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THE PHARMACEUTICAL INDUSTRIES
IN THE SECOND DEVELOPMENT DECADE ^{1/}

presented by
the Secretariat of UNIDO

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Introduction

1. This study presents a preliminary attempt to formulate suggestions and proposals on the goals and objectives in the field of pharmaceuticals manufacturing in the developing countries. Any international development strategy should be based on the techno-economic characteristics and morphology of the industry. Thus the static review will be complemented by a dynamic analysis, showing mainly that with the economic and social development of a country its pharmaceutical industry becomes a more and more integrated industrial sector of its own. The analysis demonstrates the great complexity of this industry sector and, therefore, that generalizations on the industry as a whole are no longer suitable, particularly with respect to setting priorities for the development of this sector in the developing countries. The performance approach analysis gives evidence that quality competition is a fundamental feature of the pharmaceutical industry. This cognition is of heavy consequences for the government policies to be adopted as well as for eventual technical assistance needs.
2. With this structural framework set, and with the knowledge of the basic trends in the industry, we try to define developmental stages of the pharmaceutical industry within the group of the developing countries. A quantitative forecast of the possible growth potentials in terms of production and demand in the developing countries provides the additional necessary basic information to come up with some selective conclusive recommendations for action.
3. Despite our efforts, this paper will need further elaboration. The time allotted and the means at our disposition were very limited. Nevertheless it is hoped that with this approach we have set a useful framework for further discussion and action.

A. CHARACTERISTICS OF THE INDUSTRY

1. The modern chemo-pharmaceutical industry is very different in its production structure than it was in earlier times. The processing of roots, leaves and barks has been largely superseded by the quantity production of highly complex chemical and biological products to the most exacting requirements of purity, stability and quality. The dosage form of a pharmaceutical product has become so important that in prescribing treatment the medical profession has now to give as much attention to the choice of the dosage form as to the basic drug itself.

2. Plant products in pharmaceutical manufacture represent today merely about 5 per cent of total industrial output, synthetics take the leading share with about 55 per cent and biologicals, antibiotics and other biochemical preparations the rest, with around 45 per cent.

3. The present day pharmaceutical industry emerged from such different origins as the chemist's shop, drug trade, tartar fabrication, dyes and heavy chemicals manufacture, facts which explain, to a large extent, its important structural differences throughout the developed countries and the developing world. Although the pharmaceutical manufacturers have become more and more an independent industrial branch, a large segment buys its starting materials - primary chemicals or intermediates - from other chemical or raw material producers. The industry is also closely linked to the chemical industries sector in the sense that similar research and development techniques are applied, similar skills needed and the production processes in operation based on related technology. The production of synthetic drugs requires thus, a corresponding development of the chemical industry, and it is therefore generally initially based on imported intermediate products, to be extended later into basic manufacturing stages in keeping with developments in the chemical and other chemical-based industries. The chemical industry itself is one of the most dynamic sectors in the pattern of modern industrial economies and shows on the average a growth rate markedly higher than the average annual growth of industrial production in general.

4. The average share attributed to pharmaceuticals production within the chemical sector as ascertained for the countries of the European Economic Community (EEC), Great Britain, Norway, Sweden, Poland, the Soviet Union (on the basis of estimated values), Japan and the United States was in the early 1960's between 10 and 11 per cent

the minimum share in the countries covered 2.5 per cent and the maximum share 13 per cent.^{1/} There is no general rule for the structure of the chemical industry which can be applied to all developing countries. Thus each country has to develop its pharmaceutical industry according to its specific local conditions and opportunities. Insofar as these countries have reached a certain degree of industrialisation, the share of pharmaceuticals is far above the average of industrialised countries, as can be seen from table 1. The reason for this may be found in the fact that the methods of production of pharmaceuticals, based on domestic medicinal herbs, as well as on imported basic pharmaceutical products and bulk drugs, are fairly well known in many of the developing countries and the sector supported by the governmental agencies and the large public, because of the paramount importance of the availability of pharmaceutical products for the improvement in public health and in medical treatment. It can be foreseen that this preponderance will decrease as industrialization progresses and the chemical sector becomes more balanced.

8. From the point of view of the dispersal among consumers, manufactured pharmaceutical preparations can be subdivided into three basic categories:

- (a) official drugs (standard products),
- (b) ethical drugs (ethical or medical specialities),
- (c) proprietary medicines (public specialities, household remedies, patent medicines, home remedies or also known as publicly advertised proprietaries).

9. Generally funds needed to discover, develop and market drugs varies greatly in the three groups, as well as the commercial policy pursued and the marketing methods prevailing. It is certainly easier for developing countries to establish a pharmaceutical factory based on botanical products, official drug preparations and to enter the proprietary field, which includes such products as analgesics,

^{1/} Cf. Sectoral Studies Prepared for the Symposium: Chemical Industry, Study presented by UNIDO at the International Symposium on Industrial Development, Athens, 29 November-20 December 1967. ID/CONF.1/25, UNIDO, 15 May 1967, pp.11 and 12.

Table 1

Shares attributed to the pharmaceutical industry production within the chemical sector in developing regions and countries in 1960, 1966 and 1967

	(percentages)		
	<u>1960</u>	<u>1966</u>	<u>1967</u>
World	10.8	11.5	11.6
Africa	0.5	3.6	3.6
Asia ^{1/}	13.9	18.5	18.1
India	(25.7)	(31.0)	(31.1)
Pakistan	(60.0)	(53.3)	(52.5)
Taiwan	(16.4)	(16.5)	(17.4)
Latin America	15.1	17.4	17.3
Argentina	(7.9)	(12.0)	(12.0)
Brazil	(12.8)	(14.7)	(14.2)
Colombia	(31.6)	(39.0)	(37.4)
Mexico	(19.8)	(19.3)	(19.6)
Peru	(21.4)	(24.0)	(23.8)
Venezuela	(16.7)	(20.8)	(20.0)

^{1/} Including Japan, which had the following shares: 1960 (11.9); 1966 (16.3); and 1967 (15.6).

Source: Chemische Industrie, Frankfurt/Main, vol.20, November 1968.

antiseptics, hair lotions, remedies for digestive troubles, laxatives and salts, suptics, cough preparations and vitamins, than to enter the ethical drug sector, which comprehends mainly the more sophisticated new discovered drugs, such as tranquilizers, sedatives, psychotonics, hormones, most of the antibiotics and the barbiturics. Barriers to the transfer of technology and technical know-how appears for comprehensible reasons particularly strong in the ethical drug field, but entry difficulties vary also greatly in this product line according to the specific technology required in the different therapeutic categories.

10. The variety of products manufactured by the drug industry is extremely great and product differentiation is one of the main characteristics of the pharmaceutical markets. It has been estimated that, taking into account the various presentations of each product, there existed approximately 140,000 drugs on the United States market in 1956, 90 per cent of which did not exist twenty-five years previously.^{1/}

11. Practically all the important drugs marketed since the war are protected by patents and trade marks. In the mid 1960s, approximately 90 per cent of prescriptions written in the United States were using brand names,^{2/} although more than 2,500 drugs sold on prescription could be obtained under their generic name. The much debated official (also called "generic" or "nonproprietary") versus unofficial (also called "brand", "trade", or "proprietary") name controversy remains unsolved. Impartial expert guidance on this touchy issue would be particularly welcome to developing countries. The presentation of the problem is most of the time biased by political purposes. In fact the question is a more complex one than generally thought, as prices, quality, safety, public control, advertising practices and pressure groups are involved.

12. The pattern of progress in the pharmaceutical industry is marked by high rates of invention, innovation and imitation. The research undertaken within the industry

1/ Cf. Clinical Pharmacology and Therapeutics, St. Louis, Missouri, January/February 1961.

2/ F-D-C Reports, Washington, 5 September 1966.

is connected to a large extent with the testing of promising compounds for desirable therapeutic properties. But the most important share is associated with the introduction of new products. Many of these activities are concerned with bridging the gap between the original discovery, which frequently takes place extra muros, and placing a finished product on the market. Much of the remaining effort is devoted to introduction of minor advances and adaptations which are necessary if total exploitation of a new technology is to be achieved. Industrial research and development activities is concerned mainly with different tasks than academic research, and plays what might be designated as a complementary role. Nevertheless the expenses incurred by industrial research are substantial. Thus, the biggest pharmaceutical company in the world is said to reinvest a varying amount of between 18 and 26 per cent of the group turnover.^{1/}

13. Large enterprises tend to go in for research and development to a much greater extent than small and medium-sized enterprises. Practically all the big laboratories carry on research and development work on a considerable scale, but as enterprises become smaller, the less they spend on research. Less clearly marked is the trend, among the enterprises engaging in these operations, for the large enterprises to spend, necessarily, more on research and development in proportion to their turnover than the small, and above all the medium-sized, enterprises. Many laboratories support and encourage also academic research, besides their applied research programmes.

14. It should in addition be noted that in the proprietary medicines sector, research expenditure is much smaller, although it has increased over the last few years. Mention should also be made of the very high risks encountered in this industry. The average time necessary for the development of a new therapeutically effective compound is estimated by industry at about 58,000 working hours. This corresponds to approximately 19 years of work done by one scientist. Considering the fact that nowadays research and development is done in team work almost everywhere in the world, the time necessary for the development of an economically successfully and medicinally effective product is still three to six years.^{2/}

^{1/} Chemische Industrie International, Frankfurt/Main, 4/1968.

^{2/} Hearings on Administered Prices in the Drug Industry, U.S. Senate, Subcommittee on Antitrust and Monopoly, 86th Congress, 2nd Session, Washington, D.C., 1960, p. 10724.

Product obsolescence on the other hand constitutes a heavy risk not only from the commercial point of view, but also because it may sometimes quickly render obsolete large-scale production installations.

15. Finally it should be noted that pharmaceutical processing calls for high-precision machinery and equipment of great complexity, e.g. ampoule filling machines, capsule filling machines, tablet making and coating machines.

B. Morphology of the pharmaceutical industry

16. In the light of the basic characteristics of the pharmaceutical industry - that is to say, the complex production structure which has evolved historically, the variety of technological processes, the research and promotion intensivities, the scientific, economic and market risks involved and the differences in capital requirements as well as the very specific juridical institutions developed - it is understandable that the size of pharmaceutical companies, both in the developed countries and those in the process of industrialization, varies considerably, ranging from small enterprises with only a few employees and annual sales totalling a few hundred thousand dollars, to large firms with a turnover of several million dollars and thousands of employees. The structural differences between very small and very large companies are so great that it is difficult, in many respects, to regard them as belonging to the same family; and these differences are likely to become so marked in the future that it will no longer be possible to view all these concerns from the same angle. Observations made with the help of methods borrowed from disciplines other than economics provide data differing in nature: economic facts, certainly, but also sociological, psychological and other facts which are not immediately and directly transferable into purely economic categories. In other words, economic analysis would be distorted by any theory attempting to establish economic relationships between categories that are heterogeneous or different in nature: economic, sociological, psychological, statistical, etc.

17. In view of the importance of competition and economies of scale in matters of production and operation, it is conceivable that there might be a minimum size for a laboratory, but one can speak of an optimum size only in the case of firms that are incapable of adapting the marginal structure of their organization to the needs of larger-scale transactions. As for the giants of the industry, their structure is so complex and their fields of activity are so vast that the various

influencing factors overlap and rule out any possibility of simple relationships. Consequently the elaboration of hypotheses should avoid confusion between over-simplified statistical presentation and genuine economic categories. Admittedly, empirical analysis has the disadvantage of being unable to isolate the various influencing factors satisfactorily; and this is particularly true regarding the effect of the size of enterprises and, to some extent, the form of the market, which will be discussed further on.

Typology of the industry

18. A working knowledge of the structure of the drug industry in its present state of evolution will facilitate the study of trends in the industry and their effect on the establishment or expansion of pharmaceutical manufacturing units in the developing countries by making it possible to focus on critical points of reference rather than taking a vague overall view. With the increasing complexity of the sector over the last few decades, generalizations on the industry as a whole may no longer be valid, let alone be of any help in drawing pertinent conclusions and recommendations with respect to developing countries. By examining these trends as they apply to the structural segments of the pharmaceutical industry, we are in a better position to evaluate the changes that have taken place and detect possible future features.

19. Thus the present day pharmaceutical industry can be defined in a number of interrelated ways, each of which are independently valuable for further analysis: sales volume, product areas, levels of operations, scope of the firm, and ownership.

20. From the technological point of view the organization, by positions, in the sequence of manufacturing and distribution or rather levels of operations is most important and is as follows:

- (a) Manufacturers of basic pharmaceutical products, which can be subdivided into the two sub-branches:
 - (i) biological product manufacturers and
 - (ii) medicinal chemical manufacturers;
- (b) Bulk drug manufacturers;
- (c) Dosage formulators, including the so called private formula manufacturers or custom manufacturers; and
- (d) Packagers.

21. This typology may appear somewhat academic in the sense that, for instance, a biological manufacturing group may be involved on a secondary basis in the production of veterinary preparations and a varying percentage of biological substances for human medicine are generally produced by the manufacturers of pharmaceuticals as secondary products. However it will be very useful for identifying the developmental stages of the pharmaceutical industry in the developing countries.
22. The companies engaged in all steps one through four are fully integrated producers. As in the pharmaceutical field no manufacturer is fully integrated in respect of all its products, one should speak of integration in this sector in terms of individual products only. The number of producers integrated for most of their products is small in the developed countries and even smaller in developing countries. From a producer's point of view, firms are very often partially integrated, e.g. a company may be integrated back to step two for antibiotics but may have to purchase bulk vitamins for formulation. In reality this extends down even to individual pharmaceutical preparations within the broader therapeutic fields; and that being the case even small laboratories are frequently fully integrated with respect to their specialities. An intricate production pattern exists in fact in this industry.
23. It should be particularly stressed that the extent to which manufacture of basic drugs from primary raw materials can be undertaken depends also on the state of development of chemical industries in a country. Where the chemical industry itself is not adequately developed, it has been virtually impossible for the pharmaceutical industry to switch over to basic stages of manufacture.^{1/}
24. As the therapeutic efficacy of pharmaceutical preparations is limited not only with the pharmacological activity of the basic drug, but also with the properties of the dosage form in which they are administered, the third step has become a very

^{1/} See A Sectoral Study on the Pharmaceutical Industry, document prepared by a Group of Experts for the Asian Conference on Industrialization, held at Manila, Philippines, from 6 to 20 December 1965, under the sponsorship of ECAFE with the co-operation of the United Nations Centre for Industrial Development (UNIDO), E/CONF.54/R.B.P./2, United Nations, New York, 1966, p.472.

important aspect of the industry. Quite often, the auxiliary ingredients used in formulation also profoundly modify the onset, intensity and duration of the physiological response, and the stability of the active ingredient. In certain preparations, even the particle size of the drug is important in determining the rate of absorption and hence its therapeutic effect.

25. In connexion with the structural organization of the industry and particularly with the levels of integration, it is also interesting to mention the scope of the pharmaceutical firms. No company nowadays can conduct research or manufacture in all the product fields. In fact, depending on the range of pharmaceutical products sold, both in numbers and diversity of product fields, the laboratories can be roughly classified into long line houses (carrying from about five hundred to several thousand products covering virtually every therapeutic field) and, at the other extreme, the speciality houses (concentrating all their energies on the manufacture of a relatively small line of related products), and the modified full line houses, attempting to combine the advantages of the two beforementioned categories.

26. With respect to the developing countries a distinction by types of ownership of the manufacturing units would certainly contribute to the proper evaluation of future trends and prospects in this industry. For such an analysis the following five categories are proposed: domestic privately owned firms, domestic publicly owned firms, domestic subsidiaries or divisions of domestic firms, domestic subsidiaries of foreign-owned firms, and ventures of mixed ownership.

The performance of the industry

27. In its structural organization the pharmaceutical industry is essentially oligopolistic and heterogeneous. Compared with the automobile, steel, aluminium and electrical equipment industries, it does not seem to be heavily concentrated; however, in the case of such specialities as the steroid hormones used in the treatment of rheumatoid arthritis there may be a high degree of concentration and a few large firms may dominate the market.

28. In fact economic concentration varies greatly from country to country, as well as between therapeutic categories and individual pharmaceutical preparations. This is partly the result of the different origins of the pharmaceutical sector and also

of the penetration of this branch of industry by the giants of heavy chemistry, which is due mainly to the degree of interdependence between the widely differing branches of the chemical industry. Some of these enterprises simultaneously cover several branches of para-chemistry

29. Nevertheless, there is also a fairly strong medium-sized industry. We find that even in the case of a highly developed industry, which engages in costly research, a certain degree of decentralization is by no means impossible and that even in an industry of that kind small and medium-sized enterprises can find a place and keep it. Indeed small and medium-sized firms have an important part to play in the operation of the competitive system, since the supply firms that smaller can help to fill any gaps there may be in the supply from larger enterprises. They also make a vital contribution towards satisfying customer needs. Besides, they serve to stimulate the larger enterprises which dominate the market.

30. Usually, the only small firms in the industry only do a maximum amount of research to produce numerous new variations or analogous substitute products. Consequently, in the case of such work products, the market takes the form of polypositional competition.

31. Production of basic chemicals has increased in volume of capacity since have expanded. As a result of the large number of chemicals used in the chemical-pharmaceutical industry, several thousand, various manufacturing processes have taken to specialization. The implementation of the programme for the manufacture of basic substances depends both on the programme for further processing of the basic product and on the raw materials that are available to enterprises. In the one hand, specialization has led to a more rational manufacturing process for the various chemical intermediates and, on the other hand, has increased the number of competitors. Generally speaking, the markets for chemicals have the form of oligopolies and partial oligopolies. Because of the heterogeneity of the various

Essentially same relations, general conditions, probably advanced programmatic and standard products as described and clearly defined in such recognized authoritative product lists as the National Pharmaceutical, the International Pharmaceutical, National Pharmaceutical of London

pharmaceutical chemical products, we thus find perfect markets in which firms often try to establish monopolistic positions in the form of concerted action, agreements or collective monopolies. On the whole, the distribution of the market or partial market among the members of the pharmaceutical industry is based not so much on price competition as on product competition (creative competition when entirely new products are introduced; imitative or duplicative competition when it consists of alterations to existing products) and/or on promotional competition and on competition in general sales efforts (distributional competition).

12. Differences and changes in quality may constitute either competing points or monopoly factors, insofar as substitution is practicable, and where it is not possible competitors are driven to make up for the quality lag by new technical or aesthetic features in their line of products. Quality competition will thus fulfill certain functions that cannot be undertaken by price competition. As a result, entrepreneurs observe the qualities of things that best meet the wishes of consumers. Quality competition reduces to a minimum the danger that products cannot be put to the uses for which they are intended. It increases the choice open to buyers and ensures that the varieties demanded by consumers will be manufactured. It is often hard to judge which of two or more different products is the best, and frequently it is even necessary to carry out complicated tests; but, basically, quality competition fulfills the same function as price competition. However the price is too high for a thing to be, in other words, if the quality of the product is low, the price will be high. Manufacturers must bring their side into line with the market and make their goods more attractive. For this reason quality competition and price competition bring about behavior that results in the production of generally high quality. The position of an enterprise in a market with varying prices and with fairly variable quality, seems to be similar to the position of an enterprise in a market with constant quality but with stable prices. Therefore quality competition has not necessarily led to such a large number of competitors as effective price competition.

13. In regard to promotional competition in the pharmaceutical field, publicity in a product can be in a supporting position or a monopoly position. If a pharmaceutical enterprise is concerned as an individual with publicity, publicity should clearly seem to support sales and market expansion, through its performance in the part of promotional efforts are concerned for established drugs and, consequently, the

demand curve confronting this enterprise become less elastic. Nevertheless, the end effect of informative publicity, that is not misleading, seems rather to stimulate competition in the entire branch of the industry. If it is really informative and restrained, publicity makes it easier for the doctor or direct consumer to compare qualities. It thus makes quality competition more keen, provides a better overall view of the market situation, draws attention to existing alternatives or differences in quality, etc.

M. Insofar as the price element is active - it is for most drug products kept constant and the case considered presently is more of an exception - the main pressure derives from the competitive development of similar products or of improved production techniques enabling competitors to reduce the price in order to win over a larger share of the market which originally belonged to the first manufacturer of a particular product. These circumstances tend to result in a price structure somewhat different from that prevailing in other industries, at least superficially. The initial phases are the same: as high a price as possible at the start, determined on the basis of an assessment of demand by the innovating firm, and taking into account the substitutes already on the market and their prices. After the initial price has been applied for a certain period, the launching or improvement of competing products bring down the price to a second level, at which it often remains, rather than continuing to decrease, unless the article becomes highly popular.¹ The typical course of events is for the product to be replaced by another with decisively better properties. Here, the techniques of sudden price reductions which are traditional in some industries, have no effect. The consumer is generally not interested in an inferior product, whatever the price, except on certain fringes of the market. The manufacturer thus has no interest in reducing prices, as he cannot expect to increase his sales through such a measure. However, this price rigidity is not simply the result of monopoly factors, but rather a consequence of the total indifference of the consumer towards

¹ There does not usually exist an elastic demand for pharmaceutical products in response to the change in the price structure - that is to say, markets expand very little as a result of a given price reduction, simply owing to the fact that the consumption of pharmaceutical products has a ceiling which depends less on price limits than on the incidence of the disease concerned and the dose prescribed according to medical practice.

the product owing to the existence of superior substitutes. The manufacturer can maintain his price as long as he wishes, but as long as his competitors continue to innovate he will have very little success in selling his product. If he is to compete, he must develop and launch new products himself. However, it is possible for new trade names to be introduced simply in order to avoid reductions of prices on existing products. This type of price competition ("quasi-price competition") is frequently used as a way of evading direct price competition. Differentiation in quality often makes such situations accepted in practice, since it creates an artificial fog of uncertainty behind which even moderate price differences can develop and continue.

Some trends in structural organization

35. Under the impetus of the many complex factors described partially above influencing the manufacture of pharmaceutical products, the industry is undergoing considerable changes. Although it will take some time before the new shape of the pharmaceutical industry clearly emerges, some salient trends can be discerned; the following are the most pertinent of these.
36. The trend towards economic concentration is particularly marked in the pharmaceutical industry. The strength of certain dominant groups must not lead one to forget the small size of this industry as a whole not only in most developing countries but also in many relatively industrialized countries. In most African, Asian and Latin American countries, and even in several developed countries, the concentration process at production and sales levels (control of the market) is only beginning in the pharmaceutical industry. The largest pharmaceutical laboratories in many countries are not yet big enough to take full advantage of the opportunities for continued research and discovery, therefore new forms of enterprise are required.
37. The great prestige of the large concern rests on its ability to explore, to experiment and to innovate. This ability, together with the market position, supported constantly by advertising, gives rise to many of its economies in expansion.
38. Large companies can move into fields where entry is difficult for smaller laboratories. They will tend to avoid products where gross profit margins are

too low to cover the long-range investment, research and development programmes, expensive advertising and other overhead costs that characterize their operations. Many of the profitable opportunities for diversification will bring the large companies into competition with each other; to the extent that proprietary drug houses move into ethical drugs, ethical products manufacturers into cosmetics, pesticides, insecticides, and hospital equipment, producers of household remedies into non-drug product lines and products for industrial and commercial use, etc., branch or product concentration may be reduced without any reduction in the concentration of the sector as a whole.

39. In earlier days every level in the industry was basically a segmented entity which did not compete with any other level, the exception being the dosage formulators and packagers. The industry was structured, from the viewpoint of levels, along fairly established lines. The advent of the profitable ethical drug era has given rise to a new process. A number of the established chemical process industries realized the opportunity that existed to utilize their specialized skills and the patents they were able to obtain to integrate into the more profitable dosage formulation and merchandizing levels of the pharmaceutical industry. Other companies integrated only as far as the manufacture of bulk drugs was concerned. This forward integration by the chemical-process industries has in turn brought about a defensive backward integration by many of the dosage formulators and packagers, in an attempt to get better control over raw materials and bulk drugs. Recognizing more and more the importance of economies of size and economies of growth, these companies are increasingly resorting to horizontal and vertical integration as well as product and geographical diversification, in such a way as to change the structural organization of the chemico-pharmaceutical sector.

40. Looking at the structural trends from the point of view of the scope of activities classification, mentioned in the section on industry typology, it may be noted that the full line and speciality houses are inclined to grow together towards the middle ground of the modified full-line manufacturing firm. This can partly be explained by the fact that the big full-line companies are almost as vulnerable to product obsolescence for the most profitable sales items as a speciality house. At the same time as the full-line houses are getting rid of unprofitable products and are paring their product lines down to more manageable size, the speciality manufacturers are tending to diversify their product base by adding new products

and product lines. They are obtaining these new items through their own research efforts, by purchasing the products from other companies, by acquiring licences and through mergers and acquisitions.

41. It should also be mentioned that these trends are reinforced with the introduction in many countries of new pharmaceutical laws requiring stricter control measures with regard to clinical experimentation and the manufacture of drugs. Such changes are generally unfavourable to small enterprises.

42. In view of all these forces the large international companies engaged in pharmaceutical manufacture will become even stronger and compete in more product markets and more countries (geographical diversification). The continuing process of product variation, differentiation and improvement will further tend to increase excess productive capacity in certain product categories, rise further the costs of pharmaceutical selling, "detailing" and sales training, increase research and innovational expenditures and intensify publicity in support of pharmaceutical preparations already placed on the market.

C. Developmental stages of the pharmaceutical industry within the group of the developing countries

43. The unequal distribution of world industrial output is repeated within the group of the developing countries. Unfortunately no systematic study in these discrepancies has so far been undertaken. It can, however, be roughly estimated that in 1967 three of the developing countries manufactured approximately 50 per cent of the pharmaceutical production output of the developing world, six developing countries shared the 20 per cent and nine had about 30 per cent of the total drug manufacturing operations in developing regions.

44. To catch these aspects of structural differences, it is convenient to define distinct stages of industrialization regarding the pharmaceutical sector in developing countries. These stages are not related to income levels since even the market size is larger countries favour a number of more, higher technological and diversified levels which are often partly far from income levels. Thus larger populations are substitutes for higher incomes in creating broad markets for chemical and pharmaceutical products.

45. While the borderline between the different country groups cannot be drawn sharply, we may nevertheless distinguish the following five developmental stages:

- Stage 1: Developing countries with no pharmaceutical product manufacturing.
- Stage 2: Developing countries whose pharmaceutical industry is in an early stage (engaged in packaging and dosage formulation).
- Stage 3: Developing countries with a well-established pharmaceutical sector aiming at a certain level of backward integration for, at least, certain product lines (engaged in bulk drug manufacture).
- Stage 4: Developing countries having reached a high level of self-sufficiency, oriented towards full integration at least for the main sectors of the pharmaceutical industry (starting the development of medicinal chemical manufacture).
- Stage 5: Countries with a well established pharmaceutical industry.

In the following paragraphs the countries will be identified according to this general broad classification and the groups described in more differentiated terms.

First Group of Developing Countries

46. This first group, representing developing countries without a manufacturing pharmacy sector at all, includes small countries in Africa, Asia and Latin America, mostly engaged in traditional agricultural activities with a sizable subsistence or non-market sector, both low total population and income per head, and inferior trade and communications. Public health measures to get rid of the epidemics have generally been adopted, but the widespread extension of medical facilities to private persons is still lacking. Although these countries are meeting practically all their basic medical requirements through imports in the form of final products from foreign countries, some of them may export large quantities of crude drugs, which for this purpose have at times undergone some industrial processing.

The most important recommendation that is expected to take place during the life of these countries is the extension of medical services, requiring building hospitals, training national pharmaceuticals and para-medical personnel and ensuring that these services are also available to rural areas.

47. Some group countries, still in this "pre-take-off" period are Singapore, Maldives, Mauritius, Mauritania, the Republic of Indonesia, British Honduras,

Brunei, Burundi, Cameroon, the Central African Republic, Chad, the Republic of Congo (Brazzaville), Cyprus, Dahomey, Gabon, Gambia, Guyana, Haiti, the Ivory Coast,^{1/} Kuwait, the Leeward and Windward Islands country group, Lesotho, Lybia, Madagascar, Mali, Malta, Mauritania, Mauritius, the Netherlands Antilles, Nigeria, Saudi Arabia, Sierra Leone, Somalia, the People's Republic of Southern Yemen, Surinam, Swaziland, the Syrian Arab Republic, the United Republic of Tanzania, the Republic of Tchad, Togo, Trinidad and Tobago, Uganda, Upper Volta, Western Samoa and the Yemen Arab Republic. Some of these countries may have some artisanal pharmaceutical compounding. In the further elaboration of this study it will be needed to come to a somewhat more detailed classification, separating for instance countries which should definitely abstain from entering the second developmental stage as defined above, at least for the next decenniad. Out of this large group of countries less than one fourth are expected to be in a position to enter the second group during the Second Development Decade.

Second Group of developing countries

49. The Second Group of countries, having started the industrialization process and reached the early stage of developing their own pharmaceutical industries, have generally also entered the two medical stages of development, e.g. adoption of public health and creation of medical facilities, with a certain success. In these countries between 40 to 75 per cent of pharmaceutical products are used in the hospitals or public dispensaries. The consumption of drugs and medicines is still very low, when compared with developed countries. This group of countries - including Algeria, Bolivia, Bulgaria, Burma, Cambodia, Ceylon, the Democratic Republic of Congo (Kinshasa), Costa Rica, Cuba, the Dominican Republic, El Salvador, Ecuador, Ethiopia, Ghana, Guatemala, Guinea,^{*2/} Honduras, Indonesia, Iran, Iraq, Jamaica, Jordan, Kenya, Laos, Lebanon, Liberia*, Malawi*, Mongolia, Morocco, Nepal, Niger*, Nicaragua, Panama, Paraguay, Rwanda, Senegal*, Sudan, Thailand, Tunisia, Turkey, Uruguay, the Republic of Viet-Nam and the Republic of Zambia - are

^{1/} The country has a quinine factory only.

^{2/} The countries marked with an asteric are only at the very beginning of organizing an indigenous pharmaceutical industry (very often with foreign private aid).

aiming at a certain degree of import substitution, particularly in the field of final dosage pharmaceutical products and mainly oriented towards a self-sufficient domestic market. The local production programmes include, with a few exceptions, essentially compounding of simple galenical medicines, diluting concentrated extracts to marketable strengths for the retail trade, and proprietary medicines and is generally very limited. This stage covers the industrial entrance in the marketing steps of pharmaceutical products manufacture, that is to say packaging and marketing purchased dosage forms and in many instances processing of imported bulk drugs into the final pharmaceutical preparations such as tablets, capsules, tinctures and liniments.

50. Dosage formulation is instrumental in stimulating the growth of the technical skills that eventually permit, at a later period, the start of bulk and pharmaceutical chemical manufacture. The operation levels under consideration for this group appear basically to be of a labour-intensive nature (hand labour for auxiliary operations such as moving materials, feeding machines and packaging) and uses relatively modest amounts of capital. Nevertheless the technological processes involved and the safety measures, as generally defined by the drug laws for manufacturing and marketing pharmaceutical preparations, require already a limited nucleus of high-skilled labour. Thus the dynamic role such projects may play is not necessarily restricted to the progressive upgrading of techniques and broadening of product lines within the sector. It may also have a stimulating effect on other sectors of the economy which will be reflected in the third and fourth developmental stages. Better use of local raw materials, including medicinal plants, better organization of slaughterhouses (cold storage methods, etc.), expansion of maintenance and repair work skills, improvement of effluent disposals, entrance into the agro-chemicals sector, establishment of auxiliary industries such as glass fabrication for packaging and other industrial ventures, may possibly result from the entrance into the pharmaceutical manufacturing industry. Thus technical assistance expenditures in developing countries at the starting stages of packaging and dosage formulation ventures are likely to have a certain leverage effect in terms of the development of the industrial sector as a whole.

51. From a structural point of view the industry consists at this stage of operations basically of artisan workshops, small and medium factories often built

with public funds or foreign capital. Five to 50 per cent of the local consumed pharmaceutical preparations are processed at least at the operational levels of packaging and/or dosage formulation within the country. An appropriate task for the Second Development Decade would be to lead at least one third of the countries mentioned under this group to the third stage by the end of the decenniad.

Third Group of developing countries

52. As development proceeds, import substitution on a larger basis takes place and the organization of exports based on an expanding home market - oriented mainly towards the satisfaction of sub-regional and/or regional markets in the developing regions - might slowly take shape. Pharmaceutical manufacturing is based mainly on the use of foreign patents and know-how. Yet due to the high level of specialization, the partially very sophisticated technological processes used and industrial property rights in force within the pharmaceutical sector, these countries cannot expect generally at this stage to eliminate altogether a net deficit in the pharmaceutical commercial balance, unless they reach a very high level of production and exportation. At this stage the countries - namely Chile, China (Taiwan), Columbia, Greece, Hong Kong, Israel, Republic of Korea, Malaysia, Pakistan, Peru, Philippines, Poland, Rhodesia, Portugal, Rumania, Singapore, Venezuela and Yugoslavia - may already manufacture locally several hundred pharmaceutical products and employ hundreds of persons in the pharmaceutical sector. They will be inclined to reach a certain level of backward integration producing the active principles from imported intermediates (bulk drug manufacture). According to local conditions, from downstream upwards certain manufacturing chemists will try to integrate in the dosage formulation and merchandising levels of the industry. Co-operation with international companies in the form of patent industrial know-how and licensing agreements, the use of trade marks, as well as technical assistance and common ventures or even building up of research institutions is, in many countries of this group, quite strong. Most important, the quality standards, research, promotional and financial backing of the pharmaceutical industry is, however, not yet up to world market export standards even when the industries concerned are in the hands of foreign capital. Indigenous technology, however, steadily increases and certain developmental work or clinical

research may be undertaken within the developing countries. Local manufacturers often supply on contract direct to large consumers such as hospitals, railways and mining companies. Advertising to the public is sometimes still very limited. The most important transformation occurring during this stage is the progressive emancipation of a country from the overwhelming dependency on imports of drugs products. The participation of imports in domestic consumption is, however, still high: in the 50 - 75 per cent range. This is still burdensome in view of the relatively high prices on the world market for pharmaceutical products and still a weak background of exports at this stage. However it might be expected that, during the Second Development Decade, about ten countries will join the fourth group.

Fourth Group of developing countries

53. The type of developing countries we are considering in this group have generally entered the self-generating process of industrialization, passed the so-called "pre-take-off" period, or find themselves on a close sub-stage before the take-off material infrastructure such as transport systems and power stations, as well as the political, social and institutional infrastructure are roughly established and operating at a satisfactory level.
54. The countries at the fourth stage of pharmaceutical manufacture - namely, Argentina, Brazil, China (mainland), India, Mexico, Spain and United Arab Republic, are able to produce drugs acceptable on the world market and dispose of the necessary means of effectively promoting their products. Domestic applied research imitates and duplicates foreign products. The "fundamental" research work carried out sometimes at this stage tends to be entirely disassociated from later industrial application. Original new products are developed in the country only on an exceptional basis, because the industry is oriented towards full integration of the pharmaceutical sector producing already certain medicinal chemicals. As the local organic chemical industry develops, it becomes possible for the larger countries of this group to undertake the complete synthesis of modern medicines. With the increased availability of skilled and technical manpower, the range and sophistication of domestically manufactured pharmaceuticals steadily increases and permits attaining world standards of quality and innovation, at least in some specialized product lines. At this developmental stage modified full-line houses may be encountered in the country, however, total imports of basic drugs

and medicinal preparations remain substantial - in the 10 - 30 per cent range - but this is offset by massive exports based on regional specialisation that typically amount to 20 - 50 per cent of domestic production. However, it is clear that foreign corporations - using basic drugs imported mostly from the parent factories - have been largely responsible for bringing most of these countries progressively more closely in contact with the network of international trade, and they have introduced some of the fruits of modern organisation, capital, science and technology, and in the process, they have provided vastly increased means and opportunities for native entrepreneurs. In fact these foreign corporations foster local entrepreneurship both directly, by providing training and experience to employees who later strike out on their own, and indirectly by creating demands for services, since foreign enterprises can rarely be completely self-sufficient and often find it more economical to tap the resources of local enterprise.

55. Indigenous pharmaceutical manufacturers will also investigate into the suitability of products for, let us say, tropical conditions. Manufacturers will also tend to diversify in non-drug chemical groups, such as pesticides, which are vital necessities in sanitation, preventive medicine, agricultural production, animal husbandry, etc.

Fifth Group of countries

56. This group is purely hypothetical as industrial development is in itself a continuous process. It would include those countries which are self-sustaining in technology, equipment and raw materials as well as manpower and have a continuous exchange of results of research and know-how.

2. TRENDS IN THE INTERNATIONAL PRODUCTION AND DEMAND OF MANUFACTURED GOODS

2.1 PRODUCTION OF MANUFACTURED GOODS IN THE WORLD, 1970-1977

2.1.1 The world production of manufactured goods in 1977 is estimated at almost 1000 billion compared with a value of 400 billion in 1970 and average annual growth rate in this period was 11.5 per cent (see Table 2.1). The growth of total national industry in the same period was 11.5 per cent (see Table 2.1).

TABLE 2.1

Production of manufactured goods in 1977 billion

	1970	1971	1972	1973	1974	1975	1976	1977
World	400	470	550	640	740	850	970	1000
Developing countries	100	110	120	130	140	150	160	170
Share of non-developing countries	25	23	22	20	19	18	17	17
Developing countries								
China	1	2	3	4	5	6	7	8
India	10	12	14	16	18	20	22	24
Latin America	10	11	12	13	14	15	16	17

1/ Not including the share of South Africa

2/ Including Japan with a production of 100 billion in 1977 as well as those countries which is reported to be self-sufficient with respect to manufactured goods (manufacturers to the extent of 11 per cent)

18. In the same period the average annual growth in the gross domestic product of developed market economies was about 4 per cent, compared with 2.1 per cent in developing countries. The annual growth rate of 2.1 per cent in manufacturing achieved in recent years by the developing countries was somewhat higher than the pace of growth achieved in industry here, which in the developed market economies is 2.7 per cent in manufacturing. To be the present, the light industries of some developing countries in general, as about the pharmaceutical industry being, have been the most important in terms of the total output of manufacturing output, as they usually have a high concentration in the private ownership. However, the annual rate of growth in manufacturing industries of light industries in 1970-1971 was only 2.1 per cent, little more than half the growth rate in the heavy sector which was 4.1 per cent. The average contribution for the period 1952 to 1970 was 2.1 per cent for light manufacturing and 4.1 per cent for heavy manufacturing. It can also be observed that the higher growth rate of output of light industry goods in developing countries as a whole, as compared with all developed market economies in the period 1952 to 1970, was mostly absorbed by the higher rate of expansion growth.

19. It is worth to note that since 1970 it is also very interesting to note that during the period under review, the developing countries have experienced a higher share in world production of pharmaceutical products than in the world production of chemicals. The reason for this is that developing countries are able to participate in the production of pharmaceutical products. The share average growth experienced in the pharmaceuticals field has however, also to be explained by the increasing application of technology in the pharmaceutical industry in general in developing countries, technology a leading position of other industries and the particular importance of the availability of pharmaceutical products for the development of public health and in national treatment and the general development of the importance of this sector by governments and the local public.

20. The overall development of consumer goods industries such as pharmaceutical production and other products is typical of many developing countries. They are produced in almost all of these countries which are usually found in vegetable oils and fats and the products of production of pharmaceuticals used in domestic medicine, as well as in important pharmaceutical products and their

drugs, are fairly well known in many of the developing economies and generally receive good support by governmental agencies. Nevertheless, there is very little value added in general and the actual use of pharmaceutical products per capita is comparatively low in developing countries, as will be seen below.

61. During 1950 to 1967 the share of developing countries in chemical products rose from 4.7 per cent to 5.4 per cent, whereas in the manufacture of pharmaceutical products it rose from 2.1 per cent to 9.6 per cent, thus reaching the average percentage of the position characteristic for pharmaceuticals in the structure of chemical industries in the countries of the European Economic Community, Great Britain, Japan, Norway, Poland, the Soviet Union (on the basis of estimated values), Sweden and the United States (see Table 3), considered representative of the structure of the chemical industry in the world. However, in the various regions and the developing countries the structural pattern varies greatly. Thus the percentages were, in certain countries, far above the respective values of the industrialized countries. A typical example of the situation in individual countries, for which sufficient data are available, is India. In 1962, the share of pharmaceuticals amounted to 29.9 per cent, that of soaps to 34.1 per cent. Together, these two branches reached a percentage of 64. The small share of 2.7 per cent, attributed to organic industrial chemicals, shows that in 1962 Indian chemical production was still in the early stages.

62. In spite of this apparently favourable comparison up to the present, developing countries as a whole have not developed their pharmaceutical industries to the same level as the developed countries. The figures indicated above do not take into consideration the level of backward integration achieved in this particular industry branch in the developing economies. A more advanced comparative analysis could lead in detail into such realities as production and consumption structure by therapeutic groups in each country, value added, origin of technical know-how, quality achieved, consumption per capita and comparison of prices with per capita income, productivity and types of ownership of manufacturing units, etc. Some of these factors will be discussed in broad terms further in the following sections of this chapter.

Table 3

Shares attributed to the main chemical branches (in percentages)
in industrialized countries 1/

	<u>Early 1950's</u>			<u>Early 1960's</u>		
	<u>Average share</u>	<u>Mini- mum share</u>	<u>Maxi- mum share</u>	<u>Average share</u>	<u>Mini- mum share</u>	<u>Maxi- mum share</u>
	<u>%</u>	<u>%</u>	<u>%</u>	<u>%</u>	<u>%</u>	<u>%</u>
Inorganic industrial chemicals	14.4	7.0	42.6	16.4	9.4	26.3
Organic industrial chemicals	12.8	0.7	14.9	15.0	5.6	24.5
Fertilizers	6.3	4.1	27.5	5.5	4.3	21.8
Plastics	4.9	0.7	7.1	9.9	4.1	12.3
Man-made fibres	7.1	2.0	10.6	7.3	3.9	15.0
Varnishes, paints, printing inks, mineral colours, pigments etc.	6.5	3.0	15.3	8.4	2.9	11.5
<u>Pharmaceuticals</u>	9.2	2.0	13.0	10.5	2.5	13.0
Soaps, detergents, cosmetics	12.0	2.3	20.8	10.1	2.5	12.5

Source: Sectoral Studies prepared for the Symposium : Chemical Industry, UNIDO, ID/CONF.1/25, 15 May 1967.

1/ Belgium, France, the Federal Republic of Germany, Italy, Luxembourg and the Netherlands (European Economic Community); Great Britain; Norway; Sweden; Poland; the Soviet Union (on the basis of estimated values); Japan and the United States.

In the early 1950's, these countries had an average share of 87.5 per cent in world chemical production and in the early 1960's, 84.2 per cent.

Estimation of growth in the pharmaceutical industry in the 1970's

63. As we have recalled in the above, the pharmaceutical industry differs in its technological, financial, legal and geographic structure and in its market, aspects which are particular to itself. They explain an economic development which, although being basically consistent in the broad lines to the development of the chemical industries in general, presents nevertheless original characteristics.

64. If we consider the growth perspectives of the pharmaceutical industry in a medium and long range we can describe them as very favourable. They profit basically from the continuous emphasis on the teaching of hygiene in developing countries; the socialization of medicine and the development of preventive medicine; the increase of the life expectation as a consequence of the secular growth of medical treatment itself; the continuous high population growth rate in developing countries; partial passage from inferior quality products to high quality pharmaceutical preparations particularly in developing regions; the adaptation of pharmaceutical technology to the local conditions and opportunities of the developing countries; the general technological modifications increasingly requiring mass production and continuous manufacturing processes; progress of medical and pharmaceutical research; prospective development of treatment of diseases not yet cured (e.g. for the control of cancer, mental diseases, arteriosclerosis and rheumatism in its various manifestations, no decisive breakthrough has yet been achieved); other discoveries and inventions opening new fields of progress and giving new orientations to the pharmaceutical industry not foreseeable; the reinforcement of marketing activities in developing regions; the product and geographical diversification trend; the advantages derived from enterprise and sectoral consolidation; the increasing investment into fundamental, applied and innovational research as well as in new plants and equipment; the capacity of international pharmaceutical firms to reach even superior performances through a more flexible adaptation to local, political and economic conditions and opportunities as they are proving in the different regions of the world; the relatively great resistance of the pharmaceutical industry to economic fluctuations; the increase of bi-lateral and multi-lateral technical assistance in this particular field; as well as other factors.

15. The following rough estimation of the future growth opportunities in the pharmaceutical field is based on the observation of the growth rates experienced in the recent past, and on estimates of growth rates in various countries of the industrialized and the developing world, bearing in mind the factors mentioned above and the differences in the structure of capital and in the steady state capacity of industrial countries. The following growth rates are based on the assumption that the average growth rates up to 1976 will be above the world average throughout the period 1976-1987, but will decline gradually during the period 1987-1997 towards the world average for every six development groups.

	1976-1987	1987-1997	1997-2007	1997-2017
World	10.0%	8.0%	7.0%	6.0%
Developing countries	12.0%	9.0%	7.5%	7.0%

16. In the light of the growth rates as here estimated production figures in terms of value and the change of developing countries in the world output are as follows:

Table 1

Production of pharmaceuticals in the world

	1976		1987		1997		2017	
	Value (\$ million)	% of world	Value (\$ million)	% of world	Value (\$ million)	% of world	Value (\$ million)	% of world
World	1000	100%	1200	100%	1500	100%	2000	100%
Developing countries	100	10%	150	12.5%	200	13.3%	300	15%
Share of total	10%	10%	12.5%	10.4%	13.3%	8.9%	15%	7.5%
Change	0	0%	50	4.2%	100	6.7%	200	10%
Value (\$ million)	100	10%	150	12.5%	200	13.3%	300	15%
Value (\$ million)	100	10%	150	12.5%	200	13.3%	300	15%

21. It can be deduced from the table that the share of developing countries in world production of pharmaceuticals will most probably further rise and it is also expected that the quality gap between industrialized and developing countries will narrow substantially. Between 1970 and 1980, the shares attributed to the pharmaceutical industry branch, as compared with the general growth of the national industries in the developing regions, will evolve in contrasting patterns according to the different levels of industrialization reached. In general, it can be expected that share will remain more or less stable, fluctuating around 11 per cent. Latin had in the recent past, a more pronounced growth rate of output of light industry goods than the Latin American region, and a lower rate of population increase. The share of the pharmaceutical branch is to decrease in the Latin region from about 20 per cent in 1970 to about 11 per cent in 1980. It can also be anticipated, that in the African region the ratio will move from about 11 to 17 per cent during the same period.

22. Available information on national plans for the development of the pharmaceutical industry in developing countries is very poor at the UNIDO Secretariat. Only a few reports exist on the planning or the completion of a plant, as well as some plans on projected plants up to 1970/72. The available rough regional and country data are reported as follows:

Latin American Region

23. Latin America is by far the most developed region regarding the particular industry sector considered. This dominance is documented not so much by the absolute size of the production but by the production output per capita. The centre of mass effort of the pharmaceutical industry lies in Argentina, Brazil and Mexico, with a share of 31.4 per cent in 1960 and 40.2 per cent in 1967 of the total pharmaceutical production of Latin America as can be seen from the table below.

Table 5Pharmaceutical production in Latin America from 1960 to 1967

(in US\$ million)

	<u>1960</u>	<u>1961</u>	<u>1962</u>	<u>1963</u>	<u>1964</u>	<u>1965</u>	<u>1966</u>	<u>1967</u>
Argentina	30	45	50	60	70	80	83	86
Brazil	100	115	136	150	162	170	185	200
Colombia	30	40	45	50	54	56	60	64
Mexico	105	120	140	163	182	207	236	269
Peru	15	15	20	20	25	28	35	38
Venezuela	20	22	32	42	52	55	60	65
Rest	20	28	37	45	50	54	64	69
Latin America estimated	320	385	460	530	595	650	723	791

70. As the percentage of the population of these three countries, compared with the total population of Latin America should remain reasonably constant during 1960 and 1980 (62.6

the assumption that also the share in pharmaceutical production remains nearly constant would be legitimate only if no important structural shifts occur, that is to say, if the countries remain basically oriented towards the satisfaction of the domestic needs and would not enter into large-scale export operations. The production values of Argentina, Brazil and Mexico add up to US\$647 million in 1970, US\$925-988 million in 1975 and US\$1,295 - 1,412 million in 1980. According to the projection in Table 4, the production of pharmaceutical products in Latin America in 1970 will be US\$1,000 million, in the range of US\$1,450 - 1,540 million in 1975 and between US\$2,000 and 2,140 million in 1980. Consequently the share of the three main pharmaceutical producers in the Latin American region would drop to about 65 per cent during the next Decade. This assumption seems quite realistic in the light that almost all the Latin American countries are already engaged in the second developmental stage as above.

71. The development of the per capita production in Latin American countries in the period 1960-1967 is shown in Table 6. It appears that the per capita growth was by far the most rapid in Venezuela where per capita production rose to nearly US\$7 and therefore was higher than the world average. The consumption in 1966 has been nearly US\$9 per capita, that means that about 75 per cent of the consumption was covered by national production in Venezuela. This share is lower than in Argentina, Brazil and Mexico. Probably the national production in Venezuela will rise in the period under consideration to the same share of national production like in the other countries. In only three years, 1963 - 1966 the share rose from 67 per cent to 75 per cent. Due to the relatively small production in absolute values compared with the other three countries, Venezuela will however not be under further consideration in the preliminary study.

Table 6

Production per capita of pharmaceuticals in Latin American countries in US\$

	<u>1960</u>	<u>1961</u>	<u>1962</u>	<u>1963</u>	<u>1964</u>	<u>1965</u>	<u>1966</u>	<u>1967</u>
Argentina	1.45	2.16	2.34	2.77	3.18	3.57	3.66	3.74
Brazil	1.44	1.60	1.84	1.97	2.07	2.10	2.22	2.33
Colombia	1.95	2.52	2.74	2.96	3.09	3.11	3.23	3.33
Mexico	2.92	3.22	3.64	4.09	4.41	4.85	5.35	5.89
Peru	1.50	1.46	1.89	1.82	2.21	2.39	2.92	3.07
Venezuela	2.74	2.90	4.05	5.19	5.98	6.32	6.67	6.92
Rest	0.47	0.65	0.84	1.00	1.09	1.14	1.32	1.39
Latin America	1.59	1.86	2.16	2.42	2.64	2.81	3.03	3.23

72. The same is true for Colombia and Peru, so that only the three countries, Argentina, Brazil and Mexico will be in the scope of the following paragraphs.

Argentina

73. Argentina has an important pharmaceutical industry. A large number of medicinal preparations are manufactured. Consumption of pharmaceuticals is relatively high. During the period 1960 - 1966 the consumption increased more than the production as is shown in Table 7.

Table 7Consumption pattern of pharmaceuticals in Argentina

	<u>1960</u>	<u>1961</u>	<u>1962</u>	<u>1963</u>	<u>1964</u>	<u>1965</u>	<u>1966</u>	<u>1967</u>
Production	30	45	50	60	70	80	83	
+ Import	15.3	19.0	19.3	19.9	21.7	17.1	16.6	
- Export	2.0	2.3	2.8	3.5	5.8	4.9	6.4	
Consumption US\$ million	43.3	61.7	66.5	76.4	85.9	92.2	93.2	-
Consumption/ capita in \$	2.09	3.16	3.11	3.52	3.90	4.12	4.11	-
Production/ capita in \$	1.45	2.14	2.34	2.77	3.18	3.57	3.66	-
Share of domestic production in consumption in per cent	69.4	67.7	75.2	78.7	81.5	86.7	81.1	-

74. Whereas the production per capita in that period rose by 152 per cent the consumption per capita rose only by 96 per cent. Due to these differences in the development of production and consumption the share of production to consumption rose from 69.4 per cent in 1960 to 81.1 per cent in 1966. The growth rates regarding production and consumption per capita are declining continuously from year to year.

75. The probability is high, that the slowing down of the per capita values will continue in the seventies too. The consumption value in 1970 has been calculated to US\$120 million.^{1/} This value harmonizes with a growth rate of the consumption per capita of 4.5 per cent up to 1970. A slowing down to 4 per cent per year up to 1975 will give a consumption of US\$156 million and 3.5 per cent per year up to 1980, a consumption of US\$196 million.

^{1/} Cf. La Industria Química en América Latina, Naciones Unidas, Nueva York, 1963, p.44

76. Even when assuming that the self-sufficiency with pharmaceuticals from national production can be realized, a certain part of highly sophisticated ethical pharmaceutical preparations will always have to be imported, due to the techno-economic characteristics of the pharmaceutical industry and its international market features. If necessary, an overproduction will be exported, but it cannot be assumed that the international drug trade of Argentina will be balanced. But due to new developments in the pharmaceutical sector in the seventies it can be assumed that the self-sufficiency will be in the range of 85 to 90 per cent of consumption.

77. If we assume such a development, the pharmaceutical production of Argentina will reach about US\$108 million in 1970, in 1975 between US\$130-140 million and in 1980 between US\$165-175 million. The production per capita would thus be \$4.44 in 1970, \$4.94 to \$5.32 in 1975 and \$5.94 to \$6.29 in 1980.

78. Summarizing the situation in Argentina it can be said that the pharmaceutical industry will probably further develop favourably. In this case the co-operation of significant pharmaceutical companies of the industrialized countries is of great importance. But it cannot be excluded that the interest of these companies will decrease if - by governmental acts - the possibilities for the development of this industrial branch will be limited. This may happen in the case of the very much disputed price-stop law for pharmaceuticals.

Brazil

79. Nearly all pharmaceutical products consumed in Brazil are dosaged and packaged in the country but approximately two-thirds of the raw materials have still to be imported.

80. In the early stage of the establishment of a pharmaceutical industry in Brazil, the savings of foreign exchange resulted mostly from the use of national labour, packaging and other cost components. Originally, practically all of the fine chemicals needed by the pharmaceutical manufacturers had to be imported, but several laboratories have started the development and processing of basic raw materials to the point that about 30 per cent of the active ingredients are now obtained in Brazil. Some of the international laboratories, however, are already purchasing

up to 80 per cent of their materials in the local market. Thus for instance, the antibiotic industry, which manufactures its own basic chemical raw materials, is now practically self-sufficient. The delay in Brazilian production of some of the basic products is caused by low demand for them on the local market. There is also some reluctance to invest in the expensive equipment necessary to produce even low volume items because profits in the Brazilian pharmaceutical industry are among the lowest in the industrial picture.^{1/}

81. The pharmaceutical industry in Brazil is in its capital structure international. According to a survey carried out in 1964, 28.5 per cent of the production value stems from purely Brazilian companies, 35.9 per cent from subsidiaries and associates of European firms, and 26.0 per cent from those of American companies. The remaining 8.9 per cent are accounted for by companies of different nationalities, e.g. Japan. In the years since then, the distribution of ownership has only changed to a small extent. On the other hand, the number of manufacturers has decreased further due to strong competition in the national market. Smaller firms have to struggle hard and it can be foreseen that concentration of production and concentration of sales will continue, since the Government continues to keep the prices for pharmaceutical products comparatively low in order to make available drugs easier to the poor. This is one of the reasons why the value of per-capita-production and per-capita-consumption of Brazil is lower than that of all other countries listed in Table 6. It should also be noted that this average value is not very meaningful as - according to generally accepted estimates - only one-fifth of the population of the country is in a measure to consume pharmaceutical products. Considering this fact the per-capita-consumption of each true consumer of pharmaceuticals would have been in 1960 approximately US\$7.92 and in 1966 approximately US\$12.

^{1/} 6.7 per cent of sales, before income tax, in 1962 (Cf. A Indústria Farmacêutica no Brasil, Consultec, Sociedade Civil de Planejamento e Consultas Técnicas Ltda, Rio de Janeiro, 1964, page 5.15.

82. The projection of the future growth rate, however, only is performed on the basis of the general average values as given in Table 2.

Table 2

Pharmaceutical production in Brazil

	1959	1961	1962	1963	1964	1965	1966
Production	100	115	125	130	142	150	159
+ Import	10.95	10.30	11.75	10.00	9.09	10.00	10.00
- Export							
<hr/>							
Consumption							
US\$ million	110.95	125.30	147.75	140.00	171.09	180.00	190.00
Consumption							
capita in US\$	1.59	1.75	1.99	2.11	2.19	2.20	2.20
production							
capita in US\$	1.44	1.60	1.82	1.97	2.07	2.10	2.20
Share of domestic							
production in							
consumption in							
per cent	90.6	91.4	92.5	93.4	93.9	93.9	93.9

83. The per-capita-production rose in the period 1959 - 1966 by 54 per cent and the per-capita-consumption by 50.9 per cent. Due to the relatively high level of industrialisation in the pharmaceutical field the share of domestic production in consumption rose only slightly from approximately 91 to approximately 93 per cent.

84. According to an ECLA report (Economic Commission for Latin America) ^{1/} the consumption of pharmaceuticals in Brazil is to reach US\$795.5 million in 1970.

^{1/} In 1958 Brazil exported pharmaceutical preparations and medical products for the value of US\$420 thousand. Information from a note prepared by the Banque Française de l'Amérique pour l'Amérique du Sud, September-October 1960. No other data are available at the Secretariat.

^{2/} Cf. La Industria química en América Latina, Volumen I - Situación actual y proyecciones para 1965 y 1970, Comisión Económica para América Latina, Naciones Unidas, E/CN.12/620/Add.1, Anexo I al 12.

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and for 1971 the amount was estimated at \$2,071 million. It is to be noted from Table 2, the actual domestic consumption was only \$1,825.4 million, of which nearly 50 per cent was due to domestic production.

25. Thus it can be concluded that the demand projected for pharmaceutical products for 1971 will not meet even with the actual production unless the Government could take certain measures. Hence, further, the C. I. suggestions to have, that the per capita consumption is to rise from 157 in 1966 to 161 in 1971, corresponding to an average annual growth rate of 2.5 per cent. The same is to be true for the period 1971 through 1975.

26. According to the Council Report the increasing demand of industry and commerce, the starting of new production in the pharmaceutical field by way of licensing agreements is considerably higher in India. Further, considerable investments in the chemical, pharmaceutical, and petrochemical industries are to be expected in the years to come. Under these circumstances it would be justified to presume that the growth rates of per capita consumption will continue to be relatively high in the decade up to 1975. Thus assuming an average growth rate of 3.5 per cent up to 1975 and of 3 per cent up to 1976, then a per capita consumption of 162 in 1975 and approximately a total consumption of \$2,071 million would be required.

27. In the period 1966 to 1970 the share of national pharmaceutical production in total consumption is about 25 per cent and 25 per cent. It is assumed that in the period 1971 to 1975 the share will be about 25 per cent to 25 per cent. With this assumption the production value will be about \$2,700 million in 1975, approximately \$2,600 million in 1976 and \$2,500 million in 1977. These figures show a production per capita of 162 in 1975, approximately 161 in 1976 and 160 in 1977. The average annual growth rate would be between 3.5 per cent and 4.5 per cent in the period 1971-75, and 3.5 per cent in the period 1976-77 respectively.

April 1965.

Summary

28. In the above cited study of the Economic Commission for Latin America the consumption value (respectively the demand) of pharmaceuticals in Mexico was calculated to be US\$181.6 million in 1970 only. Actually the production value reached US\$207 million in 1965 already, and the consumption went up to US\$244.8 million in that year.

29. The consumption per capita rose from US\$1.58 in 1960 to US\$5.55 in 1966, and the production per capita respectively from US\$2.92 to US\$5.35 in the same period. The self-sufficiency ratio increased from 81.6 per cent to 96.4 per cent as shown by the figures in Table 9.

Table 9

Consumption patterns of pharmaceuticals in Mexico

	<u>1960</u>	<u>1961</u>	<u>1962</u>	<u>1963</u>	<u>1964</u>	<u>1965</u>	<u>1966</u>
Production	109	120	140	161	182	207	236
Import	14.67	26.79	34.16	40.60	35.76	37.7	30.1
Export	10.76	15.64	17.99	17.84	14.83	18.2	21.3
Consumption							
million US\$	180.81	180.75	196.17	185.76	202.93	226.5	244.8
consumption							
per capita in US\$	1.58	1.51	4.08	4.66	4.91	5.30	5.55
production							
per capita in US\$	2.92	3.22	3.68	4.09	4.41	4.85	5.35
Share of domestic							
production as							
consumption in							
per cent	81.6	98.7	89.7	87.8	89.8	91.5	96.4

30. The production figure of 1965, as indicated in the above table, represented 21 per cent of the total turnover of the Mexican chemical industry. It is expected that the production value will reach US\$290 million in 1970.^{1/}

^{1/} Chemical Industry and Developing Countries, Volume IV, UNEP Sectoral Study, Technical and Policy Committee, 1966, p.192.

91. Mexican capital in pharmaceutical products manufacturing is estimated to amount to no more than 10 to 15 per cent of the total investments, for in this sector a Mexican majority holding is not essential. Most of the companies are subsidiaries of American pharmaceutical concerns. In 1965, US\$159 million were invested in this sector, and it is expected that this figure will rise to US\$215 million by 1970.

92. Providing that the estimates for 1970 are correct and assuming that the percentage of domestic self-sufficiency is in the order of 90 per cent, the total demand for pharmaceutical products will be in the magnitude of US\$310 million for 1970, corresponding to a consumption per capita of US\$6.38. An annual growth rate of 5 per cent for the period 1966 to 1970, would rise the consumption ratio to US\$6.75 per capita. It is assumed that the average growth rate of the consumption per capita will slow down to about 4.5 per cent in the period 1970/75, and to 4 per cent in the period 1975/80 respectively. With these assumptions the demand per capita for pharmaceuticals will be:

<u>1970</u>	<u>1975</u>	<u>1980</u>
US\$ 6.38	US\$ 7.95	US\$ 9.67
to US\$ 6.75	to US\$ 8.41	to US\$10.23

These per capita values would lead to a total consumption of US\$310 - 330 million in 1970, respectively US\$460 - 490 million in 1975, and US\$660 - 700 million in 1980. In the period 1960 - 1966 the share of self-sufficiency in Mexico rose from 81.6 per cent to 96.4 per cent as already stated. Due to the same causes that have been interpreted in the case of Brazil, the assumption is made for Mexico too that the degree of self-sufficiency will be in the order of 85 - 90 per cent during the period under review. The domestic production figures (assuming an average of about 87.5 per cent) would then be:

<u>1970</u>	<u>1975</u>	<u>1980</u>
US\$270 - 290 million	US\$400 - 430 million	US\$580 - 610 million
leading to a production per capita of		
US\$5.57 - 5.97	US\$6.88 - 7.42	US\$8.50 - 8.93
respectively.		

Region of Asia and the Far East

93. Less still is known of the prospects of the pharmaceutical industry in the Asian countries. In this region more than 60 per cent of the pharmaceutical production is concentrated in one country - in India. The production values of the other countries are extremely small when compared to the population so that the per-capita-production is by far - namely by the factor 10 - smaller than the world average of this figure.

94. As shown in Table 10 the production value of the region of Asia and the Far East is, even in absolute figures, smaller than that of Latin America. In relation to the population, which is in Asia about four times as high as in Latin America, the per-capita-production is about one-fifth of that in Latin America (see Table 11).

Table 10
Pharmaceutical production in Asia 1960 - 1971
(in US\$ million)

	<u>1960</u>	<u>1961</u>	<u>1962</u>	<u>1963</u>	<u>1964</u>	<u>1965</u>	<u>1966</u>	<u>1967</u>
India	147	179	211	270	304	336	375	407
Pakistan	12	15	19	23	29	34	40	46
Philippines ^{1/}	24°	25°	27°	27°	28°	29°	30°	30°
Thailand ^{1/}	2°	2°	3°	3°	3°	4°	4°	4°
China (Taiwan)	12	13	26	26	27	28	28	28
Rest ^{1/}	30°	33°	23°	43°	60°	75°	82°	88°
Asia^{2/}	227	267	316	393	461	498	537	581

^{1/} The figures marked with an asterisk represent estimated values.

^{2/} Including Japan and China (mainland).

Table 11

Manufacture of pharmaceuticals in India, 1950-1966

	1950	1951	1952	1953	1954	1955	1956	1957
India	0.20	0.21	0.27	0.30	0.30	0.34	0.37	0.37
Pakistan	0.11	0.14	0.20	0.21	0.20	0.11	0.10	0.10
Philippines	0.00	0.00	0.00	0.00	0.00	0.01	1.00	1.10
Thailand	0.00	0.00	0.11	0.17	0.17	0.20	0.20	0.20
Other Areas	1.11	1.14	1.10	1.20	1.21	1.20	1.21	1.00
Total	0.11	0.11	0.10	0.14	0.11	0.10	0.10	0.10
Share	0.10	0.10	0.10	0.11	0.10	0.10	0.10	0.10

The surplus of the pharmaceutical output of India and the per cent share from other countries in 1950 is about 100% of 1950. In 1966, the share of per cent of total surplus earned the basic needs of the five countries (India, Pakistan, Philippines, Thailand and Other Areas). This share declined to 51 per cent in 1966 which means an absolute figure of 100% of 1950. The rising consumption of pharmaceutical products in these countries was not by an increasing production but by imports. The share of national production in consumption in these countries rose from an average value of 73.4 per cent in 1950 to 56.4 per cent in 1966. In the remaining parts of India the share rose from 26.4 per cent in 1950 to about 34 per cent in 1966.

India

Specifically for the fast growing pharmaceutical industry in India the per cent share the average life expectancy rose from 11 to 50 years during the past twenty years. Since 1950 the pharmaceutical production rose by a yearly average of about 17 per cent, and even if some of the projects have not been realized during the last years the growth rate reported for the next decade up to 1966 will be of a similar order of magnitude.

Table 12

Consumption pattern of pharmaceuticals in India

	<u>1960</u>	<u>1961</u>	<u>1962</u>	<u>1963</u>	<u>1964</u>	<u>1965</u>	<u>1966</u>
Production, US\$million	147.0	179.0	211.0	270.0	284.0	310.0	335.0
+ Import, " "	21.9	18.2	17.2	17.0	17.2	18.3	23.2
- Export, " "	-	-	-	-	4.3	5.5	7.6
<hr/>							
Consumption, US\$million	168.9	197.2	228.2	287.0	296.9	322.8	350.6
Consumption per capita, in US\$	0.39	0.45	0.51	0.62	0.63	0.66	0.70
Share of domestic production in con- sumption in per cent	71.1	90.8	92.5	94.2	95.9	95.9	95.4

The pharmaceutical industry in India expects that its production out-put will be in the order of US\$525 million by 1971¹⁾. This would mean a per-capita-production of US\$0.95 in 1971 and an average annual growth rate of 9.2 per cent from 1967 to 1971. Under this assumption, the per-capita-value in 1970 would be about US\$0.87 and the total domestic pharmaceutical production about US\$470 million.

At times it has been stated by officious persons in India that the country will come to a hundred per cent self-sufficiency in pharmaceuticals in 1975. This seems not very probable. In any case, the demand for newly developed pharmaceuticals originating from foreign countries will have to be covered by imports even up to 1980 and later. Nevertheless, the tendency towards a domestic production as high as possible is very strong. India supports a programme of very advanced diversification with a high degree of backward integration.

1) "Blitz durch die Wirtschaft", 6 March 1968

99. There is almost no doubt that up to 1975 the growth rates in pharmaceutical production will be in the range of 8 to 9 per cent per year. This assumption is based on the fact that in India pharmaceuticals manufacturing - more than any other branch - represents an outstanding example of joint ventures with foreign companies which bring licences, know-how, capital, and - in many cases - trained skills.

100. During the last few years domestic research and development was organized on a larger scale in co-operation with foreign firms. Therefore, economic growth is expected to be faster than in many other branches of the chemical industry.

101. It can be assumed that per-capita-production will rise by 5 per cent per year up to 1975 and by 4 per cent up to 1980. Thus, the production per capita would be US\$0.87 in 1970, US\$1.11 in 1975 and US\$1.35 in 1980. Corresponding to these values, the total production value would reach US\$470 million in 1970, US\$674 million in 1975 and US\$907 million in 1980.

Pakistan

102. As shown in Table 10, the production of pharmaceutical products is smaller by the factor 10 approximately, than the one in India. The total value of products and by-products in 1966/67 was in an order of magnitude of about US\$40 million.

103. The pharmaceutical industry in Pakistan is still mainly engaged in processing and packaging of imported bulk materials. When all chemical industry development projects will be realized, then Pakistan will be in the transition stage from stage 2 to 3.

104. In the Second Five Year Plan 1960 - 1965, US\$11.8 million have been provided for drugs and pharmaceuticals; in the Third Five Year Plan 1965 - 1970, this amount was increased to US\$24.0 million.

105. In 1954 it was estimated that Pakistan would have an annual requirement of drugs and pharmaceutical preparations of about US\$30 million. As a result of the increasing population, the growing number of hospitals, the improving standard of living and better health policy of the Government, these requirements have risen to about US\$60 million per annum in the late sixties.

This means that consumption has doubled since 1960 (see Table 13) and now corresponds to a per-capita-consumption of US\$0.51. This, still, is only one tenth of world average.

106. In spite of epidemics and the poor health of the masses, the consumption of drugs is very limited because of the low purchasing power. It is, however, expected that the gradual increase in the per-capita income and improvement in the standard of living will bring about a considerable growth in requirements for drugs and pharmaceuticals in the Second Development Decade.

Table 13

Consumption pattern for pharmaceuticals in Pakistan 1960 - 1967

	(in US\$ million)							
	<u>1960</u>	<u>1961</u>	<u>1962</u>	<u>1963</u>	<u>1964</u>	<u>1965</u>	<u>1966</u>	<u>1967</u>
Production	12.3	15.0	19.0	23.0	29.0	33.6	40.0	42.0
+ Import	19.2*)	19.6	16.4	17.4	21.9	20.7	14.2	20.1*)
- Export	-	-	0.2	0.4	1.2	1.3	1.2	2.1*)
Consumption	31.5*)	34.6	35.2	40.0	49.7	53.0	53.0	60.0*)
Growth rate of consumption per annum per cent		9.8	1.7	13.6	24.3	6.6	0	13.2
Per-capita consumption (US\$)	0.34	0.37	0.36	0.41	0.46	0.51	0.51	0.56*)
Growth rate of per-capita consumption per cent		8.7	3.0	11.4	11.2	10.9	0	9.8

*) estimated

107. As can be seen from Table 13, pharmaceuticals are a very important import item and represent about a quarter to a third of the total chemical imports. Although remaining in the same order of magnitude, the share of

pharmaceutical imports in domestic production declined very sharply and lies now in the range of about 50 per cent of the domestic production.

108. Actually, only few pharmaceutical products are exported. Their share is less than 5 per cent of the domestic production, but prospects of pharmaceutical exports are favourable as export goals were set for the pharmaceutical industry.

109. Taking into account the historical development, future production and consumption values were calculated as shown in Table 14.

Table 14

Actual and estimated production and consumption of pharmaceuticals
in Pakistan 1960 - 1980

	<u>1960</u>	<u>1965</u>	<u>1970</u>	<u>1975</u>	<u>1980</u>
Production (US\$ million)	12	34	55	78	123
Share in total Asian production - per cent	5.3	7.0	7.5	7.8	8.6
Per-capita production US\$	0.13	0.33	0.47	0.62	0.88
Growth rates per annum per cent	23.2	10.1	7.2	9.5	

110. Under the assumption that the imports of pharmaceuticals will slowly decline but remain in a certain order of magnitude, the future consumption is estimated to be as shown in Table 15.

Table 13
Estimated consumption of pharmaceuticals in Pakistan 1960 - 1980
(in US\$ million)

	<u>1960</u>	<u>1965</u>	<u>1970</u>	<u>1975</u>	<u>1980</u>
Production	12.3	33.6	55.0	78.0	123.0
+ Import	19.2	20.7	16.0	14.0	12.0
- Export	-	1.3	3.0	4.0	5.0
<hr/>					
Consumption	31.5	53.0	68.0	88.0	130.0
Growth rate of consumption per-cent		10.2	5.8	5.3	8.1
Per-capita consumption (US\$)	0.34	0.51	0.58	0.70	0.93

111. According to the Pakistan Planning Commission the countries of the World Bank Consortium have made firm commitments totalling US\$446 million for the financing of the Pakistan Development Plan in 1967/68. Of this amount US\$168,000 were given as a loan to build a pharmaceutical firm by Searle Pakistan Ltd.

Philippines, Thailand, and China (Taiwan)

112. The production of pharmaceutical products in the Philippines, Thailand and China (Taiwan) during the period 1960 - 1967 is shown in Table 10 (see above). The projections up to 1980 are given in the following Tables:

Table 16

Actual and projected production of pharmaceuticals in
selected Asian countries 1960 - 1980
(in US\$ million)

	<u>1960</u>	<u>1965</u>	<u>1970</u>	<u>1975</u>	<u>1980</u>
Philippines	24	30	50	70	100
Thailand	2	6	15	23	32
Taiwan	12	31	50	70	105
Rest	30	75	95	112	163

Table 17

Actual and projected per-capita production of pharmaceuticals in
selected Asian countries 1960 - 1980
(in US\$ million)

	<u>1960</u>	<u>1965</u>	<u>1970</u>	<u>1975</u>	<u>1980</u>
Philippines	0.88	0.93	1.30	1.52	1.82
Thailand	0.08	0.20	0.42	0.56	0.70
Taiwan	1.13	2.50	3.58	4.43	5.61

Table 18

Actual and projected annual growth rates of pharmaceutical production
in selected Asian countries 1960 - 1980
(five years' average)

	<u>1960/65</u>	<u>1965/70</u>	<u>1970/75</u>	<u>1975/80</u>
	%	%	%	%
Philippines	4.6	10.8	7.0	7.4
Thailand	24.6	20.1	8.9	6.8
Taiwan	20.9	10.0	7.0	8.4
Rest	20.1	4.8	4.4	6.7

113. The pharmaceuticals produced in the Philippines are primarily ethical drugs and preparations classed as antibiotics, vitamins, sulphate drugs, and biological products. The per-capita consumption is estimated to about US\$1.5 in 1970, US\$1.7 in 1975, and US\$1.9 in 1980.

114. In China (Taiwan) nearly 700 manufacturing plants for pharmaceuticals are operating, most of them, however, under bad conditions. About 80 per cent of them are very small. The targets set in the Fourth Four-Year-Plan (1965 - 1968) include increased production of pharmaceutically active substances. Experts have valued the capital requirements at US\$25 million.

115. The per-capita consumption of pharmaceuticals in China (Taiwan) is the highest of the developing countries of Asia and Far East region (see Table 20).

Table 19

Consumption of pharmaceuticals in Taiwan 1960 - 1980
(in US\$ million)

	<u>1960</u>	<u>1965</u>	<u>1970</u>	<u>1975</u>	<u>1980</u>
Production	12.0	31.0	50.0	70.0	105.0
Import	9.3	9.1	10.0	11.0	12.0
Consumption	21.3	40.1	60.0	81.0	117.0
Per-capita consumption (US\$)	2.0	3.23	4.28	5.13	6.26

116. In Thailand the government has attempted to promote the domestic production of pharmaceuticals by means of tax concessions and other measures. Upon this a number of pharmaceutical companies of world-wide reputation has opened branches and packaging establishments.

Subregion West Africa

117. Only little information is available on the pharmaceutical industry in African countries. In the subregion West Africa only Senegal and Liberia have a small domestic production. All other countries are obliged to import practically all their pharmaceutical products even if some of them have entered the second development stage. The expected evolution of the consumption is given in Table 21.

Table 21

Consumption of pharmaceuticals in the subregion of West Africa, 1965 - 1980
(in US\$ million)

	<u>1965</u>	<u>1970</u>	<u>1975</u>	<u>1980</u>
Dahomey	1.0	1.6	2.6	4.1
Zambia	6.15	0.5	0.7	1.0
Guinea	2.67	3.9	5.8	8.5
Ivory Coast	4.17	6.1	9.0	13.2
Liberia	1.20	1.6	2.1	2.9
Mauritania	0.10	0.2	0.3	0.6
Niger	0.77	1.2	2.0	3.2
Senegal	2.92	4.3	6.3	9.3
Sierra Leone	1.86	2.7	4.0	5.9
Togo	0.87	1.4	2.1	3.6
	15.7	23.5	35.1	52.5

Source: Economic Commission for Africa, Research into the Chemical Industry and Fertilizers in West Africa, E/CN.14/IV/1977/Add.1, United Nations, 15 March 1977.

118. The per-capita consumption of the total subregion of West Africa is US\$0.15 in 1965, US\$0.2 in 1970, US\$0.26 in 1975 and US\$0.34 in 1980.

E. Elaboration of model development strategies in response to four developmental stages, a selective policy approach

119. The overall situation of the pharmaceutical industry in the developing countries as inherited from the First Development Decade points to the urgency of drawing up a re-orientated sectoral strategy for the Second Development Decade.

120. In a first attempt to satisfy these needs, two guiding principles are suggested:

1. The limited resources available to the developing countries for developing their own pharmaceutical industries need the rational combination of all decisions to be taken in sectoral economic policy, in other words, the elaboration of a rigorous system of priorities and self-restrictive plans needed for the benefit of a co-ordinated long-term sectoral growth. These priorities should stimulate the natural evolution of the sector and be based on projections of likely and desirable trends which seem to correspond with the intentions of the planners and entrepreneurs of the developing countries.
2. Rather than to establish a real world plan, the sectoral strategy should be a simple and acceptable method of co-ordination and information at an international level, supplemented and supported by bi-lateral and multi-lateral technical and financial assistance. The coherence of action will be increased through such measures and hopefully lead to a better overall success in the acceleration of the industrialization of the pharmaceutical sector.

121. Thus, according to the developmental stages, as elaborated in section C, selective measures for four model groups of developing countries are being proposed for consideration to the governments and for the operational programme of UNIDO, in an attempt to consolidate the results already achieved and in view of fulfilling the expected growth during the Second Development Decade in this sector. A major part of the measures suggested clearly indicate areas which belong to the terms of reference of other UN agencies, particularly WHO and FAO.

First Group of measures

122. As the purchasing power in the First Group of developing countries is particularly low, the average man has to be satisfied with traditional medication under the indigenous system, which is less expensive but which is not equally effective in all cases.

123. Extensive health programmes should be initiated during the Second Development Decade, following a proper survey of the various diseases prevalent in these countries. Cost-benefit calculations should be undertaken on a systematic basis to set priorities. With limited facilities for diagnosis and treatment, the off-take of drugs will remain limited although the incidence of disease may be high.

124. Along with the building of unified health services and the improvement of medical care, regional co-operation with more advanced developing countries could be organised (e.g. importation of pharmaceutical products from other developing countries). Imports of pharmaceutical products should be supervised and/or organised by a central agency.

125. For this group domestic manufacture of pharmaceutical products should only be initiated when local conditions and opportunities would become very favourable and the absorptive capacity permit such an industrialisation programme. Such changes will occur only in a few countries belonging to this group. In the case of local availability of raw materials of vegetable origin (crude drugs), it should be examined if their commercial cultivation for exportation to other developing countries or developed countries could be organised on a large scale. Experimental farms could be set up to work out methods for improving the contents or required single constituents of active principles that are needed by the industry of other developing countries or the developed countries.

Second Group of measures

126. For the Second Group of developing countries a large amount of economic planning and co-ordination is an absolute necessity. Attempts should be made to identify specific products (the variety of pharmaceuticals needed) most suited to domestic manufacture and domestic consumption. Once the therapeutic categories have been determined it is to choose what branches of production are of decisive importance to a specific country. A basic decision would also be as to whether operations should be directed mainly towards consideration of semi-ethereal or ethereal preparations. Long-term projections of national drug demand should be organised systematically considering (i) the type and incidence of diseases, (ii) the extent of other medical facilities available to diagnose and treat the disease, and (iii) the purchasing power of the people to pay for such

investment or the extent to which the government is able to subsidize it over a long period. On the basis of such projections national long-term industrial development programmes could be established taking into account, besides these economic factors, the feasibility of interregional specialization of pharmaceutical manufacture and participation of foreign capital (e.g. production of antibiotics and other drugs using fermentation techniques).

127. National committees of experts could be established to co-ordinate development programmes, to examine ways of obtaining appropriate outside help and to exchange experience in this field.

128. To prevent local production of drugs not in conformity with official standards and protect consumer interests, appropriate national agencies and institutions should be established by enacting suitable legislation to regulate manufacture and distribution.

129. In order to support domestic manufacturing operations and to prevent excessive import competition, such national agencies should give appropriate consideration to the customs and transport tariffs of imported capital equipment, raw and packaging materials, imports of bulk products, dosage products, and on instruments for quality control. The adoption of other incentive measures such as relief from payment of income and profit tax for a period of time, guarantee to remit funds abroad for foreign investors and appropriate compensation in case of nationalization, etc. would favour the industrialization process.

130. The governments concerned should take immediate steps for training the necessary scientific, managerial and technical skills required for manning the various projects and to avoid bottlenecks at further developmental stages.

131. Even at the operational stage of single dosage formulation many manufacturing processes require a supply of technical know-how from advanced countries; therefore the governments should consider their policy to be adapted regarding patent laws and eventually enact proper legislation.

Third Group of measures

132. Indigenous pharmaceutical manufacturers from countries which have attained the third developmental stage should aim towards a selective exportation policy,

3. According to the production standards adopted, geographical location, national preferences, etc.,

(1) Particular attention has to be paid to meet the necessary standards of manufacturing efficiency as well as safety of pharmaceutical products to be acceptable to foreign importers and to compete with the foreign products sold on the national market.

(2) Working in its broadest sense (packaging, package materials design, appearance etc.) will have to keep with the high standards of the imported drugs. The quality control work and packaging efforts may greatly increase the prestige of locally produced preparations. Interregional co-operation and exchange of experience should be organized at this level of manufacturing.

(3) Animal glands and organs required for the production of hormones and other similar preparations should be collected by setting up modern slaughterhouses with facilities for the quick collection, storage and transport of these parts under refrigerated conditions to prevent the deterioration of the active principles before the parts reached the extraction laboratories.

(4) Special efforts should also provide for full use of the installed production capacities and regrouping of firms facilitated by the authorities.

(5) Advertising practices should be regulated and controlled on a national basis. An advertising code should be elaborated for the use of developing countries.

Fourth Group of measures

(1) The development of sources of raw materials supplies depends mainly on an integrated development of all the connected industries. In other words the manufacture of drugs is inter-related with the manufacture of chemicals, solvents, nutrients media, machinery, etc. This integrated approach can be made possible by the creation of appropriate institutions at an intermediate stage of development. These political conditions may be to some extent restrictive to local manufacturing programmes being undertaken by foreign firms. Such disadvantages as insufficient demand and limited availability of chemical raw materials, which make such

manufacture less competitive, will nevertheless persist for a certain period. At the fourth developmental stage a target of expansion in the national development plan could be the establishment of new factories for the production of pharmaceutical raw materials.

139. In the health programmes of the countries of the Fourth Group, advantage may be taken of traditional medicaments, e.g. ayurvedic medicines, by organising their production on modern lines and adopting proper standardisation methods, especially in areas where modern facilities have not yet been introduced. Screening programmes and research on these drugs will also yield improved remedies which can be helpful in the modern systems of medicine and also weed out many ineffective remedies which are in use at present. The establishment of research laboratories or institutes for herbal drugs would be a target at this stage (which could in fact also be a programme point for the preceding group).

140. Productivity should be improved and appropriate actions taken to become competitive on the international market.

141. The four model groups are not of an exhaustive character. It is quite understood that the proposed classification intends only to set priorities for each developmental stage. In practice the sequence to be followed may not always be as rigid as planners and policy makers have to take into account the real situation and local opportunities encountered in each individual developing country. Under consideration of the terms of reference as well as the financial resources of UNIDO, we expect that UNIDO's technical assistance would be particularly helpful and lead to some concrete results mainly with respect to the second group as well as to a lesser extent with regard to the third group of developing countries.

142. That being the case and, in the light of our analysis, the following actions could be taken at an international level to promote the growth of the pharmaceutical industries in the developing countries:

- (a) The setting up of an international statistical service on the consumption and production of pharmaceuticals by therapeutic categories with special regard to the developments in the developing countries.

- (b) Additional research is required regarding the characteristics of developmental stages of the pharmaceutical industries with special emphasis on the experience accumulated by the developing countries during the recent years.
- (c) The research under (b) should be particularly oriented toward elaboration of appropriate policy measures to promote the pharmaceutical industries at different stages of development. The main form of this work may be the provision of active technical assistance to the developing countries in this field.
- (d) Further studies are suggested, based on more precise methods, to assess future demand in pharmaceutical products in the developing countries. This work could be connected with technical assistance in the elaboration of projections regarding the manufacture of pharmaceutical products and the expansion of production facilities.
- (e) On the basis of eventual more elaborated quantitative and qualitative country analysis, the possibilities of specialization of pharmaceutical manufacturing operations and inter-country trade between the developing regions, sub-regions and individual developing countries, could be investigated at a later stage.



