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POLICIES FOR THE PRODUCTION AND MARKETING OF ESSENTIAL DRUGS

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POLICIES FOR THE PRODUCTION AND MARKETING OF ESSENTIAL DRUGS

I. INTRODUCTION

Background

Drug policies have been a subject of continued interest to Governments and to international organizations as evidenced by the actions and deliberations of WHO, UNCTAD, UNIDO and other international agencies of the United Nations system. In May 1978 the Technical Discussions at the Thirty-first World Health Assembly were on "National Policies and Practices in Regard to Medical Products, and Related International Problems." In September of 1978, the XX Pan American Sanitary Conference held Technical Discussions on "The Impact of Drugs on Health Costs: National and International Problems." Other regional offices of WHO have also addressed this subject.

The selection of the topic "Policies for the Production and Marketing of Essential Drugs" for the XXIX Meeting of the Directing Council of PAHO provides a further opportunity to the Member Governments to examine the complex factors that affect the production and marketing of essential drugs and to identify strategies that will assist in the implementation of appropriate national policies. In accordance with the Regional Strategies of Health for All, such policies must have as their objective to "ensure the availability of critical supplies and equipment whose quantity, technology and cost are geared to the requirements of the programs and possibilities of each country." (PAHO, 1980:204)

The Scope and Dimensions of the Concept of Essential Drugs

The provision of essential drugs is recognized as a vital component of the global strategy to achieve health for all by the year 2000.

In 1977 the Thirtieth World Health Assembly adopted a resolution (WHA30.43) stating that the main social target of governments and of WHO should be the attainment by all the people of the world by the year 2000 of a level of health which will permit them to lead socially and economically productives lives. The ambitious goal was to be achieved through primary health care, as described by an International Conference on Primary Health Care held in Alma-Ata, USSR, in 1978. The global strategy for achievement of primary health care involves development of the health system infrastructure, starting with country-level programs that reach the whole population. These include measures for health promotion, disease prevention, therapy and rehabilitation. The primary health care concept also involves selection of technology that is appropriate for the country concerned. It is recognized that an acceptable level of health for all cannot be achieved by the health sector alone, but requires the coordinated efforts of other social and economic development sectors as well. As stated in the Declaration of Alma-Ata, primary health care

includes at least eight basic elements, two of which (appropriate treatment of common diseases and injuries, and provision of essential drugs) relate directly to medicines. Primary health care requires the development, adaptation and application of appropriate health technology that the people can use and afford, including an adequate supply of low-cost, good quality essential drugs, vaccines, biologicals and other supplies and equipment.

Although many gaps remain in the physician's armamentarium, outstanding scientific and technological advances over the past three decades have resulted in the development of potent and effective drugs, vaccines and sera for the treatment of a broad range of health problems. Major credit for this achievement must go not only to individual scientists in research institutions, but also to the pharmaceutical industry. Indeed, the industry has been the major factor in drug development on a worldwide basis since World War II. Little attention has, however, been paid to ensuring that the fruits of drug research and development are available to the poor and underprivileged people of the world. There are encouraging signs that both industry and governments are becoming increasingly aware of the adverse consequences which result from a failure to do so.

It is, of course, obvious that drugs cannot take the place of decent housing, clean water, sanitation and overall improvement in living standards. The cycle of poverty, malnutrition and disease cannot be broken just by medicine, or indeed, by better health care alone. Drugs must be seen in their true role, as essential partners in the provision of health care services.

The concept of essential drugs has been developed within WHO during the past decade. In 1975, by Resolution WHA28.66, the World Health Assembly requested the Director-General of WHO to advise Member States on the selection and procurement, at reasonable cost, of essential drugs of established quality corresponding to their national health needs, as defined by WHO. "Essential drugs are those considered to be of the utmost importance and hence basic, indispensible and necessary for the health needs of the population. They should be available at all times, in the proper dosage forms, to all segments of society."

In response to these instructions, WHO drew up a list of essential drugs, as a contribution to solving the problems of Member States faced with major drug needs, extremely limited funds with which to purchase them, and who find it difficult to initiate such an endeavor on their own. In developing countries, the problem of dissonance between needs and financial resources is magnified by severe shortages of trained health personnel and, most importantly, by lack of organized drug policies, including national policies commitment. In many such countries, health ministries are relatively weak and ineffective, and the health care system is skewed towards satisfying the needs and wants of

the small affluent urban elite class, to the detriment of the health of the vast majority of people. Inadequate capacities of health ministries to plan, execute and evaluate programs may be compounded by a weak legislative base for drug control, inadequate health information systems and inadequate numbers and kinds of personnel, including a lack of appropriate non-medical expertise.

In recognition of the importance of essential drugs in the attainment of health for all, and in response to the needs of Member States in this important area, WHO, with the active cooperation of UNICEF, has launched an Action Program on Essential Drugs. An account of progress made and proposals for a plan of action to further develop and implement the Program were presented to the Thirty-fifth World Health Assembly.

Some Principles to be Considered in Developing the Concept of Essential Drugs in the Americas

1. Neither national governments nor the private sector acting alone can successfully develop and implement the concept of essential drugs. To do so requires the active collaboration of national governments, the pharmaceutical industry, WHO, UNICEF and other organizations of the U.N. System, and other institutions both public and private. In addition to national efforts, intercountry cooperation must be encouraged and supported.

2. The needs of countries and potential solutions for them must be considered on an individual basis. Programs must concentrate on developing and strengthening national capabilities, including physical infrastructures, towards the achievement of greater self-reliance in the pharmaceutical sector. Government philosophies about the appropriate roles of the private and public sectors, the size and sophistication of the drug market, financial and economic realities, therapeutic needs, the nature and extent of supply and distribution infrastructures, and the availability of trained personnel are factors which must be considered by national governments in making decisions in this field.

3. Major emphasis must be placed on the development of national drug policies, as part of broader health policies aimed at achieving the goal of health for all based on primary health care. These policies must be consistent with the concept of essential drugs, take into account fiscal and economic realities, and wherever possible emphasize prevention rather than cause of disease. They should include the following components:

a) identification of therapeutic needs for primary health care and selection of essential drugs in appropriate quantities to meet those needs;

b) obtaining essential drugs at lowest possible cost while assuring drugs selected are of acceptable quality;

c) improvement of the drug supply and distribution system, including procurement, storage, distribution and logistic support;

d) ensuring proper use of essential drugs at all levels of the health care system, including provision of information and training to drug prescribers and other health workers;

e) setting up and strengthening of local formulation of finished dosage forms of certain essential drugs when such is technically and economically feasible;

f) encouraging de novo preparation of the active ingredients of drug products only in circumstances where such is technically and economically feasible and desirable;

g) ensuring proper quality control at appropriate levels in the production/supply/distribution system;

h) monitoring adverse reactions to drugs and other medicines;

i) introducing and/or strengthening appropriate drug control legislation, including enforcement thereof;

j) ensuring the development and training of needed technical and managerial personnel at all levels, including provision of appropriate long-term career opportunities;

k) ensuring multisectoral cooperation and collaboration within the national government;

l) evaluating progress and program effectiveness through the simplest possible effective systems.

Inherent in the development of effective national drug policies is a national commitment to allocate necessary financial resources and personnel to the program on a long-term basis. Preferably, a competent experienced national coordinator should be appointed to provide a clear focus of managerial responsibility for the program.

4. Pharmaceutical production within the context of the Americas Region requires special consideration. Some countries within the Region now have in place complex and sophisticated industries which undertake broad-scale research and development programs, manufacture the active ingredients of drug products, formulate a broad range of dosage forms, distribute and market drugs to the health care sector domestically, and export products to foreign markets. At the other end of the scale some small countries have essentially no manufacturing facilities, do not conduct drug research and development programs, and are fully dependent upon pharmaceuticals which are imported in final dosage forms.

Countries which wish to start or increase local production of drugs must take several factors into account. These include the cost effectiveness of small-scale production, the capital intensive nature of drug manufacturing, the need for a high level of quality control, the need for highly skilled personnel, and possible opposition by brand-name oriented physicians and other health workers to "government-issue" products. If a country decides to manufacture drugs, it must select wisely from the range of possibilities, especially if financial resources are limited. It is a difficult and expensive task to switch quickly to other more effective or safer drugs which may be developed later on.

It would seem advisable for developing countries which wish to begin drug production to do so in stages, starting with simple formulations of oral dosage forms and proceeding to formulation of more complex drugs as experience, cost and facilities permit. Extensive research and development programs aimed at finding and developing new drugs, and de novo preparation of raw materials or intermediates, would seem to be inadvisable for all but the most advanced of developing countries in the Region. It should not be assumed that public operation of drug manufacturing or formulation facilities is necessarily the best way to ensure the production of high quality products at acceptable cost. Cooperative public-private sector arrangements should be investigated. Possibilities of regional, rather than country-level production should be considered where such would result in the benefits of the economies of scale and be consistent with social, political and other realities. Similarly, consideration should be given to carrying out some aspects of drug quality control at regional rather than country level.

5. Many developing countries do not purchase drugs in the most effective and efficient ways. Countries which wish to regulate drug prices have two alternatives open to them: the national government can negotiate and set prices, leaving promotion and marketing to pharmaceutical manufacturers, or it can buy all drugs, from both domestic and international sources. To be of long-term value, centralized purchasing must take into account, in addition to drug prices, such factors as quality, reliability of supply, labeling and packaging needs and other factors which must be clearly and carefully spelled out in contract terms.

Bulk purchasing of drugs by a number of national governments working together may result in financial savings, but political, legal, financial and operational considerations must carefully be considered and agreed upon before such a project begins.

II. GENERAL POLICY CONSIDERATIONS

The pharmaceutical industry in developing countries presents policy makers with a difficult challenge. Preventive public health measures emphasizing adequate sanitation, nutrition, and primary health care facilities are clearly the most efficient long-term strategy to control and eventually eradicate a wide range of infectious and parasitic diseases. In the absence of better environmental conditions, however, developing nations have relied on pharmaceuticals as their first line of defense against disease. According to various United Nations estimates, drugs constitute around 40 to 50 per cent of the health budget of many developing countries compared to 10 to 20 per cent in the developed nations. Effective drugs and vaccines already exist for many diseases afflicting millions of people, but often they are not available in sufficient quantities and their cost is beyond the means of those who need them. In this situation, governments have sought policies that would ensure an adequate supply of appropriate, safe, and reasonably priced drugs. Most governments in the developing world also try to encourage the growth of local pharmaceutical production for the sake of security of supplies, a more favorable balance of trade, and increased domestic capabilities.

Transnational pharmaceutical enterprises, which are the dominant innovators and suppliers of drug products and technologies today, can make a major contribution to the developing countries' urgent need to improve the health care of their populations. Such a contribution could include, among other things, the sale of low-priced essential drugs, the transfer of technology under acceptable conditions for the production of essential drugs by indigenous manufacturers, and allocating a greater share of their research and development resources to the major tropical diseases. Although some companies are already moving in this direction, their efforts remain limited compared to the resources of the global industry and to the developing world's pressing health problems.

This report seeks to analyze the factors that should be taken into account by governments in the development of policy for the production and marketing of essential drugs. These drugs, whose definition and number vary from country to country, are a segment of the larger pharmaceutical industry. To understand the present and future significance of essential drugs, we therefore have to look at the structure and dynamics of the pharmaceutical industry at the global level. We also have to observe how the generic drugs sector emerged from the process of patent expirations that have dramatically increased the availability of multisource medicines for all countries.

The policies of the health ministries in the Region are conditioned, then, by a variety of parameters. These include the structure and dynamics of the pharmaceutical industry worldwide and in the Americas, the elements of a national pharmaceutical supply system, the role of

health professionals, and the role of sectors other than health in formulating and implementing drug policy. A knowledge of the forces that drive this industry will provide national authorities with a realistic basis for developing policies to obtain the maximum benefits for their people.

Policies deriving from these considerations should not necessarily exclude the private sector because private companies, and especially transnational pharmaceutical firms, are responsible for most drug innovation carried out in the industry. Nor should national policies be confined to the supply of essential drugs for the public sector because new products that today are only within the reach of the urban middle and upper classes may become the essential drugs for the broad-based public health programs of tomorrow. The potential importance of these new products implies a continuing relationship with transnational companies that ideally could benefit both the public and the private sectors.

National health authorities and global drug companies operate from different logics that need to be mutually understood. A health ministry is concerned with assuring the social well-being of a single country's population within the economic resources and political framework at its disposal. Transnational corporations, on the other hand, have global strategies that span a large number of countries and therapeutic markets. Therefore the needs of any one country or the significance of a specific subset of drugs may well be marginal to a large firm's primary concern with global efficiency and profitability. An understanding of this principle of corporate strategic thinking will help health officials devise feasible policies toward the industry.

This report will synthesize a large amount of information on the operations of pharmaceutical firms at the global and regional levels. In addition, selected national and subregional experiences throughout the Hemisphere will be presented in order to give Member Governments an overview of different strategies that attempt to provide their populations with improved access to essential drugs.

III. OVERVIEW OF THE GLOBAL PHARMACEUTICAL INDUSTRY

World Production and Trade Patterns

Worldwide production of pharmaceuticals, estimated at US$84 billion in 1980, is concentrated in the developed market economies that account for nearly 70 per cent of the industry's total output. The centrally planned economies (the Soviet Union, Eastern Europe and China) follow with 19 per cent, while the developing countries' share in world pharmaceutical production is just over 11 per cent. The geographical distribution of output in the developing world in 1980 puts Asia first with 5.6 per cent, followed by Latin America with 5.2 per cent and Africa

with only 0.5 per cent (see Table 1). A closer look reveals that relatively few nations control the bulk of global pharmaceutical production. The three largest drug manufacturing countries--the United States, Japan, and the Federal Republic of Germany--together represent one-half of the world's total output of pharmaceutical products. Over two-thirds of the pharmaceuticals manufactured in the developing world come from a half dozen nations: India, Brazil, Mexico, Argentina, Egypt, and the Republic of Korea (UNIDO, 1980; UNCTC, 1981: 4).

Pharmaceutical consumption, like the distribution of production capacity, is highly uneven. The developing countries, where nearly two-thirds of the world's population lives, consumed only 14 per cent of world production in 1980. The developed market economies accounted for 70 per cent of world consumption and the centrally planned economies for the remaining 14 per cent (Table 1). Within each of the developing regions pharmaceutical consumption is overwhelmingly concentrated in a few nations: Japan consumes 70 per cent of the drugs available in Asia; Egypt and Nigeria together account for 50 per cent of total drug consumption in Africa; and Brazil consumes 36 per cent of the pharmaceuticals used in Latin America (Reekie and Weber, 1979: 29). The two largest national drug markets--the United States of America and Japan--made up 21 per cent and 14 per cent respectively of world pharmaceutical sales in 1981, while the combined share of the top four West European markets was just over 19 per cent (Table 2).

Most Third World countries tend to depend on imports for a majority of their drug needs. The international trade of pharmaceuticals in 1980 was approximately US$13.9 billion. Developing nations imported 32 per cent of the total and exported only 4 per cent. Developed countries as a whole, including centrally planned economies, exported 96 per cent and imported 68 per cent of the pharmaceuticals traded worldwide (Table 1). Because most developing nations lack a strong chemical industry, they imported mainly finished or semi-finished drugs rather than basic or intermediate chemicals requiring extensive local processing. The majority of these imports come from transnational pharmaceutical firms headquartered in the developed market-economy countries.

Globally there are more than 10,000 companies that could be called pharmaceutical manufacturers. No more than about 100 of these are significant in terms of international market participation. These one hundred firms supply about 90 per cent of total world shipments of pharmaceutical products for human use. The top 50 drug companies based on market economies represent nearly two-thirds of this total, while the leading 25 enterprises account for about one-half (Schaumann, 1976: 16-17; Agarwal, 1978: 6). United States-based corporations are clearly dominant among the major pharmaceutical firms. In 1977, U.S. companies were responsible for just under 50 per cent of the sales of the top 50 drug firms in the world industry. The United States, the Federal Republic of Germany, and Switzerland are the base of operations for 33 of the 50

largest drug enterprises (23 from the United States, 7 from the Federal Republic of Germany, and 3 from Switzerland). Together they make up almost 80 per cent of the pharmaceutical sales of the top 50 companies (UNCTC, 1979: 112). In 1980 this pattern continues to be evident for the world's 15 largest pharmaceutical firms. The top 13 companies are all U.S., West German, or Swiss; 7 are from the United States, while the Federal Republic of Germany and Switzerland are each represented by 3 major pharmaceutical enterprises (Table 3).

The world's 50 largest pharmaceutical companies are all transnational corporations--they sell their products in foreign markets, and each usually engages in manufacturing and research and development (R & D) activities abroad as well. The European drug firms are the most internationalized in terms of foreign sales. Almost all of the principal European companies carry out over 50 per cent of their pharmaceutical sales outside of their respective home markets, with each of the three Swiss transnationals realizing more than 90 per cent of their drug sales abroad. The major United States-based pharmaceutical firms tend to sell between one-third and one-half of their output overseas, which is lower than the European percentages primarily because the first priority for U.S. companies is to satisfy the huge demand in their domestic market. The Japanese drug companies are the least internationalized, with foreign markets accounting for no more than 7 per cent of their total pharmaceutical sales in 1977 (UNCTC, 1979: 113).

A fuller understanding of the internationalization of the pharmaceutical industry can be gained by looking at when and where transnational corporations (TNCs) have gone abroad. In Table 4 the overseas expansion of the 25 largest U.S. pharmaceutical TNCs is presented by time period and geographical region. Before 1950 the top 25 U.S. drug companies had initially established just 28 foreign subsidiaries. The vast majority of these were located in a few geographically or culturally proximate countries: Canada, Great Britain (including the Commonwealth countries), and Mexico. During the 1950s and the 1960s the pace of U.S. expansion picked up sharply, with 152 and 181 pharmaceutical subsidiaries formed in these decades respectively. In the 1950s the outward thrust was primarily directed at Western Europe, the Commonwealth countries, and the relatively advanced nations in Latin America (Mexico, Brazil, and Argentina). Finally, in the 1960s there was a surge of interest in Africa, Asia, the Middle East, and the lesser-developed countries of Latin America and Europe. We can infer from Table 4 that over time a significant shift was taking place in the international pharmaceutical industry: local production--generally based on active ingredients imported from the TNC parent--was beginning to substitute for at least some of the direct importation of finished pharmaceutical products in a wide variety of host countries.

The Structure of the Pharmaceutical Industry

The structure of the pharmaceutical industry refers to such characteristics as seller concentration, barriers to the entry of new firms (e.g., patents, product differentiation, economies of scale), the conditions of demand, and buyer concentration (see UNCTC, 1979: Chapter IV). Seller concentration is probably the most commonly mentioned element of market structure because it is closely linked to entry barriers for new firms and to the nature of competition among the leading companies. Generally, the higher the degree of concentration (measured by the share of sales accounted for by a small number, usually four to eight, of the largest sellers), the more difficult it is for new firms to successfully enter the market. Furthermore, in concentrated markets with only a few large sellers of a product each company is often reluctant to provoke retaliation by cutting prices. Consequently large firms tend to eschew price rivalry and turn instead to two other competitive strategies: promotional rivalry based on high advertising expenditures and various product differentiation techniques, and product rivalry based on high R & D expenditures to create new drugs that are in some way different or better than those previously used.

In sales of finished pharmaceuticals the average 4-firm concentration ratio for the drug industry in developed countries is 25 to 30 per cent, with the figure for developing nations being somewhat higher (Burstall et al., 1981: 59; Grabowski and Vernon, 1976: 195). This degree of concentration is lower than that found in other high-technology industries such as automobiles, aircraft, computers, and chemicals. Overall indicators of concentration are deceptive, however, because the drug industry in fact is fragmented into a number of separate therapeutic markets. Pharmaceutical manufacturers do not compete on an industrywide basis. Antidiabetic drugs are not substitutes for antibiotics, nor are tranquilizers substitutes for vitamins. Within these therapeutic markets, concentration levels are quite high. The 4-firm concentration ratios for nine major therapeutic categories in the United States in 1973 ranged from a low of 61 per cent in sedatives to 96 per cent for anti-arthritic drugs and 98 per cent for antidiabetic drugs (Schwartzman, 1976: 131). Sales concentration among companies usually reflects a similar concentration among the leading drugs in a given field. In all but one (antibiotics) of the nine U.S. therapeutic markets the five top brand-named products contribute over 50 per cent of total sales (Schwartzman, 1976: 129).

The evidence for seller concentration is even more striking in the manufacture of bulk drugs. Of the 550 bulk medicinal chemicals produced in the United States in 1981, only six were manufactured by more than three companies, while nearly 430 were available from a single domestic source (United States International Trade Comission, 1982: 105-122). The capability to produce finished drugs, therefore, does not necessarily put a country in charge of its own destiny in the pharmaceutical

industry. The further back in the production chain one goes, the greater the likelihood of exceedingly high levels of seller concentration. A recent study prepared by UNIDO is a directory of worldwide sources of supply for 26 essential bulk drugs, their chemical intermediates, and some raw materials. Several of the 26 finished pharmaceuticals were manufactured by only a few companies at the global level (e.g., reserpine and primaquine are produced by just four companies each). The more common pattern, however, is a much larger number of manufacturers of the finished drug with only a few producers of the required chemical intermediates or raw materials. There are 47 companies that make tetracycline, for example, but the chemical intermediates used in tetracycline come from just five firms in the world (two from the United States, one from the Federal Republic of Germany, one from Spain, and one from Portugal). Erythromycin and piperazine are both produced as finished drugs by 22 different companies, yet certain key intermediates for each are made by just five and four manufacturers, respectively. Overall, 10 of the 26 essential drugs listed in the UNIDO study are manufactured by six or fewer firms worldwide at one or more stages in their production process (UNIDO, 1982).

The conditions of consumer demand in the pharmaceutical industry shape the ways in which market concentration affects industry performance. The pharmaceutical industry is composed of two distinct sectors: the proprietary drug sector and the ethical drug sector. Proprietary drugs (e.g., aspirin, oral antiseptics) are considered safe for self-medication if package instructions are followed, while ethical drugs generally cannot be purchased without a physician's signature. Since the proprietary drugs are advertised directly to the consuming public and do not require a prescription, the consumer himself makes the buying decision for this class of medicines. In the ethical drug sector where a doctor's prescription is required, the buying decision in the developed countries is made for the consumer by a doctor. The pharmacist typically has been obliged to fill the prescription exactly as it is written. In the aphorism made famous by the late U.S. Senator Estes Kefauver, "He who orders (the doctor) does not pay; he who pays does not order." From the consumer's point of view, the main criticism made of this situation is that doctors tend to be insensitive to price diffences between substitutable drugs.

The situation is different in most of the Third World where, although a doctor's prescription may be legally required, many patients commonly and openly obtain these products directly from a pharmacist or an untrained pharmacist's assistant without a prescription of any kind. This system of self-medication flourishes not only in the large urban drug supermarkets but also in rural areas and small villages where there may be few or even no health professionals available. Frequently the poorest segments of the population who have little money to buy medicines, much less pay for a doctor's consultation, rely most heavily on the pharmacist's advice, that of relatives and friends, or the directions

given in the package leaflets on how to take the drug and what danger signs to watch for. Under these circumstances the information that pharmaceutical companies release in standard medical reference manuals and in package inserts or labeling material becomes especially important in determining the situations in which a prescription drug will be used because this information often reaches people with little or no medical knowledge against which to evaluate promotional claims. The phenomenon or self-medication in developing countries has little or no effect on the pricing policies of pharmaceutical firms. The intermediary role of doctors is simply replaced by that of pharmacists who become the primary target of the industry's promotional activities. Price insensitivity thus remains an important problem.

Product Rivalry

The 1950s and early 1960s were a golden age of discovery in the pharmaceutical industry, and most of the major drug manufacturers distributed their research efforts across a broad gamut of therapeutic fields. The amount of pharmaceutical innovation dropped sharply in the latter part of the 1960s and the beginning of the 1970s, however. Research and development productivity in the pharmaceutical industry in the United States of America, for example, declined by about sixfold between 1960-1970, and in the United Kingdom the corresponding decrease was about threefold (Grabowski et al., 1976: 64-65, 77). One explanation for the decline in any new drug discovery in this period is that the underlying stock of research opportunities in the pharmaceutical industry was depleted by the rapid rate of innovation that occured in the first part of the post-World War II era. The worldwide industry in the 1960s and early 1970s thus found itself at least temporarily on a "knowledge plateau" (Grabowski, 1976: 19-24; Schnee and Caglarcan, 1976: 33; Cohen et al., 1975: 18-26). The fact that R & D productivity in the United States dropped twice as much as it did in the United Kingdom also lends support to the hypothesis that more stringent regulatory controls for drugs in the United States--in particular, the 1962 Kefauver-Harris Amendments--was an additional and important condition leading to innovational decline (Peltzman, 1974).

At the end of the 1970s, however, a number of exciting and potentially revolutionary drug products were introduced into the market by pharmaceutical manufacturers, leading many to claim the industry is on the threshold of a new "golden age of reseach productivity" (see Business Week, 1979; Dun's Review, 1979; Newsweek, 1979a and 1979b). The U.S. Food and Drug Administration approved the introduction of 23 compounds in 1978, the most in any year since 1967 (Business Week, 1979: 134).

What is so significant about these recent drug products is that they seem to reflect a series of breakthroughs at the level of basic research--i.e., new knowledge about how the body functions, how disease is caused, and what chemicals interfere with physiological processes.

Perhaps the most revolutionary characteristic of many of the new drugs is that, instead of simply treating symptoms, they have a direct effect on the causes of disease.

Closely linked to their revolutionary mode of therapeutic action is a profound change in the strategy used to develop these new drugs. The traditional method has been to screen at random thousands of compounds, both synthetic chemicals and natural substances, to discover pharmaceutical products that have significant medical activity and are safe. More and more, however, the development job is done today by specifying in advance the characteristics desired in a new drug. This is fundamentally a biological approach, since the molecules of the chemical compound are designed, atom by atom, to alter a pretargeted physiological process in the body; the chemists thus must create compounds with the emphasis on effect rather than chemical structure, which is the reverse of the traditional process.

While the pharmaceutical industry may indeed be on the threshold of a second "golden age" in drug discovery, the commercial benefits of these scientific advances are likely to remain highly concentrated. Merck and Company, the biggest U.S. pharmaceutical firm, increased its sales by 15 per cent and its net income by 11 per cent in 1978, largely on the basis of the five new drugs it marketed in that year, more than any other company. Eli Lilly's recent boom in performance--a sales jump of 19 per cent and a 24 per cent rise in net income in 1978--is also closely tied to its research productivity, which led to the introduction of three major pharmaceuticals in a 10-month period (Business Week, 1979: 134, 137). But for those enterprises that are lagging behind in the new products race, the economic prospects in the industry's innovative track seem bleak. Few drugmakers can maintain the kind of research and development program that Merck supported, for example, when during a recent 10-year period it spent about US$750 million without producing a single important drug for the market.

The world's 15 largest pharmaceutical companies in 1980 were all research-intensive operations. Only one firm of the 15 spent less than US$100 million on R & D, while a couple of the top enterprises had annual R & D expenditures in excess of US$600 million. In several cases the companies spent more money on new product development in 1980 than they earned in profits (see Table 3). Another important indicator of research productivity among drug firms is their number of new product launches. The two most successful pharmaceutical companies in this regard in 1980 were Schering-Plough and Johnson and Johnson, both of the United States, with 48 and 46 new product launches respectively (see Table 5). The most innovative drug firms worldwide are from the United States, the Federal Republic of Germany, and Switzerland. It is interesting to note in Table 5 that the number of new drugs introduced in Europe in 1980 was more than 10 times the number marketed in the United States and Canada, reflecting

in part the U.S. FDA's more stringent pre-marketing regulatory standards. The next most important region for new drug launches after Europe was Latin America.

Promotional Rivalry

Product rivalry and promotional rivalry in the pharmaceutical industry are closely linked by the workings of patent and brand-name systems. When a new product is developed by a drug manufacturer, it is normally patented and given a trademarked brand name. The assigned function of a patent is to stimulate inventive activity by impeding the imitation of a new product during a period of legally sanctioned monopoly (e.g., 17 years in the United States, 16 in the United Kingdom, and 7 in India), thereby allowing the innovating firm the opportunity to recoup or more than recoup its investment. Often the patent system is only partially successful in forestalling competitors; however, patents do not preclude the development of duplicative ("me-too") drugs that achieve similar therapeutic ends by means of minor chemical modifications. Furthermore a patented product can be licensed to other manufacturers, which minimizes the competitive barrier of the patent itself.

In these situations and others, the product brand-name system serves as a critical complement to the patent system. In their positive effects for the drug industry the two systems are similar: they both insulate the major drug companies from price competition. The advantage of the brand system is that a brand name may be effective where a patent is not--e.g., for products that cannot be patented, that are freely licensed, or for which the patent has expired. The brand system thus is the foundation of the drug industry's extensive promotional activity, just as the patent system is the cornerstone of its intense research activity. At one level, drug promotion is meant to provide doctors with essential scientific information about a wide variety of new products. In addition to this educational purpose, however, the goal of each top pharmaceutical enterprise's promotional program is to gain and maintain market dominance for its products through the creation of strong and lasting brand-name preferences among prescribing physicians and the consuming public alike.

The brand-name system produces a bewildering array of different names for the same drug. For the 700 active ingredients available in the United States, there exist an estimated 20,000 names (Brooke, 1975: 19)--an average of 30 names for each drug product. The situation is similar in other nations. The number of pharmaceutical brand names registered in various countries in 1974 is as follows: Argentina, 17,000; Belgium, 9,000; Brazil, 14,000; Canada, 17,000; Colombia, 15,000; the Federal Republic of Germany, 24,000; France, 8,500; India, 15,000; Iran, 4,200; Italy, 21,000; Japan, 17,400; and the United Kingdom, 9,000; (UNCTAD, 1977: 50-51). This proliferation of product presentations has greatly increased the utility of familiar brand names to the physician.

Since there are too many drugs to permit a systematic evaluation of quality and price alternatives, doctors probably find it rational to learn about and work with only a few well-promoted brands. This makes it more difficult for true price competition to take place among pharmaceuticals. The widespread use of generic names for drugs would help to counteract this.

The drug promotion of transnational pharmaceutical companies in Latin America has been the subject of detailed investigations and much recent controversy (Silverman, 1976; Ledogar, 1975: 25-51). The most systematic and influential research is Silverman's (1976) survey conducted on the promotion of 40 different prescription drug products marketed in the United States and Latin America by 23 pharmaceutical firms from the United States, Switzerland, the Federal Republic of Germany, and France. Striking differences were found in the manner in which the identical drug marketed by the same global company was described to physicians in the United States and to physicians in Latin America. In the United States, the listed indications (or diseases for which a drug is recommended) were usually few in number while the contraindications, warnings, and potential adverse reactions were given in extensive detail. In Latin America the listed indications were far more numerous, while the hazards were usually minimized, glossed over, or totally ignored.

These promotional differences were not simply between the United States on the one hand, and all the Latin American nations on the other, however. There were substantial differences in how global enterprises described the same drug product to physicians within Latin America. A transnational pharmaceutical company marketing a prescription drug frequently told one story about it in Mexico, a different one in Guatemala, and gave still other versions in Ecuador, Colombia, or Brazil. If there were corporate or national patterns or policies to account for these variations, they were not readily discernible. This would appear to invalidate, therefore, one of the most widely used industry defenses for differences in promotion: namely, that these reflect "honest differences in opinion" between regulators in the exceptionally stringent U.S. Food and Drug Administration and regulators elsewhere. A second point that should be emphasized with respect to the findings of this study is that Latin America has not been singled out for such treatment by drug companies. At least in the case of chloramphenicol similar differences are also found in non-Third World nations such as France, Italy, Spain, Australia, and New Zealand (Silverman, 1976: 107).

A third factor worth noting is that most Latin American countries have laws requiring that any drug product that is imported must be approved for marketing in the "country of origin." Yet certain prescription pharmaceuticals originally introduced in the United States but later taken off the market by FDA orders--e.g., fixed-ratio antibiotic

products--continue to be imported and sold in Latin America. The solution for transnational firms has been simple: the United States-based company needs only to set up a plant to produce the drug or put it in finished dosage form in Nation X (which is not the United States), get approval for marketing from obliging Nation X officials, and then ship the drug throughout Latin America with Nation X listed as the "country of origin." A similar device has been used by European firms with drugs that had to be withdrawn from the European market as ineffective or excessively dangerous (Silverman, 1976: 117). Some of the major pharmaceutical exporting nations have had, at least until recently, relatively lax drug registration laws that allowed them to satisfy country-of-origin requirements without meeting modern standards of safety or efficacy. The nations that generally have employed strict registration criteria for drugs include the United States, Great Britain, the Netherlands, Norway, and Sweden.

It appears that the problem of excessive claims and suppressed adverse reactions for prescription drugs might be overcome in Latin America through action by the pharmaceutical companies themselves, spurred on no doubt by the publicity this topic has received. Several months after Silverman's The Drugging of the Americas (1976) was published, the council of the International Federation of Pharmaceutical Manufacturers Associations adopted a resolution submitted by the United States delegation calling for prescription product labeling to be consistent with "the body of scientific and medical evidence pertaining to that product." Special care was to be taken in appropriately communicating "essential information as to medical products' safety, contraindications and side effects." By 1977 it was evident that some global drug firms had altered their promotion by limiting claims and disclosing hazards in the labeling of some products (Silverman, 1977: 166). In his newest book, Silverman lauds companies like Merck, Eli Lilly, Syntex, SmithKline, and Ciba-Geigy for their consistency and stringency in labeling and promoting their products (Silverman et al., 1982: 150-152).

Price Rivalry

Although some form of governmental price control for drugs exists in most countries (see UNCTC, 1979: 139-141), it generally has been ineffective. Most important drugs have been protected by patents during much of the post-World War II period. Moreover, drugs often become outmoded as they grow older and hence the sales of old drugs that have no patent protection may be too small to be attractive. Finally, it is important to recognize that the brand-name system helps the patent system shield the major drug companies from price competition, as discussed above. To the extent that price rivalry among pharmaceuticals does exist, however, it is likely to be most prevalent among multiple-source drugs sold by more than one company. This category primarily refers to

unpatented "generic" products (those whose patents have expired as well as those that were never patented), although it is also includes patented items that have been widely licensed.

The potential for price competition is high, though, because generic drugs are a large and rapidly growing part of the pharmaceutical industry. Since the mid-1960s the proportion of all United States' drug prescriptions that are written using only generic names has risen steadily--from 6 per cent in 1966 to 12.4 per cent in 1977. If one looks just at prescriptions for multiple-source pharmaceuticals and adds the large quantity of generic drugs that are sold in the institutional market (primarily to hospitals and the government), overall sales of generic drugs in the United States amount to about 40 per cent of the total sales of multisource ethical pharmaceutical products (UNCTC, 1979: 80-81).

The two principal causes for the expansion of the generic sector of the drug industry are: first, the increasing insistence of developed and developing country governments alike that generic prescribing and procurement policies be used as a tool for cost containment, if not cost reduction, in pharmaceutical spending; and secondly, the rapid rate at which drug patents have expired since the 1960s. Pharmaceutical products no longer under patent protection represented about 45 per cent of the total volume of United States ethical drug sales in the late 1970s (Business Week, 1979: 145). By 1989 patent expiry will have occurred for additional drugs whose sales in 1979 stood at US$2.2 billion (ALIFAR, 1982b: 21).

The generic drug market has two distinct segments: commodity generics and brand-name generics. The commodity-generic segment includes all products sold under their generic name only; no brand name is used nor is the manufacturer's name linked to the name of the product. Brand-name generic drugs are actually of two types. The first variant refers to unpatented pharmaceuticals that are marketed under product brand names. This includes the original manufacturer's brand name as well as brand names used after patent expiry by companies other than the innovator. The other variant of branded generics refers to unpatented drugs labeled with the company's trade name rather than a specific product brand name (e.g., SmithKline's SK-Tetracycline, McKesson and Robbins'"Kesso-Bamate" version of meprobamate, or Pfizer's erythromycin called "Pfizer-E").

The commodity-generic and brand-name generic segments of the drug industry contrast sharply in terms of size, the type of enterprises participating in each, and the nature of their clients. In the United States, branded generics accounted for 93 per cent and commodity generics for the remaining 7 per cent of 1979 generic drug sales, totaling US$4.4 billion (see Tables 6 and 7). The makers of commodity-generic pharmaceuticals are usually small firms with limited resources and narrow profit margins. An estimated 500 to 600 such companies operate in the

United States. Four transnational pharmaceutical enterprises--Eli Lilly, American Home Products, Warner-Lambert, and SmithKline--dominate the market in commodity-generic supply, however, with 42 per cent of total sales (Table 6). The branded-generic segment of the pharmaceutical industry is more thoroughly and evenly permeated by large transnational drug companies that generally promote branded generics in the same way they market their patented items. The leaders in the US$4.1 billion branded-generics field in the United States in 1979 were G. D. Searle (US$200 million), Eli Lilly (US$170 million), and a Hoffmann-La Roche subsidiary named Roche Laboratories (US$160 million) (Table 7). The final contrast relates to clients. Pharmacies, private hospitals, physicians, and the government are all major buyers of commodity generics. The pharmacy is the only significant customer for branded generics, however, accounting for nearly nine-tenths of manufacturers' sales of these products. Usually branded generics are sold at higher prices than nonbranded commodity versions of the same drug.

A two-tier operating structure appears to be emerging in the pharmaceutical industry, made up of suppliers of new drugs (i.e., product innovators) and broad-line generic suppliers. The former is the province of a select number of research-oriented companies that will continue to spend heavily on new drug development, primarily for developed country markets. United States-based firms of this type include Merck and Company, Eli Lilly, Upjohn, SmithKline, American Home Products, and Pfizer. Among the most innovative European pharmaceutical companies are Hoffmann-La Roche, Ciba-Geigy, Hoechst-Roussel, Burroughs-Wellcome, and Bayer. The second category of producers will compete mainly on the basis of price in the generic drug market, thus appealing to the cost-conscious sectors in both developed and developing countries. These firms will also tend to concentrate heavily on over-the-counter products. The largest drug enterprises like Eli Lilly, Hoffmann-La Roche, Ciba-Geigy, SmithKline, etc. will probably operate in both the innovative and generic (particularly branded-generic) tiers of the pharmaceutical market. Some medium-sized companies might opt for a specialty profile, but faced with soaring research costs most of the smaller firms will have little choice but to concentrate on generic supply if they remain in the industry. The large branded segment of today's generic market gives the transnational drug companies a distinct edge over small national competitors, especially in the developing countries, because the former can use their brand-name image as a major source of market power. Thus even in what is potentially the most competitive segment of the pharmaceutical industry in terms of price, transnational firms are becoming the dominant force and national producers seem to be losing out (see ALIFAR, 1982b: 19-21).

IV. THE PHARMACEUTICAL INDUSTRY IN THE AMERICAS

Latin America and the Caribbean is a very diverse region with regard to economic, demographic, and health indicators. This diversity is also evident in the level of development, the structure, and the performance of national pharmaceutical industries in the Hemisphere. These differences, along with some important underlying similarities, will be outlined in this section of the report.

Latin America has maintained a relatively high rate of economic growth in recent years despite the recession that has afflicted most of the developed countries since 1974. The gross domestic product of Latin America as a whole rose at an annual rate of about 6 per cent in 1979 and 1980, while the annual average growth rate for the developed market-economy countries in the same period did not exceed 3 per cent (ALIFAR, 1981: 2). One of the main factors contributing to steady economic growth has been the relatively large size, even on a world scale, of the internal markets of various nations and subregional groupings in Latin America. Brazil is the biggest country, with a population of over 120 million in 1980, followed by Mexico with 70 million people and Argentina with 28 million. The Andean Common Market is made up of five nations--Bolivia, Colombia, Ecuador, Peru, and Venezuela--with a total population of 73 million (see Table 8). If one adds to these populations figures the fact that at least seven countries in the Region had average per capita incomes ranging from US$1,000 to $2,100 in 1980 (Table 8)--compared with an average annual per capita income of less than US$500 for developing nations overall (World Health Organization, 1981: 25)--one can see why internal demand has been an important asset for a significant number of countries in Latin America.

The rate of population increase in Latin America and the Caribbean appears to be diminishing, however. The total number of inhabitants in the Region rose from 215 million in 1960 to 367 million in 1980, an overall increase of 71 per cent and an annual growth rate of 2.7 per cent. The population growth rate declined slightly in the 1970s, though, and by the year 2000 it is expected to drop further to about 2.4 per cent (PAHO, 1981: 1). Several other demographic shifts also deserve attention. First, the people of Latin America and the Caribbean are becoming more urbanized. In 1980, 64 per cent of the population lived in cities; this proportion is expected to jump to nearly 75 per cent by the end of this century, with more than half of these people living in cities of over 100,000 inhabitants. Secondly, average live expectancy in Latin America and the Caribbean is increasing. In 1975-1980 the average life expectancy at birth in the Region was 64 years, compared to 72 years for the developed countries and 55 years to developing nations as a whole. By the end of the century, the average life expectancy at birth in Latin America and the Caribbean will probably exceed 70 years. Already Costa Rica, Uruguay, and Argentina have attained average life expectancies of around 70 years (see Table 9). The principal cause of added life

expectancy at the regional level is the decline in the crude death rate per 1,000 inhabitants--down from 12.5 in 1955-1960 to 8.3 in 1975-1980, with a further drop to 5.7 projected for 1995-2000. The major reductions in death rates have been for children under five years of age, especially infants (PAHO, 1981: 1-2). Table 9 shows the variability within Latin America in terms of selected demographic and health indicators.

The trends highlighted above are very significant for the pharmaceutical industry. First, the control of the infectious and parasitic diseases that have had such a damaging effect in developing nations, especially on children, will continue to be a high priority in most public health programs. Although improvements in environmental and nutritional conditions are usually the best long-run strategy a country can pursue, a number of essential drugs and vaccines will also be needed to keep mortality rates low. There will be growing pressures to assure the availability and reduce the costs of these drugs both through centralized procurement schemes and local production. On the other hand, the shifting age distribution of the population in Latin America and the Caribbean means that newer drugs will be required in greater quantities as well, with the disease profile in the Region becoming more like that typical of advanced industrial societies. The share of the population represented by people 45 years of age and older is expected to grow from 15.9 per cent in 1980 to 17.3 per cent by the year 2000. In absolute numbers, this will be an increase from 59 million to 105 million individuals (PAHO, 1981: 1). Chronic diseases associated with industrialization, urbanization, and old age (such as cancer, heart and lung disease, hypertension, and various forms of mental illness) are already becoming more prevalent in the Region. Access to new medicines to combat these chronic ailments necessitates a close relationship with the most innovative firms in the pharmaceutical industry.

Pharmaceutical consumption per capita in Latin America varies considerably across countries (see Table 10). The high figures for Argentina and Uruguay should be interpreted with caution, since they probably reflect the overvaluation of their local currencies in 1980. Nonetheless there appears to be a moderately strong positive correlation between pharmaceutical consumption per capita (Table 10) and GDP per capita (Table 8). Table 10 also shows that, while the biggest countries in the Region have the most pharmacies, the relationship between market size and the number of pharmaceutical products and presentational forms is quite uneven. Bolivia offers the second largest number of drug products in Latin America (8,000), even though it has one of the smallest populations and the lowest GDP per capita. Colombia sells more than twice as many dosage-form pharmaceuticals as Argentina yet has fewer inhabitants, while Brazil and Peru offer similar numbers of dosage-form medicines despite the fact that the former nation has over seven times as many people as the latter. All of the Latin American countries import substantial amounts of pharmaceuticals by value, but with the exception of Mexico they export very little.

To the extent that Third World nations have attempted to establish strong local drug industries, they usually have followed one of two complementary strategies. The first strategy is vertical integration, which in its usual "backwards" direction means increasing the productive capability of the local industry--starting with packaging, working up to various kinds of dosage formulation, and ending with the manufacture of bulk drugs or intermediate chemicals. A second approach involves the use of ownership controls, which require domestic production facilities to be at least partly held by national capital (private or governmental). Whereas vertical integration affects the level of development reached by Third World countries, ownership controls try to shape its direction by tempering the global norms of TNCs with the nationalist orientation of local entrepreneurs.

Table 11 presents the level of development of the pharmaceutical industry in Latin America in terms of five different stages of vertical integration. The nations in the first stage have no pharmaceutical manufacturing activity and therefore must rely entirely on imports of finished drugs to satisfy their health care needs. Countries classified in the second and third stages of development have the facilities to package and formulate imported bulk medicines but lack the capability to produce the latter domestically. The nations grouped in the fourth and fifth stages of pharmaceutical development are characterized by the highest degrees of vertical integration. These countries manufacture a fairly broad range of active ingredients from intermediate and raw materials, in addition to formulating and packaging drugs. The nations that have reached the fifth stage--Argentina, Brazil, and Mexico--also carry out local R & D on new and adapted pharmaceutical products and processes.

Each level of development has a distinctive set of constraints (see UNIDO, 1979: 11-12). At the first or lowest level of development, the resources made available for health care from the national budget are very limited and there is a serious shortage of trained personnel. These countries tend to have small national markets, imports are unrestricted, and the proliferation of different brand-name products is great. Pharmaceutical procurement generally is not centralized, and national policy with regard to the drug industry is lacking. For Latin American nations engaged in the packaging and formulation of pharmaceutical products (stages two and three), the prices of imported bulk drugs and raw materials are often considered too high. Many countries also have had difficulty obtaining suitable formulation technology on reasonable terms. This latter problem is manageable, however, because the technology for formulation is relatively simple and can be acquired from a number of developing nations--such as Algeria, Argentina, Brazil, Egypt, India, Mexico, and Pakistan--where the similarity of environment and available infrastructure make it easily adaptable to other areas in the Third World. A final difficulty of countries that formulate their own pharmaceuticals is how to convince doctors and patients of the quality of domestically produced drugs.

For the nations that have reached the fourth or fifth stages of pharmaceutical industry development, common constraints include some of those previous mentioned: the unavailability or high price of imported intermediates and raw materials, the difficulty of obtaining foreign technology on suitable terms, and the need to assure users that local products are of high quality. In large countries where packaging and chemical industries are already well established, there is a move to begin local production of the equipment and machinery used by the pharmaceutical industry. Manufacturers in Argentina, Brazil, Egypt, India, and Mexico are willing to sell pharmaceutical plants to other Third World nations (UNCTC, 1979: 91). India is on the forefront of this movement. It has begun to concentrate on producing plants of small-scale capacity (less than one ton per day) that can make a variety of chemically related synthetic drugs on a batch basis.

The degree of domestic ownership in Latin American pharmaceutical industries, like the extent of vertical integration, is relatively low. Table 12 presents pharmaceutical market share data for 12 Latin American countries in 1980. In all cases, locally owned firms account for less than one-half of domestic drug sales. Nationally owned pharmaceutical laboratories are strongest in Argentina, where they nearly match their TNC rivals in sales volume, and weakest in Ecuador and Colombia where local market shares are barely over 10 per cent. Brazil and Mexico, which like Argentina have relatively large pharmaceutical markets in terms of sales, nonetheless have a much lower level of participation by locally owned laboratories in total industry output (22 and 28 per cent, respectively). The strength of domestically owned pharmaceutical firms in the Region is further indicated in Table 12 by their rank amidst all of the top drug firms at the national level. In Chile there are four local laboratories among the top 14 pharmaceutical enterprises in the country, and in Argentina there are four local companies among the top 16 drug firms. Uruguay, Venezuela, and Peru also have a number of prominent nationally owned laboratories. The domestic drug industries in Brazil and Mexico are shown to be weak according to this measure, however, with the largest Brazilian-owned laboratory ranking seventh and Mexico's biggest local drug firm standing thirty-first on their respective national lists.

Several additional findings can be gleaned from Table 12. First, the distribution of medicines in Latin America moves predominantly through private channels. In all of the major countries in the Region, with the exception of Bolivia, at least 70 per cent of pharmaceutical sales is to the private sector. Nevertheless, in several nations like Mexico and Brazil the public sector demand for medicines is growing faster than the private sector market, and a number of the largest local pharmaceutical enterprises are state-owned. Second, the 20-firm concentration ratios in these countries tend to be higher than the corresponding indices for developed countries, although there is considerable variation within the Region, with the smaller nations showing much higher

levels of concentration. Finally, the data on pharmaceutical employees and the number of laboratories suggest notable differences in the Region in productivity and capital intensivity. Argentina, Chile, and Uruguay, for example, are far more productive in terms of pharmaceutical sales per employee than Ecuador or Peru.

In order to increase the degree of local ownership, Third World countries have been promoting joint ventures between TNCs and domestic companies. What is particularly interesting in this context is the fact that small- and medium-sized firms in the developed countries have started to demonstrate a strong interest in helping developing nations industrialize, particularly through the mechanism of technology transfer. Swedish firms appear to have taken a lead in this area. Astra, a Swedish drug company that already has manufacturing facilities in Argentina, Brazil, and Mexico, has proposed to be a 26 per cent joint-owner with an Indian pharmaceutical company and Nitro-Nobel, another Swedish firm, in order to manufacture clofazimine (a leprosy treatment) in India. When Ciba-Geigy, which holds the patents on clofazimine, refused to transfer its rights or knowledge, Astra offered to help develop a production method based on know-how that bypassed the restrictive patents. The project may take one or two years, with an annual cost of about US$1 million (Developing World Industry and Technology, Inc., 1979: 23). SweDrug Consulting, a Swedish state-owned company, also provides developing countries with know-how on the manufacture of drugs. While TNCs normally transfer technology only on the basis of wholly owned subsidiaries or majority-owned joint ventures, SweDrug Consulting has been willing to go in on a minority basis or even to accept a lump-sum payment. The company is currently involved in several projects in Cuba and the Arab countries (Agarwal, 1978: 49-50). The Swedish Health Ministry is trying to set up another enterprise to assist developing nations with organizational know-how for their drug supply systems, including distribution, administration and plant inspection.

On the whole, the pharmaceutical industry in Third World countries has made a very limited contribution to local industrialization efforts. There are signs that this may be changing, however, as smaller firms from the developed countries have begun accommodating demands from the developing nations for increased production capacity.

V. MAJOR ELEMENTS OF AN INTEGRATED NATIONAL DRUG POLICY

Pharmaceutical supply systems have evolved to some degree in all countries. Depending on a country's constitutional, administrative, and technical structures, its pharmaceutical supply system may be part of the public sector, or it may belong to the private sector, or it may be partly in the public sector and partly in the private sector. The components of a fully developed pharmaceutical supply system include: drug legislation and regulatory control, product selection, quality assurance,

procurement, local production, distribution, pricing, research and development, the training of health workers in the proper use of drugs, the utilization of locally available natural resources for health care, and safe forms of self-medication.

Clearly designed national drug policies are needed to achieve better efficiency of the pharmaceutical supply system through the coordination of its different components and through the cooperation of the different sectors involved, such as health, trade, industrial production, finance, and planning. These problems of coordination and cooperation require a multisectoral or interministerial approach to policy formulation. This is because the pharmaceutical industry is not merely an integral element of the health care system; it is also a source of tax revenues and of foreign exchange and savings, it has a strategic value because it supplies vitally needed medicines, and it is a stimulus to research in the medical, biological, chemical, and industrial fields. The main objective of national drug policies should be to take the most effective and safe medicinal products of acceptable quality available to all people at a reasonable cost. Thus a policy for the pharmaceutical sector must be comprehensive, encompassing the procurement and production of drugs and their distribution to the entire population.

Procurement

It is now generally accepted, and has been confirmed in a report by a World Health Organization Expert Committee (WHO, 1977), that the number of drugs necessary for treating the large majority of diseases both in developed and developing countries is relatively small. A list of about 200 essential drugs has been drawn up by WHO as a basis for discussion and for the preparation of national lists. The WHO Expert Committee specifies the criteria governing the selection of essential drugs: they must be "proven to be therapeutically effective, to have acceptable safety, and to satisfy the needs of the population" (WHO, 1977: 9). Because the essential drugs are old products and the great majority (about 95 per cent) are free of production patents, they can be manufactured in any country. WHO recommends that all developing nations take steps to draw up a list of essential drugs, although this list will vary from country to country depending on its health needs, financial resources, local production facilities, and other factors.

Once a nation has identified a list of essential drugs, this preference should be reflected in the national formulary. Countries with centralized procurement and distribution systems can adopt the list immediately. In mixed economies with both private and public health sectors, the public sector institutions like social security and state hospitals can make a start in using essential drugs; the list can also be utilized by the private sector. State-owned firms should be concerned mainly with the production of essential drugs. Private sector

enterprises that manufacture these products will probably have to be given special incentives, since the profit margin in this area of the industry is low because most essential drugs are free of patents.

A centralized bulk procurement system for finished drugs, chemical intermediates, and raw materials using open international tenders has many advantages. These include the following: organized market intelligence; the benefit of large purchases and therefore greater economic bargaining power; easier management of the quality control of imported products; the assurance that domestic drug manufacturers purchase their chemical inputs at fair prices; and the ability to adopt the use of generic names with the attendant savings in foreign exchange over brand-name products. The experience of countries like Brazil, Costa Rica, Mexico, Cuba, and Peru with centralized procurement systems shows that by drawing on multiple sources of supply it is possible to buy drugs at lower prices.

The registration of new pharmaceuticals is a key instrument wielded by the Ministry of Health in implementing national drug policies oriented toward essential drugs, generic names, and limited product selection. The Health Ministry should ensure that only those new pharmaceuticals are registered which, considering the balance of efficacy, safety, and cost, have some distinct advantage for the country. This implies, among other things, restricting the number of duplicative or "me-too" items on the market. The proliferation of brand-name medicines entails dangers for public health as well as a tremendous waste of money and effort. The availability of so many similar products increases the chances of error in the prescription or use of drugs, and may result in ineffective treatment or a higher incidence of adverse effects.

Production

Pharmaceutical production involves a number of distinct stages, not all of which require large production volume or the use of complex technology in order to be economically viable. Production policies will vary from country to country, depending among other things upon the degree of industrialization, technical capability, and the size of the market. For the sake of security of supplies, the balance of trade, and the building up of domestic capabilities, some local manufacture of drugs is desirable in every nation. All countries could establish their own packaging units, and, where feasible, formulation plants. Populous or relatively more industrialized nations should consider producing large-tonnage chemical intermediates and medicinal chemicals, whereas small or less industrialized countries may find it advisable to cooperate in setting up subregional or regional pharmaceutical production units.

Packaging of pharmaceuticals is the last stage in the production sequence before the distribution of drugs to the consumer. This process, which results in major savings of foreign exchange and also trains

nationals, can easily be carried out by developing countries with a minimum of equipment and facilities. The next stage following the packaging of bulk supplies, considering the production sequence in reverse order, is dosage formulation. Dosage forms manufactured from bulk drugs are of two main types: a) those that do not require strictly sterile conditions (such as tablets, syrups, ointments, and capsules); and b) those that do require sterile conditions and are intended for parenteral administration (such as sterile transfusion solutions and sterile antibiotic powders in vials). Dosage formulation of the latter type involves well-trained staff and more stringent quality control standards for manufacturing, and thus is best undertaken after experience has been gained with less sophisticated products. The ratio of the value of the bulk drug to its value in dosage form is roughly from 1 to between 5 and 10.

Synthetic pharmaceuticals represent the largest category in drug consumption. Chemical intermediates are the basic feedstock of the synthetic drug industry. Ideally, therefore, the manufacture of basic chemicals should precede that of synthetic drugs and even antibiotics. A number of high-priced biological products, on the other hand, such as pepsin, insulin, total bile acids, cholesterol, and pituitary extract, can be manufactured as by-products of slaughterhouse and hospital wastes without requiring the establishment of a chemical industry. One option for countries interested in producing low-tonnage, high-priced pharmaceutical items with reactions of the same type is multipurpose plants.

A technology plan has to be an integral part of the development plan for the pharmaceutical sector. The two major components in a technology plan are the phasing of production, and the research and development activities and related institutional infrastructure needed to assimilate and adapt imported technology as well as to generate new technology suited to local resources. Since there is often little or no activity in this field in most developing countries, it may be necessary for the government to set up specialized research centers or to sponsor research in existing institutions.

Distribution

The distribution of drugs and the delivery of health services are among the most important elements of the pharmaceutical supply system. One of the serious difficulties affecting health services in the developing countries is that phamaceutical products do not reach more than 40 to 50 per cent of the population, except in a few nations like Costa Rica and Cuba. It is necessary to devise and implement a system of drug distribution that reaches a majority of the population, even in remote rural areas.

Many developing nations are successfully experimenting with a multiple system of distribution using trained paramedical personnel at the periphery, and the general physician and the specialist at the regional and central hospitals, respectively. At the remotest delivery point there would be a community health worker, who has some education and is adequately trained in the basics of first aid, symptomatic diagnosis of simple illnesses, and drug administration. At the next level, there would be paramedical personnel who have received more elaborate training and act as the link between the community worker and the primary health center that covers a number of villages and is staffed by a general physician. This center in turn is linked to a referral hospital and to specialized medical services.

Unconventional channels of drug distribution also should be explored to reach the people in rural areas, particularly with common household remedies such as those for coughs and colds, diarrhea, and seasonal fevers. Now that dispensing has become greatly simplified by the availability of dosage forms in convenient packaging, a special group of rural pharmacists or even rural schoolteachers and postmasters might be allowed to distribute a selected list of pharmaceutical products. Simple self-medication could perhaps be encouraged with drugs known to have a wide margin of safety.

VI. CONCLUSIONS

1. General

1.1 The major objective of a program on essential drugs should be the development of a national drug policy linked to the health needs and priorities of Member Countries. The establishment of such a policy will improve the utilization of national resources in the health sector.

1.2 The establishment of a list of essential drugs is a first step in the implementation of a national drug policy. Most countries in the Region have drawn up such a list for the public sector.

1.3 An effective drug policy is intersectoral in nature. Therefore, in its implementation national drug policy requires the leadership of the Ministry of Health and the cooperation of other ministries (e.g., Planning, Industry, Finance) and related institutions. In many countries the Ministry acts primarily in a technical-advisory role.

1.4 Since the Government has to finance drugs for the public sector, it is desirable that the public and private sectors play complimentary roles in the implementation of a national drug policy, including production of essential drugs. At present, few countries have actually undertaken the production of essential drugs using public enterprises. The more common pattern is for the public sector to finance the supply of drugs directly (through purchasing) or indirectly (through reimbursement schemes).

1.5 Transnational corporations are dominant in the pharmaceutical markets of Latin American and Caribbean countries because they have the capacity to pool capital, technology, modern management, and marketing strategies on an international scale.

1.6 The existing subregional schemes (e.g., CARICOM, ANCOM and CACM) have great potential for improving the supply of pharmaceuticals in participating countries, although to date progress has been relatively modest.

2. Production

2.1 Pharmaceutical technology, including research and development relating to new molecules, is still concentrated in the TNCs. No significant change is foreseen for the near future, unless the international community participates in the efforts to reduce the present technological gap.

2.2 The number and share of multisource (generic) drugs in the pharmaceutical market is increasing worldwide. Because of the ongoing expiration of drug patents this trend will continue. However, major breakthroughs in drug development and therapy in the near future may lead to the introduction of new drugs whose therapeutic effectiveness will be superior to that of today's products.

2.3 Transnational corporations are the leading producers of multisource pharmaceuticals, and there are indications that this segment of the market is of growing interest to them. This poses a challenge to small domestic companies who compete primarily in the generic market on the basis of price. Preferential government purchasing policies have been a major means used to support these indigenous producers.

2.4 The pharmaceutical production process is highly complex. The degree of supplier concentration in the pharmaceutical industry increases as the industry integrates backwards in the production chain from finished products to medicinal chemicals to raw materials. Most of the smaller countries in the Region have already started with simple formulation, thereby saving hard currency and developing national capabilities in the drug sector and related industries. Significant savings can be achieved, for example, in the local production of large volume infusions. The largest countries in Latin America have achieved local production of a nearly complete range of finished pharmaceutical products and of an increasing number of medicinal chemicals. In fact, one could consider the Region of the Americas to be virtually self-sufficient in the field of pharmaceuticals, given that a Member Country, the United States of America, is one of the most advanced nations in the world.

2.5 Joint ventures can be an important mechanism for promoting the transfer of technology. Recently, pharmaceutical firms from the most advanced countries in the Third World and Eastern Europe, as well as TNCs from some of the smaller developed nations, have been particularly interested in setting up joint ventures in developing countries.

3. Marketing

3.1 The Ministry of Health can have its greatest impact on marketing practices by fully exercising its authority during the process of product registration when the conditions for the sale, use and promotion of drugs ought to be defined. Suitable legislation and updated regulatory mechanisms should be developed in support of this activity within the framework provided by a national drug policy.

3.2 Brand names contribute to product proliferation and high prices in the pharmaceutical industry. The use of international non-proprietary names (generic names) is becoming increasingly accepted both in developed and developing countries worldwide. This has resulted in substantial savings in the cost of health services.

3.3 Experience has shown that centralized procurement schemes for the public sector lead to the rationalization of drug consumption, to the standardization of packing and presentations, and to considerable savings in the import of finished drugs and medicinal chemicals. Pooled procurement by several cooperating countries can also provide significant savings. However, there are a number of obstacles that must be overcome if pooled procurement is to be successful. Political commitment from all participating governments as well as careful advance planning and adequate financing mechanisms are necessary.

BIBLIOGRAPHY

Action Programme for Economic Cooperation Among Non-Aligned and Other Developing Countries--Trade Transport Industry (APEC-TTI). 1977. "Towards a Regional Pharmaceutical Policy." Georgetown, Guyana: UNCTAD and Government of Guyana.

Agarwal, Anil. 1978. Drugs and the Third World. London: Earthscan.

Asociación Latinoamericana de Industrias Farmacéuticas (ALIFAR). 1981. "La Industria Farmacéutica en América Latina: Aspectos Económicos". Mimeo, October, 23 pp. Buenos Aires.

_____. 1982a. Industria farmacéutica latinoamericana 1, No. 1 (April). Buenos Aires.

_____. 1982b. Industria farmacéutica latinoamericana 1, No. 2 (October). Buenos Aires.

Brooke, Paul A. 1975. Resistant Prices: A Study of Competitive Strains in the Antibiotic Markets. New York: Council on Economic Priorities.

Burstall, Michael L., John H. Dunning, and Arthur Lake. 1981. "Multinational Enterprise, Governments and Technology: Pharmaceutical Industry." Paris: Organization for Economic Cooperation and Development.

Business Week. 1979. "Eli Lilly: New Life in the Drug Industry." October 29: 134-145.

Central de Medicamentos (CEME). Relatório 1981 (Annual Report). Brazil.

Chudnovsky, Daniel. 1979. "The Challenge by Domestic Enterprises to the Transnational Corporations' Domination: A Case Study of the Argentine Pharmaceutical Industry." World Development 7, 1 (January): 45-58.

Cohen, Benjamin I., Jorge Katz, and William T. Beck. 1975. "Innovation and Foreign Investment Behavior of the U.S. Pharmaceutical Industry." New York: National Bureau of Economic Research, Working Paper No. 101.

Commons, Ken C. 1981. "Report on a Study of Methods of Operation of a Proposed Caribbean Pharmaceutical Centre." International Development Research Centre, and Health and Welfare Canada (Health Protection Branch).

de María y Campos, Mauricio. 1977. "La industria farmacéutica en México." Comercio Exterior 27, 8 (agosto): 888-912.

Developing World Industry and Technology, Inc. 1979. "Changes in the Terms and Conditions of Technology Transfer by the Pharmaceutical Industry to Newly Industrializing Nations: An Overview of the Past Ten Years." Paper prepared for the U.S. Agency for International Development, Washington, D.C. Mimeo, 28 pp.

Diario Oficial. Mexico City. Various issues.

Dun's Review. 1979. "Prescription for Profits." January: 39-41.

Evans, Peter B. 1976. "Foreign Investment and Industrial Transformation: A Brazilian Case Study." Journal of Development Economics 3: 119-139.

_____. 1979. Dependent Development: The Alliance of Multinational, State, and Local Capital in Brazil. Princeton, N.J.: Princeton University Press.

Feeney, Paula. 1981. "Report on a Study of the Management of Pharmaceuticals by Ministries of Health in Ten Countries of the Commonwealth Caribbean--Focus: Essential Drugs." Washington, D.C.: Pan American Health Organization. (AMR/3610).

Gereffi, Gary. 1978. "Drug Firms and Dependency in Mexico: The Case of the Steroid Hormone Industry." International Organization 32, 1 (Winter): 237-286.

_____. 1982. "Transnational Corporations and the Pharmaceutical Industry in Mexico." Mimeo, May, 42 pp. Durham, N.C.

_____. 1983. The Pharmaceutical Industry and Dependency in the Third World. Princeton, N.J.: Princeton University Press.

Grabowsky, Henry G. 1976. Drug Regulation and Innovation: Empirical Evidence and Policy Options. Washington, D.C.: American Enterprise Institute for Public Policy Research.

Grabowsky, Henry G., and John M. Vernon. 1976. "Structural Effects of Regulation on Innovation in the Ethical Drug Industry." Pp. 181-205 in Robert T. Masson and P. David Qualls (eds.), Essays on Industrial Organization in Honor of Joe S. Bain. Cambridge, Mass.: Ballinger.

Grabowski, Henry G., John M. Vernon, and Lacy G. Thomas. 1976. "The Effects of Regulatory Policy on the Incentives to Innovate: An International Comparative Analysis." Pp. 47-82 in Samuel A. Mitchell and Emery A. Link (eds.), Impact of Public Policy on Drug Innovation and Pricing. Washington, D.C.: American Enterprise Institute for Public Policy Research.

IMS Pharmaceutical MARKETLETTER. London. Various issues.

IMSworld Publications Ltd. 1979. "Health, Pharmaceutical and Development Indicators World-Wide: A Statistical Survey." London: IMSworld Publications Ltd.

Katz, Jorge M. 1974. Oligopolio, firmas nacionales y empresas multinacionales: la industria farmacéutica argentina. Buenos Aires: Siglo XXI.

_____. 1981. "Estudios de desarrollo e industria químico-farmacéutica." Cuadernos Médico Sociales (Argentina), núm. 18 (octubre): 53-75.

Ledogar, Robert J. 1975. Hungry for Profits: U.S. Food and Drug Multinationals in Latin America. New York: IDOC/North America.

Newsweek. 1979a. "Relief from Migraine." September 10: 69.

_____. 1979b. "Drugs and Psychiatry: A New Era." November 12: 98-104.

Pan American Health Organization (PAHO). 1980. "Health for All by the Year 2000/Strategies." Official Document 173. Washington, D.C.: PAHO.

_____. 1981. "El sector salud en el decenio de los ochenta. Contribución de la OPS al XIX período de sesiones de la Comisión Económica para la América Latina." Marzo. Washington, D.C.: PAHO.

Peltzman, Sam. 1974. Regulation of Pharmaceutical Innovation: The 1962 Amendments. Washington, D.C.: American Enterprise Institute for Public Policy Research.

Reekie, Duncan, and Michael H. Weber. 1979. Profits, Politics and Drugs. New York: Holmes and Meier.

Resolución Remsaa (Reunión de los Ministros de Salud del Area Andina) 9/153. 1982. "Propuesta sobre normas de operación, programa de insumos para fabricación por terceros de los medicamentos prioritarios". Bogotá, Colombia.

Schaumann, Leif. 1976. "Pharmaceutical Industry Dynamics and Outlook to 1985." Menlo Park, Ca.: Stanford Research Institute.

Schnee, Jerome, and Erol Caglarcan. 1976. "The Changing Pharmaceutical R & D Environment." Business Economics 11, 3 (May): 31-38.

Schwartzman, David. 1976. Innovation in the Pharmaceutical Industry. Baltimore, Md.: The Johns Hopkins University Press.

SCRIP. Richmond, Surrey, England. Various issues.

Silverman, Milton. 1976. The Drugging of the Americas: How Multinational Drug Companies Say One Thing About Their Products to Physicians in the United States, and Another Thing to Physicians in Latin America. Berkeley, Ca.: University of California Press.

_____. 1977. "The Epidemiology of Drug Promotion." International Journal of Health Sciences 7, 2: 157-166.

Silverman, Milton, Philip R. Lee, and Mia Lydecker. 1982. Prescriptions for Death: The Drugging of the Third World. Berkeley, Ca.: University of California Press.

Sistema Andino de Información Tecnológica (SAIT). 1982. "Acta Final de la Primera Reunión del Comité Coordinador de la Red Especializada de Información sobre Precios Internacionales." Lima, Peru.

Turnbull, John C. 1982. "The Barbados Drug Service." Mimeo, prepared for the Pan American Health Organization/World Health Organization Caribbean Workshop on Supply Management for Essential Drugs. May, 25 pp. Barbados.

United Nations Centre on Transnational Corporations (UNCTC). 1979. Transnational Corporations and the Pharmaceutical Industry." New York: UNCTC. (United Nations publication, Sales No. E.79.II.A.3).

_____. 1981. "Transnational Corporations in the Pharmaceutical Industry of Developing Countries." New York: UNCTC. (E/C.10/85).

_____. 1983. "Transnational Corporations in the Pharmaceutical Industry of Developing Countries: A Technical Study." New York: UNCTC.

United Nations Conference on Trade and Development (UNCTAD). 1977. "The Impact of Trade Marks on the Development Process of Developing Countries." Geneva. UNCTAD. (TD/B/C./AC.3/3).

_____. 1980. "Technology Policies in the Pharmaceutical Sector in Cuba." Geneva: UNCTAD. (UNCTAD/TT/33).

_____. 1982. "Technology Policies in the Pharmaceutical Sector in Costa Rica." Geneva: UNCTAD. (UNCTAD/TT/37).

United Nations Industrial Development Organization (UNIDO). 1979. "The Cairo Declaration." Vienna. UNIDO. (ID/WG.292/3/Rev. 1).

_____. 1980. "Global Study of the Pharmaceutical Industry." Vienna: UNIDO. (ID/WG.331/6).

_____. 1982. "Directory of Sources of Supply of 26 Essential Bulk Drugs, Their Chemical Intermediates and Some Raw Materials." Vienna: UNIDO. (UNIDO/PC.51).

United States International Trade Commission. 1982. Synthetic Organic Chemicals: United States Production and Sales, 1981. Washington, D.C.: U.S. Government Printing Office.

World Health Organization (WHO). 1977. "The Selection of Essential Drugs, Report of a WHO Expert Committee." Technical Report Series No. 615. Geneva: WHO.

_____. 1981. "Global Strategy for Health for All by the Year 2000." Geneva: WHO.

Annexes

TABLES

Table 1

World Pharmaceutical Production, Consumption and Trade, 1980

	Production[a/]		Consumption[b/]		Trade[c/]		
	US$ millions	Percentage	US$ millions	Percentage	Imports	Exports	Trade Balance
Developed Countries							
Market Economies							
North America	18,600	22.1	14,700	19.6			
Western Europe	27,440	33.0	25,350	33.8			
Others	11,970	14.3	12,454	16.6			
Centrally Planned Economies							
Eastern Europe	15,960	19.1	12,150	16.2			
Total Developed Countries	73,970	88.5	64,650	86.2	9,473	13,187	+3,714
Developing Countries							
Africa	470	0.6	1,730	2.3			
Asia *	4,690	5.6	5,320**	7.1			
Latin America	4,400	5.2	3,300	4.4			
Total Developing Countries	9,560	11.5	10,350	13.8	4,530	602	-3,928
Total World Market	83,530	100.0	75,000	100.0	14,003	13,789	

Source: a) United Nations Industrial Development Organization (1980), Global Study of the Pharmaceutical Industry, estimated based on 1977 figures and an annual growth rate of 9 percent.

b) SCRIP No. 509, 28 July 1980, using the "market" as proxy for consumption.

c) United Nations, 1980 Yearbook of International Trade Statistics. All amounts are in US$ millions.

*Excluding China.

**Including Japan, Southern European countries, and Oceania.

Table 2

Twenty Largest World Drug Markets: 1981

(excluding centrally planned economies)

Country	Sales (US$ millions)	Percentage of world market
United States	15,770	20.7
Japan	11,000	14.4
Germany, Fed. Rep. of	5,420	7.1
France	4,170	5.5
Italy	2,570	3.4
United Kingdom	2,560	3.4
Argentina	1,590	2.1
Spain	1,480	1.9
Brazil	1,290	1.7
Mexico	1,050	1.4
Canada	969	1.3
India	879	1.2
Belgium	670	0.9
Korea, Republic of	656	0.9
Iran	653	0.9
Australia	578	0.8
South Africa	548	0.7
Sweden	509	0.7
Switzerland	496	0.7
Netherlands	476	0.6
Total for Top 20 Drug Markets	53,334	70.3
Total Worldwide	76,278	100.0

Source: IMS Pharmaceutical MARKETLETTER, 4 January 1982, p. 2.

Table 3

The World's Fifteen Largest Pharmaceutical Companies, 1980

Company	Country of Origin	Pharmaceutical Sales[a] (US$ millions)	Profit (US$ millions)	Profit Margin (percentage)	R & D (US$ millions)	R & D as percentage of sales
1. Hoechst	FRG	2,413	NA	NA	660	4.4
2. Merck and Co.	USA	2,287[b]	607[g]	26.6	234	8.6
3. American Home Products	USA	2,193[c]	603[g]	27.5	102	2.5
4. Bayer	FRG	2,182	NA	NA	630	4.3
5. Warner-Lambert	USA	1,926[d]	271[g]	14.1	72	6.2
6. Bristol-Myers	USA	1,905[c]	379[g]	19.9	129	6.8
7. Ciba-Geigy	SWI	1,805	NA	NA	217	12.0
8. Pfizer	USA	1,644[d]	388[g]	23.6	160	5.3
9. Roche-Sapac	SWI	1,461	130[h]	3.0	389	11.8
10. Eli Lilly	USA	1,426[e]	330[g]	23.2	201	7.8
11. SmithKline	USA	1,376[b]	468[i]	30.1	136	7.7
12. Sandoz	SWI	1,339	114[h]	4.1	170	12.7
13. Boehringer-Ingelheim	FRG	1,267	27[h]	3.5	139	11.0
14. Rhone-Poulenc	FRA	1,255[b]	126[g]	9.9	302	4.5
15. Glaxo	UK	1,214[f]	194[j]	16.0	106	8.8

Source: IMS Pharmaceutical MARKETLETTER, 11 January 1982, p.4

Notes:

a) Sales figures are for human pharmaceutical preparations unless otherwise indicated.

b) Human and animal health.

c) Prescription and packaged medicines.

d) Health care.

e) Human health.

f) Includes food products.

g) Pre-tax segment of operating income.

h) Corporate net profit.

i) Operating income, health care.

j) Trading profit.

NA = Not available.

Table 4

Manufacturing Subsidiaries Established by the 25 Largest U. S. Pharmaceutical TNCs, by Time Period and Geographical Region

	Date of Establishment of First Manufacturing Plant			
	Before 1950	1950-1959	1960-1970	TOTAL
Canada	10	6	4	20
Europe	7	41	64	112
European Common Market[a]	0	25	35	60
United Kingdom	7	8	3	18
Other	0	8	26	34
Australia and New Zealand	3	12	7	22
Latin America	6	65	55	126
Argentina	1	11	4	16
Brazil	0	11	3	14
Mexico	4	12	5	21
Other	1	31	43	75
Asia and the Middle East	0	21	38	59
Philippines	0	8	3	11
Other	0	13	35	48
Africa	2	7	13	22
South Africa	2	7	7	16
Other	0	0	6	6
TOTAL	28	152	181	361

Source: Katz, 1981: 62.

(a) Federal Republic of Germany, Belgium, France, Holland, Italy and Luxembourg.

Table 5

Number of New Drug Launches
by Company and Region, 1980

Company	Country of Origin	Total	Europe	Latin America	Asia, Africa, Australia	Canada, USA
Schering-Plough	USA	48	20	17	6	5
Johnson & Johnson	USA	46	18	15	10	3
Schering A.G.	FRG	44	27	10	6	1
Boehringer-Ingelheim	FRG	39	23	11	3	2
Hoechst	FRG	39	26	5	7	1
Hoffmann-La Roche	SWI	37	18	10	7	2
Ciba-Geigy	SWI	36	20	8	5	3
Bristol-Myers	USA	35	16	7	6	6
Abbott Laboratories	USA	32	7	9	7	9
Warner-Lambert	USA	32	13	9	4	6
Eli Lilly	USA	29	9	8	4	8
Glaxo	UK	27	11	5	9	2
Pfizer	USA	27	12	6	4	5
Sandoz	SWI	26	14	8	3	1
Upjohn	USA	26	11	4	5	6
Bayer	FRG	25	19	4	2	0
Total Worldwide		2,452	1,323	557	432	140

Source: IMSworld Publications, World Pharmaceutical Introductions 1980, cited in IMS Pharmaceutical MARKETLETTER, 8 June 1981, p. 8.

Table 6

Major Suppliers of Commodity Generics in the United States, 1979

	Company	Estimated Sales (US$ millions)	Market Share (percentage)
1.	Eli Lilly	50	16
2.	Wyeth Laboratories (American Home Products)	30	10
3.	Parke Davis (Warner-Lambert)	28	9
4.	SmithKline	20	7
	Top four suppliers	128	42
	Other suppliers	178	58
	Total	306	100

Source: Asociación Latinoamericana de Industrias Farmacéuticas. 1982b: 20

Table 7

Major Suppliers of Branded Generics in the United States, 1979

	Company	Estimated Sales (US$ milliones)	Market Share (percentage)
1.	G. D. Searle	200	5
2.	Eli Lilly	170	4
3.	Roche Laboratories	160	4
4.	Ciba	135	3
5.	Upjohn	110	3
6.	Squibb	110	3
7.	SmithKline	105	3
8.	Pfizer	105	3
9.	Rorer	105	3
10.	Abbott Laboratories	105	3
	Top ten suppliers	1,305	34
	Other suppliers	2,760	66
	Total	4,065	100

Source: SCRIP, 25 August 1980, p. 8.

Table 8

Latin America: Basic Indicators

(Twelve Countries)

Country	Population in thousands, 1980	Annual rate of population growth, 1960-1980	Gross domestic product, 1980 [a] (millions of U.S. dollars)	GDP per capita, 1980 [a] (U.S. dollars)	Price index, June 1980 to June 1981 (12 months)	Exports, 1980 (millions of U.S. dollars)	Imports, 1980 (millions of U.S. dollars)
ARGENTINA	27,900	1.78% [b]	53,987	1,938	105%	8,000	9,000
BOLIVIA	5,570	2.44%	2,750	494	26%	910	800
BRAZIL	122,320	2.15%	169,311	1,384	117%	20,000	23,000
COLOMBIA	26,894	2.31%	20,352	757	26%	4,600	4,400
COSTA RICA	2,100	2.60% [c]	1,936 [d]	750	18% [e]	1,000	1,400
CHILE	11,104	1.57%	19,696	1,774	21%	4,800	5,500
ECUADOR	8,021	3.04%	5,316	663	14%	2,590	2,170
MEXICO	69,965	3.23%	90,545	1,294	29%	16,600	17,900
PARAGUAY	3,004	2.66%	2,277	758	14%	380	610
PERU	17,625	2.81%	17,726	1,006	82%	3,900	3,130
URUGUAY	2,924	0.83%	5,097	1,743	35%	1,000	1,510
VENEZUELA	14,930	3.30% [f]	31,558	2,114	18%	20,600	12,500

Source: Asociación Latinoamericana de Industrias Farmacéuticas, 1981: 3, based on data from the United Nations.

Notes:

a) In 1978 dollars.
b) For the period 1970 to 1980.
c) For the period 1970 to 1975.
d) In 1970 dollars.
e) To October 1980.
f) For the period 1970 to 1978.

Table 9

Latin America: Demographic and Health Indicators

(Twelve Countries)

Country	Births per 1,000 women between 15 and 49 years of age, 1975-1980 [a]	Crude birth rate per 1,000 inhabitants, 1975-1980 [a]	Crude death rate per 1,000 inhabitants, 1975-1980 [a]	Life expectancy at birth (in years), 1975-1980 [a]	Percentage of the population under 15 years of age, 1970	Number of doctors, 1980	Number of hospital beds (in thousands), 1979	Daily intake of calories per capita, 1975-1980 [a]
ARGENTINA	88	21	9	69	29%	71,000	153	3,347
BOLIVIA	190	44	16	48	44%	3,017	NA	1,974
BRAZIL	159	36	8	64	43%	90,700	406	2,562
COLOMBIA	168	34	8	63	46%	14,200	48	2,364
COSTA RICA	146	29	5	70	46%	1,500	NA	2,550
CHILE	107	25	8	64	38%	8,500	NA	2,656
ECUADOR	178	42	10	62	45%	3,300	NA	2,104
MEXICO	193	42	8	66	46%	45,000 [b]	96	2,654
PARAGUAY	174	39	8	64	46%	1,700	NA	2,824
PERU	171	40	12	58	44%	11,000	45	2,274
URUGUAY	83	20	10	70	28%	5,000	18	3,036
VENEZUELA	154	36	6	66	46%	12,000	40	2,435

Sources: Pan American Health Organization, 1980: 27-31; Asociación Latinoamericana de Industrias Farmacéuticas, 1982a: 25, based on data from the World Bank.

Notes:
a) The average for the years indicated.
b) 1976.

NA = Not available.

Table 10

Latin America: Pharmaceutical Industry Indicators, 1980

(Twelve Countries)

Countries	Pharmaceutical consumption per capita (U.S. dollars)	Number of products	Number of dosage forms	Number of pharmacies [c]	Pharmaceutical exports (millions of U.S. dollars)	Pharmaceutical imports (millions of U.S. dollars)
ARGENTINA	68.8	3,400	7,000	7,100	34 [c]	479
BOLIVIA	5.7	8,000	NA	NA	—	24
BRAZIL	12.7	5,043	10,843	12,600	40 [b]	215
COLOMBIA	20.8	9,000	15,000	6,000	NA	30
COSTA RICA	13.3	6,000	NA	NA	NA	34 [a]
CHILE	17.8	3,300	NA	1,400	—	38
ECUADOR	11.9	NA	NA	1,000	3.5	NA
MEXICO	15.7	NA	14,000	7,800	107	217
PARAGUAY	13.3	2,993	NA	NA	—	22
PERU	11.3	NA	10,500	2,000	NA	NA
URUGUAY	32.1	2,400	4,300	820	1.9 [c]	14 [c]
VENEZUELA	18.1	5,200	12,500	2,600	1.2 [c]	—

Source: Asociación Latinoamericana de Industrias Farmacéuticas, 1981: 12, 15.

Notes:
a) 1977.
b) 1978.
c) 1979.

NA = Not available.

Table 11

Levels of Development of the Pharmaceutical Industry in Latin America and the Caribbean, 1979

STAGE OF PHARMACEUTICAL PRODUCTION	COUNTRIES
Group 1 Countries which have no manufacturing facilities and therefore are dependent upon imported pharmaceuticals in their finished form. In many of these countries there is insufficient trained personnel, limited public health services and poor distribution channels	Dominica Grenada
Group 2 Countries which have started to repack formulated drugs and process bulk drugs into dosage forms	Bolivia Costa Rica El Salvador Guatemala Haiti Trinidad & Tobago
Group 3 Countries which manufacture a broad range of bulk drugs into dosage forms and manufacture some simple bulk-drugs from intermediates	Colombia Ecuador Peru
Group 4 Countries which produce a broad range of bulk drugs from intermediates and who manufacture some intermediates using locally produced chemicals	Chile Cuba Venezuela
Group 5 Countries which manufacture most of the intermediates required for the pharmaceutical industry and undertake local research on the development of products and manufacturing processes	Argentina Brazil Mexico

Source: United Nations Industrial Development Organization, 1978: 3, revised and amended.

Table 12

Latin America: Pharmaceutical Market Size and Market Share Data, 1980

(Twelve Countries)

Country	Pharmaceutical sales (millions of U.S. dollars)	Number of laboratories	Market share of the 20 largest laboratories (percentage)	Market share of the nationally-owned laboratories (percentage)	Rank of the 4 largest nationally-owned laboratories	Sales to the private sector (percentage of total sales)	Sales to the public sector (percentage of total sales)	Employees
ARGENTINA	1,920	225	52%	47%	1, 3, 10, 16	92%	8%	37,000
BOLIVIA	32	12	——	NA	NA	50%	50%	NA
BRAZIL	1,554	489 a/	46%	22%	7, 24, 30, 54	80%	20%	62,000
COLOMBIA	560	325	53%	12%	NA	70%	30%	15,000
COSTA RICA	28	13	82% c/	18%	NA	70%	30%	NA
CHILE	198	41	74%	42%	1, 2, 5, 14	80%	20%	5,970
ECUADOR	96	75	62%	11% b/	1, 19, 34, 49	NA	NA	6,000
MEXICO	1,100	315	45%	28%	31, 36, 48, 51	77%	23%	43,000
PARAGUAY	40	24	——	NA	NA	90%	10%	NA
PERU	200	80	61% d/	26%	4, 10, 19, 27	75%	25%	17,000
URUGUAY	94	69	71%	39%	10, 12, 15, 18	80%	20%	2,860
VENEZUELA	270	75	48%	22%	2, 5, 17, 23	74%	26%	7,600

Source: Asociación Latinoamericana de Industrias Farmacéuticas, 1981: 12, 15.

Notes:
a) 1978.
b) 1979.
c) In 1977 only three laboratories accounted for 82 percent of total production.
d) The 25 largest laboratories.

NA = Not available.

ANNEX II

SELECTED NATIONAL EXPERIENCES

Argentina

Argentina is one of the most advanced countries in the Third World in the manufacture of drugs, it has a large number of transnational corporations (TNCs) operating in the industry, and it has a relatively strong domestic pharmaceutical sector (Chudnovsky, 1979; Katz, 1974). As a result, it should be possible to see how different domestic drug firms are from the TNCs, and what social implications can be derived from these differences.

With regard to the structure of the Argentine pharmaceutical industry, the leading company in terms of sales in 1972 (Laboratorios Bagó) was domestically owned, as were three of the top five firms and six of the top fifteen companies.[1] Nonetheless, TNCs were dominant overall: they controlled 57 per cent of the total internal market for finished drugs, 65 per cent of the market for active ingredients, and 98 per cent of drug exports from Argentina. In a variety of areas, however, Argentina's domestic enterprises appear to have outperformed their TNC rivals: nationally owned pharmaceutical companies are more diversified across 24 industry submarkets or therapeutic classes than foreign-owned firms[2] (8.2 therapeutic classes on the average for the former as compared with 6.5 for the latter); nationally owned companies are more diversified in terms of the number of products sold per firm than foreign-owned enterprises (44 drugs per firm and 35 drugs per firm, respectively); and the average nationally owned company introduced more "new" drugs each year than the average subsidiary of a TNC (4.3 new drugs as against 3.1 new drugs). The difference between national and foreign firms on this latter dimension is much more pronounced among the 15 largest pharmaceutical enterprises in Argentina. The six biggest local companies launched more than twice as many new drugs on an average as the nine largest foreign firms (7.5 versus 3.5 new products, respectively).[3] The greater innovative activity of Argentine companies is also reflected in sales figures: new products account for 13 per cent of the total sales of the six largest local laboratories and for only 6 per cent of the sales of the nine major TNC subsidiaries.

That domestic pharmaceutical companies in Argentina have done so well in their competition with TNCs is due in large part to their distinctive strategy, which is made up of the following elements: an emphasis on marketing skills in product differentiation activities; the use of licenses to gain access to difficult submarkets; opposition to a

strong patent system in order to obtain active ingredients from non-patented sources;[4] and a certain degree of local generation of technology (Chudnovsky, 1979: 52).

What are the implications of these differences in business performance between domestic and foreign enterprises in Argentina? From the point of view of health services, one is led by the evidence to conclude that no tangible benefits have been achieved to date from the effort made by large domestic firms to challenge TNC domination of the local pharmaceutical industry, and in some cases the consumer is worse off. With respect to the average wholesale prices of finished pharmaceutical products in Argentina in 1972, two main findings stand out: first, big companies, domestic and foreign, charge higher average prices for their drug products than smaller firms do; and, second, among the leading 15 enterprises in the industry the prices charged by domestic companies are higher than the prices quoted by foreign firms. Thus the consumer in Argentina benefits from domestic control only when purchasing drugs from medium- and small-sized local companies. If the declared pre-tax rate of profit on net worth is considered, domestic companies are shown to be more profitable than their foreign rivals as well--the rates averaging 18 per cent and 12 per cent, respectively (Chudnovsky, 1979: 53-54). The higher profits for local firms are consistent with their higher prices for finished drugs. High prices, for foreign and large domestic enterprises alike, are a direct consequence of the type of promotion-based competition prevailing in the industry.

A somewhat different assessment of the Argentine drug supply situation could be given from the perspective of indigenous industrial development. Domestic companies had been reversing, until recently, the trend toward foreign dominance in the Argentine pharmaceutical industry,[5] and they are taking strides toward becoming technologically self-reliant. High prices of drugs thus might be considered an acceptable trade-off for the consolidation of indigenous industrial efforts. Nonetheless, subsidizing domestic firms through high drug prices is a very regressive type of subsidy.

Recently the tide seems to have turned against many of Argentina's locally owned pharmaceutical companies. Their share of the market, which was over 50 per cent during the early 1970s, had declined to 46 per cent by 1982 due largely to the exit of more than 100 small enterprises (ALIFAR, 1982b: 1; SCRIP, December 24, 1981). According to a study by the U.N. Centre on Transnational Corporations (1981: 41), this trend toward greater concentration in the Argentine pharmaceutical industry can be linked to a variety of factors, including more stringent requirements regarding quality control, the abolition of legislation that had limited royalty payments to foreign firms and regulated restrictive practices in the transfer of technology, an increase in the prices of imported chemical intermediates, and alleged "dumping" by TNCs.

In general, transnational companies have been more successful than Argentina's domestically owned firms in weathering the economic difficulties of the last few years. When confronted with higher local production costs due to the overvaluation of Argentina's currency relative to the U.S. dollar in 1980-1981, foreign subsidiaries that could count on financial support from their parent companies reacted by shutting down most of their plants, while locally owned firms were forced to continue operating at well below their production capacities. Foreign subsidiaries also have utilized their dominant positions in the manufacture of active ingredients to discourage local production of these items in periods of reduced tariff protection (such as the present time) by charging high prices for the necessary intermediate chemicals while offering competitive prices for the finished drugs. Finally, because price controls in Argentina are not applied to imported raw materials and intermediates, TNC transfer pricing has remained largely unmonitored.

Locally owned pharmaceutical companies in Argentina must compete with foreign firms on equal terms, aside from reduced tariffs granted the former for the importation of machinery and equipment. Nonetheless some of Argentina's largest domestic companies continue to prosper. Laboratorios Bagó completed a major expansion project in 1982 that will allow it to export from 25 to 35 per cent of its production capacity. In addition, it is now marketing the first new drug discovered by an Argentine pharmaceutical company, a non-steroidal anti-inflammatory agent named Talniflumato. Another national firm, Laplex, expanded and modernized its operations in 1981 so that it can obtain the advantages of scale economies in the production of basic medicinal chemicals.

In summary, the Argentine experience shows that domestic private pharmaceutical firms have achieved a considerable measure of success in their competition with transnational drug companies. A strong locally owned industry, however, does not necessarily result in lower priced medicines. Furthermore the national pharmaceutical industry in Argentina, which includes no government-owned production facilities, has resisted the concept of essential drugs because each of the companies is committed to offering a full and differentiated panoply of brand name prescription products. The success of Argentina's domestic industry has been tempered somewhat in the recent period of economic downturn. Many of the smaller locally owned companies have been hardpressed to weather the difficulties as effectively as their larger rivals.

Brazil

The Brazilian pharmaceutical industry went through a major period of denationalization between 1957 and 1977 when 34 of the largest domestic firms were acquired by TNCs. In the hope of increasing the competitiveness of local firms vis-à-vis their foreign rivals, Brazil completely abolished patent protection for pharmaceuticals in 1969. A decade after the introduction of the ban, the 10 largest national drug companies had increased their share of the market by close to 10 per cent.

This trend was broken, though, when two of the firms were acquired by TNCs in 1978-1979. It is interesting to note that despite the ban on patents, foreign investment in the pharmaceutical sector rose from US$113 million in 1971 to US$646 million in 1979, one of the highest growth rates of any industry in Brazil. This seems to contradict the argument of those who contend that the absence of patents will keep foreign investors away. In the area of trademarks, Brazil tried to prohibit brand names from being used for drugs containing a single active ingredient. The legal challenge to this measure by TNCs was upheld in the courts and the Brazilian Parliament subsequently enacted a less restrictive bill on trade names in 1977 (UNCTC, 1981: 41-42).

The Brazilian "triple alliance" (Evans, 1979) between TNCs, the state, and local private capital has led to an unusual compromise arrangement between a rationalized drug list and free market forces involving the state-owned enterprise, Central de Medicamentos (Evans, 1976: 133-136; Ledogar, 1975: 61-67). Central de Medicamentos (CEME) was created in 1971 under the direct responsibility of the President of the Republic. CEME's role was elaborated in the 4-volume Master Plan for Pharmaceuticals (Plano Diretor de Medicamentos). In order to satisfy its original objective of social service for the poor majority in Brazil, CEME set out to rationalize the procurement of medicines for the hospitals and clinics associated with Brazil's system of state medical assistance--the Instituto Nacional de Previdencia Social (INPS)--and to provide free prescription drugs to the poorest of the INPS's clients. In addition, the Master Plan proposed reviving approximately 20 state-owned laboratories and giving preferential treatment to local companies, with the ultimate goal of having the country manufacture most of its own pharmaceutical raw materials by the end of the decade. Other provisions in the plan included tight controls on the sale and promotion of drugs, regulations on the content of drug package inserts, and restrictions on the distribution of free drug samples.

Only part of the Master Plan was ever put into effect and it was done in a way that did not threaten the dominant position or continued growth of private (and especially foreign) drug firms. In 1973 CEME distributed medications to 9 million people. Its target group was those people receiving the official minimum wage or less--in other words, exactly that segment of the population that is normally excluded from the commercial market for medicines. Thus CEME was not likely to take any customers away from private firms. To the contrary, CEME's activities probably stimulated the expansion of the commercial market. A large share of the medications distributed by CEME was not produced by public laboratories but purchased from private companies, many of them foreign-owned. In 1973 CEME increased private-sector sales by a total of US$3.5 million (Evans, 1976: 135). Furthermore, whereas the logic of profitability for private firms lies in maximizing product differentiation, CEME's strategy was quite the opposite: to limit the number of medicines it deals with,

concentrating on those needed for the diseases most prevalent among the population it serves. The Master Plan initially contained a list of 134 pharmaceutical products accounting for about three-quarters of the cost of national drug imports in 1971. To the extent that CEME might try to manufacture these products domestically through its system of public laboratories, the only private enterprises likely to suffer would be locally owned ones whose output is less technologically advanced, and not the foreign subsidiaries of TNCs.

CEME's budget has risen from 65 million cruzeiros in 1972 to 11.9 billion cruzeiros (US$192 million) in 1981 (CEME, Relatório 1981). CEME coordinates a network of 22 state laboratories that supply it with essential medicines, which it distributes in 3,750 of the 3,975 Brazilian municipalities. Drug purchases by CEME in 1981 represented about 12 per cent of total pharmaceutical sales in Brazil, although this probably undervalues the State firm's importance because its prices are much lower than those prevailing in the commercial market. Sixty-two per cent of the medicines distributed by CEME are supplied by the state laboratories, 31 per cent come from private drug companies in Brazil, and the remaining 7 per cent are imported (Alifar, 1982a: 7-8). In addition to compiling the essential drug list that currently contains over 400 products and coordinating the activities of the 22 public sector pharmaceutical units, CEME is responsible for the central procurement of medicines, quality control of supplies, the setting of priorities in raw material manufacture, and the modernization of production and distribution facilities. Between 1971 and 1981 CEME spent US$1.1 million on state drug research programs (SCRIP, March 10, 1982, p. 11). CEME approved eight new research and development projects during 1981 with a total value of nearly US$600,000, over half of the amount spent in the previous 10 years (Alifar, 1982a: 8). Late in 1981 an Interministerial Group on the Pharmaceutical Industry was established in Brazil to develop the national pharmaceutical industry and to promote greater self-sufficiency (SCRIP, January 27, 1982, p. 9).

The case of CEME in Brazil shows how a government-sponsored procurement scheme, if given political support and sufficient financial and technical resources, can simultaneously rationalize drug purchasing and distribution in the public sector as well as contribute to the country's pharmaceutical research capabilities. The purchasing power of CEME can also be used to influence the production profile of Brazil by stimulating national companies to manufacture essential drugs.

Mexico

In Mexico, where drug sales totaled over US$1 billion in 1980 (75 per cent in the private sector and 25 per cent in the public sector), local consumption of finished pharmaceuticals was almost fully met by local production. Over half of the raw materials used are still imported,

however, and TNCs account for about 85 per cent of total sales[6] and an even larger share of Mexico's pharmaceutical exports (see Gereffi, 1982). Despite the fact that Mexico is one of the leading Third World exporters of pharmaceutical products, the absolute level of its drug imports greatly exceeds drug exports and thus the country has experienced a steadily growing negative trade balance in the pharmaceutical sector.[7]

In response to this high level of TNC dominance, the Mexican Government has taken a series of measures between 1972 and 1982 to try to reduce the impact of foreign subsidiaries and increase domestic control of the industry. These include three new laws,[8] the creation of two state-owned enterprises (Proquivemex and Vitrium) to control the commercialization of barbasco and the manufacture and distribution of basic pharmaceutical products,[9] the formation of an Intersecretarial Commission for the Pharmaceutical Industry as a technical coordinating organism for public sector activities,[10] and the establishment and initial implementation of an essential drug list to standardize public sector purchases of basic medicines according to their generic name and in the dosages and presentational forms (tablets, capsules, injectable solutions, etc.) most often used.[11]

Of the three laws, the 1972 Technology Transfer Law is generally considered to be the most successful. It established a National Registry of Technology Transfer to review all agreements in which a foreign company charges a Mexican company for technological or marketing know-how. If an agreement is judged too harsh in terms of price, duration, export restrictions, purchase requirements, etc. it is denied registration. Most of the proposed agreements that have been rejected are redrawn and submitted on terms more favorable to Mexico. The 1973 Foreign Investment Law requires that all new foreign enterprises have at least 51 per cent Mexican capital irrespective of activity. Despite the intent of this law, however, the vast majority of pharmaceutical firms in Mexico remained wholly owned by foreigners as late as 1977 (see Gereffi, 1982, Tables 5 and 6). This apparent anomaly is explained by a "grandfather clause" in the 1973 law which stipulates that companies estabished prior to the law will not be affected by the "Mexicanization" requirement unless and until they decide to expand their operations. This expansion will be treated as a new investment, which means it will be approved only if the foreign enterprise sells a majority share of its stock to Mexicans. Since almost all of the principal pharmaceutical firms in Mexico were set up before 1973, the original owners still can retain full control of their company. The Mexican market for drugs is growing rapidly, though, and existing TNCs will be forced to increase the size of their activities just to keep pace. Sooner or later, they will have to give up their long-standing resistance to Mexicanization or withdraw from the market altogether.

The 1976 Law on Inventions and Trademarks is a very ambitious piece of legislation that reduces the period of patent protection in Mexico from 15 years to 10 years, and requires that patents be exploited within four years of the date they are issued or they will expire and fall into the public domain.[12] Trademarks, under the 1976 law, will be registered for 5-year periods. Registered trademarks may be renewed indefinitely every five years provided that it can be shown they have been in use in the previous period.

Although its ostensible objective is to "promote and regulate the pharmaceutical industry so that its development contributes to solving health problems at the national level," the Intersecretarial Commission for the Pharmaceutical Industry in fact represents the first governmental body entrusted with formulating policy for the industry as a whole in Mexico. The main lines of policy developed and supported by the Intersecretarial Commission are found in the "Program to Promote the Pharmaceutical Industry" ("El Programa de Fomento a la Industria Farmacéutica"), published in Mexico's Diario Oficial on April 25, 1980. This program sets forth objectives for the period 1980-1983. While the program is quite comprehensive, its main goals can be summarized as follows: to increase the annual output of pharmaceutical firms at a rate of 15 to 20 per cent and to export between 5 and 20 per cent of this output;[13] to keep imports of finished drugs at the present level of 3 per cent of local consumption and restrict the importation of raw materials; to increase the market share of Mexican firms from 30 to 50 per cent and to increase the local equity share of Mexican capital from its current level of 28 per cent to at least 51 per cent; to raise the share of local inputs to at least 50 per cent of the total production cost of pharmaceuticals; to limit royalty payments to a range of 0.5 to 3 per cent depending on the type of product and the percentage of equity held by foreign firms; to standardize public-sector purchases through use of the essential drug list;[14] and to divide the Mexican market for pharmaceutical products into three types--private, public, and social interest--with lower prices for identical drugs in the latter two markets.[15]

In order to help implement this sectoral program, the Mexican Government announced in 1981 that it was setting up a second state pharmaceutical company called Vitrium (Diario Oficial), 27 October 1981). Vitrium is, in a number of respects, a far bolder initiative than Proquivemex whose primary function was to control barbasco supply. Capitalized at P $30 million (US$1.2 million), Vitrium will be 75 per cent owned by the Mexican Government and 25 per cent owned by a Swedish state pharmaceutical enterprise, KabiVitrium. The new Mexican firm will be responsible for the manufacture, import and distribution of basic pharmaceutical products.

A coordinated, intersectoral effort is being made in Mexico to increase the share of domestically owned firms in pharmaceutical

production, to foster the development of local research and technology, and to reduce royalty and technical assistance payments to foreign countries. Mexico's achievements in these areas have required major legislative initiative at the highest levels (including presidential decrees) in order to promote an integrated plan for the development of the industry.

Costa Rica

Costa Rica is an example of an ambitious attempt by a small Latin American nation to implement a series of reforms in the importation, distribution, and export of pharmaceutical products.[16] In the late 1960s drug imports supplied virtually all of Costa Rica's demand for medicines and local manufacturing was negligible. By 1977 total local production had grown to US$21 million and half of this output was exported by TNCs to other Central American countries, thereby making pharmaceutical products Costa Rica's leading manufactured export in 1975. In addition, the Costa Rican Social Security Fund (Caja Costarricense del Seguro Social (CCSS)) now provides health care coverage for 85 per cent of the population, it is the country's major purchaser of imported finished drugs, it has set up its own quality control laboratory to inspect imported as well as locally produced medicines, and it has achieved considerable foreign exchange savings through public tenders and bulk purchasing. In order to understand the reasons for Costa Rica's apparent success in pharmaceuticals and also some of the attendant shortcomings, one needs to look at the division of labor that has evolved between TNCs, local private capital, and the state.

The national consumption of pharmaceutical products was US$36 million ($17 per capita) in 1977. Seventy per cent of this domestic demand was met through imports and the remaining 30 per cent by local production. Transnational firms are predominant in local production with three foreign-owned laboratories accounting for 82 per cent of Costa Rica's total drug output of US$21 million in 1977. Although Costa Rica had not been of much interest to TNCs before 1960, several firms came in after the country joined the Central American Common Market (CACM). Besides allowing for the free flow of goods within an enlarged regional market, the CACM offers pharmaceutical companies a generous package of fiscal incentives if they set up manufacturing operations.[17] The three pharmaceutical TNCs use Costa Rica as a base to export between 50 and 85 per cent of their production to other CACM countries. Two of the TNCs specialize in the manufacture of ethical drugs, while the third produces over-the-counter pharmaceuticals for the domestic market and makes ethical drugs for export only. The foreign exchange earned from these exports was about US$10 million in 1977, but almost all of these export earnings (US$9.4 million) were absorbed by imports of raw materials and other inputs required in the production process. Thus the trade balance advantage to Costa Rica from the TNCs' pharmaceutical exports was very small.

The 10 domestic pharmaceutical companies in Costa Rica supply 18 per cent of all drugs produced locally. The nature of their contribution has changed radically since the entry of the transnationals, however. Unable to cope directly with large-scale foreign production units, Costa Rica's nationally owned laboratories have taken one of three courses of action: 1) most stopped producing drugs as their main activity and instead began making cosmetics under licensing arrangements with TNCs; 2) others specialized in the manufacture of popular remedies that had limited therapeutic effect and did not involve competition with the foreign firms; and 3) a few laboratories began to produce generic drugs for CCSS, thus tying their financial security to the purchasing policies of the state social security agency. In short, national firms in Costa Rica's pharmaceutical industry shifted to cosmetics, over-the-counter products, or generics--if they survived at all.[18] The three TNCs, on the other hand, have limited their production to formulating and packaging imported raw materials and semi-finished drugs despite the larger scale of output made possible by the CACM. As a result, Costa Rica continues to import more than two-thirds of the finished drugs it consumes and up to 95 per cent of the raw materials needed for local formulation and packaging (Alifar, 1981: 23).

One of the important lessons that can be learned from the Costa Rican experience is the role played by CCSS in acquiring bulk drugs and in using public tenders for that purpose. Created in 1941, the social security agency has increased its health-related coverage of the population from 47 per cent in 1970 to 85 per cent in 1979. It has been responsible for the procurement and distribution of bulk and finished drugs, it conducts its own formulation and research activities, and it has adopted a list of essential drugs that serves as a guideline for imports and local production. In 1978 the savings to the public sector made possible by CCSS's public tender purchases of drugs were estimated at US$3.2 million--i.e., 27 per cent of the total value of 1978 orders. The average market price for imported pharmaceuticals (after adjusting for inflation, wholesale and retail margins, and import tariffs) was still three times higher than CCSS's procurement prices. To achieve these savings Costa Rica's social security agency has moved to suppliers of generic drugs whenever possible without sacrificing quality. This is expected to eventually help national firms increase their share of the local market.

Cuba

An examination of the pharmaceutical industry in Cuba illustrates the profound impact of a state monopoly on pharmaceutical purchasing, production, and distribution. According to a recent report prepared by Cuba's Ministry of Public Health for UNCTAD (1980), prior to 1959 the pharmaceutical industry was dominated by transnational firms that controlled about 70 per cent of the market. Seventy to 80 per cent of the pharmaceuticals consumed in Cuba were imported as finished products and drug prices were very high.

This situation has changed considerably. In 1961 the Cuban Government consolidated 14 existing drug manufacturing plants to form the state company, "Empresa Consolidada de Productos Farmacéuticos." This firm, under the jurisdiction of the Ministry of Industry, was responsible for reorganizing and expanding pharmaceutical production, issuing quality control guidelines, and training (often in other socialist countries) sufficient numbers of Cuban technical personnel. The Ministry of Health decided what pharmaceutical products were needed in the country based on essential drug lists drawn up by the National Formulary Committee that it created in 1962. The Ministry of Foreign Trade was in charge of all imports and exports of medicines. Within this Ministry two specialized state trading agencies were set up: "Medicuba" handled all pharmaceutical imports and exports, including finished drugs, active and inert ingredients, and bulk orders of medicines and medicinal herbs; and "Empresa de Suministros Médicos" (EMSUME) was responsible for a wide range of medical supplies for surgical, clinical, and laboratory use. The distribution of medicines within Cuba came under the jurisdiction of the Ministry of Internal Trade, which established a national network of pharmacies capable of supplying even remote rural areas. This bureaucratic division of labor was in effect until 1968, when all of these activities were centralized under the authority of the Ministry of Public Health.

Of particular importance to the Public Health Ministry is the essential drug list. When the first national formulary was published in 1963, it contained 611 generically named pharmaceutical preparations (compared to the 20,000 registered drug products on the market prior to 1959). Only drugs listed on the formulary could be produced within the country. By 1979 the national formulary had adopted the new title of "Therapeutic Guide" and contained 689 pharmaceutical products in 855 dosage forms. Medicuba used this essential drug list in its bulk procurement of medicines, which has produced foreign exchange savings ranging from 30 to nearly 70 per cent.

Cuba has advanced to the stage where it now exports both inputs and finished drugs to developing nations in Asia, Africa, and the Americas. Through cooperation with other socialist countries, Cuba has made efforts to develop a technological infrastructure that is potentially self-sustaining. Tha annual pharmaceutical consumption per capita in the late 1970s was US$37.40, which compares favorably with many highly industrialized countries.

A conscious policy decision has been made in Cuba to give health a very high national priority. In a period of just over 20 years, Cuba has moved from a situation of extreme dependency on foreign pharmaceutical products and technology to a position of enhanced autonomy in the industry. Cost does not appear to have been a limiting factor in the evolution of Cuba's state health sector. Local manufacturing of drugs and pharmaceutical research are promoted as long-term strategic goals even though in the short run imports of certain pharmaceuticals may be cheaper.

Footnotes

[1]The data in this section are from Chudnovsky (1979).

[2]When the degree of submarket diversification is weighted by the share of that submarket in the whole pharmaceutical industry in terms of sales, foreign firms in Argentina are in a better position than domestic ones for the sample of 76 companies for which information was available.

[3]Laboratorios Bagó, the leading domestic company, participated in 19 of 24 pharmaceutical submarkets in 1972, introduced 16 new drugs, and sold a total of 80 different products, making it by far the most diversified and innovative drug firm in Argentina.

[4]In Argentina product patents for pharmaceutical substances are not recognized, nor can process patents be used to prevent imports of products or ingredients made under that process in other countries.

[5]The market share of local drug firms in Argentina increased relative to that of TNCs between 1962 and 1970 (Katz, 1974: 62-63).

[6]Thirty-eight of the 40 largest pharmaceutical companies in Mexico are foreign-owned.

[7]Mexico's drug imports exceeded its drug exports by P $501 million in 1970. By 1975 this deficit had risen to P $1,035 million, a growth rate of 16 per cent annually (de María y Campos, 1977: 898).

[8]These are: the Law on the Transfer of Technology (1972), the Law to Promote Mexican Investment and Regulate Foreign Investment (1973), and the Law on Inventions and Trademarks (1976).

[9]For an analysis of Proquivemex's role in the Mexican steroid hormone industry, see Gereffi (1978; 1983).

[10]This commission was established in Mexico by executive decree on 17 November 1978. It is composed of representatives from five Ministries (Treasury, Commerce, Health, Patrimony and Industrial Development, and Agriculture), the Mexican Institute of Social Security (IMSS), and the Institute of Social Security and Services for Government Workers (ISSTE).

[11]The essential drug list ("Cuadro Básico de Medicamentos del Sector Público") was published in Mexico's Diario Oficial on 28 March 1978. It includes a total of 614 pharmaceutical preparations, derived from 426 different generic medicines. It is estimated that the present essential drug list covers about 95 per cent of all pharmaceutical sales to the public sector in Mexico.

[12]In the Mexican pharmaceutical industry, TNCs hold 85 to 90 per cent of all patents granted (de María y Campos, 1977: 897).

[13]With respect to both output and exports, the lower percentage refers to finished drugs and the higher percentage to active ingredients.

[14]This is related to a program sponsored by the Mexican government called COPLAMAR (Coordinación de los Planes para los Marginados) that concentrates on a subset of about 60 products from the essential drug list for free distribution to the rural poor.

[15]In the private market, all pharmaceutical products registered in Mexico can be sold; in the public sector market, those products from the essential drug list can be sold; and in the social interest market, composed of indigent persons who neither work for the government nor are covered by social security, a selected number of products from the essential drug list receives top priority. Each pharmaceutical firm is encouraged to participate in each of these three markets.

[16]The information on Costa Rica's pharmaceutical industry is drawn primarily form UNCTAD (1982).

[17]These incentives include total exemptions from customs duties on imported equipment for 10 years and on raw materials, chemical intermediates, and packaging materials for 5 years. Total exemptions are also granted from income tax for 8 years and from taxes on fixed assets for 10 years (Article 11 of the Central American Agreement on Fiscal Incentives for Industrial Development, 31 July 1962).

[18]Between 1958 and 1975 the market share of small drug firms (less than one million colones) decreased from 78 per cent to 25 per cent (UNCTC, 1983).

ANNEX III

SELECTED SUBREGIONAL SCHEMES

Caribbean Community Countries (CARICOM)

The Caribbean Community comprises some 15 countries whose territories occupy about 100,000 square miles and whose combined population in 1976 was 5.2 million people. Among the nations of the Caribbean Community there is diversity in terms of pharmaceutical policies as well as in the state of the pharmaceutical sector. Policies range from that of Guyana, where all imported drugs for the public and private sectors are based on a national formulary, to that of Barbados where the private sector imports drugs for its own use as well as for the public sector. Pharmaceutical manufacturing is carried out in four countries in the region --Barbados, Guyana, Jamaica, and Trinidad and Tobago--but this production is not integrated or rationalized, so every factory in the region has excess capacity. In effect the companies are competing among themselves for a relatively small regional market. Quality assurance, inventory control, market information, transportation and communication networks, and storage facilities for drugs are very uneven in the region, which tends to accentuate the problems in drug distribution and cost effectiveness generally faced by smaller nations.

The CARICOM Health Secretariat, on the assumption that the pooled procurement of drugs at the regional level is both feasible and advantageous, devised a CARICOM Master Contract system to collate regional drug requirements by centralizing public sector purchases of those member countries wishing to participate. The Master Contract covered eighty dosage-form pharmaceuticals in 1981. However a comprehensive report sponsored by the Pan American Health Organization (PAHO) on 51 of the 80 dosage forms available through the CARICOM Master Contract discovered that only four of the ten countries[1] studied utilized the Master Contract during the period from January 1, 1980 to September 15, 1981 (Feeney, 1981: 7). The four nations that used the Master Contract for pooled procurement of pharmaceuticals were St. Kitts/Nevis (24 times), Grenada (20 times), Montserrat (5 times), and Dominica (1 time) (Feeney, 1981: 30).

The underutilization of the Master Contract by the Health Ministries of the Caribbean Community contributed significantly to the wide price variations found in the PAHO study. For the dosage-form pharmaceuticals included in the survey that were available through the CARICOM Master Contract the difference between the highest landed (CIF) purchase price and the lowest purchase price was greater than 100 per

cent in three-quarters of the transactions and exceeded 500 per cent in one out of every five transactions. The CARICOM Master Contract purchase price represented the lowest price paid for a pharmaceutical in 57 per cent of the cases in which the Master Contract was available and used. For all drug purchases by the public sector in the 10 CARICOM countries studied, including those that utilized the Master Contract as well as those that did not, the percentage difference between the highest and lowest prices paid was over 100 per cent in one-half of the cases and greater than 500 per cent in one-tenth of the cases (N=240) (Feeney, 1981: 7).

The reasons for these substantial price variations in the CARICOM countries are many. One factor already mentioned is inadequate utilization of the regional pooled procurement mechanism offered by the CARICOM Master Contract. It is interesting to note that Barbados paid the lowest price for dosage-form drugs more frequently than any other country surveyed (Feeney, 1981: 8). This is due primarily to a computerized system of procurement based on the Barbados National Drug Formulary, which may be a useful model to other countries in the Region. Another reason for these price variations has to do with deficiencies in materials management practices throughout the Region. In order to promote cost containment measures in pharmaceutical purchasing, national supply officers will need manangement training in procurement methods, inventory control and forecasting, and drug distribution. There is still some resistance to the use of generic names in product selection and prescribing.[2] Finally, not enough attention has been paid to existing opportunities for regional trade in pharmaceuticals. At least eight Caribbean manufacturers supplied the Ministers of Health in the region with drugs in 1980-1981, and in 12 per cent of all purchases reviewed in the PAHO study a Caribbean firm provided the lowest priced item[3] (Feeney, 1981: 9, 26). Of the 10 highest volume capsules purchased by CARICOM countries six are produced in the Caribbean, of the 10 highest volume injectable medicines bought three are made in the Caribbean, and of the 20 highest volume tablets purchased 14 are produced in the Caribbean (Feeney, 1981: 12-15). Despite the potential demand for their products, in 1977 every factory in the region had a significant amount of excess capacity in tableting, capsuling, liquid manufacture, ointments, creams, powders, and intravenous solutions (APEC-TTI, 1977: 17).

To address the needs of the region in terms of ensuring the availability of reasonably priced and good quality essential drugs, the establishment of a Caribbean Pharmaceutical Centre was approved at a meeting of Health Ministers in 1978. It was suggested that the primary functions of the Centre include the following: a) operating the regional pooled procurement system; b) promoting rationalized pharmaceutical production in the region; c) compiling a Caribbean Formulary; d) disseminating product information through a regional publication; e) assisting

countries in setting up pooled procurement systems, inventory control, etc. at the national level; f) assisting countries in revising their pharmaceutical patent legislation; g) helping local drug manufacturers in obtaining equipment, technology, and other inputs under the best terms and conditions; h) organizing training programs at the regional level in international drug procurement, quality control, stores management, etc.; and i) exploring the possibilities of cooperating with other developing nations and regional organizations regarding market information, trade, cooperation in production arrangements and technology transfer, etc. (APEC-TTI, 1977: 26).

In 1980 a report was commissioned to consider alternative methods of establishing the Caribbean Pharmaceutical Centre (Commons, 1981). The study, which dealt primarily with the proposed pooled procurement function of a pharmaceutical center, found that the six countries in the region on which it focused could be divided into two groups. The lesser developed countries (LDCs), represented by Dominica, St. Lucia, and Grenada, shared a common set of problems within their national operations and in addition had similar methods and procedures for the procurement and distribution of pharmaceuticals. Each of the LDCs faced significant problems with regard to cash flow, market and product information, quality assurance, transportation, product specifications, generic nomenclature, stock control, and storage facilities. Although there was uneven development in the elaboration of satisfactory essential drug lists, all of the LDCs recognized their importance and were working toward a national formulary. The report concluded that the LDCs would benefit greatly from a conbined approach to their common problems in pharmaceutical supply, with particular emphasis to be placed on a joint pooled procurement program and suitable training for personnel employed in medical supply operations in the LDCs (Commons, 1981: 2, 55-63).

The more developed countries (MDCs) in the region, represented by Barbados, Trinidad and Tobago, and Guyana, have evolved in different directions and have distinct pharmaceutial supply systems and problems. Barbados and Trinidad/Tobago are both oriented towards free enterprise and are in favor of promoting cooperative programs between the public and private sectors with regard to drug procurement and distribution. In Guyana, on the other hand, the purchasing, importation, and warehousing of all pharmaceuticals used in the country is exclusively controlled by the Guyana Pharmaceutical Corporation, which is a government agency. Whereas neither Barbados nor Trinidad/Tobago have serious cash flow problems, Guyana is currently undergoing a period of extreme financial constraint due to a serious shortage of foreign exchange currencies. This problem often leads to limiting sources for offshore drug procurement to areas where favorable financing can be arranged and it would pose considerable difficulties to any attempt to integrate Guyana's pharmaceutical needs with a regional pooled procurement program. Barbados and Trinidad/Tobago would also find it difficult to participate in a

CARICOM-pooled procurement program because this would necessitate circumventing the private sector which both countries feel is performing this function efficiently. Thus it is considered unlikely that these MDCs will join the CARICOM pooled procurement system in the near future (Commons, 1981: 63-67).

Before concluding, it is useful to look briefly at the Barbados Drug Service that was introduced in April 1980 and is now fully operational. The Barbados Drug Service is "a drug management and service system designed to reduce the cost of prescribed drugs in both the public and private sectors while at the same time ensuring the continuous availability of quality drugs of known therapeutic effectiveness" (Turnbull, 1982: 1). These objectives are reached through the cooperation and mutual participation of the public and private sectors. In addition to its administrative component, the Barbados Drug Service has three integrated service components: 1) National Drug Formulary; 2) Drug Benefit Service; and 3) Drug Supply Section.

The Barbados National Drug Formulary (BNDF) is the cornerstone of the three service components. This formulary contains 500 drugs in 1,100 dosage forms listed by their generic names plus, in most instances, interchangeable products designated by brand names. One or more of the items in the formulary under each generic title is designated by an asterisk, which indicates those drugs for which the Barbados Drug Service has made bulk quantity supply arrangements. Procurement within Barbados does not involve the actual purchase of drugs but rather the negotiation of a contract agreement with a manufacturer or his agent for the supply of a product through private wholesalers in Barbados at a fixed unit price for the negotiated period. The inventory of all government dispensaries is limited to the asterisked products listed in the formulary, although drugs not included in the BNDF are available in Barbados subject to the conditions of supply and demand. The BNDF is continually updated, with the most recent (fourth) edition released in 1982. The overall savings that could be achieved by using BNDF in 1980-1981, its start-up year, have been estimated at over 20 per cent, although the savings for individual drugs are frequently much higher (Turnbull, 1982: 4-7).

The Drug Benefit Service provides for free or subsidized drug services to special groups of Barbadians. These include senior citizens 65 years of age and over and children under six years of age, the indigent or handicapped, all public ward hospital patients, and those needing drugs for the treatment of diabetes, hypertension, or cancer. The Drug Supply Section is not itself engaged in the physical procurement, warehousing, and distribution of drug products. Its role is to negotiate, guide, and monitor the entire acquisition and distribution process. Wholesalers

deliver drugs directly to government facilities or private pharmacies. The price of all drugs listed in the BNDF includes a 28 per cent mark-up over the item's landed (CIF) price to compensate the wholesaler for transportation, delivery and handling services. Within the private sector formulary drugs are obtained at the same negotiated price that applies to the public sector. Non-formulary drugs are subject to a 15 per cent import duty.

To date the CARICOM pooled procurement system has not been widely utilized, with several of the major countries in the region not participating. Because of this fact the scheme does not have much purchasing power that could be used to rationalize production patterns in the area. The availability of low cost essential drugs is limited as a result.

Andean Common Market Countries (ANCOM)

The Andean Common Market is made up of five countries: Bolivia, Colombia, Ecuador, Peru, and Venezuela. The Cartagena Agreement (Acuerdo de Cartagena) signed by these countries in 1969 committed them to design and implement a series of joint economic initiatives at the subregional level with the aim of furthering the integration and level of development of the member nations. The pharmaceutical industry has received special attention in the Andean region. The Cartagena Agreement and the Hipólito Unanue Convention (Convenio Hipólito Unanue) put forward the achievements and aims of ANCOM countries up to 1979 with regard to the pharmaceutical sector: 1) an essential drug list with approximately 350 medicines has been adopted; 2) product registration criteria have been developed; 3) a set of good manufacturing practices has been agreed upon and is being implemented; 4) a common pharmacopoeia is being used in the region; and 5) internationally accepted quality control standards are being applied to all pharmaceutical products imported into or exported from ANCOM.

More recently, ANCOM countries have undertaken the additional objective of lowering the prices of medicines sold in the region. Consequently two new programs are underway. In 1980 the Andean System for Technological Information (Sistema Andino de Información Tecnológica (SAIT)) was created in order to increase the bargaining power of appropriate governmental agencies and local firms with regard to technology suppliers. The ultimate objective is to help foster endogenously generated technology. One of the mechanisms to be used by SAIT is a Special Information Network on International Prices (Red Especializada de Información de Precios Internacionales, or REIPI) which will gather and disseminate price information on selected products throughout the region. The governing bodies of the Cartagena Agreement decided that REIPI would be tried first in the pharmaceutical and medicinal chemical sectors. Data gathered from various countries in the region showed that the prices of imported pharmaceutical fluctuated widely, with the

difference between the lowest and highest prices for the same drug imported into a country during a given 6-month period reaching levels as high as 600 per cent (SAIT, 1982: Appendix II). If the entire supply of essential medicines in ANCOM countries in 1980 had been purchased at the lowest available price, it is estimated that the region would have saved 48 per cent of the foreign exchange actually spent on these drugs (SAIT, 1982: 39, Appendix III).

The REIPI for pharmaceutical products is initially being implemented on a pilot project basis. A group of 20 essential drugs has been selected, together with a second group of 20 medicinal chemicals that are used as inputs in manufacturing the first set of products (see SAIT, 1982: Appendix IV). After the import prices for these pharmaceuticals are obtained from national centers in the region, they will be catalogued and sent out to ANCOM members as a guideline for future drug purchases. Once the pilot project is underway and functioning efficiently, it can be extended to cover all of the products on ANCOM's essential drugs list.

The other major ANCOM initiative in the area of pharmaceuticals is a program to purchase in bulk the inputs required for the local production of a certain number of essential drugs (Resolución REMSAA 9/153, "Programa de adquisición y suministro de insumos para la fabricación de medicamentos prioritarios por contrato con laboratorios existentes en la subregión"). The program will begin with a list of 42 essential medicines, with activities scheduled to begin in 1983.

The ANCOM countries are taking specific steps towards self-reliance and lower prices of essential drugs in the region through programs that will systematically exchange price information on imported pharmaceuticals among member nations and that will encourage bulk purchasing of medicinal chemicals to be converted locally into finished drugs. Because the Andean region represents a far larger market than the Caribbean Community does, ANCOM's chances to achieve a significant degree of bargaining power vis-à-vis the pharmaceutical industry look better than CARICOM's. Nonetheless much will depend on how effectively ANCOM's programs are implemented.

Footnotes

[1]The CARICOM countries included in the PAHO study are Antigua, Barbados, Dominica, Grenada, Guyana, Montserrat, St. Kitts/Nevis, St. Lucia, St. Vincent and the Grenadines, and Trinidad/Tobago.

[2]The majority of the pharmaceutical procurement offices surveyed did not have a copy of WHO's "Selection of Essential Drugs" (Technical Report Series 641, 1979) for their personal reference.

[3]A Caribbean manufacturer charged the highest price for a dosage-form drug in 6 per cent of all purchases.