The economics of pharmaceuticals and health sector reform in the Americas¹

Yvette Madrid,² Germán Velásquez,³ and Enrique Fefer⁴ Increasing pressures on health systems and significant economic changes in many Latin American and Caribbean countries make reforms to the health and pharmaceutical sectors imperative. While health and pharmaceutical needs continue to mount, trade and price liberalization policies implemented to revitalize economies are frequently associated with higher pharmaceutical expenses. Such conditions affect the poor disproportionately, further aggravating existing imbalances in society.

The fundamental principle of optimal health sector reform is that access to quality health services is a right of all individuals. From this principle, three objectives are identified: universality and equity in access, quality, and efficiency. Each country must shape health sector reform in accordance with its priorities and social and economic conditions, but pharmaceutical reform must be incorporated within health sector reform and should seek to ensure that all individuals have access to essential drugs and to quality health services. The essential drugs concept, advocated by WHO through its Action Programme on Essential Drugs and PAHO, stresses availability, affordability, quality, and rational use of drugs. Five areas are central to reform strategy: the roles of the public and private sectors, drug financing alternatives, pricing policies, generics strategies, and rational drug use.

ESSENTIAL DRUGS IN CONTEXT

Socioeconomic development

Many Latin American and Caribbean countries have traveled the road to debt reduction, restricted government spending, and fostered privatization, market liberalization, globalization, and democracy. Progress has been made, but at the expense of economic and social well-being. The proportion of the population living in poverty, which had been declining, increased in the 1980s. The macroeconomic situation has partially stabilized, but unemployment is increasing and real wages for those who are employed continue to decline (1). About one-third of the population lives in poverty and has no access to regular health care (2). The inequities in education, health, and income in Latin America and the Caribbean must be addressed if

Based on: Madrid I, Velásquez G, Fefer E. Pharmaceuticals and health sector reform in the Americas: an economic perspective. Washington, DC: Pan American Health Organization, Regional Program on Essential Drugs and Technology; 1998.

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the Region is to achieve sustainable social and economic progress.

The role of markets in reforming and strengthening economies is growing. Markets, however, do not address the human and social aspects of development. It is the State's responsibility to ensure that everyone has adequate access to quality health systems.

The health demands of the Region are increasing as a result of population growth, disease patterns reflecting the illnesses of both underdevelopment and industrialization, the appearance of new diseases such as AIDS, and the emergence of new technologies. Yet, in efforts to reduce debt and stabilize economies, several countries have limited public funding for health. As a result, those who most need basic health services are increasingly unable to meet their needs. Ministries of health must focus the momentum for change on developing mechanisms to meet such needs, and they must do so by involving both the public and private sectors.

True reform, which is characterized by discontinuity with past ways of thinking, planning, and functioning, seeks to reformulate systems through a mixture of the creative and the pragmatic. Reform is also comprehensive, because the health sector is composed not of separate parts but of complex interdependent systems. Changes that focus on specific issues are not reform.

Optimal reform considers the macroeconomic environment of a country but adheres to the fundamental principle that access to quality health services is a right belonging to all individuals. This principle gives rise to three reform objectives: universality and equity in access, quality, and efficiency. To be successful, reform must achieve these objectives in a sustainable fashion.

Reform measures cannot be appropriately formulated and implemented without certain enabling requirements such as social solidarity, social participation, adequate financing, cost-effective resource utilization, transparent processes, diversity of options and choice, and appropriate regulation and control. Success also requires an understanding of how to use political processes to drive change.

Pharmaceutical reform

The goals of pharmaceutical reform are the same as those of health sector reform: equity and access, quality, and efficiency. However, because of differences in financing and providing services, certain problems such as inequity may be more severe within the pharmaceutical sector. Drugs are often the first interventional response to illness, but beyond their therapeutic utility they are tangible el-

ements in what is primarily a service sector. Consequently, the availability of drugs may be an indicator of the effectiveness and equity of health systems.

Harmonization of pharmaceutical regulation, initiated in conjunction with the creation of regional free trade zones, can yield gains to consumers, private enterprises, and governments. For example, consumers gain from rapid access to new products, enhanced competition, and better quality. The private sector gains from expanded market potential and faster regulatory approval. National regulatory agencies benefit from the work of other agencies and streamline their own efforts, while better ensuring the quality and safety of products. Harmonization is generally a positive trend, but these are long-term efforts that must not lose sight of national health priorities.

The essential drugs concept is an important component of optimal reform. It was introduced in the late 1970s and early 1980s, well before current notions of health sector reform were formulated, and is advocated by WHO through its Action Programme on Essential Drugs and PAHO. The concept focuses on improving access to affordable quality drugs and the efficiency of pharmaceutical systems by increasing efficacy and reducing unnecessary expenditures.

THE ROLES OF THE PUBLIC AND PRIVATE SECTORS⁵

Reform and changing roles

Many reform processes are characterized by taking responsibilities away from governments and enhancing private roles and competition in the health sector. Decentralization is another measure that involves changes in the public sector. Optimal reform should shape the mix of public-private and central-local participation in health care for the maximum benefit of all.

Perspectives on privatization

The main approaches used to increase the role of the private sector are transfering ownership, contracting out services, creating an enabling environment for the private sector, and shifting financing to the private sector. Governments have also tried

This section is a condensed version of a more extensive document prepared by J. Quick, G. Velásquez, and S. Holand for the World Health Organization's Action Programme on Essential Drugs (3).

to introduce competitive features into health care while maintaining public financing and provision of services.

Role of the State in health care markets

Several considerations support the need for Government involvement in health care and pharmaceuticals: equity, information imbalance, failure of competition, and externalities (e.g., immunization and treatment of contagious diseases benefit people who consume the services as well as other people, whose chance of being infected is reduced). Concern about these points argues strongly for assigning State roles in issuing and regulating policy, assuring quality and access, and promoting rational drug use. Rationalizing and strengthening these functions will not weaken privatization and other reform measures, but will, instead, render them more effective.

The public-private duality

When they compete, the public and private sectors should do so fairly and on equal grounds, and their respective structures and procedures of business should be transparent. Public-private roles in the pharmaceutical sector must be considered in the context of the overall goals of national drug policies. Equitable access to essential drugs, rational drug use, and product quality are important criteria for assessing policies that affect the public-private mix. Efficient use of resources is another important issue because it is often a point of comparison between the public and private sectors.

Reform processes that involve augmenting and strengthening the role of the private sector require modifications in the type and focus of State interventions, but the responsibility of the Government to oversee equity of access and quality of health services should not be curtailed (3).

Decentralization

Potential advantages of delegating responsibilities to regional, district, and local levels are improved efficiency, stimulation of local participation and responsibility in delivering health care, and improved quality. In general, activities that benefit from standard infrastructure and economies of scale should remain centralized, whereas those that can be improved by responding to the needs of the local population should not. The ideal arrangement will vary among countries.

Certain essential functions, such as developing a national drug policy, drug registration criteria, and standards for quality control must remain with the central Government. Some degree of centralization is also desirable for the development of essential drugs lists and formularies as well as for bulk tendering.

DRUG FINANCING ALTERNATIVES

Health and pharmaceutical expenditures

In most Latin American and Caribbean countries the majority of drugs are paid for privately; despite the growing availability of private health insurance, direct out-of-pocket spending constitutes much of these expenditures. This tends to aggravate inequities and, in markets with insufficient or lax controls, it is probably not the most cost-effective way to provide for the pharmaceutical needs of society. Current pharmaceutical spending in many countries, if more efficiently handled, should be able to cover the basic needs of the population.

Finance reform

Because optimal health sector reform is based on the principle that all individuals should have access to health services, the main challenge is to define and implement those options that will most efficiently ensure universal access to essential drugs. In many countries, this implies integrating pharmaceutical coverage into health coverage, increasing overall funding for health and pharmaceuticals, improving equity in financing, and eliminating waste.

The private sector may be involved in finance reform, but the State bears the responsibility for ensuring that public health objectives are met. Individual or household contributions to health should be proportional to the ability to pay, but service provision should be based on need.

Government financing from general revenue

Governments are fully justified in financing drugs that have significant social value (such as medicines for treating tuberculosis and sexually transmitted diseases) or in subsidizing the poor to ensure adequate access when there is a need. Government allocations for drugs should be given priority and must be protected from foreign exchange variations and budget cuts. Innovative efforts to increase public funding for health and pharmaceuti-

cals and to maximize efficiency in the use of these funds should be encouraged.

Insurance and related mechanisms

Insurance, public or private, can augment the resources dedicated to health, make them less susceptible to public budget fluctuations, give individuals a greater sense of responsibility for their health care, and create greater incentives for maintaining quality in service provision. Social insurance can coexist with general revenue funding. Public general revenue contributions may be necessary to subsidize the poor but should not be used to subsidize those who are affluent (4). Public sector involvement in defining insurance is necessary to protect individuals, develop a fair competitive environment, and ensure the participation of people from various groups (in terms of age, health, income distribution), and this in turn enhances the equity and sustainability of such mechanisms.

An extension of social insurance benefits to the poor, including pharmaceutical coverage, is highly desirable but may not be feasible for many countries, particularly in the short term. This is especially true in countries where only a small portion of the population is employed in the formal sector and where gross domestic product per capita is low. In these cases, locally managed, not-forprofit community insurance schemes can be useful and should also strengthen decentralization efforts, although the equity benefits would not be on the same scale as with a universal plan.

Universal, comprehensive insurance mechanisms, to which people contribute based on their ability to pay, help improve equitable access and stimulate market demand for essential drugs. Such plans may not be possible in all countries, but they merit serious consideration.

User fees

It is particularly easy to charge fees for drugs because they are goods as opposed to services and people have demonstrated a willingness (though not necessarily an ability) to pay for them. Nonetheless, charging fees exclusively for drugs creates strong incentives to overprescribe and fosters differences in affordability between diagnostic services and treatments. This situation is not compatible with improving overall equity, efficacy, and efficiency.

Revenues from fees are generally modest. Thus, user fees are not highly effective tools for generating sufficient, sustainable revenue in an equitable fashion and alone do not constitute a long-

term, comprehensive solution for health financing. They are probably most effectively and beneficially used as tools for moderating demand, particularly for nonessential goods and services.

Despite their shortcomings, cost recovery plans are a practical reality in many countries and can bring relief to distressed health systems. User fees may be considered as transitional measures to bring improvements, stimulate community involvement, and serve as precursors to development of more comprehensive financing measures such as insurance. For cost recovery to assume its transitional role in reform processes, certain guidelines should be followed: (a) user charges should complement public financing, not replace it; (b) it is preferable to integrate pharmaceutical financing within overall health financing and not to charge patients exclusively for pharmaceuticals; (c) inasmuch as is practically achievable, charges should be based on an ability to pay; and (d) community cost recovery efforts should not be undertaken in isolation but as part of a larger plan for finance and health sector reform (5).

External sources of financing

Donors can provide technical assistance, financing for the purchase of drugs, and drugs themselves. Donations should be made through effective channels of communication between donors and recipients, respond to local needs, respect the authority of recipient countries, and involve products that are not inferior in quality, efficacy, or safety to those used in donor countries.

Loans should be used to support reform programs that are internally driven and seek to achieve national health objectives. Use of loans for drug procurement is open to debate; in general, it is not desirable because drugs are recurrent expenses. Middle income countries must focus on developing sustainable financing mechanisms.

DRUG PRICING POLICIES

Price and trade liberalization and health sector reform

Over the past 10 to 15 years the concept of market liberalization has taken a stronghold in Latin America and the Caribbean. A recent survey found that 41% of the countries of the Region (sample group of 17) allow nearly total market freedom for setting pharmaceutical prices (6); only 24% have complete price control. In several countries, pricing freedom has simplified procedures, reduced the

work required by the State, provided markets with a greater variety of products, and ensured a more stable drug supply.

Despite such advantages, freedom in pricing and trade liberalization have been accompanied by price and expenditure increases, a proliferation of products, and excessive promotion leading to overconsumption. Sudden price increases may be a short-term reaction to prices that were held unrealistically low, but there are concerns that market competition and free trade may be insufficient to control costs and guarantee equitable access to drugs. Trade and price liberalization can have a dramatic social impact because the prices for nontraded goods (i.e., services) and wages do not parallel the increase in the price of traded goods in the short term. Lack of Government intervention may result in stimulated economies but in deteriorated social outcomes.

Pharmaceutical markets

Given that (a) markets can provide pharmaceuticals to meet the wants of some segments of society, (b) it is difficult to eradicate naturally forming markets, and (c) there are risks associated with unregulated informal markets, governments should not try to eliminate markets. Instead, they should determine how these can be incorporated into a policy aimed at meeting the objectives of the health sector.

Pharmaceutical markets are imperfect in many ways: information about products is not widely available, barriers to entry (e.g., patents) exist, conditions are oligopolistic (few competitors dominate the market), and competitive products are not perceived as perfect substitutes for each other. In addition, prices are not properly regulated by supply and current demand and are not necessarily at levels that will lead to an appropriate consumption of goods with high social value or to universal access to essential drugs.

Government involvement

Market failures alone may not constitute sufficient grounds for Government intervention, but when failures are considered together with the essential role of pharmaceuticals for health and with the precept that health is a social right, a role for Government is justified. Even if prices are set by the market, governments still need to be involved in promoting price competition and market efficiency. The State has a responsibility to ensure product safety, quality, and efficacy; equity in access; and fairness in health costs to society.

Price control alone does not solve the problems of ensuring equitable access and achieving cost control. The decision to implement price control is specific to each country and should be made only after a realistic evaluation of the resources available for developing and implementing pricing mechanisms, as well as an evaluation of the difficulty of enforcement. Limited but more successful measures are preferred to comprehensive, unrealistic ones. Regardless of the choices made, prices should be evaluated on a regular basis because evolving health systems and national scenarios may require parallel changes in pricing mechanisms.

Price control options

Producers' prices and distributors' margins provide a variety of ways to control prices (7). The choice should consider practical realities in terms of resources available and the feasibility of implementation.

A growing trend in industrialized countries is pharmacoeconomic analysis, which seeks to maximize the value obtained from drug expenditures by evaluating costs and outcomes. One potential application is in drawing up a list of essential drugs; another is in Government control of producers' prices. Pharmacoeconomics applied to pricing decisions is generally inappropriate for countries without universal, comprehensive health coverage. In many countries these evaluations are best suited to the selection of drugs and therapeutic modalities.

GENERIC DRUG STRATEGIES

Generic drug strategies in the context of reform

Strategies involving generic drugs are composed of two main features: widespread use of nonproprietary or generic names for pharmaceuticals and availability of a selection of equivalent products (generics) that can be identified as substitutes for each other and that can compete based on price. Generics strategies can improve affordability, reduce costs, increase choice, and help to rationalize selection and use of pharmaceuticals. These strategies make markets more competitive and efficient and can contribute to the goals of improved equity, quality, and efficiency in health care. The current economic and health sector changes in Latin American and Caribbean countries represent excellent opportunities to introduce these strategies and reap their benefits.

Generics policies are frequently associated with the public sector and with the substantial cost

savings that may be attained by the bulk procurement of drugs sold in international markets. These strategies can be just as beneficial in the private sector because they promote efficiency within pharmaceutical markets. With a successfully implemented strategy, competitive products are perceived as substitutes for each other, more information on products (particularly pricing) is made easily available, and increased competition reduces the predominance of a few competitors.

Among the factors that are necessary to promote the use of generics are supportive legislation and regulation, quality assurance, professional and public acceptance, and economic incentives (Table 1). A recent PAHO/WHO publication provides a review of many of these measures (8).

Experiences with generics strategies

Several Latin American and Caribbean countries already have some legislation on generics strategies, but in most cases implementation is limited and sometimes extends only to the public sector. Overall, lower prices have been observed where legislation exists, but problems such as a lack of confidence in product quality have also arisen (6).

In countries that have introduced generics strategies affecting the private sector, such as Nigeria, Pakistan, and the Philippines, experience has shown that the difficulties involved in implementing these strategies should not be underestimated. Setbacks, however, do not necessarily imply long-term defeat if policies are viewed as processes, are adapted to respond to problems, and are persistently supported over the course of many years.

ECONOMIC IMPACT OF RATIONAL DRUG USE

Rational drug use and reform

Health and economic reforms will affect the way drugs are used—which drugs are chosen, how frequently they are prescribed, how many are consumed, and for what reasons. Market liberalization policies can increase both the number of drugs available and the number of retail distributors, which may have undesirable effects. They may focus, for instance, on the curative aspects of health and foster a dependency on drugs as a quick solution to health problems.

Rational drug use includes properly selecting, storing, and using drugs for therapeutic purposes, but preventive measures to ensure health and reduce the need for drugs are an important aspect. The con-

TABLE 1. Mechanisms for promoting a generics strategy

Supportive legislation and regulation

- · Abbreviated registration procedures (focus on drug quality)
- Product development and authorization during patent process
- Provisions that permit, encourage, or require prescriptions using generic names and substitution with pharmaceutical equivalents (generic substitution)
- Requirements that labels and drug information contain generic names

Quality assurance capacity

- · Development of substitution, nonsubstitution lists
- · Procedures to demonstrate bioequivalence
- · National quality assurance capability
- National drug manufacturer and drug outlet inspection capability

Professional and public acceptance

- Involvement of professional associations in policy development
- Phased implementation, beginning with permission to substitute
- Required use of generic names in all education and training of health professionals
- Brand-generic and generic-brand name indices available to health professionals
- Required use of generic names in clinical manuals, drug bulletins, and other publications
- Widespread promotional campaigns targeting consumers and professionals

Economic factors

- · Public and professional price information
- · Reference pricing for reimbursement programs
- · Retail price controls that favor generic dispensing
- Support by social and private health insurance organizations
- Incentives for the drug industry to produce unbranded generics
- Tradeoffs with industry (reduced price regulation, increased patent protection)

Source: Reference 3.

cept that medicines are not substitutes for patients' efforts to maintain their health is fundamental.

Within health sector reform, the reasons for incorporating activities that promote rational drug use involve both ethics and economics. It is important for each individual to receive maximal curative benefits with minimal risk from medical treatments. The ethical precepts that underlie this goal are valid regardless of any other considerations. But society also needs to maximize health benefits to the population vis-à-vis its expenditures on drugs. This need forms the link between rational drug use and economic concerns.

Cost burden of irrational drug use

Given the sum of choices that must be correctly made for drugs to be used appropriately, it is

not difficult to imagine that irrational drug use is a common problem. Prescribing drugs irrationally can lead to higher pharmaceutical expenditures due to the inclusion of unnecessary, inappropriate, or overly expensive products and to the use of excessively high doses or long treatment periods (9). Patient noncompliance also accounts for a significant amount of waste. In industrialized countries, studies have shown that compliance rates may be as low as 50%, and it is difficult to imagine that the situation is better elsewhere (10).

A more comprehensive view reveals that, in economic terms, this is only part of the problem. Other expenditures that could have been avoided if the right therapy had been used need to be considered. These include, but are not limited to, increased use of health facilities, increased drug resistance, spread of disease to other individuals, and lost days of work. The magnitude of these costs frequently exceeds the original excessive or wasteful expenditure on the drugs. Therefore, the total costs associated with improper use of drugs may be multiples rather than fractions of overall pharmaceutical spending.

When true societal costs are considered, irrational drug use appears to be the largest contributor to waste in the area of pharmaceuticals and may have a notable negative impact on the overall economy of a country. Because even relatively few instances of irrational behavior can result in high social costs, efforts to improve the use of drugs should be a priority.

Improving rational drug use

Allocating funds for the promotion of rational drug use is a worthwhile social investment in terms of health as well as long-term cost savings and should be incorporated within health sector reform. Strategies to improve rational drug use should cover both the public and private sectors and apply to self-medication and to prescribing habits. Priority areas include (a) creating interventions that make initial product selection more rational; (b) improving access to and education about drugs whose misuse or unavailability can lead to significant costs in terms of poor health and lost work days; (c) focusing on drugs that are the most misused; (d) improving access to drugs for serious communicable diseases and educating the public on their correct use; (e) targeting groups that use the most drugs; and (f) focusing on people who influence others' medication habits. Further studies in this area are urgently required.

It may be worthwhile to highlight an area of particular interest in the context of increasingly liberalized markets: promotional activities and controls. With increasing market liberalization, it is not unusual for firms to try to influence market growth as well. But because drugs are unlike many other goods, their indiscriminate promotion is not acceptable on ethical grounds and guidelines for marketing practices have been developed (11). The economic gains accrued through increased pharmaceutical sales stimulated by overzealous or inappropriate marketing practices are overwhelmingly offset by the societal cost of subsequent irrational drug use. Markets cannot ensure that drugs are used appropriately. The State and the consumers must intervene in this area if health sector reform objectives, particularly concerning quality and efficiency, are to be met. The issue is not whether to eliminate promotion, but rather to determine how governments can best ensure that it does not contribute to irrational drug use.

A policy that establishes transparent and effective limits on promotion and advertising is synergistic with a generics strategy. In many countries, this may not imply creation of regulations, but rather an enforcement of what already exists. If implemented together, marketing controls and generics strategies can lead to a reduction in irrational drug use and its societal costs while stimulating competitive markets.

CONCLUDING REMARKS

It is no small challenge to dynamically reconfigure health systems to improve equity, quality, and efficiency in the context of multiple and simultaneous demands and constraints. There are no blueprints for health and pharmaceutical reform, only guideposts. As such, reform is not so much a construction project as it is a journey; rather than a rigid structure, it produces a malleable form, much like a sculpture. Each country must shape its reform in light of its health priorities and social and economic conditions, but invariably some common issues will arise. This document has sought to identify certain guideposts and to open to discussion those common issues that affect many Latin American and Caribbean countries.

This review has highlighted the important role of health economics in chiseling measures that maximize health benefits while efficiently allocating resources. But the sculpture should have a human dimension. Health sector reform, and pharmaceutical reform within it, needs to be fundamentally concerned with improving the human condition; developing models that seek to integrate social and economic objectives; and protecting the right of each individual to quality, affordable health services.

Acknowledgments. A draft of this document was revised by a working group that met at the Pan American Health Organization in Washington, DC, United States of America, 8–10 April 1997. We thank the participants of this meeting—Jorge Bermúdez, Ayrton Fausto, Rosario D'Alessio, Pablo Isaza, Raúl Molina, Federico Tobar, and Jorge Enrique Vargas—for their valuable recommendations and suggestions. We also gratefully acknowledge the comments of Jonathan Quick.

SINOPSIS

Aspectos económicos del mercado de medicamentos y la reforma del sector de la salud

Las crecientes presiones que enfrentan los sistemas de salud y los notables cambios económicos que han tenido lugar en muchos países de América Latina y el Caribe hacen que sea necesario reformar los sectores de la salud y del mercado de medicamentos. Aunque las necesidades de salud y de productos farmacéuticos siguen aumentando, las políticas que

liberalizan la venta y el precio de los productos y que se adoptan con el fin de revitalizar las economías a menudo provocan un aumento del gasto en productos farmacéuticos. Tales circunstancias afectan a los pobres más que a otros grupos, lo cual agrava las desigualdades ya presentes en la sociedad.

La reforma del sector sanitario, si ha de ser de óptima calidad, se basa en el postulado de que el acceso a buenos servicios de salud es un derecho de todo individuo. De ello se desprenden tres objetivos: equidad en el acceso para todos, calidad y eficiencia. Cada país debe moldear su reforma del sector de la salud según sus prioridades y sus condiciones sociales y económicas, pero la reforma del sector farmacéutico debe incorporarse a la reforma del sector sanitario y dirigirse a que todo individuo tenga acceso a los medicamentos esenciales y a servicios de salud de calidad. El concepto de los medicamentos esenciales, promovido por la OMS mediante su Programa de Acción sobre Medicamentos Esenciales y la OPS, subraya la importancia de la disponibilidad, accesibilidad económica, calidad y uso racional de los medicamentos. Son cinco las áreas fundamentales que abarca la estrategia de reforma: el papel de los sectores público y privado; la disponibilidad de diferentes opciones para el pago de medicamentos; las políticas de fijación de precios; las estrategias en torno a los productos genéricos, y el uso racional de los medicamentos.

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