

Learning from the Experience:  
The Inter-American Development Bank  
and Pharmaceuticals

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**Inter-American Development Bank**  
Washington, D. C.

**Sustainable Development Department**  
**Technical Papers Series**

**Cataloging-in-Publication data provided by the  
Inter-American Development Bank'  
Felipe Herrera Library**

Antonio Giuffrida is an Economist in the Social Development Division of the Sustainable Development Department. The author express its gratitude for the extensive and useful comments offered by Jillian Cohen, Rosario D'Alessio, Roberto Iunes and William Savedoff. This document also benefited from suggestions provided by many individuals at the Inter-American Development Bank.

The opinions expressed are those of the author and not necessarily those of the Inter-American Development Bank.

May 2001

This publication (No. SOC-123) can be obtained through:

Publications, Social Development Division  
Inter-American Development Bank  
1300 New York Avenue, N.W.  
Washington, D.C. 20577

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# Foreword

The last century witnessed revolutionary progress in improving human health, leading to dramatic declines in mortality and equally dramatic increases in life expectancy. Development of drugs played a significant role in these achievements. Nowadays effective drugs exist for most of the leading diseases. Therefore, increasing access to essential and safe drugs will contribute significantly to reduce poverty, which does so much to delay development in Latin America and the Caribbean.

In the last decades the IDB has grown to become a significant policy advisor and international financier of governments' efforts to improve the efficiency, efficacy, and effectiveness of their health services. Many of Bank's activities in this sector have included actions directed to improve the pharmaceutical sector. The Bank's commitment is denoted by the *Shared Agenda for Health in the Americas* recently signed with the World Bank and PAHO, which includes pharmaceuticals as one area of collaboration.

This paper reviews Banks' activities to improve access to and quality of essential medicines in Latin America and the Caribbean. Beginning with a description of the fundamental characteristics of the pharmaceutical sector in the region, the paper provides a review of the projects financed by the Bank and of the future challenges in this sector. It can be useful to policymakers who are seeking ways to improve the pharmaceutical system of their countries, and technical staff seeking to design better operations in pharmaceuticals. It is hoped that this paper will help the IDB to address future challenges in the pharmaceutical sector and in closer collaboration with our colleagues at PAHO, World Bank and other partner institutions.

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# Introduction

Since Alma-Ata, medicines have been an essential component of the delivery of primary health care services. The 1975 World Health Assembly Report introduced the concept of essential drugs defined as “those that satisfy the health care needs of the majority of the population and should therefore be available at all times in adequate amounts and in appropriate dosage forms” (WHO, 1975).

Pharmaceutical innovations and improvements in their availability and use have contributed significantly to the reduction of mortality and morbidity worldwide. Moreover, appropriate use of pharmaceuticals can reduce the hospital stay and the need of surgical procedures resulting in a more efficient use of health care budgets (Lichtemberg, 1998).

The Inter-American Development Bank (IDB) recognizes that pharmaceuticals play an important role in the health policy of its member countries. The Bank’s operational policy for public health<sup>1</sup> mentions three main concerns about the pharmaceutical sector: the first is for the quality of drugs, which must meet well-recognized standards. The second concern is assuring an adequate access to medicine. The third issue relates to the problem of maintaining prices at a level that makes drug production economically feasible, but also makes consumption affordable.

The IDB has supported the governments of Latin America and the Caribbean in their efforts to improve their pharmaceutical systems. Pharmaceutical components were included in many of the health projects financed by the Bank, but there is no systematic information regarding IDB activities in this sector. The objectives of this paper are twofold. First, it intends to present a brief description of the characteristics of the pharmaceutical sector in the region and discuss the rationale for Bank involvement. The second aim is to carry out a systematic review of IDB activities in this sector, analyzing the scale and scope of these activities during the last decade.

Section 2 describes the pharmaceutical sector in Latin America and the Caribbean and discusses the characteristics that make medicines different from standard commodities. Section 3 describes Bank activities in the pharmaceutical sector and its evolution through time and by regions. Section 4 provides a detailed analysis of Bank interventions in the various areas of the pharmaceutical sector. Section 5 concludes with a discussion of future challenges for IDB activities in this sector.

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<sup>1</sup> The operational policy (OP-742) is available at <http://www.iadb.org/cont/poli/OP-742E.htm>.

## Characteristics of the Pharmaceutical Sector

Pharmaceutical products can be classified according to various criteria. Firstly, we distinguish between pharmaceuticals for human use, which represent around 90 percent of the market in the region, and veterinary drugs – this paper focuses solely on the former group.<sup>2</sup> Among pharmaceuticals for human use, we distinguish between *ethical* drugs, which require a doctor's prescription, and over-the-counter (OTC) drugs, which can be bought without a medical prescription. Ethical drugs are further divided according to whether the active ingredient of the compound is under patent or not.

Pharmaceutical firms that discover a new active ingredient have the right to patent it, thus acquiring the exclusive right to produce and sell it for a number of years. When the patent expires other firms may begin to produce and sell exact replicas of the original drug, which are then referred to as *generic*. However, while the producer of the original drug, now off patent,

may still market its product using its brand name, the new generic version is identified by the name of the active ingredient.

The size of the Latin American pharmaceutical market was estimated in 1998 at US\$24.2 billion at ex-manufacturers prices, representing approximately 8 percent of the world market (Scrip, 1999). In the same year, the private sector accounted for approximately 70 percent of the total value of the market.<sup>3</sup> Table 1 presents the total value of drugs sold through retail pharmacies in Latin America during the last two years. Pharmaceuticals valued at US\$17 billion were sold in the 12-month period from May 1999 to May 2000. For comparison, the value of pharmaceuticals sold in the United States during the same period was five times higher. The table also shows that contrary to the rapid expansion of the U.S. market, the Latin American market experienced a small contraction. Argentina, Brazil and Mexico represent around three-quarters of the regional

**Table 1 Drug Sales through Retail Pharmacies**

	12 months to May-2000 US\$ million	% Growth constant exchange	12 months to May-1999 US\$ million	% Growth constant exchange	12 months to May-1998 US\$ million
Latin America and the Caribbean	16,890	-1	16,987	-2	17,448
Brazil	4,982	-15	5,850	-13	6,752
Argentina	3,436	-4	3,571	9	3,369
Mexico	4,415	26	3,492	11	3,152
USA	90,277	15	78,742	12	69,862

Sources: IMS Health (2000) and PhARMA (1998).

<sup>2</sup> The IDB has also financed activities in the area of veterinary drugs. For instance, a project in Belize (BL-003, Modernization of Agricultural Health) included a

component on animal health that aimed to improve the registration and quality control system for veterinary drugs.

<sup>3</sup> For a detailed description of the pharmaceutical system in each country see Velásquez and Fefer (1999).

market. Both the Brazilian and Argentinian markets declined, the former more markedly. By contrast, the Mexican market surged, outperforming the United States.

The pharmaceutical sector has some distinctive characteristics, which make it different from a perfect market:<sup>4</sup>

*Risk and Uncertainty* – For an individual, illness and the cost associated with the consumption of the medicines are unpredictable. In an unregulated market, this situation will lead to the development of insurance markets and the resulting problems of diseconomies of scale, moral hazard and adverse selection.

*Information Failure* – The range of drugs is so vast and complex that information failure abounds. All governments recognize that information failure requires drug safety and therapeutic efficacy regulations. For example, because the average consumer cannot assess which drugs are appropriate for a particular ailment, many drugs are available only by prescription from a medical doctors with appropriate training. The provision of pharmaceuticals suffers from a special type of principal-agent problem (Blomqvist, 1991). Because of the combination of both information asymmetry and third-party financing, physicians (the prescribing agents) act as *double agents*, both in the interest of the patient and of the insurance provider. Moreover, since doctors do not bear the financial consequences of their prescribing behavior they may not be concerned with its cost-effectiveness.

*Externalities* – Pharmaceutical consumption generates positive externalities because, in some situations, people benefit from other people's consumption. *Selfish externality* may arise when products are used to treat contagious diseases (e.g. tuberculosis and STDs) or people are inoculated. In such cases, the rest of the population benefits from a reduction in the risk

of contracting these diseases. *Caring externalities* may also arise because people care that others are receiving needed health care, even if it does not necessarily affect their own health status. If externalities are significant, then an unregulated market will lead to underconsumption of medicines (i.e. lower than the social optimum).<sup>5</sup>

*Market Power* – The pharmaceutical sector has been defined as a *differentiated oligopoly* (ECLAC, 1987; Scherer, 1993; 2000). New molecules are usually covered by patents and are typically supplied by a single firm.<sup>6</sup> Moreover, pharmaceutical products are not homogenous, but differentiated in therapeutic areas and, within a specific therapeutic group, the market concentration can be significant. When a pharmaceutical patent expires, manufacturers of generic compounds may enter that market and produce replicas of the original drug, which are usually sold at prices that are a fraction of the cost of the original branded products. However, there is a large body of empirical evidence that shows that price rivalry between branded and generic drugs is quite limited. Physicians tend to continue prescribing trade-name drugs even if cheaper generic substitutes are available because they are risk averse, insensitive to cost and subject to inertia in their habit (see Hellerstein, 1994; 1998; and Ryan et al., 1996). Moreover, even if the law permits or encourages generic substitution consumers purchasing drugs at retail pharmacies normally lack the necessary knowledge to consider the alternative of buying generic drugs rather than the prescribed brand-name product. The scarce adherence to the practice of generic substitution also derives from the fact that the profit margins of pharmacies are a function of their sales volumes, thus they may encourage the marketing of more expensive branded drugs over generics.

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<sup>4</sup> See Donaldson and Gerard (1993) for a detailed review of market failures in health care and Scherer (1993; 2000) for an examination of the issues specific to the pharmaceutical sector.

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<sup>5</sup> Externalities in the case of vaccinations are discussed by Stiglitz (1988; p120) in his textbook on public economics. The economic theory underlying caring externalities in health care was developed largely by Culier (1971).

<sup>6</sup> Issues related to patent protection in pharmaceuticals are discussed in the last section of the paper.

*Conflicting Goals* – Pharmaceuticals are at the crossroads of the health and industrial sectors. The production, distribution, and consumption of pharmaceuticals has major implications for both public health and industrial policy. Thus, there are two different and sometimes conflicting public policy goals. The first is the enhancement of the health of the population that imply health policies and social interventions directed to expand access to essential drugs, improve drug safety and therapeutic efficacy, and contain costs. The second policy goal deals with strengthening innovation, competitiveness and the economic efficiency of the national pharmaceutical industry, and is the purview of industrial policy.

Thus, there is a difficult policy trade-off between protecting the national pharmaceutical industry and providing medicines at a reasonable cost (see Bloom and van Reenen, 1997; 1998).

To summarize, the pharmaceutical sector suffers from market failures that are common in the health care sector, but also presents some distinctive features due to the presence of limited competition and potentially conflicting public policy goals. There is widespread agreement that an unregulated market would not produce a socially desirable outcome, either in terms of product safety or patients' access to life-enhancing medicines.



## IDB Activities in the Pharmaceutical Sector

All the countries of the region are making important efforts to improve the availability and the quality of drugs. The IDB supports government actions through loans and technical cooperation operations.

For the purpose of this paper we have examined all health and social sectors loans approved by the Bank between January 1990 and December 2000, looking for pharmaceutical components.<sup>7</sup> To ensure that all the relevant projects were identified a systematic search of the IDB Database of Approved Project and the Index of Documents Registered by the Secretariat was performed. In addition, we interviewed various health specialists at the IDB headquarter and we requested information using the electronic mailing list *HealthList*.

To keep the review manageable and make it systematic, the search was limited to Bank loans. However, the discussion that follows details projects approved before 1990 as well as nonreimbursable technical cooperations.

We have classified IDB loans into the following five categories:

- ? Acquisition of essential medicines and vaccines to improve access to life saving drugs among the poor.
- ? Improvement of the procurement and distribution systems to make sure that drugs are available when they are needed and at a reasonable price.
- ? Improvement of the drug regulatory authority in order to ensure that drugs are

registered properly, that pharmaceutical establishments are licensed and inspected according to well defined procedures and that the quality of their products is acceptable when they reach the market.

- ? Development of sustainable drug financing and pricing mechanisms (e.g. maintaining a significant drug allocation in the health budget, developing insurance or other solidarity systems, regulating prices in the private sector, promoting competition through increased availability of generics, etc.).
- ? Ensuring the rational use of drugs by providing printed information, treatment guidelines, drug information, training and continuing education materials, etc.

### DESCRIPTION OF IDB LOANS

Eighteen of the 32 health sector loans approved by the Bank in the last decade included a pharmaceutical component (see the Appendix). The 18 loans with pharmaceutical components were executed in 14 countries and totaled around US\$71 million.<sup>8</sup> The pharmaceutical components varied in size. In some cases they represented a significant share of the financial resources of the overall health project, but in most of the cases they were quite small. On average, pharmaceutical components represented about 3 percent of the total resources devoted to health sector loans during the period considered.

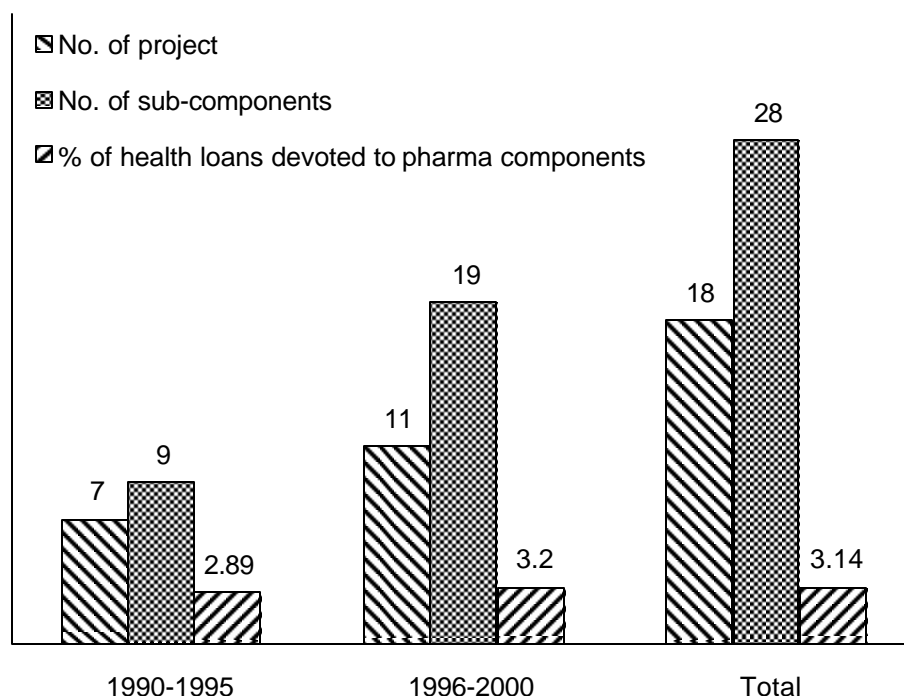
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<sup>7</sup> For a survey of World Bank activities in the pharmaceutical sector in Latin America see Cohen (2000b).

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<sup>8</sup> The estimations of the monetary values of the pharmaceutical components are based on documents produced at the time of project's approval. In some cases the exact figures were not given and were estimated using available information. Moreover, figures may have changed during the implementation of the project.

**Figure 1 Evolution of IDB Loans with Pharmaceutical Components**



Most of the projects financed acquisition of drugs (9 loans) and improvements in the public procurement and distribution systems (10 loans). Actions directed to improve drug quality were incorporated in 5 loans. Components to improve the financial sustainability and rational use of drugs were included in only 2 project each.

Figure 1 compares the projects financed during the years 1990-1995 with the ones approved in the period 1996-2000. Both the number of loans with pharmaceutical components and the number of pharmaceutical components increased in the second part of the decade. In monetary terms five times the amount allocated in the first half of the 1990s was allocated during the second half. However, considering the share of pharmaceuticals lending in the total health lending, the increase was slight (from 2.9 percent to 3.2 percent).

Figure 2 compares the types of pharmaceutical components approved in the period 1990-1995 with the ones approved in 1996-2000. It shows important changes in the type of IDB interventions. First, the number of projects aimed at financing the acquisition of drugs felt from 5 to 4. Second, there was a substantial increase in the number of components to improve the procurement and distribution system (from 3 to 7). Finally, the number of components to improve drug quality increased from 0 to 5. This pattern follows the evolution of Bank loans in the health sector. During the first half of the decade, most IDB loans went to the construction of physical establishments such as hospitals and health centers, while the aim of more recent interventions is the reform of health care systems in the region.

**Figure 2 Types of IDB Loans with Pharmaceutical Components**

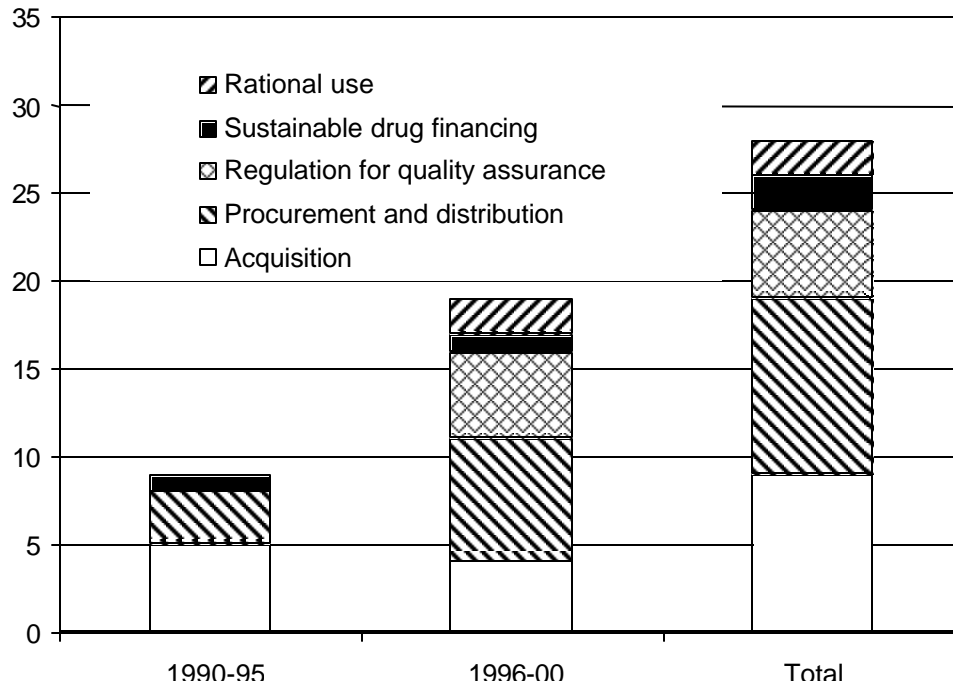
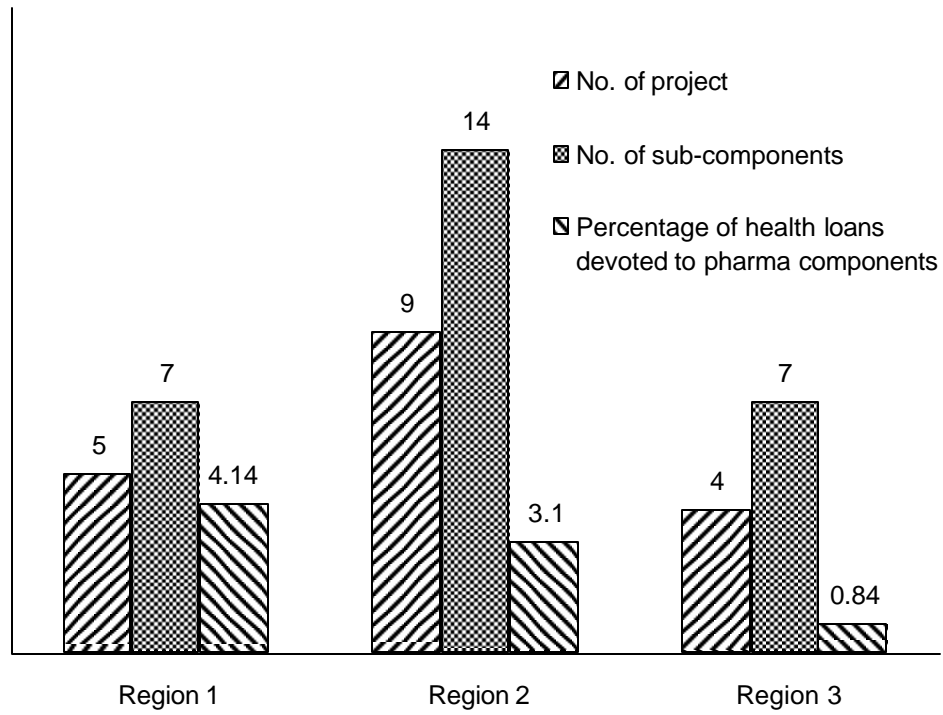


Figure 3 presents a regional comparison.<sup>9</sup> More resources (4.1 percent) were allocated to pharmaceutical activities in Region 1 than elsewhere and pharmaceutical components were included in 5 of the 8 health sector loans identified.

Nine of the 13 health sector loans approved in Region 2 had a pharmaceutical component and the resources involved represent about 3.1 percent of all health sector loans. In Region 3, only 4 of the 11 health related loans approved had a pharmaceutical component and the resources involved represent less than 1 percent of total health sector loans financed.

<sup>9</sup> Region 1 comprises Argentina, Bolivia, Brazil, Chile, Paraguay, and Uruguay. Region 2 includes Belize, Costa Rica, Dominican Republic, El Salvador, Guatemala, Haiti, Honduras, Mexico, Nicaragua, and Panama. Region 3 consists of Bahamas, Barbados, Colombia, Ecuador, Guyana, Jamaica, Peru, Suriname, Trinidad and Tobago, and Venezuela.

**Figure 3 IDB Loans with Pharmaceutical Components by Region**



## Main Areas of IDB Activity

In this section we provide a detailed description of Bank's activities in each of the five areas of the pharmaceutical sector we have identified.

### ACQUISITION OF DRUGS AND MEDICAL SUPPLIES

Acquisition of drugs and medical supplies is one of the most common pharmaceutical activities financed by the IDB and was included in at least nine health loans in the last decade. Although pharmaceuticals are a recurrent expense in national health budgets and Bank rules bar the use of loan resources to finance recurrent costs (see OP-742 Public Health), exceptions are made in the case of drugs. Loan resources may be used to purchase drugs needed to stock newly established health centers, for example. They may also be used to seed revolving drug funds. Loan resources may also be used to acquire drugs as part of a larger loan to support essential social services for a limited period of time and in response to an economic disruption. Finally, loan resources may be used to purchase pharmaceuticals aimed at eliminating specific diseases, which can be effectively treated by drugs that are not widely employed for other health problems.<sup>10</sup> A more detailed discussion of IDB loans used to finance the acquisition of drugs follows:

#### Example 1: Initial Drug Stock for a New Health Establishment

There were several projects of that included components of this type during the period considered. The IDB approved loans to finance the purchase of medicines for health care centers in Guyana (GY-0047),<sup>11</sup> Haiti (HA-0081 and

HA-0037), Nicaragua (NI-0024) Peru (PE-0030) and Panama (PN-0029). Because drugs and medical supplies are recurrent costs, the usual strategy is to finance one hundred percent of the expenditure in the first few years of the loan. With time, Bank financing decreases and the government is expected to be able to finance an increasing share of the cost of drugs and medical supplies. In some cases, like in Nicaragua and Peru, the acquisition of drugs was linked to other pharmaceutical components aimed at improving the procurement, distribution and regulation systems.

#### Example 2: Revolving Drug Funds

A project in Bolivia approved in 1991 (BO-0056) included a component to finance the creation of revolving drug funds in a number of health establishments. The project also led to the creation of a uniform normative framework for the organization of revolving drug funds in Bolivia (MSPS, 2000). The project originally, contemplated three procurement modalities: procurement at the central level and subsequent distribution to the local districts; decentralized procurement at the health district level and subsequent distribution to the health establishments; and acquisition arranged directly by the health establishments.

The implementation of the project showed that the most effective method was to decentralize decision-making to the health establishment level because the elimination of intermediates reduced prices and made the process quicker. Decentralization was accompanied by a strengthening of health district administration that integrated the supervision of the revolving drug funds into its overall monitoring activities (MSPS, 2000).

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shortcomings in procurement planning and management of drugs.

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<sup>10</sup> See Broun (1998) for a survey of issues related to pharmaceutical procurement in World Bank's projects.

<sup>11</sup> In 1987, the IDB approved another loan for Guyana (GY-0028) for the purchase of drugs and medical supplies for the Georgetown hospital. The loan was required to overcome the acute shortage of drugs and medical supplies that resulted from the scarcity of foreign currency and the

Revolving drug funds improved the physical and financial access to essential drugs defined as such in the *Seguro Básico*. Health establishments ensured the availability of these drugs, which were available freely to the population. Revolving drug funds also improved physical availability of drugs that were not included in the *Seguro Básico* package and prices were, on average, lower than market prices because the funds imposed lower profit margins.

Another important result was a satisfactory level of cost recovery, which permitted maintaining and often increasing the monetary value of the drugs covered by the funds, thus assuring the financial sustainability of the project. This result was mainly attributed to organizational improvements and to better planning, supervision and control (MSH, 1997).

### **Example 3: Pharmaceuticals as Part of Larger Social Protection Projects**

Acquisition of essential drugs has been included in projects to support essential social services for limited periods of economic disruption. Examples of this type of programs are the US\$1 billion loan approved jointly by the IDB and the World Bank for Mexico in 1995 (ME-0187)<sup>12</sup> and the US\$2.2 billion loan for Brazil in 1999 (BR-0308). Both projects aimed to protect social spending during periods of economic downturn by financing the provision of basic pharmaceuticals and vaccines. In addition, the Brazil project included, among the conditions for the disbursement of the health component, the realization of a study to improve public sector procurement and distribution of medicines. This was particularly significant because it recognized explicitly that the acquisition of drugs was only a short-term solution. Development loans should be better aimed at improving the efficiency of the pharmaceutical system to ensure financial sustainability.

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<sup>12</sup> Although the loan was co-financed by both institutions, the World Bank supervised the pharmaceutical components.

### **Example 4: Pharmaceuticals for the Elimination of Diseases**

The IDB has been involved in financing various campaigns to eradicate endemic diseases in the region. Some of these projects were financed using regional technical cooperation resources because eradication programs often require the coordinated efforts of a number of countries.

Examples include a project to eradicate the poliomyelitis virus in the Americas (regional technical cooperation ATN/SF-2851-RG). This project was successful and the last registered case of polio occurred in August 1991. Another regional technical co-operation (ATN/TF-4610-RG) approved in 1994 provided financing for the implementation of a program to distribute ivermectin (*Mectizan*) in communities with endemic onchocerciasis (commonly referred to as “river blindness”). More recently, a project in Bolivia (BO-0115) included a subcomponent aimed to control, prevent and treat Chagas’ disease that financed the acquisition of drugs to treat the disease in children under the age of five.

Access to effective drugs is only one of the elements of a successful disease eradication program. Also important are epidemiological surveillance, staff training and the distribution of drugs and vaccines. Thus, the costs related to the acquisition of drugs often represent only a small part of the total financial resources needed to implement a successful disease eradication program.

### **IMPROVING THE PUBLIC PROCUREMENT AND DISTRIBUTION SYSTEM**

The pharmaceutical procurement and distribution system is a major determinant of drug availability and health expenditures. An effective system should:<sup>13</sup>

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<sup>13</sup> For a detailed analysis of the issues related to pharmaceutical supply see Quick et al. (1997).

- ? Procure the right drugs in the right quantities and at the lowest possible price.
- ? Ensure that all drugs procured meet recognized standards of quality.
- ? Set the purchasing schedule, formulas to order, and safety stock levels to avoid shortages and stock-outs and to achieve the lowest total cost at each level of the system.
- ? Maintain accurate inventory records, rationalize drug storage points and provide information for forecasting drug needs.
- ? Keep drugs in good condition throughout the distribution process, minimize drug losses due to spoilage, expiry, theft and fraud.
- ? Achieve these objectives in the most efficient manner possible.

A drug supply system involves several distinct, but linked activities. Careful planning and coordination between different agencies is necessary to ensure that the selection, acquisition and distribution of products is based on therapeutic efficacy, safety, accessibility and economic efficiency. However, in many cases local governments lack planning and coordination in drug procurement and supply. For instance, studies conducted during the preparation of a health loan in Guatemala (GU-0023) indicated that the system for the distribution of medication was flawed and that over 30 percent of the resources spent on drugs and medical supplies were wasted. Failure to control purchasing and inadequate procurement regulations meant that most health establishments paid from two to four times the average international price for medical and pharmaceutical supplies.

The efficacy and transparency of administrative procedures, particularly those related to acquisition, should be clearly specified and closely followed. A suitable organizational structure, trained personnel and adequate funds, facilities and equipment, are the necessary structural components. Centralized pharmaceutical buying has proved successful in

many countries (e.g. Guatemala) because large-scale purchases reduce costs, making the health care resources go further.

Most of the interventions financed by the IDB shared the following goals:<sup>14</sup>

- ? Bring together the drug supply system of the various government bodies to maximize efficiency and to facilitate the integration of the procurement systems.
- ? Improve pharmaceutical procurement practices by using generic procurement; concentrating on a predefined list of essential drugs; carrying out a rational needs assessment; pre-qualifying suppliers; using competitive tendering; carrying out a systematic monitoring of supplier performance; making prompt payment; purchasing goods packaged in the most economical units, buying in bulk and selecting the most economical method of transportation.
- ? Enhance quality control and information systems covering inventories, suppliers and prices.
- ? Provide incentives for local purchaser to streamline demand and exercise responsibility; create a “demand-driven” supply system. For example, projects in Nicaragua (NI-0024) and the Dominican Republic (DR-0078) introduced a budget for the acquisition of drugs and medical supplies made at local level.
- ? Introduce partnerships with the private sector to reduce the storage and distribution responsibilities of the public sector.

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<sup>14</sup> The Bank has carried projects in this area in Belize (BL-0014), Bolivia (BO-0056), Brazil (BR-0199; BR-0308), the Dominican Republic (DR-0078), El Salvador (ES-0053), Guatemala (GU-0023), Nicaragua (NI-0024), Paraguay (PR-0028) and Peru (PR-0030).

## **IMPROVING QUALITY ASSURANCE REGULATION**

Pharmaceutical quality is essential, yet the situation in the region is far from adequate. In many countries, street sales of medications are a growing problem and counterfeit and adulterated products find their way into formal distribution networks. The countries of Latin America and the Caribbean fall into three fairly distinct groups with respect to the quality of drugs. The first group comprises Argentina, Brazil, Chile, Costa Rica, Mexico and Venezuela. In these, legal and administrative mechanisms function more or less effectively. The second group includes Colombia, Ecuador, Panama and other countries that have recently established new legal and operational tools and have taken some actions. The third group of countries is made up of Bolivia, Haiti, Peru, and most of the nations of Central America. Although there are some improvements, these countries have not yet developed suitable instruments for quality control of pharmaceuticals. Drug quality is an issue also in the Caribbean. The Caribbean Regional Drug Testing Laboratory (CRDTL), which provides services to 14 English-speaking Caribbean countries, reported in 1997 that 35 percent of the samples tested were found to be unsatisfactory (Velásquez and Fefer, 1999).

The IDB has helped governments to improve their regulatory framework for pharmaceutical quality as well as their capacity to monitor pharmaceuticals and carry out quality control and health surveillance. IDB action focused on Region 2 countries such as the Dominican Republic (DR-0078), El Salvador (ES-0053), Guatemala (GU-0125) and Nicaragua (NI-0024). However, these projects are recent and evidence of their results is still lacking.<sup>15</sup>

## **THE RATIONAL USE OF DRUGS**

The concept of rational use of drugs relates to the behavior of physicians (e.g. appropriate prescribing), pharmacists (e.g. respect of

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<sup>15</sup> A health sector loan for Colombia (CO-0088) included a study to assess pharmaceutical quality and to formulate policies to improve to the country's pharmaceutical system.

prescription requirement, appropriate practice of generic substitution) and consumers (e.g. compliance with treatment, appropriate self-medication). Rational use plays an important role in pharmaceutical policies, particularly in relation to restraining expenditures. Poor prescribing practice is a major problem in the region and various drug utilization studies have amply demonstrated that inappropriate use and overprescribing of many pharmaceutical products to treat simple episodes continue to divert attention and available resources away from appropriate treatment.<sup>16</sup> This wastes resources and causes avoidable harm to patients that receive improper or ineffective treatments. The reasons for this are many. They include inadequate training in clinical pharmacology, the promotional activities of the drug companies, pressure from patients and the paucity of information. In particular, the drug industry seems to have considerable power to influence the medical profession against policies calling for the use of generic drugs on prescriptions and substitution of generics at the pharmacies.

Drug advertising is another issue that has a particularly important bearing on the rational use of drugs. While some countries, such as Bolivia and Peru, have incorporated ethical criteria for drug promotion in their legislation, compliance has been minimal.<sup>17</sup> Drug information centers may be a useful channel to reach health professionals and general public. Public information campaigns showing the risks of uninformed self-medication, and the properties and role of drugs are another potential avenue. The use of generic drugs in information campaigns should be encouraged to rationalize use and reduce expenditures.

Notwithstanding the importance a rational use of drugs, only two examples of IDB activity in this area were found. They are a project in Nicaragua (NI-0024) that advocated the use of

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<sup>16</sup> Examples are the over-prescription of antibiotics and the use of unnecessary medicine in the treatment of acute diarrhea in children (Paredes et al., 1996).

<sup>17</sup> The standard reference is the WHO ethics criteria for the promotion of pharmaceuticals contained in resolution WHA.39.27 of the WHO Assembly.



**Table 2 Criteria to Evaluate Drug Financing Mechanisms**

Feasibility measures	Outcome measures
<b>Financial viability and sustainability:</b> Can mechanism generate enough resources over long-term?	<b>Equity:</b> Does the mechanism promote universal access to essential drugs?
<b>Institutional/administrative requirements:</b> What institution and/or managerial elements are required for the mechanism to be successful?	<b>Efficiency:</b> For the resources invested, is the maximum health benefit obtained?
<b>Acceptability:</b> What is the public and political acceptability of the mechanism?	<b>Rational use:</b> Does the financial mechanism encourage appropriate prescribing and use of pharmaceuticals?

Source: Velásquez et al. 1998.

standardized therapeutic protocols to improve prescription and purchasing practices and a study to assess ways of improving the use of drugs in Colombia (CO-0088).

### SUSTAINABLE FINANCING

Financing drug expenditure is an important matter with ramifications for public as well as private sector financing.

Public spending on pharmaceuticals is determined by a combination of factors, including political will, gross domestic product (GDP), the share of GDP devoted to health, the existence of a public health care system and the share of health spending devoted to pharmaceuticals, among others. Lower levels of government revenue and relatively lower health allocations in the countries of Latin America and the Caribbean, imply that actual per capita public spending on pharmaceutical is much lower than in established market economies. As a result, many countries struggle to maintain a sustainable public financing of drugs.

There are a number of alternatives available for financing pharmaceuticals, which are basically the same as those for financing health services;

namely, public financing through general revenues, health insurance and user charges (Bennet, 1997; Madrid et al., 1998; Velásquez et al., 1998). Ultimately, the level of public commitment to health care and pharmaceuticals and the method to finance them reflects national decisions. The discussion of the appropriate method of financing public pharmaceutical expenditure is outside the scope of this review, but Table 2 lists suggested criteria to evaluate the options available.

Private expenditure for pharmaceuticals in Latin America and the Caribbean accounts for over three-quarters of total drug spending and represents around 35 percent of direct private expenditures on health (Velásquez and Fefer, 1999; Bennet et al., 1997).<sup>18</sup> Public cost-recovery schemes and community revolving drug funds often involve private contributions (user fees) to cover the cost of drugs. However, the largest portion of private expenditure refers to drugs bought by individuals in private pharmacies.

<sup>18</sup> The opposite occurs in the established market economies, where about 59.8% of pharmaceutical expenditure takes place in the public sector (Bennet et al., 1997; p. 32).

Following free market reforms in other areas of the economy regional trend in the last decade has been toward dismantling administrative price control mechanisms for pharmaceuticals (see Katz, 1998). A dynamic and well-supplied market with adequate information, rules governing competition and genuine opportunities for choice were considered the best guarantees that drug prices would match the underlying cost structures. However, as discussed in this paper, market failures inhibit this outcome. In effect, after the removal of price controls and the liberalization of the pharmaceutical sector pharmaceutical prices rose faster than average consumer prices. This phenomenon was documented in Brazil after the price liberalization introduced in 1992 (MSB, 1999)<sup>19</sup> and in Mexico after the liberalization of the pharmaceutical market in 1991 (GDF, 1999). Moreover, a recent study in Costa Rica found that the average retail price of a representative sample of 32 drugs in private pharmacies was more than 20 times higher than the price paid by the main public sector provider (the *Caja Costarricense del Seguro Social*) (MSCR, 2000). A similar study found that in Peru in 1996 consumers making their purchases in private pharmacies were charged a price that was, on average, 6 times higher than the one paid by the Ministry of Health (MSP, 1997).

High prices impair access to essential pharmaceutical products and discriminate against lower-income individuals. Thus, interventions directed to reduce pharmaceutical prices in the private sector are necessary. The main strategies to contain pharmaceutical prices are supply-side regulation and incentives to competition.

Supply-side regulation refers to policies directed to control prices or producer's profit. Interestingly, policies that were considered "wrong" for less developed countries during the past decades and led to a drastic reduction in price fixing interventions in the region, are the

norm in most of the industrialized countries.<sup>20</sup> The main criteria for fixing drug prices are the cost of producing the product (i.e. cost-plus regulation); the therapeutic value of drug; the price of similar products; the price of the same product in other countries; the rate of return on capital. The success of supply-side regulations is highly debated in the literature. There is some evidence that prices are lower in countries with price regulation, though there are serious difficulties in comparing drug prices across countries (see Danzon and Li-Wei, 2000). On the other hand, price control mechanisms are often bypassed, increasing the volume of drugs consumed. Moreover, it is argued that price control mechanisms may be cumbersome and open to manipulation (see Bennet et al., 1997).

Another policy is to foster the use of generic drugs in order to increase price competition among producers. This is an important tool because more than 90 percent of the drugs in the WHO Model List of Essential Drugs (WHO, 1999) are no longer under patent. The first step to do this is to overcome the resistance of physicians, pharmacists and consumers so that *generic prescribing* (physicians prescribe drugs by their active principle rather than brand name) and *generic substitution* (pharmacists substitute a cheaper equivalent product containing the same principles) can take place.

Experience from countries at all levels of development (see Bennet, 1997; Griffin, 1996; Mrazek, 1999) suggests that four factors are crucial to achieve a high level of generic use.

- ? First, a supportive legislation and regulation, which permit, encourage or require the generic prescribing and generic substitution. In addition, guidelines requiring that labels and drug information contain generic names may be useful.
- ? Second, a reliable national quality assurance system, to eliminate the health risk of using

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<sup>19</sup> For a detailed analysis of the Brazilian pharmaceutical sector, see Cohen (2000a).

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<sup>20</sup> For a survey of pharmaceutical policies in the OECD countries, see Jacobzone (2000).

generic products rather than the branded version.

- ? Third, gain professional acceptance introducing the use of generic names in clinical manuals, drug bulletins and other publications. Moreover, promotional campaigns may be used to target both consumers and health professionals.
- ? Fourth, provide economic incentives by making price information available to consumers and physicians. In addition, it may be necessary to regulate retail price and distribution margins so generic dispensing will not be at a disadvantage and to provide incentives for the development of the generic drug industry.

Only few countries in the region, such as Colombia, can claim success in introducing a generic drugs policy. Efforts in this country included the publication of a price comparison guide that drew the attention of consumers to the cost advantage of generic products. Publication of the guide was originally undertaken with support from the WHO and the Ministry of Health, but its popularity led the local manufacturers' association to take over its publication (see Velásquez and Fefer, 1999).

IDB activities in this area have been very limited; only two IDB loans were identified. The first loan was in Venezuela (VE-0091) and provided funds for the study of SEFAR, the independent service that oversees the production of generic drugs and pharmaceuticals. The second loan was in Colombia (CO-0088) and financed a study on the introduction of generic drugs.

## Discussion and Conclusion

Pharmaceuticals are indispensable commodities. The IDB has helped to improve access to life-enhancing medicine in the majority of its regional member countries. The analysis of the Bank's portfolio during the last decade shows a clear increase in both the scale and the scope of its activities in the pharmaceutical sector. In particular, the Bank has concentrated its activities in the areas of reform of the procurement and distribution systems and improvements in the quality of medicines. The discussion that follows highlights some aspects that are likely to be of particular importance for future IDB activities in the pharmaceutical sector.

### INTER-AGENCIES COLLABORATION

On May 2000, the IDB, the World Bank and the Pan American Health Organization (PAHO) signed an agreement for a *Shared Agenda for Health in the Americas*, which indicates the pharmaceutical sector as an area of collaboration among the three organizations.

Both PAHO and the World Bank have a large experience of activities in the pharmaceutical sector. These two Institutions – likewise the IDB – have the capacity of engaging the highest policy decision-makers in the region and each of them has comparative advantages in the region.

A clear comparative advantage of PAHO is the close collaboration with the Ministries of Health, the strong network of country offices, regional, sub-regional centers, and affiliated institutes throughout the region. PAHO possesses the highest know-how in public health fields in the region. Its approach to strengthen the health sector capacity in the region is based on an intersectoral action, and the promoting of an integral approach to health problems. PAHO's regional program on essential drugs has these three objectives: first, the development of national pharmaceutical policies and programs geared toward ensuring a continuous supply of

and access to essential drugs that meet established criteria in terms of quality, effectiveness, and safety. Second, the strengthening of national regulatory, service, and educational institutions, as well as human resources, promoting and facilitating the transfer of knowledge. Third, the development and dissemination of programs on the rational use of drugs.

The comparative advantage of the World Bank and the IDB is in providing loan and credit to support investment projects and programs designed to meet priority economic and social needs. They provide financial support to help governments undertake reform that are crucial to effective private and public sector development, and to poverty reduction. Moreover, they offer interest-free loans, technical assistance and policy advice.<sup>21</sup> In particular, the IDB is seen as an institution that understands the region and its problems well. A governance structure which gives a majority shareholding to borrowing member countries, along with the practice of recruiting staff from the region, gives the institution a distinct perceived advantage in understanding the borrowing member countries and their problems. This capacity is facilitated by the presence of resident representatives in each borrowing countries, and a strong linkage between the IDB's country offices and the political authorities in the country.

On the basis of their common objectives and the core values underlying them, the three institutions have established a working group on pharmaceuticals, which represents a formal effort to co-ordinate, complement and strengthening their activities in the region.

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<sup>21</sup> The World Bank's role in the pharmaceutical sector is summarized in the paper by Govindaraj et al., (2000). Information about the pharmaceutical policy of PAHO can be found in the papers mentioned in the reference list.

## INTERNATIONAL TRADE AND ECONOMIC INTEGRATION

In the 1950s and 1960s many Latin American countries (notably Argentina, Brazil and Mexico) developed small to mid-sized family-owned pharmaceutical companies. These enterprises were able to grow rapidly thanks to the protection they enjoyed in their national market, which often granted special rights such as early approval for certificates to manufacture and distribute drugs. This policy was defended on foreign exchange and trade balance grounds, namely, that pharmaceutical imports drained foreign exchange and caused negative trade balances. These concerns were recognized in some IDB operational policies (see OP-741 Population; OP-742 Public Health).<sup>22</sup>

At the beginning of the 1990s, these import substitution policies were seriously questioned and the region embarked on a series of reforms aimed to trade liberalization and market deregulation. The result was a process of consolidation and rationalization of the local pharmaceutical industries and the start of new type of partnerships and co-marketing between the local industry and multinational companies.

Governments of the region have committed themselves to an ambitious agenda of trade liberalization, market opening, and regional market development, which includes the proposed creation of the Free Trade Area of the Americas, and various sub-regional free trade areas. This process is likely to produce long-run economic benefits, but also considerable short-term disruption of the existing patterns of production. Some countries have already started a process of integration in the pharmaceutical market. For example the *Common Market Group* of the MERCOSUR<sup>23</sup> has approved a range of technical resolutions regarding the harmonisation of pharmaceuticals regulation in

the areas of good manufacturing practices, registration requirements and quality control (see Vernengo et al., 1998). In the Andean Community the registration of a drug in one country is automatically extended in all the others member countries (*Commission of the Andean Community*: Decision No. 418 and No. 437, June 1998).<sup>24</sup>

As regional integration deepens, there is a need to help governments to overcome problems that are difficult to manage at the national level and to improve policy coordination in areas such as safety standards, and health. The IDB is committed to work with the member countries in pursuit the agenda of economic integration (IDB, 1999).

### PATENT PROTECTION AND THE TRIPS AGREEMENT

Until recently, patent protection legislation was relatively weak in the region, allowing domestic companies to copy new molecules discovered by international firms and produce the resulting drugs without paying royalties. The IDB played an active role in strengthening the protection of property rights and patents in many Latin American countries during the first part of the 1990s through the use of investment sector reform loans to support broad legal and regulatory reforms. This kind of operation provided fast disbursing funds subject to compliance with precise conditionalities (see Puente et al., 1998; IDB, 1998). For example, loans to Argentina (AR-0059), Uruguay (UR-0057) and Paraguay (PR-0003) specifically considered the need to strengthen intellectual property protection for pharmaceutical products. More recently, the Trade-Related Intellectual Property Rights (TRIPs) agreement that came into effect on 1 January 1995 requires all WTO member countries to adapt their laws to comply with some minimum standards, which include a minimum of 20 years patent protection from the date of filing the application.

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<sup>22</sup> IDB operational policy for population (OP-741) and public health (OP-742) are available at the web pages <http://www.iadb.org/cont/poli/OP-741E.htm> and <http://www.iadb.org/cont/poli/OP-742E.htm>, respectively.

<sup>23</sup> MERCOSUR includes Argentina, Brazil, Paraguay and Uruguay, plus Bolivia and Chile as associated member.

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<sup>24</sup> The Andean Community includes Bolivia, Colombia, Ecuador, Peru and Venezuela.

There is a broad recognition of the role that intellectual property rights can have in stimulation health-related research and development (R&D) (Rozek and Berkowitz, 1998; Rozek and Tully, 1999). Stronger patent protections may lead to inventions of potential use to all countries. However, it is unlike that R&D would direct to the specific needs of the region, because at the current levels of income scarce profits could be reaped in these markets (see Lanjouw, 1997). There is also the recognition that the level of protection conferred on inventions may influence foreign investment in the region. However, even if intellectual property rights are important to pharmaceutical companies in deciding where to locate their R&D facilities, the empirical evidence on such influence are controversial and inconclusive (UN, 1993; Maskus, 1998).

On the other hand, it has been pointed out that since the local pharmaceutical industry rely heavily on the production of copies of in-patent products, the enforcement of more stringent patent protection may have a serious negative impact on local industry (see CENES et al., 2001; Kanavos et al., 2000). Moreover, the price of patented drugs will increase with the strengthening and prolongation of the patent holders' monopoly (Challu, 1991). The denial of affordable access to pharmaceuticals can have life-or-death consequences as prices are critical to determine access to medicines for the low-income segments of the population (see Pérez-Casas et al., 2000).

WTO member countries have considerable room to develop their own patent laws in response to the characteristics of their legal system, development needs and public health priorities (see Correa, 2000). Some countries – particularly developed countries – have opted for legal systems that confer strong patent rights, in order to protect revenue streams from their already established technological base and promote investment in technological innovation. On the other hand, less advanced countries may prefer to adopt less stringent patent laws to promote the transfer of new medicines, and to preserve and enhance competition in order to

secure access to drugs on the most favorable market terms.

The TRIPs accord is quite permissive in terms of what is permitted in terms of government decisions to authorize third parties to use patents without the permission of the patent owners. For example, for public non-commercial use, a country may use or authorize a third party to use a patent without negotiation or without a license, the only obligation being the payment of "adequate" compensation. This approach too can be used for emergencies, including public health emergencies (see Correa, 2000; Love, 2001).

Financial access to drugs that are under patent is an area of great concern, particularly with reference to those that fight AIDS (see Boulet et al., 2000; Reich, 2000). The availability of new antiretrovirals has resulted in substantial declines in the AIDS death rate in the United States, Western Europe and Australia. However, the large majority of individuals worldwide who are infected with the Human Immodeficiency Virus (HIV) live in less developed countries where these new drugs are not affordable at western prices. In the region HIV/AIDS epidemic is an increasing concern especially in the Caribbean and Brazil.

Major pharmaceutical companies have recently agreed to halve the price of HIV/AIDS drugs sold in less developed countries. However, prices are still too high and remain unaffordable to most Latin American governments as well as to individuals. Various international organizations such as UNAIDS, WHO, and the World Bank have combined their efforts to increase the accessibility of life-saving drugs to the poor and the IDB is joining in many of these global initiatives.

#### **RESEARCH AND DEVELOPMENT FOR ENDEMIC DISEASES**

Less developed countries account for a disproportionately large share of the global burden of disease (Murray and Lopez, 1996). Yet, research on drugs to treat and/or eradicate diseases endemic to developing countries is a

very small part of total world pharmaceutical R&D. For instance, it has been estimated that of the US\$56 billion spent on health-related R&D worldwide, only 0.2 percent is spent on pneumonia, diarrhea and tuberculosis, which together represent 18 percent of the global disease burden (WHO, 1996). Private firms do not find R&D in these areas attractive because markets are weak and the capacity to pay of patients in developing countries is low. When private investment in pharmaceuticals falls short of what is considered to be the social optimum, public support for research and development may be justified.

This type of research is best funded and coordinated at the international level because the benefits accrue to many countries. An example is the *Special Program for Research and Training in Tropical Diseases* established in 1978 by the World Bank, the UN Development Programme, and the WHO to facilitate research on the prevention and treatment of six major tropical diseases: malaria, schistosomiasis, filariasis, trypanosomiasis, Chagas disease and leishmaniasis. The IDB, together with other international organization has an important role to play in this respect.

### **REGIONAL COOPERATION**

Some degree of regional cooperation already exists in LAC, but there are a number of areas in which stronger cooperation would pay rich dividends. They include quality control systems; the complementary production of raw materials and finished products; the systematic exchange of information on every aspect of drug supply, research and development; technology transfer; clinical pharmacology and joint procurement.

Regional cooperation in pharmaceuticals is strong among the Caribbean countries (see Greene, 1996). The Caribbean Regional Drug Testing Laboratory (CRDTL), which is based in Jamaica, was created in 1975 and now provides services to 14 English speaking countries in the region. The laboratory performs microbiological and pharmacological tests on sample drugs submitted by participants' governments. It also performs biological availability tests on selected types of drugs, investigates the stability of drugs, and serves as a liaison among appropriate agencies in the region interested in drug testing. Cooperation is also evident in the purchase of pharmaceuticals. The Eastern Caribbean Drug Services (ECDS) operates as the public sector's purchasing agent, buying drugs on a wholesale basis for the countries of the Organization of East Caribbean States (OECS).

This organization was launched with a start-up grant of US\$3.5 million from USAID, which covered its 1986-90 operating costs, but no other significant donor funds were received. The ECDS cut the total cost of pharmaceuticals by 44 percent during its first year of operation and an additional 18 percent in the second year. Lower costs resulted, not only from economies of scale, but also from the ECDS's monopsony status which gave it more bargaining power. In addition, ECDS purchases were paid for on a more timely basis and there was a better rationalization of drugs.

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## Appendix

### IDB Loans with Pharmaceutical Components, Jan. 1990 - Aug. 2000

Region	Country	Project number	Year of approval	Pharmaceutical component in US\$('000)	Pharma comp. as % of the health loan	Acquisition	Procurement and distribution	Quality assurance Regulation	Rational use	Sustainable drug financing
1	Bolivia	BO0056	1991	2,600	7.67%	<del>///</del>	<del>///</del>			
1	Bolivia	BO0115	1999	670	1.49%	<del>///</del>				
1	Brazil	BR0199	1996	9,000	2.57%		<del>///</del>			
1	Brazil	BR0308	1999	30,972	5.85%	<del>///</del>	<del>///</del>			
1	Paraguay	PR0028	1997	10,100	26.51%		<del>///</del>			
2	Belize	BL0014	2000	26	0.21%		<del>///</del>			
2	Dominican Republic	DR0078	1997	2,000	3.27%		<del>///</del>	<del>///</del>		
2	El Salvador	ES0053	1998	560	2.71%		<del>///</del>	<del>///</del>		
2	Guatemala	GU0023	1995	610	1.58%		<del>///</del>			
2	Guatemala	GU0125	1999	1,230	2.22%		<del>///</del>	<del>///</del>		
2	Haiti	HA0081	1991	110	5.00%	<del>///</del>				
2	Haiti	HA0037	1996	394	10.00%	<del>///</del>				
2	Nicaragua	NI0024	1998	3,693	7.60%	<del>///</del>	<del>///</del>	<del>///</del>	<del>///</del>	
2	Panama	PN0029	1993	4,617	10.99%	<del>///</del>				
3	Colombia	CO0088	1995 <sup>(a)</sup>	127	0.33%			<del>///</del>	<del>///</del>	<del>///</del>
3	Guyana	GY0047	1993	43	10.00%	<del>///</del>				
3	Peru	PE0030	1993	3,985	5.86%	<del>///</del>	<del>///</del>			
3	Venezuela	VE0091	1995	480	0.32%					<del>///</del>
Totals				71,216	3.10%	9	10	5	2	2

(a): the project did not include any pharmaceutical component in its original design approved in 1995, but were included in a recent reformulation of the loan. Thus for the purposes of the classification presented in Figures 1 and 2 the pharmaceutical components were considered as approved during the 1996-2000 period.