

Pharmaceutical System Performance Within the Context of Health Sector Reform

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PHARMACEUTICAL SYSTEM PERFORMANCE WITHIN THE CONTEXT OF HEALTH SECTOR REFORM

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About RPM Plus

The Rational Pharmaceutical Management Plus (RPM Plus) Program, funded by the U.S. Agency for International Development, works in more than 20 developing and transitional countries to provide technical assistance to strengthen medicine and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

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ACRONYMS

DAS	Dirección de Área de Salud (local health authority)
GDP	gross domestic product
HSR	health sector reform
INN	international nonproprietary name
LAC/HSR	Latin American and Caribbean Health Sector Reform [Initiative]
MOH	ministry of health
MSH	Management Sciences for Health
MSPAS	Ministerio de Salud Pública y Asistencia Social (Ministry of Public Health and Social Assistance)
NGO	nongovernmental organization
PTC	pharmacy and therapeutics committee
RPM Plus	Rational Pharmaceutical Management Plus [Program]
UO	<i>unidad operativa</i>
VSM	<i>venta social de medicamentos</i> (social pharmacy)

BACKGROUND

In the early 1990s, the convergence of social, economic, and political factors in Latin America triggered what is known today as health sector reform (HSR). Among those factors were the consolidation of market economies; the increasing costs of health care; the renewed importance of human capital as an engine of economic development; and a perceived inefficiency and inequity of the public sector, particularly in the areas of health and education. Within this context, the Inter-American Development Bank and the World Bank decided to include HSR in their technical and financial agendas for the region (PAHO 2002). With their support, by the end of the decade most Latin American countries were somewhere between the design phase and the initial implementation phase of reform. In 1997, recognizing the need to support implementation and evaluation of reform efforts, the Latin America and Caribbean Regional Bureau of the U.S. Agency for International Development funded the Latin America and Caribbean Health Sector Reform (LAC/HSR) Initiative, and in 2002 the Rational Pharmaceutical Management Plus (RPM Plus) program was invited to participate in the initiative.

Although public health sector reforms differ from country to country, most of the planned reforms adopted similar approaches and combinations of strategies that considered decentralization; separation of functions; increased social participation; contracting services from the private sector; and adapting alternative administrative, financial, and clinical care models. These strategies have presented particular opportunities and challenges for the design and management of the pharmaceutical system, a key support subsystem of the larger health care system. Although public sector pharmaceutical supply systems in the region have been undergoing changes, decisions to change these systems have not always been able to benefit from an analysis of lessons learned from reform experiences.

As its contribution to the LAC/HSR initiative, RPM Plus has prepared this guidance document for health system planners and managers to use as they think through how to ensure the effective and efficient functioning of the pharmaceutical system within the context of health sector reform.

INTRODUCTION

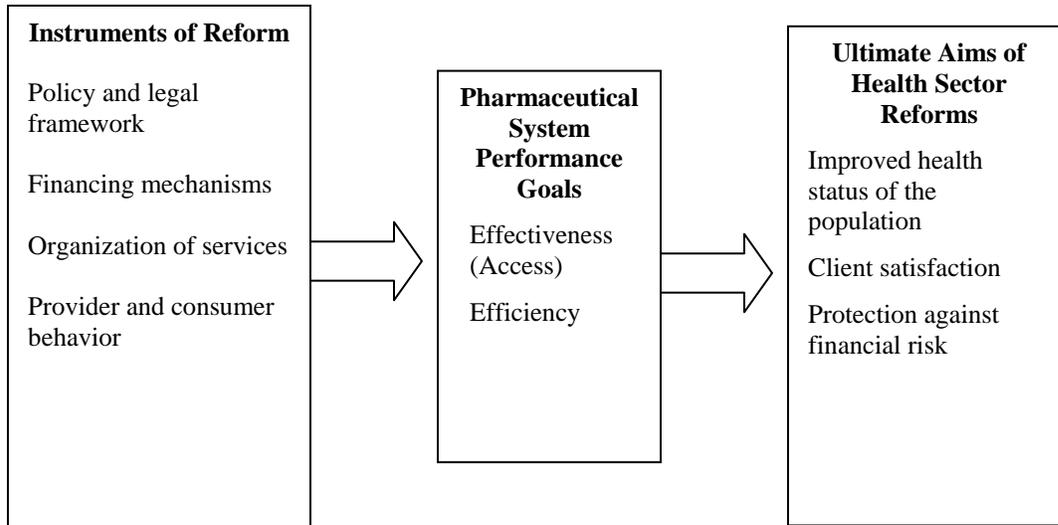
Health reform initiatives can present new opportunities and challenges for improving the performance of health care systems. Reform proposals are often bold undertakings that involve some degree of reconfiguration, reorganization, and restructuring of the way health services are managed and financed. The sine qua non of most modern health care services is pharmaceuticals,¹ and despite significant public and private expenditures on pharmaceuticals, large segments of the population in many countries still do not have access to safe, effective, low-cost medicines (WHO 2004). Arguably, pharmaceuticals are such a powerful symbol of health care services that lack of access to them can signal the failure of health sector reform initiatives and can be politically devastating to a government (political liability).

Throughout the 1990s, numerous countries in the developing world embarked on health sector reforms, and researchers and planners began to formalize conceptual models and methods for measuring the performance of health systems against important outcomes such as access, equity, and quality of care (compare Knowles et al. 1997; Murray and Frenck 2000). Out of this research grew an appreciation for the complexity of actions and changes required to effect the desired reactions and adjustments in such complex entities as a health system (for example, Mills et al. 2001; Roberts et al. 2004), including the supporting subsystems (PAHO 2002). However, despite the recognized centrality of pharmaceuticals to quality of service delivery, the factors affecting the subsystem's ability to ensure the availability of pharmaceuticals may be inadequately integrated or uncoordinated with other reform efforts (Romero 2002).

This paper describes an evidence-based approach for the critical and systematic analysis of a pharmaceutical system that is largely consistent with the stepwise approach of Roberts and colleagues (2004; see Figure 1). This approach is general and not specific to the Latin American context, but examples from Latin America are presented to illustrate particular points.² The paper begins with a presentation of the key functions of a pharmaceutical system. It follows with discussion of how performance goals can be measured. The overall approach promotes the use of standard indicators to evaluate system strengths and weaknesses as well as to identify appropriate intervention points. Reforms are implemented through any one or a combination of four types of instruments, which include policies and laws, financing mechanisms, reorganization of services, and behavior change. Specific examples of instruments that have affected pharmaceutical systems in Latin America are discussed.

¹ *Pharmaceuticals* are defined as medicinal products, vaccines, contraceptives, and the diagnostics and medical supplies needed to ensure the safe and effective use of medicinal products.

² It is not the intent of this document to provide a comprehensive review of the evolution or evaluation of health sector reforms. Background documents covering these topics may be found at <http://www.lachsr.org/es/index.cfm>.



Source: Adapted from Roberts et al. 2004.

Figure 1. Framework for evaluating pharmaceutical systems

HEALTH CARE SYSTEMS AND PHARMACEUTICAL SYSTEMS

Assessments of health system performance often include questions on the availability of key pharmaceuticals at the facility level as a measure of quality of care (Knowles et al. 1997). Indeed, it is widely recognized that the ability of health care systems to successfully address most modern health problems rests largely on the availability of these products, and that people will seek care when they are available. Thus, we can conceptualize the pharmaceutical supply system as a critical subsystem of the larger health system whose effective functioning is essential to access to and use of health care services (see Figure 2).

Pharmaceutical management is defined as the set of practices implementing four key functions that are aimed at ensuring the timely availability and appropriate use of safe, effective, quality pharmaceutical products and services in a given health care setting. A pharmaceutical supply system is defined by the procedures and methods used to accomplish these key functions.

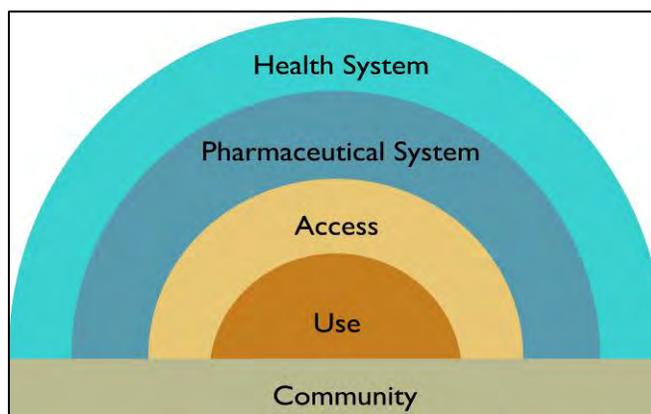


Figure 2. Health and pharmaceutical systems

The parameters that determine how these practices may be performed are determined by prevailing laws and regulations, such as those regarding the import/export, manufacture, sales, and use of medicines, as well as laws that govern general labor, commercial, and financial matters. How and, to a great extent, how well a pharmaceutical system performs is mitigated by the availability and quality of human and financial resources, and the relative priorities for these scarce resources are expressed through national development, health, and pharmaceutical policies.

The next section describes the key functions of the pharmaceutical system. Often, these functions are directly addressed through reform initiatives, whereas in other cases they are affected indirectly. The following section discusses how the performance of a pharmaceutical system may be measured to identify opportunities for improving and affecting HSR initiatives.

UNDERSTANDING KEY FUNCTIONS OF A PHARMACEUTICAL SYSTEM

This section provides an overview of the key functions of a pharmaceutical system. These functions must be carried out in any system, although how they are accomplished may vary from system to system, and many health reform initiatives may directly and indirectly affect these functions. One reason for this effect is that the management of pharmaceutical supply is cyclical in nature. As such, these functions are characterized by dependent relationships wherein the quality of one function can affect the quality or outcome of another (Figure 3).

Selection

The number of pharmaceutical products marketed in any given country can be in the thousands, yet only a few may be of direct relevance to the most important public health problems in the country. Being able to distinguish those products that are most useful and restrict practitioner choices to these selected products is of clinical and financial significance to health systems.

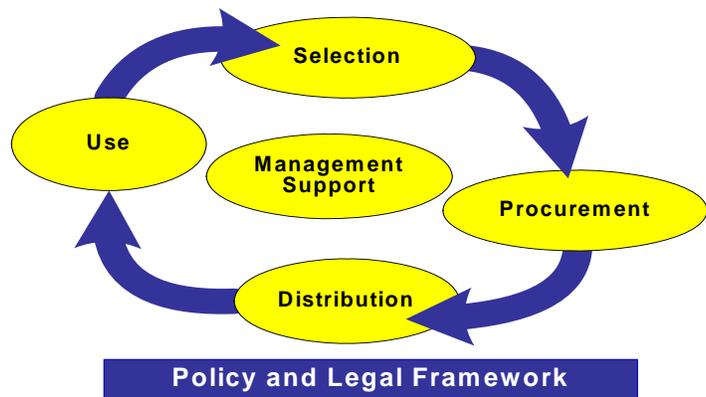


Figure 3. Functional components of a pharmaceutical system

The selection function includes the decisions and actions required to determine which products will be permitted to circulate in the system. The priorities and criteria for selection are typically detailed in a national health or drug policy and should correspond to the clinical and therapeutic needs of the population, as well as meet acceptable standards for product safety, efficacy, quality, and cost-effectiveness (WHO 2002). Selection should also reflect appropriateness for the level of care (products needed at the clinic level are different from those needed at the hospital level). The output of a selection process may take the form of a national formulary or essential medicines list, typically with the pharmaceutical products listed by international nonproprietary name (INN).

The use of INNs aids in avoiding reliance on any single brand name and helps focus on the particular molecule of interest. When used to guide procurement, much like a shopping list, essential medicines lists function as cost-control tools by preventing purchases of nonessential or “luxury” items. Health systems seeking to improve efficiencies to be able to improve some dimension of effectiveness (availability, affordability, access, acceptability) will always be well served by implementing or updating and maintaining national essential medicines lists.

The primary responsibility for the selection of pharmaceuticals for most public health systems is at the national level, to take advantage of the expertise and technical resources available at that level, although mechanisms may exist that allow for some local adaptation. Strong forces exist

may not support the concept of a national essential medicines list, most notably pharmaceutical manufacturers that feel that they will be blocked from accessing a potential market for their goods. Selection committees need adequate training and recognition as well as the support of a national policy or legislation to be able to carry out their function in a transparent manner. National regulatory processes, particularly registration, should support the selection function to ensure that selected products are available to be marketed in the country and that adequately trained health professionals are available to ensure their appropriate use.

Procurement

The goal of the procurement function is to ensure that the right quantity of quality products is purchased at the best price possible and that they are delivered when expected. Key activities under the procurement function include quantification of needs, purchase, receipt, and payment. In established systems with centralized procurement, quantification usually involves a methodology of obtaining information from the facility level on actual consumption and aggregating it to the level where procurement is realized. Weaker systems, however, may need to rely primarily on historical data, previous quantities sent to the facilities, or population-based estimates rooted in expected services use to determine quantities to be ordered at the national level.

The strategies (for example, centralized or decentralized) and methods (for example, international competitive tenders, restricted tender, competitive negotiation, direct procurement) that may be used to procure supplies are determined by the prevailing laws and regulations that govern the system and should be appropriate for the types of products sought, budgetary cycles, and available financing mechanisms. Because most centralized systems are based on an annual fiscal cycle, procurement is typically an annual exercise, although small procurements throughout the year may take place for emergency purposes or for special products. These large procurements lend themselves to international competitive bidding and can benefit from economies of scale. However, one of the problems with highly centralized systems is that they may be too cumbersome to be responsive to local variations; needs and incentives are often not in place to curb waste and loss at the local level.

Some reform initiatives have sought to improve efficiencies and grant more autonomy to the local levels through decentralization and deconcentration of procurement functions. However, specifically with respect to pharmaceutical procurement, this policy can be problematic. The potential problems associated with complete decentralization and deconcentration include loss of economies of scale; decreased access to suppliers; lack of local expertise to evaluate needs, prepare procurement documents, and make purchases, as well as reduced access to quality assurance mechanisms (see Barillas 2005b).

In the course of realizing larger reforms that aim at achieving the benefits of more-decentralized management of public health services, some countries have opted to retain some procurement functions at the central level. For example, public tenders with qualified suppliers can take place at the national level to preserve economies of scale and to address critical quality assurance issues, while actual purchases are made from these preselected suppliers at the tendered price (as

in Brazil, Ecuador, Guatemala, and Peru). Where fiscal responsibilities are deconcentrated, resources may be pooled at subnational levels to create buying groups in order to gain some economies of scale, as has occurred in El Salvador and Peru. Regardless of the plan, a need remains for local fiscal controls and functional management systems to ensure that needs estimates and quantifies for procurement are accurate, reliable, and up to date, and that funds are available as planned.

Distribution

The distribution function covers both storage and transportation of items procured, and it should aim at ensuring that products flow to the facilities with a minimum of waste and loss. Inventory management, a core responsibility in this component of the cycle, involves close monitoring of the movement of stock both into and through the system. This information is used to guide procurements, as well as to ensure that there are no stockouts or gluts throughout the chain.

Centralized systems are characterized by one or two central medical stores that receive procured items and process orders from lower-level facilities. Larger countries are more likely to have multiple stores. A multitiered system generally requires greater consideration of expiry periods and offers increased opportunities for loss caused by damage and theft associated with transportation from one level to the next. Transportation may be the responsibility of the central store or of the lower levels.

Storage and transportation represent significant recurrent costs for ministries of health and are therefore the most obvious areas to be considered for privatization or contracting out. Such options are limited by laws regarding disposal and replacement of government property, restrictions on privatization and contracting of services, and civil service laws. For this reason, however, opportunities to explore alternatives arise when countries undergo larger reforms that may not be specific to the health sector. For the distribution component, for example, one alternative to the classic medical store model is to have supplies delivered directly from the supplier to the service delivery point. Stipulations for this alternative can be written into the procurement documents. This type of distribution system requires that suppliers have the capacity to make programmed deliveries and that the facility has the capacity to appropriately program shipments and to receive and store supplies. Moreover, for a country to consider this alternative, legal and political considerations have to be considered as it is likely to result in the elimination of jobs.

Use

This function of the pharmaceutical system refers to the behaviors and practices associated with prescribing, dispensing, and actual consumption of pharmaceuticals. The concept of rational drug use encompasses the constellation of factors that lead up to the availability of pharmaceuticals (selection, procurement, distribution) as well as ensuring that the desired therapeutic outcomes are achieved. Whereas public health systems might focus on public sector provider behavior,

many countries aim to also align the behaviors of private practitioners with public health concerns.

Interventions to improve the use of pharmaceuticals include development and enforcement of laws and regulations regarding the selection and sale of certain products or the actions of prescribers and dispensers. Drug laws specify the types of facilities that may dispense or sell drugs, and who may prescribe certain products. Registration and inspection procedures aim at supporting enforcement of these laws and regulations. In many countries, however, the ability to conduct these activities is weak or nonexistent.

Other types of interventions may be educational or informational in nature, or managerial. The development and use of standard treatment guidelines represent a type of intervention that aims at influencing prescribing behavior through information. Providers may be trained to these guidelines, but the desired behavior is more likely to be achieved and sustained when supported by managerial interventions (such as supervision and drugs and therapeutics committees).

Managerial Support

The component of managerial support includes the financial, human, and informational resources required to ensure the effective functioning of the supply system. Many of the targets of sectoral reform and modernization in general directly affect this component. Of particular relevance to the pharmaceutical system are questions about changing financing systems, civil service reforms, and changes in the locus of decision making for all other components of the pharmaceutical system. Without the requisite management support, the entire system can screech to a halt. Health sector reforms typically affect this function of the supply cycle heavily.

Among the greatest challenges facing health systems is the shortage of qualified human capacity in management and clinical areas. The causes of shortages include the maldistribution of staff (concentration in urban centers); lack of resources to recruit, train, and support health workers; and migration of qualified staff to areas that offer more opportunities for professional growth and development (MSH 2004). This human resources gap has also affected the availability of staff to carry out the functions of the pharmaceutical system. Shortages of pharmacists and other pharmacy professionals have forced consideration of what pharmacy functions can be responsibly carried out by other health care staff, such as nurses or pharmacy assistants, provided they receive appropriate training.

EVALUATING THE PERFORMANCE OF A PHARMACEUTICAL SYSTEM

A significant portion of all health expenditure is related to the pharmaceutical system, and, for this reason, health planners, whether within the context of health sector reform or not, should be concerned about being able to measure the performance of their pharmaceutical system. Within the context of HSR, being able to compare the performance of the incumbent system with an alternative or modified model is extremely informative for decision makers responsible for proposing or accepting reform initiatives. Evaluations of performance will allow the determination of whether initiatives have had the intended effect.

The performance of a pharmaceutical system may be evaluated in terms of effectiveness (Are the outcomes achieved?) and efficiency (What level of inputs are required to achieve outcomes?). Evaluations are necessarily comparative in nature. Comparisons may be made with the performance of other health systems (social security versus ministry of health versus private sector). Being able to measure and monitor performance over time is clearly useful to determine whether targets are being met and whether adjustments are merited. To the extent that pharmaceutical systems support the larger health care system, the performance of the latter system is dependent on the performance of the former; for this reason, many of the criteria for evaluation of each system correspond to each other.

The following sections define important performance dimensions for the pharmaceutical system. Key indicators are presented. The data needed for these indicators may be obtained from standard reports generated from health information systems, health accounts information, and pharmaceutical management information systems. However, in many cases, data are simply not available for various reasons: information systems that were created before reforms took place did not allow for some of the line items of interest following reform; information is not available in the format needed for analysis; or information is too incomplete because the systems in general are weak and ineffective (often an area for improvement under reform). Obtaining the data required from the facility level often requires a special effort.³

Effectiveness (Access)

The effectiveness of a pharmaceutical supply system may be defined by the degree to which it achieves access to essential, quality pharmaceuticals and pharmaceutical services (those services required to ensure the appropriate use of pharmaceuticals).

³ The detailed methodology for how to conduct a pharmaceutical sector assessment is available in Management Sciences for Health (MSH), *Rapid Pharmaceutical Management Assessment: An Indicator-Based Approach* (1995) and is available at <http://erc.msh.org/mainpage.cfm?language=English&file=8.60.htm&module=toolkit>.

Access to pharmaceutical products and services has been defined to reflect four critical dimensions of access, each of which affects overall use of health services: availability, geographic access, affordability, and acceptability.⁴

- *Availability*: The continuous presence of the desired or selected product in the necessary quantities in the facilities where they should be found.
- *Geographic accessibility*: The relationship between where the product or service is located and the location of the eventual user of any of these (coverage).
- *Affordability*: The relationship between the price of the product or service and the ability of the user to pay for it.
- *Acceptability*: The relationship between the characteristics of the products and services offered and the user's or provider's attitudes and expectations about the products or services.

Availability of Pharmaceuticals and Pharmaceutical Services

Health services depend heavily on the availability of essential medicines. For this reason, the regular availability of pharmaceuticals is considered a key indicator of quality health services. The regular availability of quality pharmaceuticals and the services associated with their proper use may be considered the quintessential measure of the effectiveness of a pharmaceutical system. The key indicators to measure availability are—

- Average percentage of a set of unexpired tracer pharmaceuticals available in a sample of pharmacies/dispensaries at a particular moment in time (day of visit)
- Average percentage of time out of stock over a period of one year (at least as long as one procurement period) for a set of unexpired tracer pharmaceuticals in a sample of pharmacies/dispensaries
- Presence of a qualified provider/dispenser at the time of visit

Tracer pharmaceuticals are a subset of essential products that should be available at the type of facility studied. For this reason, the tracer list that would be used in primary care facilities will be different from the list that would be used at tertiary-level facilities. It is also important to note that expired products that may be on the dispensary shelves are not considered to be available (although in reality they may be used anyway).

The determination of appropriate qualifications for providers and dispensers is based on the local laws and regulations and licensing requirements related to these functions. These qualifications should relate to the formal training received as well as any additional training that might be received, including continuing education.

⁴ See MSH/Strategies for Enhancing Access to Medicines background documents and country programs using this approach at <http://www.msh.org/seam/3.1.htm>.

Low levels of availability of pharmaceuticals may be related to failures in the procurement function, from inadequate quantification and budgeting to poor supplier performance. Low levels of qualified providers may reflect low levels of enforcement, but may also reflect real human resources shortages.

Geographic Accessibility

This dimension of access reflects the distribution of services and equity of their availability. Geographic accessibility takes into consideration the time and distance required to access essential medicines and services. Of particular interest are differences between urban and rural populations, but other comparisons may be relevant in any particular context. The specific criteria for determining acceptable time and distances should be relevant for the particular context being evaluated. Indicators that may be used to assess this dimension of access include the following—

- Percentage of population living more than two kilometers from a legitimate source of pharmaceuticals
- Average time to walk to the nearest legitimate source of pharmaceuticals
- Ratio of the average time to travel to nearest legitimate source of pharmaceuticals for urban and rural populations

In many countries the private sector has a broader geographic reach than the public sector, and for this reason partnering with the private sector, in particular with private pharmacies, may be an interesting option for countries that aim to expand their geographic reach. The investment in public sector facilities may be better focused in areas where there are no natural market forces to attract private sector activity.

For the supply of pharmaceuticals in particular, the distinction between legitimate and illegitimate sources of pharmaceuticals is important to note. In many countries, pharmaceuticals may be found in every marketplace, in the baskets of street vendors, and in all varieties of shops. Although these sources of pharmaceuticals may be well distributed, they are not considered to be legitimate. Poor geographic distribution of legitimate sources may be related to adverse market forces, lack of qualified human resources, and poor enforcement of laws and regulations regarding the dispensing and sale of pharmaceuticals. Alleviating this problem inevitably requires strong political support to redirect resources to compensate for adverse market forces, an investment in upgrading the skills and qualifications of illegitimate dispensers, or both.

Affordability

Economists define affordability as a relative concept that includes an appreciation of the notion of willingness to pay and price elasticity. From a pharmaceutical system perspective, however, the measure of affordability considers comparative prices to the patient by unit and by treatment. Key indicators include—

- Average unit price differential between public sector and private sector for a set of unexpired, quality tracer pharmaceuticals
- Average number of days of work required to pay for a standard recommended course of therapy for tracer conditions (indexed to income category)
- Ratio of average percentage of income required to pay for a standard recommended course of therapy for tracer conditions between highest- and lowest-income quintiles

As countries sought to expand services without being able to increase contributions from the public coffers, charging patients for health services—including pharmaceuticals—became a more common way to finance health care. Various types of payment and cost-recovery schemes were developed. Some schemes covered all pharmaceuticals as a flat fee, irrespective of the actual unit costs, and others charged separate fees for the clinical visit and the pharmaceuticals provided. Allowances may have also been made for special groups, such as the indigent, women with small children, and the elderly. These different ways that prices are determined and how patients may have to pay for their treatments should be considered in the selection of appropriate indicators of affordability.

High price differentials may be related the penchant for branded or imported products in the private sector. If the procurement function in the public sector is able to take advantage of economies of scale, the unit prices should reflect this advantage relative to the prices in the private sector.

Acceptability

This dimension of access relates most directly to the concepts of quality and satisfaction from both the provider and the client or patient perspectives. Indicators of acceptability include—

- Percentage of clients/patients who report satisfaction with the outcome of the last visit to the public or private facility that dispenses pharmaceuticals.
- Percentage of prescriptions that reflect current standard treatments for tracer conditions
- Percentage of facilities with source of up-to-date, unbiased information about pharmaceuticals for providers
- Percentage of facilities with source of up-to-date, unbiased information about pharmaceuticals for patients
- Presence of expired or unregistered products in dispensaries/pharmacies

Reporting on levels of client or patient satisfaction with pharmaceutical services requires an understanding of the expectations for the services, which can be a problem when the notion of the potential for the services is very limited and expectations are very low. For this reason,

movements that aim to defend client/patient rights also have an educational component to raise awareness and expectations.

Improving access to services, and therefore medicines, is one of the main goals of most health sector reforms and, as such, is the most commonly measured indicator. As reforms gain momentum and experience with implementation, increasing numbers of studies are being published that examine the effectiveness of the reforms using clear measures of access (for example, Mejia Restrepo et al. 2002; Romero 2002). Much less information is available about the effect of reform initiatives on the efficiency of the pharmaceutical system.

Efficiency

Efficiency is a measure of effectiveness that specifically focuses on the relationship between inputs (generally financial and human resources) and desired outputs (effect). In terms of pharmaceutical systems, we can consider measuring the efficiency with which each major component or function of the cycle is accomplished in order to ensure that quality pharmaceuticals are available where and when needed. Measures of efficiency compared over time or across systems are used to identify opportunities for cost reduction or the need for cost increases. Ultimately, because pharmaceuticals and the management of the pharmaceutical system represent one of the biggest costs to the health system (financial costs as well as the political costs associated with nonperformance), the efficiency of a pharmaceutical system affects the sustainability of the larger health system. For this reason, ensuring that efficiencies are regularly addressed should be a central concern for those involved in the design of health reform initiatives.

Allocative Efficiency

Many health sector reforms seek to expand the reach of health services to previously underserved populations. *Allocative efficiency* refers to whether the health budget and expenditures reflect the priorities of the system. For example, in a system that aims at ensuring access to primary care services for the population, one would expect the larger share of the drug budget to be spent on essential medicines as opposed to medicines typically used only in specialized tertiary care facilities. Several indicators may be used to compare spending on pharmaceuticals to address the question of “how much” is enough. Many of these indicators do not allow for separating the costs of managing the pharmaceutical system from the prices paid for pharmaceuticals, but they may be used to gauge performance of one program against programs in countries in the same region and with similar levels of development and gross domestic product (GDP). Comparisons between relevant subgroups of the population (by income level or special interest group) will also yield information that may influence allocative decisions.

- Per capita pharmaceutical expenditure
- Pharmaceutical expenditure as a percentage of GDP

- Private spending for pharmaceuticals as a percentage of total spending on pharmaceuticals
- Pharmaceutical expenditure as a percentage of total health expenditure
- Out-of-pocket expenditure on pharmaceuticals as a percentage of household income

Technical Efficiency

Technical efficiency refers to how well each function of the pharmaceutical cycle performs. It is much more difficult to measure and yet is where many health reform initiatives have a significant effect. Technical efficiency addresses both therapeutic decisions (selection and use) and operational issues (management, procurement, and distribution).

Therapeutic efficiency is addressed by establishing and maintaining essential medicines lists or formularies and drug use reviews. Expenditure and consumption data can be evaluated by therapeutic category to determine whether use reflects what would be expected or is appropriate given morbidity data. Savings might be incurred by identifying therapeutic duplications or by substituting less costly products for more costly ones from the same therapeutic category. Drug use reviews may also reveal irrational prescribing practices that result in more expensive treatment costs. Because this type of evaluation requires access to good information and the skills to evaluate it, the responsibility for ensuring therapeutic efficiencies rests with qualified pharmacy and therapeutics committees (PTCs), which may exist only at the national level in several countries. Even then, the PTC may not have the skills to conduct this type of evaluation.

Health sector reforms that raise the possibility of contracting out and privatizing services are generally based on the notion that greater operational efficiencies will be gained. The initiative is related to efforts to modernize heavily bureaucratic systems that are traditionally stymied by civil service laws and the recognition that the private sector, particularly in a competitive environment, has incentives to maximize efficiencies. Such options for working with the private sector should always consider the strength and maturity of the private sector and the level of competitiveness. Reform planners who do not conduct a serious evaluation of the private sector before designing and implementing initiatives calling for a larger role of the private sector may be very disappointed.

Key indicators of pharmaceutical system performance are derived from the following four cost categories (see MSH 1997, 645–49, for a more comprehensive discussion)—

Acquisition costs: The cost of making the regular planned purchases of pharmaceuticals in a period reviewed (usually a budget cycle, or one year). This cost includes not just the prices paid for the products but also any additional fees and charges (such as those for shipping and insurance) associated with the procurement. This information is usually readily available from a procurement office. If procurement is conducted at lower levels, that information should also be captured for the analysis.

Purchasing costs: As opposed to the acquisition costs, these costs are related to the act of realizing the purchases. It includes the salaries of those involved, supplies, and communication costs related to managing tenders, placing purchase orders, and receiving goods. This information is often difficult to obtain, in part because it is unlikely to be available in any one place or compiled in a way that is easy to assess. Personnel costs may not be tracked in a way that makes it easy to determine who is involved in the procurement process, how much of their time is actually spent on these activities, and what portion of all supplies are used specifically for procurement. In these situations (which are very common), costs need to be estimated based on available data.

Inventory holding (distribution) costs: All costs associated with managing inventory, including rent for warehouses, utilities, salaries, communications, equipment (including depreciation), and other supplies, as well as transportation-related costs (fuel, maintenance, repairs) and costs associated with inventory loss caused by wastage, theft, and expiry, contribute to distribution costs. Many of these costs may be available at a medical store, but some are costs that are only captured at the national level so estimates would be required. The costs should be obtained from all levels of the system (such as regional and district stores).

Shortage costs: Quantifiable costs include expenditures on emergency purchases (generally available) and estimates of revenue loss (if cost recovery is in place); more difficult to quantify are costs associated with increased morbidity and mortality that may result from stockouts, and the political cost of loss of goodwill from beneficiaries.

A comparative analysis of the performance of the existing system with another system operating in the same country is extremely useful for identifying potential areas for improving efficiencies. Public and private for-profit sector comparisons are the most common, although comparing the performance of nongovernmental organizations (NGOs) is also very useful. Key indicators of efficiency to assess include—

- The average percentage difference between unit prices paid for a set of selected items and comparable prices paid (at appropriate levels). Although the acquisition costs include the prices paid and any associated fees, the prices alone can be evaluated. Factors affecting prices include economies of scale and level of competition. International competitive bidding, for example, tends to maximize opportunities for competition among suppliers for most products. Prices paid for products obtained through local or emergency purchases can be compared with prices paid for tenders, but it would not be appropriate to compare international tender prices with retail prices.⁵
- Purchase costs as a percentage of drug acquisition costs, to compare the efficiency of the purchasing function. Because each procurement implies purchase costs, the number of procurements should be minimized.

⁵ For example, the MSH *International Drug Price Indicator Guide*, published regularly, posts the tender results from reputable sources by product and generates an average, or median, price paid against which other programs can compare their own results. The guide is available online at http://www.msh.org/resources/publications/IDPIG_2004.html.

- Inventory loss (due to expiry, theft, damage, and so on) as a percentage of average inventory value. Private sector values tend to be lower than those of the public sector.
- Average inventory turnover, calculated as the value of products distributed divided by the average inventory value. Although influenced by the procurement cycle to some degree, turnover is an indicator of whether the holding cost is reasonable. In the private sector, the turnover may be nearly monthly, whereas three to six turnovers per year are more common in public systems.
- Personnel costs, space costs, transport costs, and other direct operating costs as a percentage of total holding costs. These measures are used to evaluate the relative proportion of total costs attributable to each category of costs.
- Total holding cost as a percentage of the value of pharmaceuticals distributed (or average inventory). This ratio is a measure of cost-effectiveness of maintaining in-house services as opposed to contracting out some or all aspects of storage and distribution.
- Shortage costs (for example, value of emergency purchases) as a percentage of total costs, which measures cost-effectiveness of procurement practices. High shortage costs relative to total costs should generate questions about why shortages occur (may be caused by poor quantification; “mismatched” budget cycles; excessive inventory loss due to expiry, theft, or spoilage).

Armed with these various measures, the health system analyst is ready to characterize the effectiveness and efficiency of the pharmaceutical system, and with an understanding of the functioning of the supply cycle, to identify sources of those problems. Unfortunately, such analyses may be difficult to perform properly because quality data are scarce, and in some cases they do not exist. When data are not available (nonexistent or inaccessible), reasonable estimates may sometimes be derived by taking the time to become familiar with the cost structures in other agencies or organizations in the same or otherwise comparable contexts. With this information and a solid understanding of the particular socioeconomic and political context, health planners can consider options for more realistic interventions.

IDENTIFYING OPPORTUNITIES AND CHALLENGES PRESENTED BY HEALTH SECTOR REFORM

The approach presented in this document begins with an understanding of the key functions of a pharmaceutical system and how to measure system performance. This knowledge provides the basis for the definition of performance problems and how they might be addressed through reform initiatives. Performance goals and targets, derived from the strategic prioritization of problems, ethical review, and political and technical analyses, need to be clearly defined and put into operation to be useful.

One of the challenges that planners and managers face is not to atomize the pharmaceutical system. Focusing on only one or two performance areas can blind one to the unintended effects of initiatives on all components and levels of the system. Although several opportunities exist for win-win situations, trade-offs are often required, especially when performance goals are not based solely on economic efficiencies. By the same token, although reform efforts that specifically target the pharmaceutical system share the same principles of the larger sector reform, analysts should be sensitive to the possibility of the existence of duplication of functions, unexpected gaps, and unnecessary costs (Romero 2002).

This section discusses types of strategies for improving system performance. It concludes with a brief presentation of two country examples.

Instruments of Reform Applied to the Pharmaceutical System

Four types of instruments or strategies through which reform initiatives aim to achieve their goals are described by Roberts and colleagues (2004) and presented in Figure 1. The instruments most commonly relevant to pharmaceutical system performance include—

Policy and legal framework: National medicine policies define the principles and values that guide the development of a pharmaceutical system, such as the concepts of essential medicines, rational drug use, and equitable access. They should be consistent with or support the overall health policy. National medicines laws and regulations (such as national generics laws and registration) lay out the parameters for how specific functions and activities within the pharmaceutical system will be accomplished. These parameters include, for example, determination of what cadres of professionals and facilities are permitted to prescribe and dispense, what products will be permitted to circulate in the marketplace (public and private sectors), and how to import and export products.⁶ A common difficulty countries have in this regard is the lack of sufficient resources or political will to follow through on enforcement and to ensure that the policy is kept up-to date and relevant to the health needs and priorities.

Many initiatives may be seriously delayed or never implemented because they are not supported by or are contrary to a national policy or law. Existing laws that may need to be addressed are

⁶ The World Health Organization has developed general guidelines on how to develop and implement national medicines policies primarily geared to countries that do not have any policy in place (WHO, 2003).

civil service laws, importation and sales of pharmaceuticals, laws and regulations regarding qualifications of dispensers, and pricing procurement and policies. In some cases, the process for introducing a new law or change of a law is lengthy, and initiatives risk proceeding before having the sanction of law, as is the case in Ecuador where several reform initiatives were implemented before a comprehensive supporting legal basis for them was adopted (Barillas 2005b).

Financing mechanisms: Prior to reforms, most health systems in Latin America financed their pharmaceutical systems entirely through the central ministry of health (MOH) budget. Under reform initiatives that aim at expanding access to previously unprotected populations, these funds were clearly no longer sufficient, leaving two options that are not necessarily mutually exclusive: find new sources of revenue and improve the management (efficiency) with which existing funds are used. Reform initiatives have introduced alternative mechanisms that tend to shift some of the responsibility and burden for financing closer to the facility and the user levels for cost-recovery (revenue-generating) purposes. Where financial responsibilities are decentralized or deconcentrated to lower levels, options include pooling resources for procurement (as in El Salvador). Cost-recovery and cost-sharing mechanisms that affect the patient include patient fees that cover medicines, pharmacy benefits programs, and revolving funds. Unfortunately, many funds fail because of inadequate design or poorly implemented management controls (as in Peru). Pharmaceuticals may also be financed through capital or in-kind donations. For some countries, donated funds can account for as much as 40 percent of the budget for pharmaceuticals (as in Nicaragua). However, costs are associated with receiving donations, and if donations are of products that are of poor quality or do not conform to the clinical needs of the population, they can cost more than they are worth.⁷

Organization of services: In order to meet the objectives of expanding access to quality care and to increase efficiencies, many health reforms in Latin America have considered options for privatizing or contracting for services. In those countries in which local capacity exists in the private sector and contract management capacity exists in the public sector, options could include contracting with the commercial sector for all or some of the key management functions. For example, systems may consider contracting with prime vendors, or prime distributors, for pharmaceutical procurement management, distribution (storage and transportation) management, and pharmaceutical use review. Other options include providing incentives for alternative sources of affordable essential medicines in regions neglected by the traditional commercial sector, such as access to lower-cost products (as in Guatemala and Nicaragua).

Provider and consumer behavior: Behaviors related to the use of pharmaceuticals that reforms aim to influence, or the demand side of the system, are as important as the supply side, related to the way resources are managed. The two key behaviors that are of particular relevance are prescribing and medication use. In general, three main types of interventions aim at changing behavior: managerial, educational, and regulatory. Managerial interventions aimed providers are designed to guide diagnoses and prescribing and include tools such as standard treatment

⁷ A guideline document to help programs develop and enforce pharmaceutical donations has been developed by the World Health Organization and may be found at <http://www.who.int/medicines/library/par/who-edm-par-1999-4/who-edm-par-99-4.pdf>.

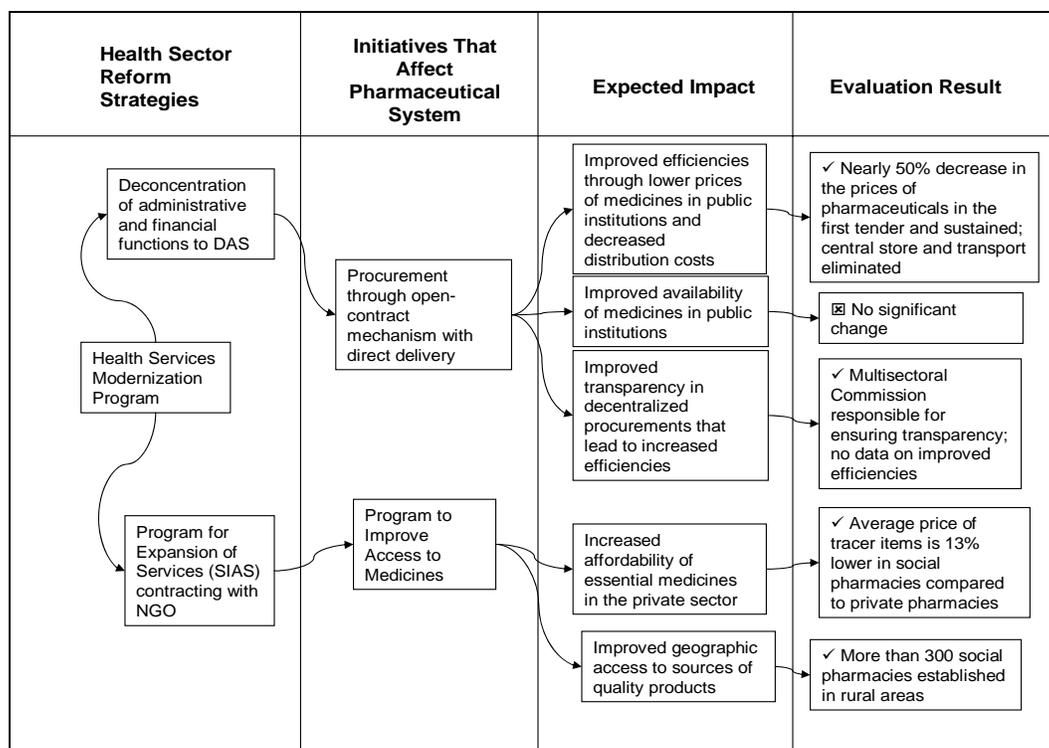
protocols, restricted formularies (such as essential medicines lists), and audits and corresponding incentives. Managerial interventions to guide patients similarly include incentives for seeking generics instead of more-expensive brand names. Educational interventions are based on the assumption that when properly informed about appropriate behavior, people will change their behavior accordingly. Educational interventions include various types of continuing education programs for health care staff as well as informational brochures and pamphlets for both providers and patients. Regulatory interventions aim at coercing individuals to behave appropriately. Greater and more sustained changes are achieved when combinations of two or more types of interventions are used (Le Grand et al. 1999; Radyowijati and Haak 2003). Within the context of health sector reform in particular, opportunities for ensuring that providers and patients understand the need for rational pharmaceutical management (from selection through use) are presented through the formation of multisectoral and local health councils and committees that include representatives from the community.

Country Examples

Guatemala: Improving Efficiencies, Affordability, and Geographic Access through Centralized Tendering for Prices by Generic Name, Direct Delivery, and Social Pharmacies

In 1996, Guatemala initiated a rapid process of HSR that has had significant implications for the management of pharmaceuticals. Two main goals of the reform were to improve efficiencies of the Ministry of Public Health (MSPAS) and to address inequities in access to care, especially for the rural population. This policy followed the lead of the Peace Accords, which defined the social and economic priorities and values for the development of the country and based upon which the government adopted the strategy to “modernize.”⁸ Together, these two strategies gave impetus to the modification of the already existing open-contract mechanism to allow for the procurement of generic medicines in the public sector. The procurement included terms for direct delivery to the local health authority (Dirección de Área de Salud, DAS). Extending coverage was to be achieved by contracting with NGOs working in rural areas and the Access to Medicines Program (see Figure 4).

⁸ This reform was government wide and affected all agencies, not just the MSPAS.



Source: Adapted from Barillas 2005a.

Figure 4. Reform initiatives affecting the pharmaceutical system in Guatemala

Open contract: The deconcentration of administrative and financial functions to the local health authority level (DAS), considered to be a stronger authority than the states, together with an increase in funds for the existing revolving drug fund for decentralized purchases, allowed some critical improvements in payment lead times to suppliers. While suppliers could negotiate purchases directly with the DAS, the advantage to the DAS of economies of scale were lost. In order to regain it, the government modified the existing procurement mechanism known as the open contract (*contrato abierto*) to allow the procurement of pharmaceuticals. Under this mechanism, tendering for prices by generic name is centralized (under the Ministry of Finance and Planning), based on combined quantities from the three main public institutions involved in procuring medicines. The winning suppliers contract with the government to sell the designated products, including delivery, for the adjudicated price, to the DAS.

The tender prices combined the price for the medicines and distribution to the DAS, so comparing the prices of medicines separately from the cost of distribution was not possible. However, from the first tender under the open-contract mechanism, the net gain to MSPAS over the previous completely decentralized approach is estimated at approximately 33 million U.S. dollars.⁹ This figure would not include the savings gained from the closing of the central medical store and elimination of MSPAS transportation services. It is not clear whether DAS experienced

⁹ These surplus funds were applied toward salary increases for MSPAS employees and contributed to extending coverage of basic services.

costs as a result of increased responsibilities, volume of inventory received, or new staff requirements.

The availability of essential medicines in the MSPAS health centers and posts did not improve significantly: from 60 percent in 1992 to 68 percent in 2002. The average length of time out of stock, however, decreased from 32 percent to 17 percent. It is not clear whether the stockouts have been a result of poor inventory management or deficiencies on the part of suppliers.

Social pharmacies: In 1997, MSPAS began contracting with NGOs to provide basic health services in order to expand access to services, with the medicines supplied through MSPAS and dispensed free of charge to patients. The NGOs were permitted to establish not-for-profit pharmacies known as social pharmacies (*venta social de medicamentos, VSM*) that sold essential medicines purchased from the NGOs at open-contract prices. VSMs located in rural areas can add up to 35 percent to their purchase price for sale to the public, while those located in urban areas can add no more 33 percent.

Geographic access increased dramatically as the number of VSMs grew from 50 at the outset of the program to 866, covering 35 percent of the population, in 2004. Affordability was also addressed positively. In 1999, the prices of medicines in the private pharmacies were about 6 times greater than those sold in the VSMs; in 2004, the difference doubled.

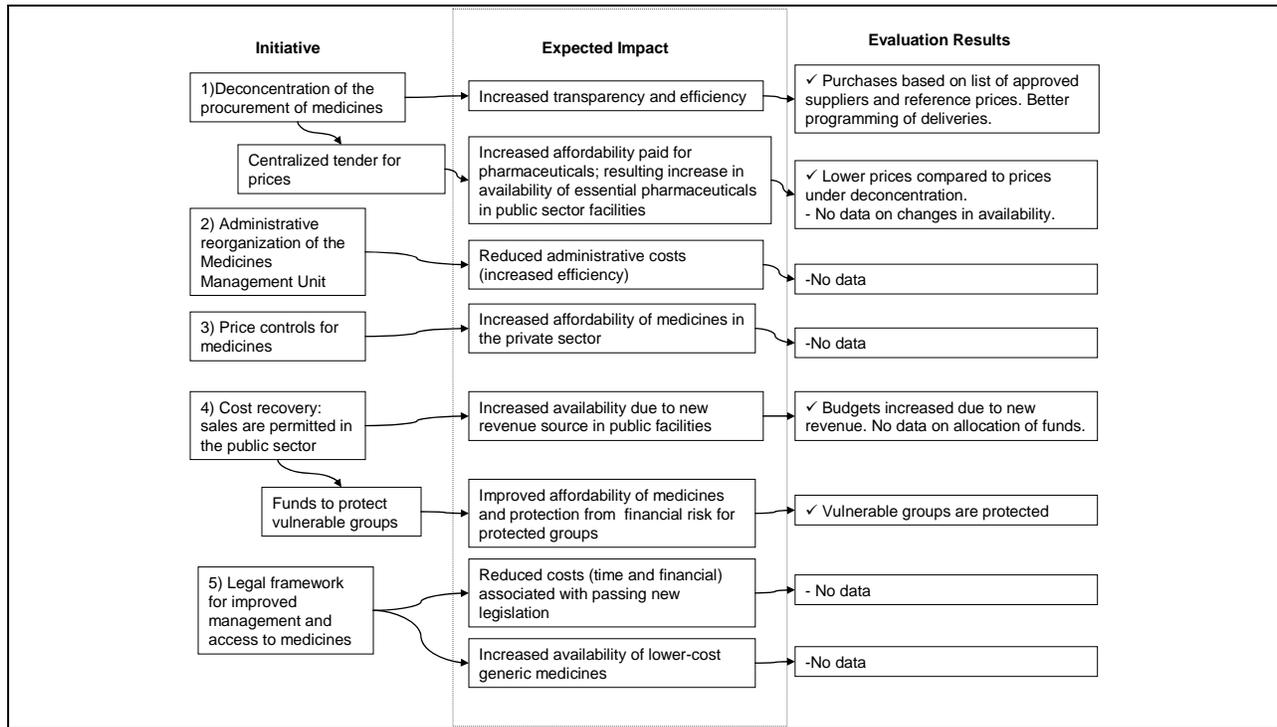
Challenges and opportunities: Among the greatest challenges to the implementation of the initiatives to improve the pharmaceutical system was the opposition expressed by some suppliers of pharmaceuticals to the open contract. The open contract posed a threat to small-scale vendors that depended on the particular relationships they had with their clients rather than entering tender competition. Their expressed concern was that the large suppliers with international connections would displace the smaller national firms, which would be contrary to the larger economic development goals of the country. In order to ensure that the suppliers' concerns were heard and considered, they were invited to have representation on the Multisectoral Committee for Medicines that was responsible for ensuring that appropriate modifications were made.

Some providers also had expressed concerns about the possibility of opening the door to the procurement of poor-quality generic medicines. In order to address this issue, the national quality control laboratory was moved, it was newly equipped, its staff was retrained, and new employees were hired.

A significant weakness in the system that also needed to be addressed was the capacity at the local level to properly estimate needs. The unreliability of the quantities was difficult for suppliers to cope with and generated distrust. It also affected payments. In response to this issue, MSPAS sought to hire a pharmacist for each DAS to develop procurement lists and quantities. Now, when shortages occur they are said to be more likely caused by failures on the part of suppliers not being able to keep up with demand.

Ecuador: Centralized Procurement with Local Purchases, Price Controls, Cost Recovery, Protection for Special Groups, and Legal Framework

Health sector reform in Ecuador may be characterized as a series of frustrated efforts, driven largely by forces outside the health sector itself and directed by the broader social and political reform movement. Most initiatives that relate in any way to the pharmaceutical system were not directed specifically to it. The initiatives that potentially could affect the performance of the pharmaceutical system are presented in Figure 5, although some have been implemented too recently to evaluate.



Source: Adapted from Barillas 2005b.

Figure 5. Reform initiatives affecting the pharmaceutical system in Ecuador

The two central themes for reform in Ecuador, as with most other countries in the region, are modernization and decentralization, with the aim of improving efficiencies and addressing social inequities. Since the beginning of the 1990s, initiatives began to be implemented to achieve these goals. It was not until 1998, however, that the National Health Policy was published, allowing for a clear statement of health priorities and strategies to address them.

Beginning in the early 1990s, administrative financial responsibilities were increasingly deconcentrated to the hospitals and to provincial health areas, collectively known as operative units (*unidades operativas*, UOs), including for cost recovery for medicines, which remained a key strategy.

Other sources of funds for UOs included an annual budget from the MOH, special funds received through a program specifically for maternal and child health. Social participation in decision making for health services management was to occur through provincial- and canton-level health councils and the committees for social participation, sanctioned in 1999.

Deconcentration with centralized procurement: As is often the case, the deconcentration of functions yielded some benefits, but at considerable cost. Although not well documented, local procurement likely resulted in an increased level of effort for staff and a loss of economies of scale. As a corrective measure, the MOH decided to implement centralized procurement for prices to be realized through local purchase. In accordance with the Generics Law, passed in 2000, the products to be procured had to be generics. The first tender for prices took place in 2004.

According to Barillas (2005b), evidence exists to suggest that availability improved, at least in part because of the introduction of decentralized procurement: in 2004, the average availability of a set of tracer items had increased 37 percent, up from 46 percent in 1993. The average time out of stock over a period of 12 months decreased to 8 percent, from 12 percent in 1993. However, Barillas also notes that the more remote areas still ran greater risk of more and longer stockouts.

Price controls: The system for price controls aimed at setting ceilings for prices for medicines sold to the public in private pharmacies. The ceilings were supposed to be calculated on the basis of the costs of production. In principle, price controls would aim to ensure against price gouging. Unfortunately, insufficient data exist, as well as some question as to the validity of existing data, to determine whether the prices to the public were controlled or reduced in any way because of this intervention.

Cost -recovery and funds to protect vulnerable groups: The receipts from the sale of medicines to patients contribute to the overall budget of the OUs. However, the expenditures on medicines have grown exponentially compared to receipts, indicating that other funds (from the MOH, the maternal and child health program, or both) have become more important, and therefore that vulnerable groups are being protected. Anecdotal evidence suggests that the number of patients exempted from payment has been increasing.

Challenges and opportunities: Ecuador has only recently implemented some initiatives that potentially could affect significantly the availability of quality, low-cost medicines. It is not clear whether information systems are in place to monitor and evaluate changes over time on key performance indicators. The high level of political instability in the country has proved to be a significant challenge to the reform efforts. One can only hope that, armed with good evidence of the performance of the pharmaceutical system, management decisions can supersede politics.

REFERENCES

- Barillas, E. 2005a. *Efectos de la Reforma del Sector Salud en el Suministro de Medicamentos de Guatemala*. Submitted to the U.S. Agency for International Development by Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health.
- Barillas, E. 2005b. *Efectos de la Reforma del Sector Salud en el Suministro de Medicamentos de Ecuador*. Submitted to the U.S. Agency for International Development by Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health.
- Knowles, J.C., C. Leighton, and W. Stinson. 1997. *Medición de Resultados de la Reforma del Sector Salud en Cuanto al Desempeño del Sistema: Guía de Indicadores*. Bethesda, MD: Partnerships for Health Reform/Abt Associates, Inc.
- Le Grand, A., H. V. Hogerzeil, and F. M. Haaijer-Ruskamp. 1999. "Intervention Research in Rational Use of Drugs: A Review." *Health Policy and Planning* 14: 89–102.
- MSH (Management Sciences for Health). 1997. In collaboration with the World Health Organization Action Programme on Essential Drugs. *Managing Drug Supply: The Selection, Procurement, Distribution, and Use of Pharmaceuticals*. 2nd ed., revised and expanded. West Hartford, CT: Kumarian Press.
- . 2004. "Tackling the Crisis in Human Capacity Development for Health Services." *The Manager* 13(2). http://erc.msh.org/TheManager/English/V13_N2/V13_N2_En_Issue.pdf.
- Mills, A., S. Bennett, and S. Russell. 2001. *The Challenge of Health Sector Reform: What Must Governments Do?* Houndmills, Great Britain: Palgrave.
- Murray, C. J. L., and J. Frenck. 2000. "A Framework for Assessing the Performance of Health Systems." *Bulletin of the World Health Organization* 78 (6): 717–31.
- PAHO (Pan American Health Organization). 2002. *La Salud en las Américas*. Volume 1. Scientific and Technical Publications No. 587. Washington, DC.
- Radyowijati, A., and H. Haak. 2003. "Improving Antibiotic Use in Low-Income Countries: An Overview of Evidence on Determinants." *Social Science and Medicine* 57: 733–44.
- Mejia Restrepo, S. M., A. L. Velez Arango, O. C. Buritica Arboleda, M. C. Arango Mejia, and J. A. Rio Gomez. 2002. "La política farmacéutica nacional en Colombia y al reforma de la seguridad social: acceso y uso racional de medicamentos." *Cadernos de Saúde Pública, Rio de Janeiro* 18 (4): 1025–39.
- Roberts, M. J., W. Hsiao, P. Berman, and M. R. Reich. 2004. *Getting Health Reform Right: A Guide to Improving Performance and Equity*. Oxford: University Press.

Romero, C. P. 2002. "Reforma del sector salud y la política farmacéutica en Perú." *Cadernos de Saúde Pública, Rio de Janeiro* 18 (4):1121–38.

WHO (World Health Organization). 2000. *World Health Report 2000: Health Systems: Improving Performance.*, Geneva: WHO. www.who.int/whr.

_____. 2002. "The Selection of Essential Medicines." *WHO Policy Perspectives on Medicine* 4. <http://www.who.int/medicines/library/general/PPMedicines/ppm04eng.pdf>.

_____. 2003. "How to Develop and Implement National Drug Policy." *WHO Policy Perspectives in Medicine* 6. http://www.who.int/medicines/library/general/PPMedicines/PPM_No6-6pg-en.pdf.

_____. 2004. *The World Medicines Situation*. Geneva: WHO/EDM/PAR/2004.5.