

Policy and legal framework

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SUMMARY

Most leading causes of death and disability in developing countries can be prevented, treated, or at least alleviated with cost-effective essential medicines. Despite this fact, hundreds of millions of people do not have regular access to essential medicines. Many of those who do have access are given the wrong treatment, receive too little medicine for their illness, or do not use the medicine correctly.

MDS-3 addresses practical ways in which government policy makers, essential medicines program managers, nongovernmental organizations (NGOs), donors, and others can work to ensure that high-quality essential medicines are available, affordable, and used rationally. Medicines are of particular importance because they can save lives and improve health, and they promote trust and participation in health services. They are costly, and special concerns make medicines different from other consumer products. Moreover, substantive improvements in the supply and use of pharmaceuticals are possible.

Within a decade after the first modern pharmaceuticals became available, efforts began to ensure their widespread availability. From the mid-1950s to the mid-1970s, basic pharmaceutical management concepts began to evolve in countries as diverse as Cuba, Norway, Papua New Guinea, Peru, and Sri Lanka.

In 1975, the World Health Organization (WHO) defined *essential medicines* as those medicines that meet the health needs of the majority of the population. In 1982, Management Sciences for Health published the first edition of *Managing Drug Supply*, which incorporated the essential medicines concept and has become known as the seminal guide to managing pharmaceuticals in developing countries. Over the last thirty years, countries have acquired considerable experience in managing pharmaceutical supply. Broad lessons that have emerged from this experience include the following—

- National medicine policy provides a sound foundation for managing pharmaceutical supply.
- Wise medicine selection underlies all other improvements.
- Effective management saves money and improves performance.
- Rational medicine use requires more than medicine information.
- Systematic assessment and monitoring are essential.

Although much has been achieved, challenges remain—

- Achieving financial sustainability through greater efficiency and financing mechanisms that increase

availability while ensuring equity (financing options include public financing, health insurance, voluntary and other local financing, and donor financing)

- Improving efficiency in public pharmaceutical supply through strategies that build on public-sector strengths while incorporating greater flexibility and competitiveness
- Changing the behavior of providers, patients, and the public to promote effective, safe, and economical prescribing, dispensing, and patient use of medicines
- Reorienting the role of government to improve the availability, affordability, and rational use of medicines in the private sector, which supplies 60 to 90 percent of the medicines consumed in many developing countries
- Regulating safety, efficacy, and quality through adoption and enforcement of legislation and regulations that ensure that all medicines meet basic quality standards

MDS-3 is organized around the four basic functions of the pharmaceutical supply management framework—

- Selection
- Procurement
- Distribution
- Use

These functions are supported by a core of management support systems—

- Planning and administration
- Organization and management
- Information management
- Human resources management

Effective pharmaceutical management rests on a policy and legal framework that establishes and supports the public commitment to essential medicines supply and is influenced by economic issues (Part I of this manual). Other major sections of the manual are devoted to each of the main functions of the pharmaceutical management framework (Part II) and management support (Part III).

This manual provides concepts and approaches that can produce measurable health improvements through greater access to and more rational use of medicines. Governments, private organizations, donors, and others who use this manual must provide the will and the resources to put these concepts and approaches into action.

1.1 Introduction

Interest in human health and illness is as old as humanity. Scientific study of human anatomy and human diseases can be traced to the Greek physician Hippocrates and earlier. Yet as recently as one hundred years ago, the best that medicine could offer was a handful of demonstrably effective preparations. Penicillin, one of the first antibiotics, and chloroquine, the first modern antimalarial, are about seventy years old. Medicines for common conditions such as diabetes are only fifty years old. Oral contraceptives have been generally available for only forty years.

In industrialized countries, the age of modern pharmaceuticals has eliminated or dramatically reduced mortality from most common infections, allowed families to plan their growth, extended the lives of millions of people suffering from chronic illnesses, and provided relief from pain and suffering for hundreds of millions more people. From the first mass production of penicillin in the 1940s has grown a pharmaceutical industry valued at 600 billion U.S. dollars (USD) annually. The research efforts of that industry continually provide safer, more effective products. The industry's distribution networks ensure ready access to thousands of products for people throughout the industrialized world.

In many other parts of the world, however, people have not fully benefited from these medical advances. In the late 1970s, 60 to 80 percent of people in developing countries were estimated as lacking regular access to even the most essential medicines. By 2003, WHO estimated that less than half the citizens in 32 percent of the world's poorest countries lacked regular access to essential medicines, which improved on 1999 access estimates (WHO 2006c). Lack of access is directly related to income—81 percent of the countries with the lowest access to medicines also had the lowest incomes (WHO 2006c).

The large share of the world's population that does not benefit from simple, safe, effective pharmaceuticals—and the millions of children and adults who die each year from common conditions that can be prevented or treated with modern medicines—signal a fundamental failure of health care systems.

Those who do have access to essential medicines often receive the wrong medicine, the wrong dosage, or a quantity insufficient for their needs. In some countries, many modern medicines are dispensed without prescription by untrained and unlicensed drug sellers. Even when patients and consumers receive the correct medicine, half do not consume it correctly (WHO 2002).

MDS-3 is concerned with practical ways in which government policy makers, essential medicines program managers, NGOs, donors, and others can work to close the huge gap between the need for essential medicines and public access to them—between the vast number of

people who could benefit from modern pharmaceuticals and the much smaller number of people who actually do benefit. This manual is also concerned with closing the gap between the availability of medicines and their rational use.

This chapter focuses on the role of medicines in health care and health policy. It describes the essential medicines concept, reviews major lessons in pharmaceutical management since the 1980s, and summarizes major challenges still facing the pharmaceutical sector.

1.2 Why worry about medicines?

To clinicians facing the sick and injured on a daily basis, the importance of medicines is obvious. Nonetheless, summarizing the reasons that ministers of health, directors of health programs, donors, and others involved in the health sector should be concerned with medicines is useful. Accessible health services and qualified staff are necessary components of any health care system, but medicines have special importance for at least five reasons—

- Medicines save lives and improve health.
- Medicines promote trust and participation in health services.
- Medicines are costly.
- Medicines are different from other consumer products.
- Substantive improvements in the supply and use of medicines are possible.

These observations were the primary motivation for preparing this manual. The following chapters focus on the richness and diversity of opportunities for practical, effective improvements in pharmaceutical supply and use.

Medicines save lives and improve health

Most leading causes of discomfort, disability, and premature death can be prevented, treated, or at least alleviated with cost-effective essential medicines. Although the relative frequencies of specific conditions vary among countries, outpatient services throughout the world are presented with a fairly common set of health problems for which essential medicines have an important role: acute infections, skin diseases, gastrointestinal complaints, musculoskeletal conditions, and injuries.

Mortality figures across developing regions (see Table 1-1) reflect a huge burden of illness that can be substantially reduced if carefully selected, low-cost pharmaceuticals are available and appropriately used. Essential medicines significantly affect the common causes of morbidity and mortality, including acute respiratory infections, diarrheal diseases, HIV/AIDS, measles, malaria, maternal

Table 1-1 Mortality from infectious, chronic, and other conditions in WHO member countries worldwide and in select WHO regions, 2004

Conditions	All WHO member countries	Africa	Southeast Asia
Respiratory infections	4,259	1,437	1,416
Diarrheal diseases	2,163	1,005	684
Tuberculosis	1,464	405	519
Malaria	889	806	36
HIV/AIDS	2,040	1,651	206
Other infections and parasites	2,963	982	1,229
Nutritional deficits	487	159	179
Cardiovascular disease	17,073	7,175	3,875
Diabetes mellitus	1,141	172	280
Malignant neoplasms	7,424	480	1,195
Maternal and perinatal conditions	3,707	1,236	1,367

Source: WHO 2008a.

and perinatal mortality, tuberculosis, and cardiovascular and other chronic diseases (see Box 1-1).

Not only are essential medicines effective against common health problems, they are also cost-effective. Undeniably, long-term health gains can be made by investing in prevention through health education and other programs to improve nutrition, sanitation, water supply, housing, environment, and personal health habits. At the same time, essential medicines provide a direct, low-cost response for many diseases.

Medicines promote trust and participation in health services

The credibility of health workers depends on their ability to save a dying village elder with a course of penicillin, to restore life to a limp child with oral rehydration, or to relieve an irritating skin infection with a simple ointment. In addition to the direct effect on health, the availability of essential medicines attracts patients, who can then also receive preventive and public health messages. The provision of essential medicines is one element of primary health care that families everywhere take an interest in and that brings them to health facilities.

Over the years, household and patient surveys around the world have found that pharmaceutical availability is a major determinant of where patients go for health care and how satisfied they are with that care. Availability of medicines and supplies also affects the productivity of health staff. When pharmaceutical supplies fail to arrive, patient volume drops, and health workers are left idle. Irregular pharmaceutical supply can be a greater constraint on program effectiveness than inadequate numbers or inadequate training of health workers.

Medicines are costly

Although medicines are cost-effective, they can be quite costly for an individual, a household, a government health system, or a country.

At the individual and household levels, medicines represent the major out-of-pocket health expenditure; 60 to 90 percent of household health spending may go toward medicines (WHO 2000). In northern India, at least 57 percent of a family's average out-of-pocket cost of a newborn's illness was for medicines (Srivastava et al. 2009). The trend of private spending by households as the principal source of worldwide pharmaceutical spending increased during the 1990s (WHO 2004c). In addition to those direct costs, income is lost when family members are sick, and this loss reinforces the poverty-illness cycle. Women are especially vulnerable because they are usually the main family caregivers.

For ministries of health in most developing countries, expenditures on medicines are second only to those made on staff salaries and benefits, which can cost up to half of total health expenditures (WHO 2006d). Payment of personnel costs is largely unavoidable as long as staff are employed. Medicine expenditures, therefore, represent the largest expenditure over which ministries have year-to-year discretionary control. This fact makes medicine expenditures both extremely important and extremely vulnerable—particularly to fluctuations in the availability of public funding as well as to various political and economic pressures, such as rampant inflation and currency fluctuations.

At the national level, pharmaceuticals represent 10 to 20 percent of health expenditures for leading industrialized countries. But for most developing countries, they may

Box 1-1**Impact of essential medicines on common causes of morbidity and mortality**

HIV/AIDS still kills about 2 million people per year, even though global initiatives to combat the epidemic have increased dramatically. The widespread treatment of HIV/AIDS with antiretrovirals (ARVs) in resource-limited settings is relatively new, and prices for treatment have dropped dramatically in recent years making it available to far more people. Even with the increase in ARV treatment, however, medicines to treat opportunistic infections are still an important aspect of treating patients with HIV/AIDS.

Respiratory infections, which accounted for more than 4.25 million deaths in 2004, are usually cured readily with inexpensive oral antibiotics. About 20 percent of all deaths in children under five years of age are caused by acute lower respiratory infections (pneumonia, bronchiolitis, and bronchitis); 90 percent of these deaths are caused by pneumonia.

Diarrheal diseases, a top cause of childhood mortality, can be prevented through improved water and sanitation. Diarrhea can be treated in the home with simple oral rehydration solution and selective use of antimicrobial medicines. Recent case management advances such as reformulated oral rehydration solution and zinc supplementation have helped significantly decrease mortality caused by diarrhea.

Measles, another leading cause of childhood mortality, is preventable through immunization. But when immunization is missed, much of the resulting mortality can still be eliminated through the treatment of respiratory, diarrheal, and other potentially fatal complications.

Malaria threatens almost half the world's population and is responsible for nearly 1 million deaths each year; over

80 percent of fatal cases are in African children under four years of age. Early diagnosis and treatment with effective medicines can cure infections and save lives.

Maternal and perinatal mortality can be reduced through prenatal care and nonmedicine interventions such as high-risk case management. Postpartum hemorrhage can be avoided with the use of oxytocic drugs, and maternal anemia, a major contributing factor to maternal and perinatal morbidity and mortality, can be reduced with preventive doses of iron folate preparations. In addition, spacing the birth of children through family planning (using largely oral, injectable, and implanted contraceptives) improves both maternal and neonatal outcomes.

Tuberculosis (TB), once on the decline, is now a leading cause of death worldwide from an infectious disease. Although drug resistance is growing and second-line TB drugs are costly, short-course chemotherapy is curative, and the investment is highly cost-effective. Other strategies to bring TB under control include testing for TB drug resistance and treating TB/HIV co-infection.

Cardiovascular and other chronic diseases are rapidly increasing in developing countries as socioeconomic development, immunization, and other improvements increase life expectancy. In some countries, such as Russia, life expectancy has declined because of cardiovascular disease. Health services are facing a growing demand for essential medicines to treat hypertension, ischemic heart disease, diabetes, and other chronic diseases.

Sources: Jamison et al. 2006; WHO 2008b.

represent 20 to 40 percent of total public and private health expenditures (WHO 2006b).

In absolute figures, the sums that countries spend on pharmaceuticals vary tremendously. In 2000, the world's population in low-income countries spent an average of USD 4.4 per capita per year, whereas the population in high-income countries spent an average of USD 396 per capita (WHO 2004c). For example, Afghanistan spent USD 9 on pharmaceuticals, Cambodia spent USD 11, and Haiti spent USD 3; for industrialized countries in the same year, the figure ranged from USD 272 in Norway and USD 253 in the United Kingdom to USD 382 in Switzerland and USD 528 in Japan (WHO 2004c) (Table 1-2). In general,

medicine expenditures increase with gross national product (GNP).

Medicines are different from other consumer products

Because pharmaceuticals are produced by a competitive industry that responds primarily to economic demand, one might expect their production and sale could be left almost wholly to the play of market forces (see Chapter 10). In that case, politicians and lawmakers would have only the same sorts of concerns that apply to other forms of trade—prevention of fraud, protection of trademarks, and so forth.

Table 1-2 Per capita pharmaceutical and health expenditures in selected developing countries, 1990 and 2000

Country	Per capita expenditures (USD)			
	1990		2000	
	Medicines	Health	Medicines	Health
Bangladesh	2	6	5	14
Brazil	16	146	61	265
Chile	30	100	46	328
China	7	11	20	45
Costa Rica	37	132	42	280
Ghana	10	15	4	11
India	3	21	3	23
Indonesia	5	12	5	20
Kenya	4	16	7	30
Mexico	28	89	8	327
Morocco	17	26	20	54
Mozambique	2	5	2	12
Pakistan	7	12	5	18
Philippines	11	16	15	34
Turkey	21	76	58	150

Sources: Ballance, Pogány, and Forstner 1992; Murray and López 1994; WHO 2004c.

But medicines are different and require special attention, because—

- The consumer (patient or parent) often does not choose the medicine—it is prescribed by a clinician or recommended by pharmacy staff.
- Even when the consumer chooses the medicine, he or she is not trained to judge its appropriateness, safety, quality, or value for money.
- Neither the average medical practitioner nor the average pharmacist is equipped to independently assess the quality, safety, or efficacy of each new medicine.
- Fear of illness can lead patients to demand costly medicines from health workers, or to buy such medicines for themselves, when cheaper medicines—or no medicines—would achieve the same result.
- The consumer often cannot judge the likely consequences of not obtaining a needed medicine. This problem is most troublesome when the decision maker is a parent and the patient is a child.

These knowledge gaps, anxieties, and uncertainties associated with both acute and chronic illnesses create special concerns about the supply and use of medicines.

The issues that make medicines different from other consumer products also help make the pharmaceutical sector a likely target for mismanagement, bribery, and fraud. Contributing factors to this vulnerability to corrup-

tion include knowledge gaps and information imbalances between manufacturers, regulators, health care providers, and consumers; a lack of legislation or regulation or enforcement mechanisms; and the high value and volume of medicines in the marketplace (see Cohen 2006 and WHO 2009).

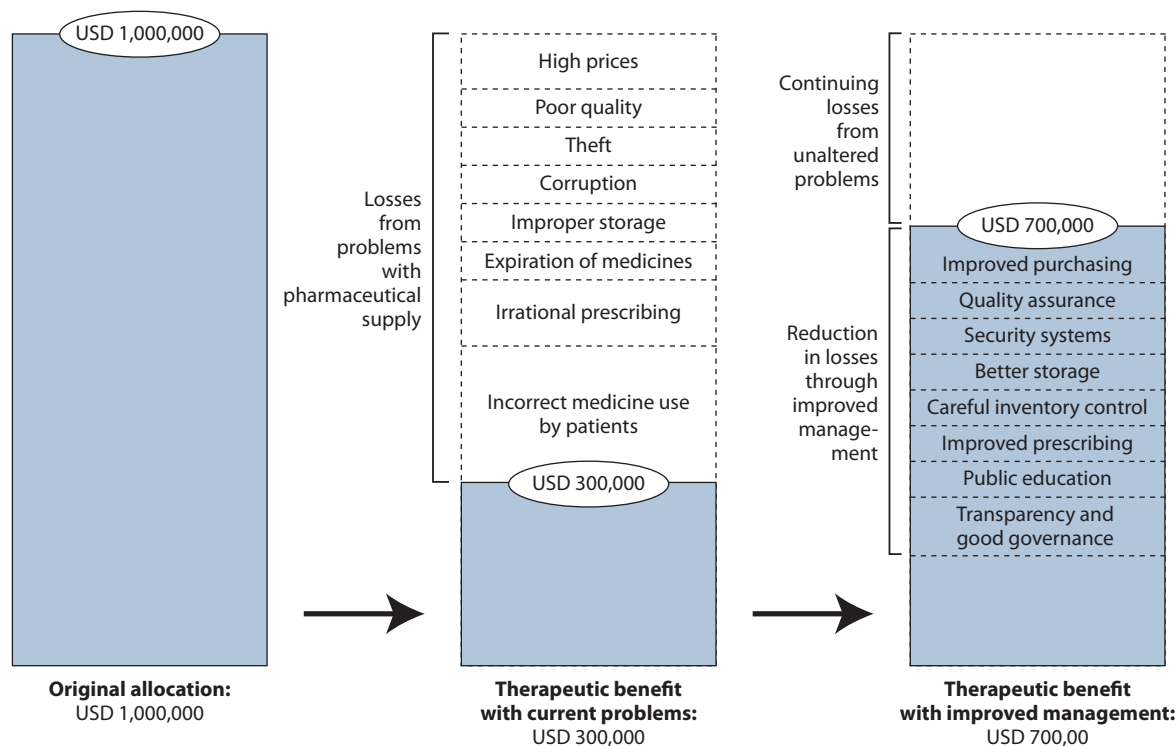
Substantive improvements are possible

In most health systems, the potential for improving the supply process is tremendous, reflecting in part the magnitude of current inefficiencies and waste.

Figure 1-1 shows a hypothetical program in which an annual expenditure of USD 1 million on pharmaceutical supply results in only USD 300,000 worth of therapeutic benefit to the patient. Lack of careful selection, incorrect quantification, high prices, poor quality, theft, improper storage, expiration of medicines, irrational prescribing, corruption, and incorrect medicine use by patients cause losses totaling 70 percent of the original expenditure.

However, much can be accomplished with substantial effort, a moderate amount of know-how, and relatively little additional funding. Some pharmaceutical management improvements require an initial investment in systems development, training, physical infrastructure, and other development initiatives, but the potential cost reductions and therapeutic improvements are dramatic. Even small improvements, when made in a number of related areas of

Figure 1-1 Waste in pharmaceutical management and potential for improvement



pharmaceutical management, can yield substantial overall savings.

1.3 Public health objectives and the essential medicines concept

Public health programs are concerned with using available resources to achieve maximum health improvements for the population. The perspective is not that of the individual patient, who may well benefit from a costly medicine, but of the entire community or population, which will benefit most if safe, effective medicines are accessible to all who need them.

Within a decade after the first modern pharmaceuticals became available, efforts began to ensure their widespread availability. From the mid-1950s to the mid-1970s, basic medicine management concepts began to evolve in countries as diverse as Cuba, Norway, Papua New Guinea, Peru, and Sri Lanka. In 1975, WHO defined *essential medicines* as “indispensable and necessary for the health needs of the population. They should be available at all times, in the proper dosage forms, to all segments of society.” In 1978, the International Conference on Primary Health Care at Alma-Ata, Kazakhstan, recognized essential medicines as one of the eight elements of primary health care. (See Chapter 2 for additional historical background.)

The first WHO Model List of Essential Drugs, containing about 200 products and a description of the essential medicines concept, was published in 1977. Since 1977, the WHO model list has been revised every two to three years, and as of 2007, at least 156 countries had adopted essential medicines lists (WHO 2007a).

Consistent with a public health perspective, the essential medicines concept embraces the following guiding principles—

- The vast majority of health problems for most members of the population can be treated with a small, carefully selected number of medicines.
- In practice, most doctors and other health professionals routinely use a small fraction of medicines produced. Training and clinical experience should focus on the proper use of these few medicines.
- Procurement, distribution, and other supply activities can be carried out most economically and most efficiently for a limited list of pharmaceutical products.
- Patients can be better informed about the effective use of medicines when the number of medicines they are confronted with is limited.

Implementation of these principles occurs through the adoption of national medicine policies and through

practical pharmaceutical management initiatives. The major goals of such initiatives are outlined in Box 1-2.

1.4 A paradigm for defining and improving access to medicines

Access to health care, including essential medicines, is a fundamental human right. Realization of this right may involve various combinations of public and private financing and service provision. The public health challenge is to work with the private sector and NGOs to achieve universal access to essential medicines and rational use of medicines. This work involves building mutual understanding, constructive partnerships, and the right incentives.

Access to health care can be defined as a construct that encompasses distinct dimensions, which are distinguished by sets of specific relationships (CPM 2003) (Figure 1-2). Four dimensions of access have particular relevance to essential medicines, vaccines, and other health commodities—

- *Availability*, defined by the relationship between the type and quantity of product or service needed, and the type and quantity of product or service provided
- *Affordability*, defined by the relationship between prices of the products or services and the user's ability to pay for them
- *Accessibility*, defined by the relationship between the location of the product or service and the location of the eventual user of the product or service
- *Acceptability* (or satisfaction), defined by the relationship between the user's attitudes and expectations

about the products and services and the actual characteristics of products and services

In addition, a cross-cutting characteristic of access is—

- *Quality of products and services*, an essential component of access cutting across all the dimensions, but which specifically applies to products in terms of their safety, efficacy, and cost-effectiveness

Indicators for measuring these dimensions of access are described in Chapter 36.

The pharmaceutical management framework (Figure 1-3) provides the underpinning for improving access to medicines as described in the paradigm above. Pharmaceutical management involves four basic functions: selection, procurement, distribution, and use. Selection involves reviewing the prevalent health problems, identifying treatments of choice, choosing individual medicines and dosage forms, and deciding which medicines will be available at each level of a health care system. Procurement includes quantifying medicine requirements, selecting procurement methods, managing tenders, establishing contract terms, assuring pharmaceutical quality, and ensuring adherence to contract terms. Distribution encompasses clearing customs, stock control, stores management, and delivery to drug depots and health facilities. Use comprises diagnosing, prescribing, dispensing, and proper consumption by the patient.

In the pharmaceutical management framework (Figure 1-3), each major function builds on the previous function and leads logically to the next. Selection should be based on actual experience with health needs and medicine use, procurement requirements follow from selection decisions, and so forth. A breakdown in one part of the framework leads to

Box 1-2

Goals for national medicine policies and pharmaceutical management initiatives

Health-related goals

- Make essential medicines physically available and geographically accessible to the entire population.
- Ensure the safety, efficacy, and quality of medicines manufactured and distributed in the country.
- Increase attendance at health facilities by increasing the credibility and acceptance of the health system.
- Promote rational prescription, dispensing, and patient use of medicines.

Economic goals

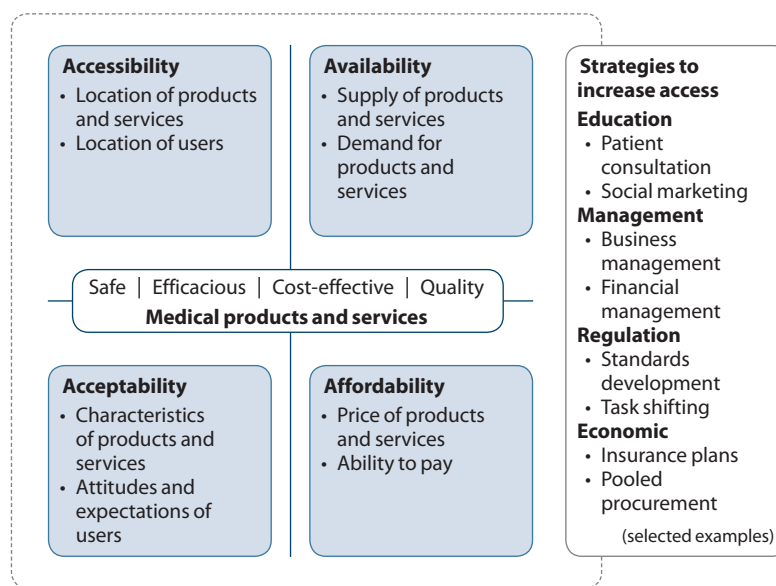
- Lower the cost of medicines to the government, other health care providers, and the public.

- Reduce foreign exchange expenditures for pharmaceuticals without reducing the supply.
- Attain sustainable financing through equitable funding mechanisms such as government revenues or social health insurance.
- Provide jobs in pharmaceutical supply and possibly production.

National development goals

- Increase skills of personnel in management, pharmacy, and medicine.
- Improve internal communication systems.
- Create reliable supply systems that incorporate a mix of public and private supply services.

Figure 1-2 Increasing access framework



Source: CPM/MSH 2011.

failure of the whole pharmaceutical management process. Costs rise, shortages become common, and patients suffer when the separate tasks are performed not as part of a system but independently and disjointedly.

At the center of the pharmaceutical management framework is a core of management support systems: organization, financing and sustainability, information management, and human resources management. These management support systems hold the pharmaceutical management framework together. Although individual parts of the framework may function independently for a short time, the framework as a whole will soon cease to operate, and patient care will suffer without a functional organizational structure, adequate financing, reliable information management, and motivated staff.

Finally, the entire framework relies on policies, laws, and regulations, which when supported by good governance, establish and support the public commitment to essential medicine supply.

1.5 Lessons learned in pharmaceutical management

Since the 1980s, countries have acquired considerable experience in managing pharmaceutical supply. Although many important lessons have emerged from this experience, five broad themes capture the most important insights—

- National medicine policy (NMP) provides a sound foundation for managing pharmaceutical supply.

- Wise medicine selection underlies all other improvements.
- Effective management and good governance save money and improve performance.
- Rational medicine use requires more than just the dissemination of medicine information.
- Systematic assessment and monitoring are essential.

These five broad areas contain many specific lessons, some of which follow and most of which are covered in detail in the rest of the manual.

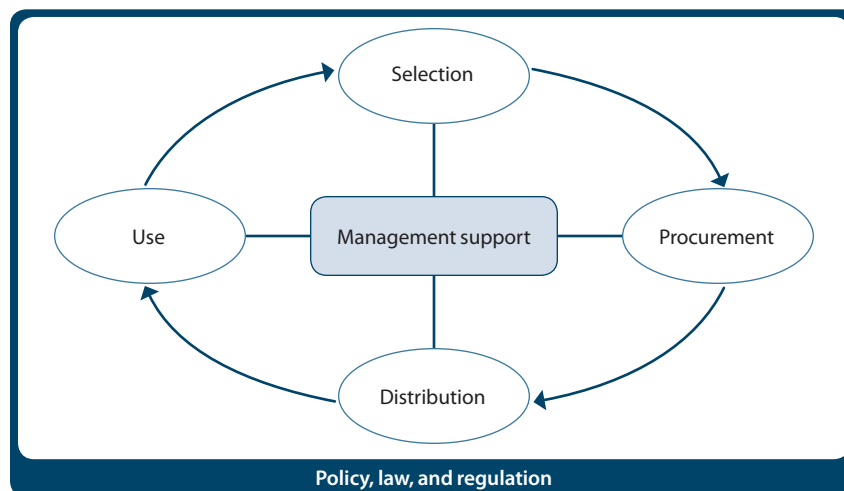
National medicine policy provides a sound foundation for managing pharmaceutical supply

A national medicine policy is a guide for action; it is generally a document containing the goals set by the government for the pharmaceutical sector and the main strategies for reaching those goals. It provides a framework to coordinate activities by the various actors in the pharmaceutical sector: the public sector, NGOs, the private sector, donors, and other interested parties (see Chapter 4).

The NMP concept began receiving support during the 1980s, when piecemeal approaches to policy were leaving important problems unsolved. A focused NMP, suited to the needs of the particular country and with clear priorities, was found to significantly affect the availability and use of pharmaceuticals in such countries as Australia, Bangladesh, Colombia, and the Philippines.

Comprehensive, officially adopted policies can focus efforts to improve access to medicines, medicine use, and

Figure 1-3 Pharmaceutical management framework



Source: CPM/MSH 2011.

medicine quality. Sometimes, however, the policy formulation process engenders such strong opposition that all energy becomes focused on the policy, effectively stalling other useful but less controversial efforts to improve the availability and use of medicines.

Formal NMPs provide a sound foundation for managing essential medicines programs. Of equal or greater importance, however, is the underlying strategic planning process: What are the long-term goals for the pharmaceutical sector? What strategies should be involved? How can key stakeholders be engaged in the process? The experiences of the last three decades suggest that governments and programs with clear objectives and strategies can make progress in the pharmaceutical sector.

Wise medicine selection underlies all other improvements

Establishing and using a limited list of carefully selected essential medicines is perhaps the single most cost-effective action that any health care system or health care provider can take to promote regular supply and rational use of medicines (Chapter 16).

As mentioned, more than 150 countries reported having adopted national essential medicines lists (WHO 2007a). In contrast, in the mid-1970s, few countries had selective medicine lists organized by generic name. Many of the national formularies that did exist were unselective and often contained more than one thousand products. Ministry of health procurement lists were commonly dominated by brand-name medicines.

Studies of the economic effect of essential medicines lists and formulary lists demonstrate that considerable savings can be achieved, primarily through careful choices for those few high-unit-cost and high-volume items that consume

the major share of the pharmaceutical budget. Chapter 40 describes how to analyze medicine expenditures.

An essential medicines list or formulary list that identifies medicines by level of care becomes the basis for training in therapeutics; for estimating pharmaceutical requirements; for competitive procurement by generic name; for planning distribution to health facilities; and for efforts to promote rational, cost-effective medicine use. The national essential medicines list or formulary list can also guide public education efforts, local production, and private-sector medicine management. The list, based on WHO criteria, should be updated regularly (usually every two to three years), divided by level of care, and accompanied by a clear policy on its application for procurement, distribution, and use of medicines (see Chapter 17).

Changing national policies to add or substitute a new treatment or diagnostic tool is a complex decision for a country's ministry of health. Major policy changes, such as switching to artemisinin-based combination therapy (ACT) for malaria, require intensive preparation and planning that involve multiple national and international stakeholders. For example, fluctuations in the demand for ACTs as countries changed their first-line treatment policies, then a delay in implementation, resulted in a global shortage of medicine that could have been allayed with better planning and communication.

Effective management and good governance save money and improve performance

Effective management and good governance make a vital difference in all aspects of pharmaceutical supply, especially with respect to the procurement and distribution of essential medicines. The basic principles of efficient procurement and distribution have been known for several decades, but

the view of the public sector as the lead player in a country's pharmaceutical supply has evolved. Countries are increasingly adopting the concept of multisector collaboration among public, NGO, and private entities to improve efficiencies in supplying pharmaceuticals.

Examples of the positive consequences of good management at the national level include savings in pharmaceutical costs through competitive procurement in El Salvador, Ghana, and the eastern Caribbean; improved medicine availability as a result of better quantification in Namibia and Kenya; and more reliable delivery as a result of redesigned distribution systems in South Africa.

Good pharmaceutical procurement practices include restriction of purchases to the essential medicines list (national formulary list), determination of order quantities based on reliable needs estimation, competitive tendering from qualified suppliers, separation of key functions, prompt payment, regular audits, and a formal system of supplier qualification and monitoring (Chapter 18). WHO has developed an assessment to measure transparency and governance in a country's pharmaceutical sector, including procurement procedures; for example, an assessment showed that four Southeast Asian countries all used an objective quantification method and that the post-tender system to monitor and report suppliers' performance was effective. However, WHO recommended that the appeals process for rejected tender applicants be instigated or strengthened, and noted that the procurement auditing process was weak (WHO 2006a).

Effective distribution management comes from—

- Defining appropriate roles in the distribution system for the public and private sectors
- Designing an efficient network of storage facilities with the fewest number of levels appropriate to the country's geography
- Selecting the appropriate strategy for delivery
- Keeping reliable records of medicine stocks and consumption
- Allocating supplies based on actual workload and treatment needs
- Maintaining accountability procedures and secure storage at each level of the system
- Constructing or renovating facilities appropriate for storing medicines
- Managing storage facilities to maintain pharmaceutical quality and efficiently serve health units
- Making reliable transport arrangements
- Reinforcing reporting and supervision arrangements

As mentioned, the most efficient system may result from collaboration among the public, private, and NGO sectors. Kit system distribution has both benefits and costs; it should be used only when necessary to ensure that supplies reach

lower levels of the system. Chapter 26 describes how kit systems are used to distribute pharmaceuticals.

Rational medicine use requires more than medicine information

Although 50 percent or more of pharmaceutical expenditures may be wasted through irrational prescribing, dispensing, and patient use of medicines, many methods for promoting rational medicine use have never been scientifically evaluated (Le Grand, Hogerzeil, and Haaijer-Ruskamp 1999). Among those methods that have been properly studied, not many have had much measurable effect on medicine use when implemented individually (Arnold and Straus 2005).

The actual use of pharmaceuticals is influenced by a wide range of factors, including pharmaceutical availability, provider experience, economic influences, cultural factors, community belief systems and patient attitudes, and the complex interactions among these factors. Medicine use patterns reflect human behavior and must be viewed from a social-science perspective rather than a biomedical perspective.

Pharmaceutical companies succeed in changing the habits of doctors and patients because they understand what influences these habits. Interventions to promote rational medicine use often fail because they are based on the notion that simply improving knowledge will improve medicine use. Examples of interventions that are likely to fail include dull medicine bulletins that drily present “the facts,” standard treatment manuals distributed to health staff without an active orientation, withdrawal of dangerous or ineffective products with no advice for prescribers on substitutions, and campaigns to discourage injection use that do not address the reasons why many patients prefer injections.

Fortunately, we have learned much in recent years about principles for promoting rational medicine use. These principles involve informed, focused, active, and engaging approaches for changing medicine-use practices by prescribers, dispensers, and patients (Laing, Hogerzeil, and Ross-Degnan 2001). Box 1-3 lists WHO's recommended interventions to promote the rational use of medicines.

Systematic assessment and monitoring are essential

One of the most basic, yet most significant, advances in pharmaceutical management has been the introduction of objective standard indicators for assessing, comparing, and monitoring medicine policies and management effectiveness. Since their introduction in the early 1990s, medicine-use indicators have been developed to assess virtually all key aspects of pharmaceutical management and NMPs. Examples of standard indicators include the percentage of government pharmaceutical purchases conforming to the national essential medicines list, the ratio of local

Box 1-3**Recommended interventions to promote the rational use of medicines**

- Establishing a mandated multidisciplinary national body to coordinate policies on medicine use and monitor their impact
- Formulating and using evidence-based clinical guidelines for training, supervision, and supporting critical decision making about medicines
- Selecting on the basis of “treatments of choice” lists of essential medicines that are used in drug procurement and insurance reimbursement
- Setting up drug and therapeutics committees in districts and hospitals and giving them the authority to improve the use of medicines
- Promoting problem-based training in pharmacotherapy in undergraduate curricula
- Making continuing in-service medical education a requirement of licensure
- Promoting systems of supervision, audit, and feedback in institutional settings
- Providing independent information (including comparative data) about medicines
- Promoting public education about medicines
- Eliminating perverse financial incentives that lead to irrational prescribing
- Drawing up and enforcing appropriate regulation, including that of promotional activities for medicines
- Reserving sufficient governmental expenditure to ensure equitable availability of medicines and health personnel

Source: WHO 2006c.

pharmaceutical prices to world market prices, the number of medicines per patient prescription, and the percentage of key medicines available at health facilities (see, for example, MSH/RPM 1995; CPM 2003; WHO 2007b).

Measured at one point in time, such indicators allow a program to compare itself to a target level of performance, to identify areas of relative strength and weakness, and to make comparisons with other programs for which data are available. Measured over time, such indicators can be used to set and monitor performance targets for pharmaceutical sector improvements.

Systematic assessment and monitoring based on standard indicators are a routine part of planning, program management, and donor evaluation in the field of essential medicines and pharmaceutical management. For example, the Global Fund to Fight AIDS, Tuberculosis and Malaria requires that grantees meet targets on certain indicators to receive additional funds. Each country and program needs to select, develop, and adapt indicators to suit local circumstances and needs, but the basic concept of objective indicators should be incorporated into any essential medicines program (see Chapter 48).

1.6 Challenges for pharmaceutical management

Major challenges for policy makers and managers include achieving financial sustainability; improving efficiency in public pharmaceutical supply; changing the perceptions and behaviors of providers, patients, and the public; reorienting the role of government and the private sector to improve

access to medicines; and regulating safety, efficacy, and quality, which may be the biggest challenge of all.

Achieving financial sustainability

Financial sustainability is achieved only when expenditures and financial resources balance and are sufficient to support a given level of demand. If demand for medicines exceeds the available resources, the health system is left with only four options: improve efficiency, increase financial resources, reduce demand, or accept a decline in quality of care. When the components of financial sustainability are not in balance, it simply defies economic reality to promise constant availability of high-quality essential medicines without improving efficiency, increasing financing, or limiting demand.

Efficiency means getting the most benefit from available resources. Much of this manual is devoted to improving therapeutic efficiency through better selection and use of medicines and improving operational efficiency through better organization, procurement, and distribution of medicines.

To achieve financial sustainability, policy makers and managers of essential medicines programs must become familiar with economic concepts and methods related to cost containment, efficiency, cost-effectiveness analysis, public expenditure decisions, the roles of the public and private sectors, and the economics of regulation. High-income countries increasingly rely on economic methods and perspectives. Countries with more limited resources must also make maximum use of the insights offered by the field of pharmaco-economics.

Health-sector reform is concerned with improving efficiency through changes in the organization and allocation of health care resources. It is also concerned with health care financing.

People pay for health care in different ways: collectively, through national health insurance or through the taxes they pay on goods, services, or income; in groups, through premiums paid for voluntary health insurance; or individually, through user fees at government facilities or private out-of-pocket health expenditures. In most countries, the primary burden for health financing falls directly or indirectly on the people of the country; the proportion of health care that is paid out of pocket actually increases in many low-income countries, where more than 60 percent of the total health spending comes from out of pocket (Gottret and Schieber 2006).

Local funding for recurrent health expenditures is often supplemented by external development assistance. In fact, the poorest countries may find it impossible to provide certain basic health services, including essential medicines, without some external assistance. External funding is a growing source of financing in low-income countries, especially in sub-Saharan Africa and South Asia. Although health aid increased from USD 2.6 billion in 1990 to USD 10 billion in 2003, experts are calling for increases in external assistance ranging from USD 25 billion to 70 billion a year to reach the UN Millennium Development Goals and other, disease-specific treatment goals (Gottret and Schieber 2006). For example, the U.S. Institute of Medicine estimated that instituting ACT for malaria worldwide would require USD 300 million to 500 million each year (Committee on the Economics of Antimalarial Drugs 2004), which would clearly be impossible for developing countries to cover with local funds.

Public financing provides an essential foundation for a country's health system and, in particular, for health promotion and preventive services. But providing free medicines through public resources has proved unsustainable in many developing as well as developed countries. Government budgets are squeezed, and donor funds are directed to a variety of other worthy causes. The policy of free medicines is often, in practice, a policy of shortages. Although global initiatives to provide ARVs to people in developing countries have brought free HIV/AIDS treatment to many, the sustainability of this arrangement is unknown. Most agree that, even with the introduction of lower-priced ARVs, HIV/AIDS treatment in developing countries will continue only as long as external funding continues.

Full or partial cost recovery through user fees is one way to supplement public financing. Revolving pharmaceutical funds and community medicine schemes linked to strengthening primary health care have been tried in countries in Africa, Asia, and Latin America. Some programs have led to a serious decline in utilization, with no visible improvement

in pharmaceutical availability. Yet some user-fee programs increased both equity of access and quality. Some global development organizations have called for the abolition of user fees as a barrier to access to poor people (UNMP 2005), but others point out that if the removal of user fees is not compensated for by other funding, patients may be forced to spend more on medicines or health care services in the private sector (Gottret and Schieber 2006).

Social health insurance (compulsory health insurance or social security), private health insurance, and community health insurance schemes finance pharmaceutical supply for a small but growing portion of the population in developing countries. People in most high-income countries are already covered by some form of public or private health insurance; however, the median coverage is only 35 percent in Latin America, 10 percent in Asia, and 8 percent in Africa (WHO 2004a). Health insurance coverage that includes pharmaceuticals has expanded access to medicines in many countries, including Argentina, China, Egypt, South Africa, and Vietnam (WHO 2004b). WHO has committed to promoting the provision of medicines benefits through social health insurance and prepayment schemes (WHO 2004b). Chapter 12 discusses health financing through insurance in detail.

In the face of changing epidemiologic patterns, increasing demand for modern health care, and growing populations, the challenge for countries is to implement those pharmaceutical financing strategies that best ensure equity of access and a continuous supply of medicines. For many countries, reaching this goal means taking a pluralistic approach—one that uses different ways to serve different needs and different groups and that combines the benefits of public financing, health insurance, voluntary financing mechanisms, and donor support.

Improving governance and efficiency in public pharmaceutical supply

Aside from the problem of financing, public-sector pharmaceutical supply in many countries continues to be plagued by ineffective management systems. They often lack sufficient qualified human resources and are characterized by systems that are not transparent and do not promote accountability. As such, they become susceptible to political pressures, fraud, and abuse.

In fact, corruption is increasingly recognized as a barrier to social and economic development, and many governments and international development organizations are placing the issue high on development and health agendas. For example, in 2004, WHO launched its program on good governance in pharmaceutical systems (see Box 1-4); the United Nations Convention Against Corruption became effective in 2005; Transparency International's Global Corruption Report for 2006 focused on health systems; and the Medicines Transparency Alliance came together in

2007. Figure 1-4 shows a framework for improving governance and accountability.

The international donor community has recognized and is addressing the need to increase access to lifesaving medicines: new funding sources, such as the U.S. President's Emergency Plan for AIDS Relief, the President's Malaria Initiative, UNITAID, and the Global Fund to Fight AIDS, Tuberculosis and Malaria, are making unprecedented sums of money available to procure medicines for deadly diseases. However, the two greatest threats to successfully increasing access to medicines are weak and vulnerable pharmaceutical supply systems and the worsening human resources crisis. The scope of the challenge to countries in terms of the

drastic effect the new funding is having on pharmaceutical systems is unparalleled.

Sustainability is the extent to which a program will continue to achieve its policy and pharmaceutical supply objectives without additional outside financial or technical support. Key factors for program sustainability, in addition to financing, are motivated, capable staff; effective management systems; and political support. Low pay, inadequate training, lack of incentives, inappropriate recruitment, and ineffective disciplinary measures undermine staff performance, which is already decimated in many countries by the loss of trained human resources from "brain drain" and HIV/AIDS.

Box 1-4 WHO's Good Governance for Medicines program

The pharmaceutical sector is highly vulnerable to corruption and unethical practices, in part because pharmaceuticals have a high market value; regulating and procuring pharmaceuticals is complex; and the sector involves many international, national, and local entities.

Poor governance in the pharmaceutical system can lead to severe health and economic consequences. For example, corruption in the regulatory system can result in approval of medicines that are inappropriate because of safety, efficacy, quality, or price. Similarly, if inspection, postmarketing surveillance, or quality-control systems are corrupt, counterfeit and substandard medicines can easily enter the marketplace, causing harm or even death. Waste associated with corruption can also be a major drain on the public budget and decrease the resources available not only to buy medicines but also to pay health care workers. Corruption affects the public's trust in the government as well as in the whole health profession.

Recognizing how these problems affect the health sector negatively, WHO initiated the Good Governance for Medicines program in late 2004. The program offers a technical-support package for governments to tackle unethical practices in the public pharmaceutical sector. The goal of the program is to curb corruption in pharmaceutical systems by applying transparent and accountable administrative procedures and promoting ethical practices among health professionals.

Tackling corruption in the pharmaceutical sector requires a long-term strategy. WHO has identified a three-step approach—

1. Assess the level of transparency and vulnerability to corruption of key functions in national pharmaceutical regulation and management systems.

2. Use a national consultation process to develop a national program on good governance for medicines that increases transparency and accountability in the pharmaceutical sector and promotes ethical practices.
3. Implement and promote the national good governance for medicines program.

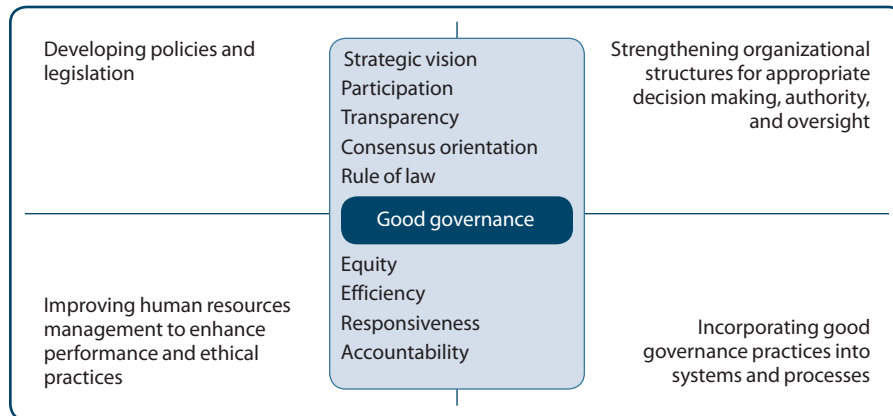
From 2004 to 2007, WHO gradually introduced the project in ten countries: Bolivia, Cambodia, Indonesia, the Lao People's Democratic Republic, Malawi, Malaysia, Mongolia, Papua New Guinea, the Philippines, and Thailand. National assessors used the WHO transparency assessment tool to measure the level of transparency in national medicines regulation and public-sector pharmaceutical procurement systems.

Information collected from the first four countries where the program was introduced—the Lao People's Democratic Republic, Malaysia, the Philippines, and Thailand—revealed that although they have different public-sector procurement and medicines regulation profiles, they have some common strengths and weaknesses. For example, all have publicly available standard operating procedures for procurement, but none requires members of the registration or selection committees to fill out a conflict-of-interest form.

WHO will continue to work with governments and WHO regional offices to select new countries and activities related to the Good Governance initiative.

For additional information, access WHO's Good Governance website at <http://www.who.int/medicines/ggm/en/index.html>.

Figure 1-4 Governance framework



Source: Adapted from United Nations Development Programme (UNDP), *Governance for Sustainable Human Development*, <http://mirror.undp.org/magnet/policy/> (Geneva, 1997).

Growing pressure to scale up access to medicines, combined with the influx of funds mentioned above, is exposing weaknesses in how developing countries procure and distribute pharmaceuticals to their citizens. Examples abound in which the conventional central medical stores (CMS) approach to pharmaceutical procurement and distribution continues to result in chronic medicine shortages—even after considerable investment has been made in training, management systems, and physical infrastructure. Public-sector supply systems in affected countries—primarily in Africa—have to adapt existing systems to manage hugely increased volumes of medicines and commodities. Alternative strategies for public pharmaceutical supply are attracting interest. They include formation of an autonomous supply agency, direct delivery, the primary distributor system, various privatized models, and mixed systems. Successful scaling up will require a dramatic transformation of the systems traditionally used for procurement and supply of medicines. Alternative strategies for public pharmaceutical supply have been implemented with varying degrees of success in countries such as Benin, Botswana, Colombia, Guatemala, South Africa, Tanzania, and Zambia.

With an autonomous supply system, an autonomous or semi-autonomous agency manages bulk procurement, storage, and distribution. With the direct delivery (non-CMS) system, the government tenders to establish prices and suppliers for essential medicines, which are then delivered directly by suppliers to districts and major health facilities. With the primary distributor system (another non-CMS system), the government pharmaceutical procurement office establishes a contract with a single primary distributor as well as separate procurement contracts with pharmaceutical suppliers. The primary distributor is contracted to manage pharmaceutical distribution by receiving medicines

from the suppliers and then storing and distributing them to districts and major facilities. In fully privatized models, public administration of pharmaceutical supply is minimized, with independent pharmacies or other mechanisms providing medicines within or outside government facilities; various financing and reimbursement arrangements can be used. Chapter 8 covers supply strategies in detail.

Selection, procurement, and distribution can each be carried out in centralized, partially decentralized, or fully decentralized systems. Decentralization aims to improve the responsiveness, quality, and efficiency of health services. Improvements are far from certain, however. Problems with attempts to decentralize pharmaceutical management functions have included lack of local management and supervisory capacity, increased costs (caused by loss of savings from bulk purchasing), lack of local staff trained in pharmaceutical management, inadequate financial resources, self-interested interference by local officials, and poor pharmaceutical quality (caused by difficulty in selecting and monitoring suppliers).

For managing pharmaceutical supply, a task-specific approach to decentralization may be useful. Examples of tasks that may be better performed centrally include development of essential medicines lists, preparation of standard treatment guidelines, management of competitive tenders, selection and monitoring of suppliers, quality assurance, and development of training programs in rational medicine use. Tasks that can be decentralized include those that do not require uncommon technical skills. Decentralization is advisable when local information is required, local circumstances are important and variable throughout the country, and local interests favor improved performance. Examples of such tasks include adapting medicine lists or standard treatments to local needs, quantifying medicine requirements, coordinating local distribution, conducting training

Country Study 1-1**Working with the private sector to improve malaria outcomes in Tanzania, Ghana, and Nigeria**

In many African countries, informal medicine sellers are the first point of contact for caregivers seeking treatment for childhood illnesses. These individuals typically have little or no health training and frequently misdiagnose malaria, provide inappropriate treatment, give an incorrect dose, and/or give inaccurate advice. Several programs designed to improve practices among this group for treating childhood illnesses have shown promising results.

Tanzania

Management Sciences for Health's Strategies for Enhancing Access to Medicines (SEAM) Program, in collaboration with the Tanzanian government, created a new category of accredited drug dispensing outlet (ADDO) to improve access to affordable, quality medicines and pharmaceutical services in retail drug outlets in rural or peri-urban areas where there are few or no registered pharmacies. To achieve this goal, the SEAM Program took a holistic approach that combined changing the behavior and expectations of individuals and groups who use, own, regulate, or work in retail drug shops as well as that of community members. Major program activities included changing behavior of dispensing staff through training, education, and supervision; improving awareness of community members regarding quality and the importance of treatment adherence through marketing and public education; and focusing on regulation and inspection and improving local regulatory capacity.

Postintervention assessment results showed that—

- Thirty-two percent of malaria treatment encounters at ADDOs included the sale of an appropriate first-line antimalarial, compared with only 16 percent at baseline. Twenty-four percent of encounters were dispensed exactly according to standard treatment guidelines, compared with 6 percent at baseline.

- The average availability of antimalarials increased from 74 to 90 percent in the ADDO region compared with 71 percent availability in the control region.

After the SEAM Program ended, the government of Tanzania adopted the ADDO program and announced the program's nationwide rollout.

Ghana

The strategy in Ghana involved implementing a franchise system called CAREshops among participating chemical sellers' shops to establish uniform standards, train personnel, monitor adherence to franchise standards, and create business incentives for adherence to those standards. The goal of this initiative was to improve access to reasonably priced, quality-assured essential medicines and health supplies and high-quality dispensing services in underserved rural areas. Other key elements of the franchising program include a ten-week, five-module training program, including appropriate dispensing practices in malaria management, designed and delivered to the selected group of licensed chemical sellers.

Postintervention assessment results showed that—

- At endline, there was an increase from 50 percent to 62 percent in dispensing any antimalarial to simulated malaria clients at CAREshops (compared with a decrease from 58 percent to 55 percent in the control regions).
- However, only 18 percent of CAREshop facilities dispensed the antimalarial exactly according to treatment guidelines at endline, compared with 10 percent and 13 percent of chemical sellers in two control regions. Clearly, additional training, supervision, and monitoring are still necessary.

in rational medicine use, and monitoring medicine use at health facilities.

The effectiveness of the pharmaceutical supply system in achieving a reliable supply of essential medicines must be continually and objectively assessed. Fundamental restructuring of pharmaceutical supply arrangements challenges the status quo and may threaten a variety of interests. But continuing to support an ineffective supply system wastes precious resources and denies patients access to lifesaving essential medicines.

Changing the perceptions and behaviors of providers, patients, and the public

One of the greatest challenges is to change the way in which providers, patients, and the public view and use pharmaceuticals. Major problems, noted earlier, include prescribing and dispensing incorrect, harmful, or unnecessary medicines; failure by patients to use needed medications correctly; and wasteful or harmful self-medication practices.

However, three years after implementation, the franchise organization had not reached the break-even point and continued to lose money, although many shops were independently performing well. Discussions between the original implementing organization and an outside organization to restructure the franchise business plan were unsuccessful, and by the end of 2008, the head of the implementing organization said that the franchise was in serious financial peril.

Nigeria

The Basic Support for Institutionalizing Child Survival (BASICS) Program designed an intervention in Nigeria that combined a short, highly focused training for private-sector patent-medicine vendors with the promotion of age-specific, color-coded, prepackaged antimalarials for children under five. These activities were supported by a comprehensive social marketing and behavior-

change strategy, which included mass media promoting the new prepackaged antimalarials and medicine sellers displaying shop identifiers from the training. More than eight hundred patent-medicine vendors were trained in a two-month period at the relatively low cost of approximately USD 8 each. Training materials focused on immediate treatment of children under five with fever using an appropriate-dose (preferably prepackaged) antimalarial.

Postintervention assessment results showed that—

- The number of patent-medicine vendors giving the correct antimalarial and dose increased from 9 percent to 53 percent.
- Patent-medicine vendor knowledge about the need to use insecticide-treated nets tripled (from 21 percent to 65 percent) between pre- and postintervention surveys.

Sources: Greer et al. 2004; MSH/SEAM 2008a; 2008b

Given the huge share of public and private pharmaceutical expenditures that may be wasted through irrational medicine use, governments, NGOs, and others must continue to explore effective, sustainable ways of improving medicine-use patterns. For example, the International Conferences on Improving the Use of Medicines in 1997 and 2004 brought together leading national and international policy makers, program managers, researchers, clinicians, and other stakeholders to produce state-of-the-art consensus on interventions to improve medicines use in nonindustrialized countries, to define evidence-based recommendations for program implementation, and to generate global research agendas to fill gaps in knowledge (www.icium.org). See also Chapters 29 and 33, which address rational prescribing and use by the public.

Reorienting the role of government

Access to health care, including essential medicines, is a fundamental human right. Realization of this right may involve various combinations of public and private financing and service provision. In high-income countries, public financing of pharmaceuticals predominates. In low- and middle-income countries, the public-private mix varies remarkably, from over 90 percent public provision of medicines in Slovakia and the Solomon Islands to roughly 90 percent private market supply and financing of pharmaceuticals in Cambodia and Georgia (WHO 2004c).

From a public health perspective, therefore, the specific concerns with improving access to medicines in the private pharmaceutical market are improving the availability, geographic accessibility, affordability, and accept-

ability of quality medicines and related services. Measures to improve *availability* include certification and training of pharmacy aides and other drug sellers; focus on efficiency in the supply chain, including the private sector; licensing and incentives for wholesalers, pharmacies, and other drug outlets; and community-based medicine schemes. Innovative franchising and accreditation initiatives have been used successfully to increase the quality of medicines and pharmaceutical services from retail drug sellers, which are often more *geographically accessible* and therefore people's first source of health care (Country Study 1-1). *Affordability* can be improved with greater insurance coverage, better price information, competitive procurement and price competition through generic substitution, regulation of producer and resale prices, and modification of retail sales margins. *Acceptability* can be promoted by regulating medicine information and marketing; including essential medicines concepts in basic medical education; providing focused continuing education for health professionals; and actively educating the public and patients. Finally, *quality* of services is increased by enforcing licensing requirements for doctors, pharmacists, and other health professionals, and *quality* of products is improved by putting into place good procurement practices, such as using prequalified suppliers, and an effective regulatory system that includes monitoring, testing, and enforcement (Chapter 6).

The public health challenge is to work with the private sector and NGOs to achieve universal access to essential medicines and rational use of medicines. This work involves building mutual understanding, constructive partnerships, and the right incentives.

Regulating safety, efficacy, and quality

Regulatory control, often neglected in the pharmaceutical sector of developing countries, is an indispensable foundation for ensuring the safety, efficacy, and quality of pharmaceuticals in a country. Governments must ensure that all pharmaceuticals available on the local market meet basic standards. Moreover, the same quality standards applied to the open market must be applied to medicines procured through the public sector. Pharmaceutical legislation and regulation should also establish basic professional standards in both the public and the private sectors.

In industrialized countries, regulatory capacity has developed in phases over many decades. Most developing countries also will require time to develop effective regulatory capacity. Such capacity requires a firm legislative basis, trained personnel, specific technical resources, adequate funding, and—perhaps most important—public commitment to establishing and enforcing basic standards (Chapter 6).

1.7 Managing pharmaceutical sector improvements

This manual is meant to provide policy makers and managers with practical, accessible advice on a wide range of topics relevant to managing pharmaceutical supply. The basic functions of management are planning, implementation, and monitoring. Effective planning requires thoughtful reflection on basic goals, systematic assessment of the current situation, identification of root causes of problems, creative consideration of all reasonable strategies for improvement, and selection of strategies based on defined criteria.

Program implementation is an interactive process that involves organizing people, finances, and other resources to achieve the desired results. The test of any policy or plan is in its implementation. Gradual phasing-in of new initiatives can help build management systems, which can then support full-scale implementation. Active decision making and problem solving are fundamental to the implementation process.

Finally, ongoing monitoring and periodic evaluation are needed to measure progress, to adjust implementation plans, and to assess the effect of pharmaceutical management improvements. Objective indicators and specific program targets provide concrete measures against which actual performance can be compared. Without such indicators, judging the success and, therefore, the value of human and financial investments in pharmaceutical sector improvements is difficult.

The experiences of countless countries and programs demonstrate that substantive, sustainable improvements in the supply and use of medicines are possible. But an equal

or greater number of negative experiences demonstrate that success is by no means assured. Clear goals, sound plans, effective implementation, and systematic monitoring of performance are essential ingredients in pharmaceutical sector development. ■

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