. Sales to government agencies are usually handled on a competitive tender or bid basis and the central purchasing agency is then responsible for distribution to clinics, hospitals and other institutions in the public sector. Such public procurement results in lower costs of pharmaceuticals to the government, since the drug suppliers can pass on the substantial savings in promotional costs to the government. Also, bids are usually for large quantities, so the supplier can provide substantial discounts on quantity sales.

Another saving is in packaging. And, of course, the bidding is open - allowing the government to obtain the most competitive prices. On the other hand, these advantages have to be weighed against the expenses incurred by the agency in packaging and distributing the product, and the loss of the technical support which is obtained only through the active involvement of the pharmaceutical firm in the market.

Three alternatives could be taken into account for developing countries for handling distribution in the public sector.

- The Government is to set up their own distribution network to cover every region of the country. Large countries must be divided into regions, with depots both for warehousing and distribution established at strategic locations. Cost accounting procedures should be practiced to minimize overheads.

- To subcontract distribution to a private wholesaler on a cost - plus basis, with the profit negotiated at a mutually agreed percentage. This has interesting benefits for both the government and the wholesaler/distributor.

- Combination of government and contracted distribution. Under this system a private distributor/wholesaler would distribute government supplies in his territory and the government would be responsible for distribution where no such arrangement is currently available. This would result in considerable savings since the contractor could piggyback government distribution with his own operation.

Marketing

The world production of pharmaceuticals increases by about 8 - 10 per cent per year.

The marketing of finished drugs is a more complicated procedure than the marketing of many other types of products. On the average one trained man is required to visit on regular basis at least 200 - 250 physicians. He has to sell not only products but also their proper use. He must be able to acquire knowledge about the specific needs of the country.

The costing strictire of the pharmaceutical industry shows that the marketing costs vary between 10 - 15 per cent in developed countries.

Environmental pollution control.

The pharmaceutical industry is generally involved in the production of medicinal chemicals, biologicals, and botanicals having therapeutic value for humans and animals. This industry employs a vast array of complex processes, many of which are proprietary. Wastes from pharmaceutical operations are usually strong and concentrated, difficult to handle, and require some of the most complex and expensive treatment and control systems of any industry.

Major waste parameters of importance in the pharmaceutical industry include BOD*, toxicity, and nitrogen reduction. Other parameters include COD+, solids, pH, phosphorous, color, odor, and a wide array of trace metals.

The pharmaceutical industry can be conveniently divided into five categories having similar processes, waste disposal problems and waste treatment practices:

(1) Fermentation plants;
(2) Synthesized organic chemicals plants;
(3) Fermentation/Synthesized organic chemicals plants;
(4) Biologicals production plants;
(5) Drug mixing, formulation and preparation plants.

In the case of fermentation plants, spent fermentation beers can have a BOD value of greater than 35,000 mg/l. Synthesized chemical production wastes are also strong and can be inhibitory to biological treatment systems. Biological production wastes are strong and contain animal remains, culture media, pathogenic organisms, and sometimes toxic elements.

The pharmaceutical industry employs a wide variety of waste treatment and disposal methods. Activated sludge and trickling filters are most commonly used. Other treatment methods include anaerobic filters, spray irrigation, oxidation columns and deep well injection. More advanced waste treatment facilities at pharmaceutical plants nearly always consist of activated sludge and/or trickling filter processes deployed as multi stage systems. These systems are rather generally applicable to all types of pharmaceutical establishments.

Waste problems can often be significantly reduced by recovery of valuable solvents, recovery of selected waste streams, especially spent fermentation broth as animal feed, and through specific waste water reduction programmes instituted within the plant.

---

* Biochemical oxygen demand

+ Chemical oxygen demand

Four pharmaceutical companies presented specific information to UNIDO on costs of environmental management (all costs refer to 1977 US dollars). Three of these firms carried out waste water treatment utilizing the activated sludge process, the other used a trickling filter. The treatment efficiency generally ranged about 98% removal of BOD. The pollution control costs expressed as percentage of capital costs ranged from 4.5% to 8%. One firm reported pollution control costs as 1.35% of annual sales. Removal cost per lb. of BOD was generally in the range of $0.12 to $0.21 per lb.

One firm with good environmental practices has extensive fermentation, organic synthesis processing and chemical finishing and packaging facilities. Waste treatment is carried out utilizing the activated sludge process which provides a BOD reduction of greater than 99%. Waste streams high in ammonia are recovered for bulk fertilizer sales. The estimated replacement cost of existing pollution control facilities is about $15 million which represents approximately 8% of the cost of the plant. Based on new construction, the pollution control facilities would represent a range of 12% to 15% of the cost of the plant.

Annually, costs of the waste water treatment works are reported to be $1.2 million which is equivalent to $4.50 to $5.50 for each 1,000 gallons of process water treated. The removal cost for BOD is approximately $0.21 per lb. This company estimates overall environmental operating costs to be divided as 65% for water pollution control, 25% for air pollution control and 10% for disposal of solid wastes.

It is recommended that an environmental impact evaluation procedure should form part of the planning procedure for any new pharmaceutical plant. The purposes of evaluating environmental impact are two-fold:

(1) To prevent the deterioration of natural resources, such as the river which is to receive plant waste waters, so that these resources can continue to provide a basis for further economic development; and

(2) To give ample warning of deleterious side-effects of the projects, which may result in economic or social costs not normally identified in the project review procedure.

It is further recommended that developing countries should develop pollution control regulations. A problem specific to the developing countries when endeavouring to protect the environment through pollution regulations is a lack of experience. Never previously having had to face environmental problems due to industrial pollution, a large number of the developing countries have no specific regulations at hand. Such regulations are, however, indispensable to the contractor for the design of pollution control systems and should be in effect at the time the tender documents are sent out. It is recommended therefore that the ministries concerned, such as those of industry, health or development, should draw up the relevant regulations, referring as necessary to the experiences of other countries.

Resources:

Chemicals

By dealing with the establishment of the pharmaceutical industry on a large-scale basis it should be realized that large-scale operations are economic generally in the case when the number of effective consumers is more than 10 million.

Chemical substances which are used in the course of production represent 15 per cent of the production costs on the average, with the following distribution :

	percentage
Intermediates	about 9
Solvents	" 3
Organic chemicals	" 2
Packaging materials	" 1

The chemical substances which are used are mainly of petro-chemical origin.

Medicinal Plants

Medicinal plants represent an important raw material resource for a relatively wide scale of pharmaceutical products. Their importance is significant for the developing countries in establishing their own medicinal supply.

In order just to indicate the importance of this resource it should be realized that the world production of pharmaceuticals on the basis of medicinal plants amounts to more than 1 billion dollars per year and shows a constant growth. There are more than 120 different kinds of medicinal plant which are used at present in the pharmaceutical industry.

Among the many important problems which should be solved in order to arrive at an increased production based on these raw-materials in developing countries are the organized production and collection of medicinal plants, efforts for keeping the quality during storage and handling of the medicinal plants so to preserve their effective substance and avoid deterioration due to harmful substances or conditions.

The majority of the medicinal plants are utilized in the form of galenicals. Even relatively simply equipped laboratories are able to isolate active substances of the plants, which is an important fact.

Animal resources

Active substances of animal origin for drug production are derived from slaughterhouses, slaughtering and processing of mammals, such as cattle and pigs. The most essential requirement in this respect is that only organs of completely healthy animals may be processed and during the whole system of processing strict hygienic standards should be kept, which involves the existance of proper infrastructure for this operation.

Energy

It has to be taken into consideration that the energy costs can amount to about 6 - 11 per cent of the production costs, whilst these figures related to the active substance production can rise up to as much as 20 - 25 per cent.

As an indication, the power demand of a tablet producing factory with a capacity of 5 - 800 millions of tablets per year, requires 1 - 1.5 MEW energy.

Water

Water is one of the most vital and important elements of pharmaceutical production which should be taken care of both regarding the industrial and drinking water quality. Much about this problem can be seen in the part of this summary dealing with environmental problems.

Manpower

Another critical element of establishing pharmaceutical industry in developing countries is the availability and formation of proper manpower at every level, from floorshop up to the highest management, both of technical and economic nature.

Furthermore the pharmaceutical products distribution needs a proper health infrastructural system for the distribution of drugs, which includes pharmacies, hospitals, drug supply centres with adequately trained personnel, etc. All these questions will be handled in detail by the study.

III. THE PHARMACEUTICAL INDUSTRY IN THE YEARS 1985 AND 2000

Factors influencing the world pharmaceutical development up to 1985 and 2000

Due to continuing changes in the social, political, economic, technological and commercial environments the pharmaceutical industry will be operating in a fundamentally new world from now to 2000. Policy and decision makers in the future will not be faced solely with the past tasks which centred around discovering, financing, producing and marketing ethical drugs under relatively laissez faire conditions but with a set of societal variables in a highly controlled environment largely determined by government acting at the behest of, and as the guardian of, society.

This new set of operating conditions will have a significant impact on the strategies adopted by the actors in the pharmaceutical industry if they are to continue to function successfully in the future.

To have a better understanding and outlook of the development and world production and consumption in the future, a set of groups of variables should be noted and taken into account - but not in very details because of the rather limited possibilities of a summary.

Demographic factors

The population of the world will rise from 3.97 thousand million people of 1975 to 4.62 thousand million in 1985 and to 5.67 thousand million people in 2000 according to UN estimates. Life expectations are scheduled to grow of the world, also in the developing countries as a result of which the share of age-classes requiring drugs above the average will increase within the entire population. The share of city dwellers within the entire population is growing all over the world. This trend of the world demographic development will inevitably lead to an increase of drug consumption the precondition of which is the increase in the pharmaceutical production. The civilisation harms will be added too, even in the case the protection of the environment becomes more intensive and efficient.

Polit cal factors

- The right to health care and equal access are widely established as a major socio-political goal in the majority of the countries to meet social demands.
- The establishment of universal publ c health care systems and services.
- The objectives of public health care systems.
- Financial considerations will largely determine the extent of the provision of existing services and new services will be provided under socio-political directives.
- State acquisition of the drug distribution systems.
- Rationalization of drug supply and enforced concentration of indigenous companies by the state
- Reactions in developing countries against restrictive commercial practice.
- Concern of developed countries against over-consumption of drugs.

Social factors

- In the developing countries the share of population involved in the health service keeps on expanding and at the same time the level of health service is improving. In these countries spe ial attention is to be paid to the organization of health service.
- The supply of medicines of vital importance should be assured for the population which has been rendered possible on the basis of national lists of drugs.
- Consumerism remains a force in the industrialized countries, however, some restraint of consumer sovereignity is exercised in the areas of complex scientific evaluation and particularly in drug regulation.

Economic factors

- Medicine prices will be rising as research espenditures become more and more expensive but this could be seriously affected by government actions and long-range policies.

- The universal demand for quantitative and qualitative increases in the public provision of health care will continue and will probably outpace the ability of governments to finance demand.
- Economic necessity will impose an upper limit of GNP expenditure on health care and higher levels of government economic controls in both the public and private sectors of the economy will have considerable effect on the growth of capital and labour intensive public health care systems and their services.
- Best-buy economic policies by the public health care systems become the rule and these systems initiate a greater number of measures to control both prices and profits.
- Pressure on physician prescribing in both quantity and cost as well as promotional restraints will increase.
- Accessibility to profit and cost data to justify prices will become widespread.
- Raw material prices will continue to have a significant impact on overall operating costs

Technological factors

- A rate of new product innovation of between ten and twenty new chemical enitities per annum is maintained worldwide.
- Innovative activity becomes increasingly concentrated in the epidemiologically important states. Government funding, through state owned pharmaceutical companies and universities should increase for innovation in the epidemiologically less important states and in tropical medicine.
- Close linkage with medical research and discoveries.

Forecast of the world pharmaceutical industry up to 1985 and 2000

It could be noted from the previous paragraphs of this part of the summary that there are numerous factors influencing the development with strong inter-relations and interactions with effects to strengthen or weaken the role of individual factors. This fact makes tremendously difficult to develop a very precise and accurate forecast with a very high probability. However,

by indicating only some routes of development, an estimation of the future actions of the game could be deducted and imagined - based not only on one event but a series of interreaction caused ones.

Production

The production of the pharmaceutical industry in the coming decades is expected to increase. According to the former trends of development, it could be presumed that the production share of developing countries will increase from about 10 - 12 per cent at present to 22 - 24 per cent, surpassing the value of the world production in the year 1975. It should however be noted that further work is essential for developing the hypotheses for the future development of the pharmaceutical industry, with the aim of having a more realistic forecast for the years 1985 and 2000.

Share of domestic industry

The share of domestic industry will be increased in developing countries as indicated in Figure 1. It is estimated that the final share of domestic industry will vary between 50 and 60 per cent in the market economy countries, the remaining percentage will be produced by international companies in their local production facilities. The countries with centrally planned economy (nationalized industries) will keep their present share of domestic production.

Consumption

The expansion of world population among others is a major cause to lead to increase in consumption of pharmaceuticals. The level of per capita consumption will ultimately effect the production of pharmaceutical industry. Figure 2. indicates the relation between consumption versus world population. Some variations are elaborated assessing the effect of the consumption share as variables versus the number of world population.

Various levels are plotted on Figure 2. The main supposed levels are as follows:

level 1.	50 % of the population consume	$ 10 per capita yearly
level 2.	50 % " "	$ 50 "
level 2.	50%	10
	50%	60
level 3.	50%	10
	50%	100
level 4.	50%	10
	50%	150
level 5.	50%	10
	50%	200
level 6.	50%	5
	50%	50
level 7.	50%	5
	50%	100
level 8.	50%	20
	50%	60
level 9.	50%	20
	50%	100
level 10.	50%	20
	50%	150
level 11.	50%	25
	50%	100
level 12.	50%	25
	50%	150
level 13.	75%	10
	25%	50
level 14.	75%	10
	25%	60
level 15.	75%	10
	25%	100
level 16.	75%	10
	25%	150
level 17.	75%	10
	25%	200
level 18.	75%	5
	25%	50
level 19.	75%	5
	25%	100
level 20.	75%	20
	25%	60
level 21.	75%	20
	25%	100
level 22.	75%	20
	25%	150
level 23.	75%	25
	25%	100
level 24.	75%	25
	25%	150

As it may be seen from Figure 3 the following levels may be regarded as:

Unrealistically high and improbable: level 5, 12, 10, 4, 11, 17, 24

Unrealistically low: level 18, 13 and 14

The modest increase of living standard in developing countries will apply to level: 2, 14.

The unbalanced development in favour of developed countries will lead to levels: 3, 15, 16, 4, 5, (the latter two irrealistic)

The supported development in favour of developing countries will apply to levels: 8, 20, 21.

Catastrphes in the health conditions will justify levels: 23, 24, 11 and 12.

Developing of new pharmaceuticals will involve levels: 9, 21.

Improvements of sanitary conditions all over the world may introduce levels: 2, 15.

Increase of social care to broader strata of society will lead to increased drug consumption and levels: 9 and 10 (the latter irrealistic) may be applied.

Unbalanced increase of birth-rate in developing countries will involve levels: 6, 7, 19, and 18 (the latter irrealistic).

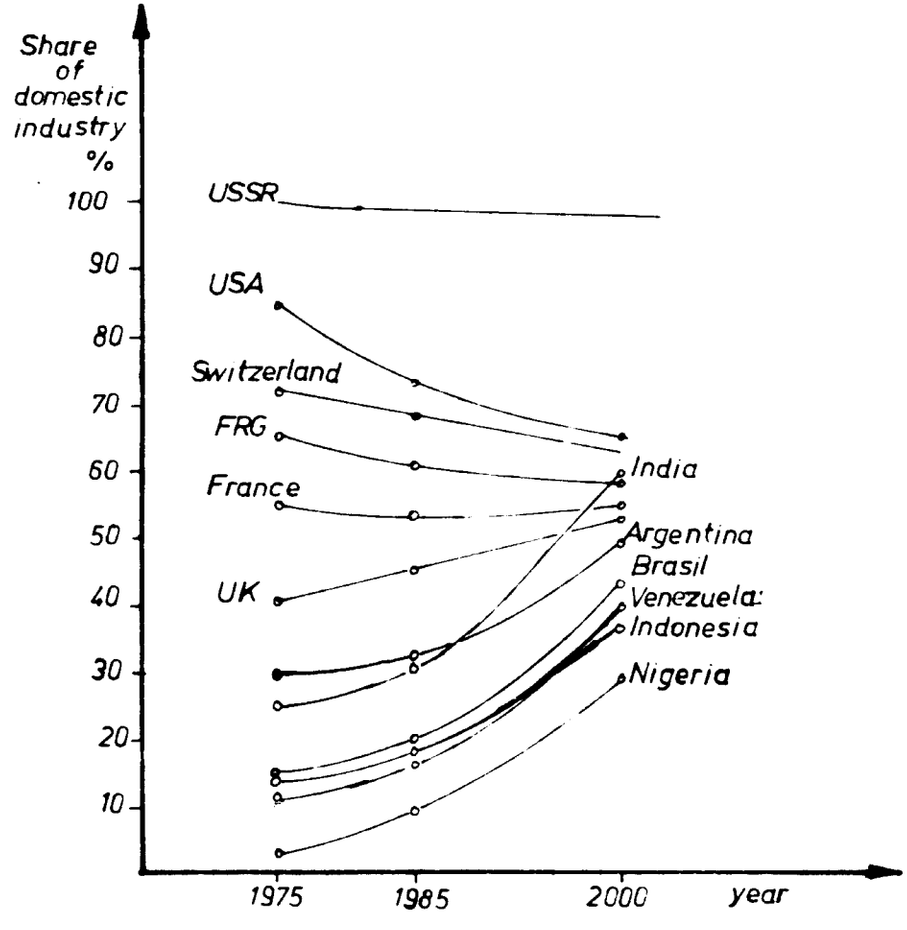
Research

The main efforts of the pharmaceutical research in the future will probably be directed to the following fields:

- diseases of the heart and the circulatory system
- rheumatic diseases
- infectious diseases
- psychical disturbances
- disturbances in the metabolism
- malignant tumors
- contraceptives

The above list can be completed with diagnostics, sera, vaccines and - without the demand of completeness - with numerous other groups/ prostagladines: peptide hormones, immunsupressives and immune stimulant agents: platelet aggregation inhibitors, agents influencing learning and memory, etc.

Figure 1.



Source: Pharm. ind. dyn and outlooks 1985
Stanford Res. Inst 1976

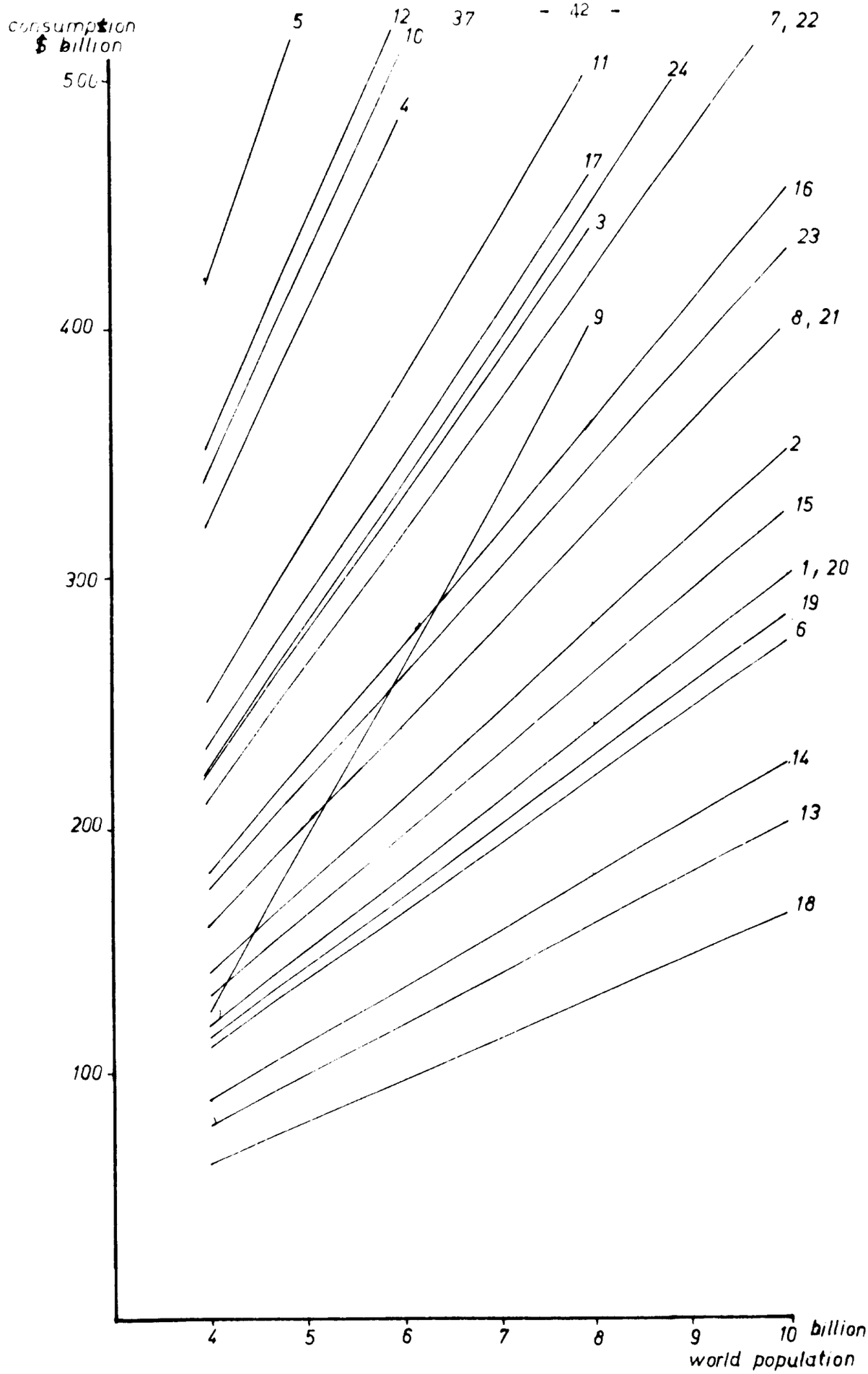

consumption
$ billion
500
400
300
200
100
4
5
6
7
8
9
10
billion
world population
5
12
10
4
11
24
7, 22
17
16
3
23
9
8, 21
2
15
1, 20
19
6
14
13
18

Figure 2.

IV. CONSTRAINTS, OPPORTUNITIES AND STRATEGIES

The major constraints in the development of the pharmaceutical industry may be classified as technical and economic. In the developed countries the major economic constraint is the need of an expansion of the market for pharmaceuticals in their domestic and overseas markets. In developing countries, however, the situation is much more complex and involves a wide variety of factors at all levels from the packaging, production of ready-made pharmaceuticals, through the different stages of processing, to the final market. The technical constraints in developed economies are those largely associated with new product development and new processing techniques. If a new pharmaceutical is developed in a laboratory, it needs 8 to 12 years till it is available in drugstores (due to toxicological and teratological, clinical trials, etc. tests and analysis). The costs of the research and developing of a new chemical entity amount to some $ 15 - 25 million in 1978 averages. Many of the developing countries, in contrast, face technical constraints in the implementation of comparatively well tested processing methods.

Production constraints.

Major production constraints in developing economies mainly arise from inadequacies in the traditions of the production - the different kinds of health care systems and forms of capital, for example. The effect of a lack of the capital, installing infrastructure, promoting research and training, and acquiring equipment is serious. The constraints apply to both the industry and the government. Developing countries generally have very limited capital resources to undertake investments and international loans, even at favourable interest rates, often only add to a growing debt burden.

The commercial initiatives of some multinational companies are politically sometimes unacceptable, and many developing countries are exercising restraint even in entering into joint ventures to overcome a shortage of capital. Capital shortage therefore remains a major constraint on the expansion of pharmaceutical production in most developing countries.

Technical constraints includes the lack of high economical capacity, the highly developed and organized forces of production, a high concentration of the scientific technical and economical forces. The big pharmaceutical companies assign 15 to 20 per cent of their income to research and development. Improved storage facilities, extension services and government priority for the sector are also important.

Production constraints are numerous, involving matters of regularity and quality of supplies, raw materials, intermediates, efficiency and availability of infrastructure, skills and entrepreneurial ability of manpower, managerial skills and, on a technical level, the adaptability of equipments.

Only when these constraints are satisfactorily overcome, can a factory expect to produce high quality products at minimum cost, and the manufacturer to compete successfully in the domestic and world markets. Although the market depends upon the quality and price of the product, there are additional constraints that can affect the functioning of the marketing system and can therefore reduce the effectiveness of any improvements made at the manufacturing level. Because of their complexity and widespread implications, marketing constraints are dealt with below at somewhat greater length.

Marketing constraints

Market constraints occur at both the domestic and international level. At the domestic level, demand for the pharmaceuticals, the price of its production and the marketing mechanism are all vital to the level of possible constraints.

The consumption of pharmaceuticals is very largely determined by the level of income, which, in the majority of developing countries, undoubtedly affects overall demand for these products adversely. Consequently, a rapid expansion of domestic markets for pharmaceuticals cannot be expected without a real increase in incomes and growth in the economy and health care system generally. It would be unrealistic to propose a significant expansion of pharmaceuticals for the domestic market, without a corresponding underlying growth tend in the economy

as a whole.

At the producer level there must be adequate economic incentives. In some countries producer prices have been allowed to stagnate, but the prices of ready-made pharmaceuticals are increasing, particularly those of new drugs (for the same therapy).

Connected to the problem of drug-store prices is the need for an effective marketing mechanism capable of distributing products from production areas to consumption areas with an efficient delivery system.

Strategies

The expansion of the pharmaceutical industry, or any part of it, requires a commitment on the part of governments, so to encourage such developments. Government policy in the form of a clear strategy with specific targets is a prerequisite for the industrial developments in developing countries.

It has already been pointed out that the main source of future demand for pharmaceuticals should come from the developing countries rather than from the developed ones; consequently there is substantial potential to be realized in the manufacture of these products in developing countries. This applies not only to the basic production of pharmaceuticals but to the whole health care system.

Although potential exists throughout the world, a great number of factors are involved, which were discussed earlier.

The final problem is strategies for the reduction of constraints in order to improve the performance of the developing countries. The choice of strategy depends on the degree of influence exercised by each actors in the pharmaceutical industry over the variables and constraints in the sector. As a final approximation it is convenient to define the actors as: Governments, enterprises, physicians and consumers, with the complex task of solving the research and development problems, the production of pharmaceuticals and the build-up of a national health care system in case of necessity.

The developing economies have a greater degree of control over their own internal industries and markets; an obvious strategy for them is to encourage the development of these industries and markets. Since the developed countries' markets for pharmaceuticals are expected to expand only relatively slowly, it will be difficult for producers from developing countries to increase their share of these markets. The developing countries have the difficult task of ensuring the long-term protection of their own developing industries. The situation should be seen as one not of conflict but of globally efficient allocation of resources.

If protection is to be eliminated and resources allocated efficiently, agreement is also needed among the developing countries themselves; with such a variaty of products spread over, agreements must be sustained, especially if there is any tendency for over-supply.

It is within a general framework of this nature that policies and strategies have to be evolved that will enable developing countries to realize their maximum industrial potential in pharmaceutical products up to the year 2000, in accordance with the Lima Declaration. It has been shown in the last two sections that there is great potential for the developing countries from now until the year 2000; and what major constraints are likely to prevent the realization of this potential, unless they are tackled. The strategies should therefore focus attention on the elimination of constraints.

Measures and strategies to eliminate constraints could include:

a) Measures to expand the capacity of pharmaceutical products industry in developing countries;

b) The unconditional use of bilateral and multilateral funds for developing the pharmaceutical industry in developing countries;

c) The provision of improved market information services to developing country producers of pharmaceutical products;

d) Improvement of the flow of information on technological trends and innovations in the pharmaceutical industry;

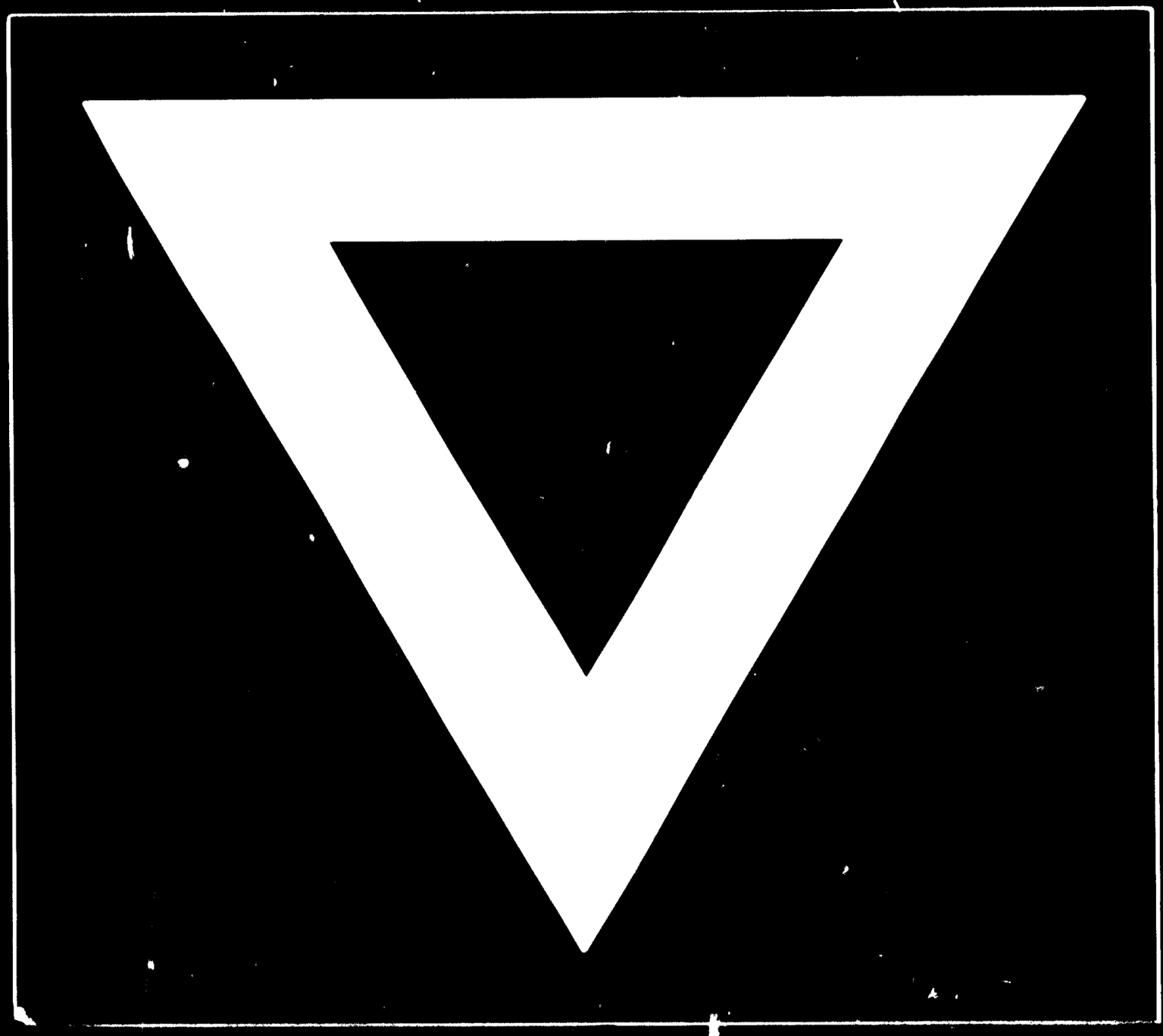
e) Agreement among developing countries on the best way to co-ordinate the interests of developing countries whose pharmaceutical industries are comparatively well advanced with those that are still at an early stage of development;

f) The establishment of means for increasing international co-operation in the promotion of the pharmaceutical industry.

It is also important that strategies should form part of a co-ordinated effort to improve the position of the developing countries and that their combined effect should be an integrated attack on the major constraints. This requires agreement on the implementation of the strategies not only between the developed and the developing countries, but also between the developed countries themselves and the developing countries themselves.

We regret that some of the pages in the microfiche copy of this report may not be up to the proper legibility standards, even though the best possible copy was used for preparing the master fiche.

C-665



78.11.06