Part II: Pharmaceutical management

Part I: Policy and economic issues

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SUMMARY

The basic goals of national medicine policies and publicsector pharmaceutical supply systems are to provide access to needed medicines and supplies, promote the rational use of medicines, and ensure the quality, safety, and efficacy of medicines. Various strategies exist to achieve these goals through different combinations of public and private involvement in the pharmaceutical management cycle. National systems vary with respect to public and private roles in financing, distribution, and dispensing of pharmaceuticals, ranging from fully public to fully private systems.

At least five alternatives have traditionally existed for supplying medicines and supplies to governmental and nongovernmental health services—

- *Central medical stores (CMS):* Traditional publicsector pharmaceutical supply system, in which medicines are procured and distributed by a centralized government unit.
- Autonomous supply agency: An alternative to the CMS system, managed by an autonomous or semiautonomous pharmaceutical supply agency.
- *Direct delivery system:* A decentralized, non-CMS approach in which medicines are delivered directly by suppliers to districts and major facilities. The government pharmaceutical procurement office selects the supplier and establishes the price for each item, but the government does not store and distribute medicines.
- *Primary distributor (or prime vendor) system:* Another non-CMS system in which the government pharmaceutical procurement office establishes a contract with one or more primary distributors as well as separate contracts with pharmaceutical suppliers. The contracted primary distributor receives medicines from the suppliers and then stores and distributes them to districts and major facilities.
- *Primarily private supply*: An approach used in some countries that allows private pharmacies in or near government health facilities to provide medicines for public-sector patients. With such an approach, measures are required to ensure equity of access for the poor, medically needy, and other target populations.

These systems vary considerably with respect to the role of the government, the role of the private sector, and incentives for efficiency. Mixed systems in which different categories of pharmaceuticals are supplied through different mechanisms are frequently seen, and countries that take advantage of the capacities in both the public and private sectors usually have systems that are more effective; they also tend to be more resistant to shock from disaster events.

In many countries, missions, charities, and other not-forprofit, nongovernmental organizations (NGOs) provide an important share of health care. NGOs in some countries have established not-for-profit essential medicines supply agencies to provide high-quality, low-cost pharmaceuticals for their health facilities. Some of these have been very successful, but the model has not worked in all countries.

In most countries, the commercial sector is able to provide a range of services that can enhance public access to essential medicines. In general, this sector would potentially respond well to new opportunities for providing supply services; however, the private commercial sector is not always sufficiently well developed or motivated to provide critical supply services to the public sector and should not be seen as a cure-all remedy for solving problems with existing systems.

The commercial sector also plays a vital role in providing access to many people, especially in rural and underserved urban areas where retail drug outlets are the first stop to treat common illnesses. Because these outlets operate in a relatively uncontrolled environment, improving and monitoring the quality of products and services is challenging, and drug sellers generally lack qualifications or training in pharmaceutical management. Much work remains to be done to solve these problems, although strategies that engage the interests of shop owners, dispensers, the government, and the public have recently been developed and tested with some success. Chapter 32 covers drug seller initiatives.

In many countries—especially in countries that have been rolling out large-scale HIV/AIDS programs—the relative roles of the public and private sectors in pharmaceutical supply management are undergoing change in both the pharmaceutical sector and the overall health sector. Changes in public and private roles need to be designed to account for the planned magnitude of scaleup and to promote accessibility to medicines and rational medicine use.

Perspectives on the role of government in health care vary from a solidarity, or social welfare, approach (which holds that the state should provide all health and other social services except when it is unable to do so) to a selfhelp, or market-economy, approach (which holds that the private market should provide most health services). This chapter does not argue for or against either approach but advocates that, for most countries, the best strategy is a balanced approach drawing on the strengths and capabilities of both public and private sectors.

This chapter provides an overview of systems and strategies for organizing pharmaceutical supply for public health services and issues related to health-sector reform, including the decentralization of pharmaceutical management functions. Issues and options related to meeting public health needs through the private pharmaceutical sector are also considered, including the potential contribution of private nonprofit essential medicines services. In the context of rapidly growing programs to treat critical diseases, such as HIV/AIDS, the chapter outlines approaches for addressing supply problems. Finally, the chapter summarizes different government roles, including periods of transition from one model of service delivery to another.

8.1 Systems for pharmaceutical financing and distribution

Approaches to pharmaceutical supply can be described in terms of public and private roles in financing, wholesale distribution, and retail distribution. The six main approaches range from fully public to fully private, as summarized in Table 8-1.

- 1. *Fully public:* The classic public system follows a CMS approach, in which a centralized government unit finances, procures, and distributes medicines. The state is the owner, funder, and manager of the entire supply system. Many countries in Africa, Asia, Europe, and Latin America have made this their standard strategy.
- 2. *Private supply to government health services:* Through direct delivery or prime distributor contracts (described later in this chapter), private channels are used to provide publicly funded medicines to government-operated health facilities. Although most common in North America, where it is known as a prime vendor system, this approach can also be found in Africa, Asia, and Latin America.
- 3. *Social health insurance systems:* Public funding from central budgets and social health insurance premi-

ums can be used to reimburse pharmacies or patients themselves for medicines that are provided through private pharmacies. Australia, many countries in Western Europe, and North America have followed this approach in recent years.

- 4. Private financing and public supply: Government medical stores or state-owned wholesalers may supply medicines that are dispensed by government health facilities but paid for (in whole or in part) by patient fees. Many former socialist economies followed this approach. In the 1990s, it was being used by China and by government health services in Asia, Africa, and Latin America that implemented user fees for pharmaceuticals but continued to operate government medical stores. China specifically has shifted its health financing scheme from a socialized system to a marketoriented one. Some countries, such as Uganda, have eliminated user fees and increased public spending, whereas others are working toward instituting social health insurance systems in place of user fees (WHO 2003; WHO/WPRO n.d.).
- 5. *State wholesale monopoly:* At least through the 1980s, in parts of Europe and Africa, pharmaceuticals were imported and distributed by a state monopoly that supplied private pharmacies as well as government

	Distribution		
Financing	Wholesale	Retail	
Public			
Fully public	Public	Public	
Private supply to government health services	Private		
Social health insurance systems	Private	Private	
Private			
Private financing and public supply	Public	Public	
State wholesale monopoly	Public	Private	
Fully private	Private	Private	

Table 8-1 Systems for financing and distributing medicines



Figure 8–1 Supply chain management framework

health services in some cases. Although this model has historical significance, it is rarely seen now.

6. *Fully private*: Patients pay the entire cost of medicines and purchase them from private retail pharmacies and drug sellers, which now exist in nearly every country in the world and account in some cases for a large percentage of pharmaceutical distribution. Outside the market economies that have high levels of social and private health insurance, this approach is also the major source of prescription medicines in many countries, including many of those that nominally provide free pharmaceutical services.

The context of financing public health in resource-limited countries has changed because of global funding initiatives to combat specific diseases—primarily HIV/AIDS and malaria. The Global Fund to Fight AIDS, Tuberculosis and Malaria; the Global Drug Facility; the U.S. President's Emergency Plan for AIDS Relief; and others are dramatically changing the public health financing paradigm for these programs, with a particular emphasis on pharmaceuticals. More information on these donor initiatives can be found in Chapters 2 and 14.

Public financing includes government budgets (central, regional, and local) and compulsory social health insurance programs. Private financing includes out-of-pocket payments by individuals and households, private health insurance, community medicine schemes, cooperatives, employers, and financing through other nongovernmental entities. Chapter 11 includes more information on financing, and Chapter 12 covers pharmaceutical benefits in insurance.

Public distribution includes wholesale distribution and retail dispensing by government-managed pharmaceutical supply and health services as well as distribution through state-owned enterprises (state corporations). Private distribution includes private for-profit wholesalers, retailers, and nonprofit essential medicines supply services. Figure 8–1 illustrates a pharmaceutical supply chain framework featuring the public and private sectors and possible partners.



8.2 Perspectives on the role of the state in health care

Different perspectives on the role of the state in providing health care result in differences in assigning the responsibility for pharmaceutical supply. The debate over the proper role of government is as old as government itself. This debate has been heightened, on the one hand, by the failure of centrally planned economies to ensure economic security for their populations and, on the other hand, by the inability of some market economies to ensure access to basic social services such as health care. Two views of the role of government can be identified—

- *Social welfare perspective:* the government should provide all health and other social services, except in specific instances when it is unable to do so.
- *Market economy perspective:* the private market should be left to provide all health and other social services, except when the private market fails to do so and the state can be expected to achieve better outcomes.

Such totally divergent views may exist in theory, but in practice, neither approach sufficiently provides adequate access to health services for all population groups. Increasingly, countries recognize that they must strike a balance between public and private control to create the most efficient service delivery system, and each country's context for making these decisions differs.

Governments everywhere, regardless of level of economic development, are subject to a common set of constraints. These include—

- Inefficiency in service delivery, which may result from lack of individual incentives for good performance, bureaucratic inflexibility, and overemployment
- Interest-group pressures from political supporters, business partners, members of one's local community, or concerned parties, which may lead to inefficient or inequitable use of public resources

• Lack of good governance, which may manifest itself in self-interested manipulation of the medicine selection process, corruption in the award of tenders, nepotism in the appointment of key staff, or theft of pharmaceutical products by health staff

Although government effectiveness has its limits, leaving the supply of pharmaceuticals entirely to the market economy may also fail to achieve public health objectives. Issues that must be considered include—

Equity: Because of the relatively high cost of medicines compared with incomes, without government involvement, the poor and medically needy may be denied access to necessary and often lifesaving medicines.

- *Information failure:* Patients and some health professionals do not have full information about the quality, safety, efficacy, value for money, and appropriateness of individual medications.
- *Competition failure:* Patents and brand names may establish a virtual monopoly for some products, and cumbersome or obstructive registration procedures, combined with the high initial investment required to build manufacturing facilities and develop new medicines, may limit the number of new competitors.
- *Externalities:* Health services such as vaccination and treatment of contagious tuberculosis or sexually transmitted infections benefit people besides those who receive the services.

Chapter 10 has more information on pharmacoeconomic issues.

The remaining sections of this chapter discuss major areas of public involvement in pharmaceutical supply: organizing pharmaceutical supply for government and NGO health services, decentralization and pharmaceutical management, and use of private channels to meet needs for essential medicines and health commodities.

Government action in each of these areas should be informed by a realistic assessment of the appropriate role

Table 8-2 Comparison of basic pharmaceutical supply systems

Responsibilities		S			
Model	Contracting suppliers	Storage and delivery	Monitoring medicine quality	Advantages	Disadvantages
Central medical stores Conventional supply system; medicines procured and distributed by centralized government unit	CMS	CMS	CMS, DRA	 Maintains government control over entire system Is easy to monitor 	 High capital cost for offices, storage, and transport facilities Recurrent cost of staff, transport, other operating costs Limited incentive for efficiency Open to political and other interference
Autonomous supply agency Bulk procurement, storage, and distribution managed by autonomous or semi-autonomous agency	Autonomous agency	Autonomous agency	PPO and autonomous agency, DRA	 Maintains advantages of centralized system Flexibility in personnel and management systems may improve efficiency Is less open to interference Separate finances facilitate revolving drug funds 	 Cost and effort of establishing supply agency May retain some constraints of CMS Limited competitive pressure for efficiency if operated as monopoly
Direct delivery system Decentralized approach; tenders establish the supplier and price for each item; medicines delivered directly by supplier to districts and major facilities	ΡΡΟ	Suppliers	PPO, DRA	 Eliminates cost of government-operated storage and distribution Decentralized order quantities and delivery help adjust to variations in seasonal and local demand Maintains price benefits of centralized tendering Reduces inventory costs and expiration for high-cost, low-volume medicines 	 Coordination and monitoring of deliveries, payments, and quality are demanding Feasible only where adequate private infrastructure exists Suppliers limited to those able to ensure local distribution (may reduce competition, increase cost) Direct delivery by multiple suppliers (especially to remote areas) is inefficient, may raise costs
Primary distributor system PPO establishes contracts with pharmaceutical suppliers and separate contract with a single primary distributor, which warehouses and distributes medicines to districts and major facilities	PPO	Primary distributor	PPO and primary distributor	 Maintains advantages of single distribution system Potential primary distributors compete on service level and cost 	 Monitoring of service level and pharmaceutical quality is demanding Competition depends on well-developed private distribution system
Primarily private supply Private sector manages all aspects of pharmaceutical supply	Procurement and distribution by private enterprises	Procurement and distribution by private enterprises	DRA	Least demanding and least costly for the government	 Does not ensure equity of access for poor, medically needy, or other target groups Medicine quality is more difficult to monitor

CMS = central medical stores; DRA = national drug regulatory authority; PPO = pharmaceutical procurement office (ministry of health or other government office).

of the state, given the country's circumstances. Whatever a society's expectations or a government's promises, constraints exist to government involvement, and dangers arise in an unregulated market approach to pharmaceutical supply. Government supervision of the private pharmaceutical market involves complex and often contentious issues. Public health objectives may conflict with short-term commercial interests. Ideological or political considerations not directly related to either public health or commercial perspectives may further cloud discussions.

8.3 Basic pharmaceutical supply systems

Of all the decisions policy makers and managers face, the most complex and costly often concern the financing and supply of medicines for government health services. In some countries, public-sector pharmaceutical supply is well financed and administratively efficient. In other countries, the pharmaceutical supply system is unreliable and shortages are common; such systems suffer from inadequate funding, outdated procedures, interference of various sorts, and a variety of other problems.

The pharmaceutical management framework—including all aspects of procurement and distribution—is the subject of Part II of this book. Before confronting the particulars of the pharmaceutical management framework, however, the basic structure of the supply system must be established, and pharmaceutical and supply chain management practices should be applied to achieve maximum efficiency.

Although many variations exist, five basic approaches are used for organizing pharmaceutical supply for public health services (see Table 8-2)—

- Central medical stores
- Autonomous supply agency
- Direct delivery system
- Primary distributor system (also known as prime vendor system)
- Primarily private system

A mixed system is frequently seen in practice, where different approaches are used for different levels of health facilities or different categories of products. Sometimes, separate supply systems for disease-specific programs operate parallel to the primary supply system; these *vertical supply systems* are discussed in Section 8.6.

This discussion speaks primarily from a government perspective. However, the mechanisms described here are equally relevant to faith-based and other nonprofit health services, private hospital purchasing groups, for-profit health systems, and other institutional health services. This is particularly true for the autonomous agency, direct delivery, and primary distributor approaches.

Central medical stores

The traditional approach to public-sector pharmaceutical supply is the CMS, in which medicines are financed, procured, and distributed by the government, which is the owner, funder, and manager of the entire supply system. The government handles selection, procurement, and distribution—usually through a unit within the ministry of health. Financing is usually from central treasury allocations and donors, although this model can be adapted to a revolving drug fund (see Chapter 13). In countries that have decentralized budgeting and procurement, lower-level units, such as districts, may have the authority to purchase directly from the CMS.

With the CMS approach, problems with financial management, quantification of requirements, management of tenders, warehouse management, transport, and security of pharmaceuticals are common. These problems often arise from political or administrative interference; civil service constraints on discipline or dismissal of poorly performing or dishonest staff; overall inadequacy of financial resources; procurement constraints arising from the treasury payment cycle, erratic release of ministry of health funds, or slow payment from districts; and transport difficulties resulting from the need to maintain a large vehicle fleet. In Malawi, for example, regulations force the CMS to continue shipping medicines to districts that have not paid, which provides a disincentive for districts and creates decapitalization in the CMS.

One way to address some of these constraints is to contract out (or outsource) specific aspects of the supply system (see Section 8.4). Outside contractors that specialize in certain services may be able to provide them at lower cost and higher quality. Port clearing, warehouse management, and transport are among the services that are sometimes contracted out to the private sector.

Autonomous supply agency

Problems with CMS systems have led some governments to establish systems that place the responsibility for bulk procurement, quality assurance, storage, distribution, and financial management in the hands of an autonomous or semi-autonomous supply agency. This model has been tried in several countries, particularly in Africa and Latin America (Country Study 8-1).

Autonomous supply agencies are often established as parastatals, either under the ministry of health or as independent organizations with a board of directors with representatives from several government ministries and sometimes from the private and nonprofit sectors. These supply agencies operate like the nonprofit essential medicines supply services described in Section 8.7, except that their primary client is the government's health services. The

Country Study 8-1

An autonomous medical supply service: Medical Stores Department in Tanzania

Before 1994, Tanzania functioned with a traditional CMS model for procurement, storage, and distribution. Throughout the 1980s, CMS management became increasingly ineffective, and operational and financial sustainability were major issues. Recognizing the seriousness of the situation, the Ministry of Health made reforming the CMS a cornerstone of its 1992 Pharmaceutical Master Plan. The reforms resulted in the development of an autonomous Medical Stores Department (MSD) to procure, store, distribute, and sell health commodities to the public sector and authorized private organizations. The department had a mandate to make available essential medicines and supplies on a nationwide basis, to be financially self-sustaining, and to base decision making on "sound commercial principles." Although MSD is still a government-owned institution, it has autonomous status and makes its own rules, regulations, and procedures.

Now MSD is the predominant single distributor of pharmaceuticals and medical supplies in Tanzania. It operates a self-sustaining revolving drug fund with eight zonal stores. MSD serves national referral hospitals, regional health facilities, district health facilities, health centers and dispensaries, faith-based health facilities, and approved NGOs.

MSD improved the supply of essential medicines and health commodities to the public sector compared with the CMS, but major increases in workload in recent years have stretched MSD's physical and managerial capacity. At one time, MSD had a virtual monopoly on distributing pharmaceuticals and supplies to all public-sector and mission or faith-based health facilities. Now, however, because of decentralization, districts and hospitals have control over their own budgets and can procure medicines and supplies from sources other than MSD. A 2007 survey showed that only 33 percent of health facilities procured exclusively from MSD, whereas most also procured medicines and supplies from private pharmaceutical wholesalers and private pharmacies. The government provides no guidelines to health facilities on when they should procure from private sources. Between 2000 and 2007, the number of private wholesalers had doubled to almost 200. Although facilities may not use MSD as their exclusive supplier, MSD sales turnover has been steadily increasing (see table).

MSD Total sales and percentage markups: 2004–2006

	2004	2005	2006
Sales in U.S. dollars	38,417,481	52,000,000	86,980,000
Percent markup of total sale	17.0	17.0	15.5

Storage space and general stock availability from MSD have been problematic. In a 2001 assessment, on average, MSD was able to supply less than 80 percent of items requested, with some zonal stores achieving less than 70 percent. A spot assessment in 2003 showed that the MSD facilities had an average of 49 percent of vital medicine items available, although its target is to have 100 percent availability for these medicines. In 2007, however, the availability of tracer items in the MSD zonal stores was only about 50 percent when measurement included buffer stock; not surprisingly, primary health facilities received only 67 percent of their orders from MSD. MSD and its zonal stores reported product delivery delays and insufficient forecasting as the main problems resulting in stockouts; product rationing at different levels of the supply chain distorts the perception of demand. The assessment did find good practices in place for storage and stock management operations at the central and regional stores. At every MSD warehouse visited, stocks were secure, protected from light, in properly ventilated areas, and well organized. The information technology stock management system was functioning.

A major concern in 2007 was the effect of vertical program supply systems, which, because of their large value relative to the essential medicines supply system, distort health priorities. The assessment concluded that government-funded essential medicines were being "crowded out" by the disproportionate funding and attention given to vertical programs. In addition, the report noted that vertical systems caused duplication and overburdened staff, who have to manage parallel information and funding flows. Evidence also suggests that MSD receives only a fraction of what it is owed for distributing vertical program goods.

Sources: CPM 2003; Euro Health Group and MSH Tanzania 2007; MoHSW 2007.

successful transition from a CMS system to an autonomous supply system requires substantial time and resources to upgrade and develop infrastructure, such as a pharmaceutical information system. Moreover, political commitment is needed to support the wide-ranging changes in government regulations and laws that are often required to ensure the necessary autonomy for the new system.

For example, Zambia's pharmaceutical distribution agency is a parastatal called Medical Stores Limited (MSL). MSL is publicly financed but is an independent entity with its own management and board. Because it has management and operational flexibility, MSL has instituted practices that are more often seen in the private sector, such as creating performance incentive schemes for its staff and workers and investing in technologically advanced systems for warehouse management and fleet tracking. MSL also outsources its senior operational management to Crown Agents, Ltd., under a fixed-term contract, which requires Crown Agents to build local management capacity using global best practices in warehousing, inventory management, and distribution (Dalberg Global Development Advisors/MIT-Zaragoza International Logistics Program 2008).

Autonomous supply services are established to achieve the efficiency and flexibility associated with private management while maintaining sufficient public-sector supervision to ensure that the services provide essential medicines, at reasonable prices, with adequate quality control. The basic concept is that, under the right conditions, a well-constituted management board or board of directors will appoint qualified senior managers, who will ensure an efficient, accountable supply service. In practice, however, finding and retaining qualified senior management staff are often difficult, which can result in poorly managed autonomous agencies. In addition, success relies on sufficient human and financial resources to create and maintain the needed infrastructure and management systems.

Pharmaceutical supply agencies may be established in the context of a public-sector revolving drug fund or in a system in which government institutions purchase medicines with centrally allocated treasury funds. In either system, funds are best used to purchase medicines on a cash-and-carry basis; not extending credit is a key to sustainability.

Experience to date, though limited, suggests that the following features are necessary to establish a successful autonomous supply agency (see Figure 8-2)—

Figure 8-2 Checklist for evaluating an autonomous essential medicines supply agency

Essential medicines and public health mandate

- □ Medicines limited to those on the national essential medicines list or formulary?
- Dressings, diagnostic agents, and other medical supplies included in range of products?
- □ Distribution restricted to government facilities?

Legal status

- □ Operating unit under the ministry of health? Parastatal? Fully private agency?
- □ Status established by ministry directive? Legal notice? Act of law? Other measure?
- □ For-profit or nonprofit organization?

Management board (board of directors)

- □ Membership: How appointed? How representative? How independent?
- □ Role and authority: How broad? How independent?
- □ Chairperson: How selected? How independent?

Senior managers

- □ Recruitment: By whom? Approval by board required?
- □ Job descriptions and required qualifications clearly spelled out in writing?
- □ Authority to manage: Hire and fire? Set salary and benefit packages?

Personnel system

- □ Civil service system?
- $\hfill\square$ Parastatal system with some civil service characteristics?
- □ Private-sector flexibility, incentive structure, and controls?

Supply management and quality assurance

- Professional personnel experienced in supply chain management and supervision?
- Professional pharmacists involved in management and supervision?
- □ Adequate quality assurance procedures in place and enforced?

Capital financing (working capital needed for infrastructure, replacing vehicles)

- □ Source: Central government allocation, donor, development bank, commercial bank?
- □ Type: Grant, "soft" development loan, commercial loan?
- □ Adequacy: Capital sufficient for current size and anticipated growth of supply demands?

Recurrent financing (working capital for the purchase of medicines and payment of suppliers may come from a mix of sources)

- □ Medicines financed from district or facility central allocations?
- □ Medicines financed through user fees?
- □ Medicines financed through insurance?
- □ Salary and other recurrent operating costs financed through central allocations? Through markup on medicines distributed by the agency? Through fixed supply fee?

Financial control and accountability

- □ Able to maintain its own bank accounts?
- □ Annual independent public audit required?
- □ Annual report to ministry of health and central government required?
- Protection from decapitalization through unfunded distribution, distribution during emergency situations, credit sales?

- Sufficient autonomy to allow efficient operations that are free from political interference
- · Oversight by an independent management board
- Professional pharmaceutical supply managers with substantive decision-making powers
- Good personnel management and adequate salaries for staff
- Adequate financing
- Public accountability and sound financial management
- Continued focus on essential medicines (rather than "profitable" alternatives)
- Focus on quality assurance of both products and services
- High-quality storage, distribution, and information technology infrastructure

An autonomous supply agency may achieve value for money and improved pharmaceutical availability through more efficient management. The two important questions are: Does the agency have the flexibility to be efficient? Does the agency have the incentive to be efficient? Such agencies are likely to improve pharmaceutical supply only if they are structured to overcome the constraints of the CMS approach. Competitive pressure encourages efficiency.

Difficulties can be anticipated if any of the following occur—

- Senior managers are political appointees rather than professional managers appointed by an independent management board.
- The government retains the authority to require distribution of medicines without charge or on a credit basis (without ensuring payment).
- Special interests outside the agency influence medicine procurement.
- The agency is required to retain staff members regardless of their ability or performance.
- A well-functioning agency is expected to handle additional responsibilities beyond its capacity.
- The agency acts as a monopoly, with no pressure to maintain low prices, reliable service, and high quality.

Professional managers should have full authority to make decisions regarding hiring and firing, set terms and conditions of employment, and create or revise in-house policies and regulations. Finally, countries considering an autonomous supply agency should recognize that this approach will not solve problems related to overall lack of funding for medicines.

Direct delivery system

CMS and autonomous supply services involve bulk procurement and distribution from a central warehouse. The costs and logistical problems associated with central storage and distribution are substantial. An alternative may be a direct delivery system in situations where suppliers have that capacity.

In this non-CMS model, a government procurement office tenders to establish prices and suppliers for each essential medicine, but the suppliers deliver the medicines directly to individual regional stores, district stores, or major health facilities. Variations of direct delivery contracts have been implemented in many countries.

Besides its general use for supply of essential medicines and commodities, direct delivery can be used successfully in very specific situations, such as the supply of nonstandard equipment (for example, X-ray machines), where a central procurement office contracts with a supplier that delivers, installs, and commissions expensive capital equipment.

Direct delivery contracts may specify fixed quantities with scheduled deliveries or estimated quantity tenders with orders placed by the local warehouses or health facilities as needed. Financing arrangements can be tricky. Debts can quickly accumulate if pharmaceutical supplies are not balanced against available funds. Separate accounts must be maintained for each supply point (if funding is from central allocations) or all supplies must be paid for at the time of delivery. Like most procurement systems, direct delivery contracts require a sole-source commitment—that is, for the tender medicines, the local warehouses and facilities order from the supplier that holds the tender contract. The local purchasers are free to order medicines that are not on the tender from any supplier. (See Chapters 21 and 39 for details related to preparing and tendering direct delivery contracts.)

Direct delivery supply agreements depend on and encourage further development of private-sector distribution systems. In principle, they reduce storage and transport requirements for the government by specifying in procurement contracts that medicines are to be delivered directly to district stores and major health facilities. The government only has to store medicines at the district level and deliver them to health centers and peripheral health units.

Direct delivery contracts can preserve the benefits of centralized selection (the essential medicines list), bulk procurement (suppliers offer favorable prices to get all the business for the products they are awarded), and centralized quality control. Hospitals and districts benefit from being able to manage their own funds and determine the exact quantities needed. Finally, the problems of security, central storage, and transport are shifted from the ministry to the private suppliers.

With a direct delivery system, however, district-level and facility-level pharmaceutical management responsibilities are much greater, because they can include ordering, receiving, and paying for medicines. Success depends on adequate financing and management systems and the ability and willingness of staff to undertake the increased responsibilities.

Primary distributor system

The primary distributor system (also known as the prime vendor system) often involves the public procurement agency tendering for two types of contracts. First, the public procurement agency contracts with any number of suppliers to establish the source and price for each medicine, but the medicines are not delivered by the suppliers directly; instead, a separate contract is negotiated (through tender, if feasible) with one or more private-sector distributors, the primary distributors. In some cases, a single primary distributor serves the whole health system. In larger systems, different primary distributors may serve different regions or different levels of the health system. Another variation is to contract with private or NGO systems to supply only a particular geographic area or a specific group of health facilities, thus easing the burden of the public-sector system (Country Study 8-2).

The suppliers deliver tender medicines to the primary distributors, which are responsible for maintaining sufficient stock to fill orders from regional warehouses, district stores, or health facilities. The local warehouses and health facilities order medicines from the designated primary distributor, and the primary distributor fills the orders from medicines

Country Study 8-2 Developing a prime vendor pharmaceutical supply system for the Tanzanian mission sector

Church-owned hospitals, health centers, and pharmaceutical dispensaries in Tanzania are principally located in rural areas, where 70 percent of the population resides. Historically, they had no central pharmaceutical procurement body and relied mostly on the Medical Stores Department, international donations, and private-sector pharmacies for medicines and supplies. However, church hospitals reported dissatisfaction with services provided by the MSD, such as unacceptable out-of-stock rates. The Mission for Essential Medical Supplies (MEMS), a not-for-profit organization established by the Evangelical Lutheran Churches in Tanzania, had a history of providing laboratory services and supplies to health facilities. These facilities asked MEMS to expand its supply list to include pharmaceuticals and medical supplies.

The Strategies for Enhancing Access to Medicines (SEAM) Program agreed to help MEMS develop and implement a private-sector prime vendor pharmaceutical supply system that would improve medicine quality, supply, availability, and affordability for participating not-for-profit hospitals. The system would use pooled procurement to purchase from a single supplier and offer participating health facilities supplementary services from MEMS, such as purchase requisition review, a strategy for pharmaceutical quality assurance, training in rational use and pharmaceutical management, and medicine information services. The contractual requirements were for the prime vendor to stock and supply more than 500 items, initially to twelve rural hospitals and expanding to forty hospitals as the project progressed. The contracted delivery time was either ten or twenty-one days, depending on the goods. The prices of the goods were fixed for twelve months, starting in November 2004.

From November 2004 until April 2005, fourteen hospital orders were received electronically from ten health facili-

ties. The prime vendor made twenty-nine deliveries, with an average of two deliveries per order (and a range of one to six). Despite considerable procurement experience, however, the contracted prime vendor (Diocare/Crown Agents) had difficulty meeting the terms of the contract, mainly because it underestimated the complexity and costs of the program: substantial variations occurred in stock demand from the health facilities, warehouse systems were overstretched, and contract expectations were unclear. Although the prime vendor worked to resolve its own infrastructure and inventory deficiencies and worked with MEMS to address supply chain management issues extending from the distributor to the end user, the negatives-out-of-stock situations, partial shipments, and poor service—outweighed the positives, and the parties agreed to discontinue the contract in late 2005.

Even with the failure of the original prime vendor relationship, MEMS continued with much of the original strategy developed during the SEAM Program, including quantifying requirements for pharmaceuticals and medical supplies for church hospitals, pooling procurement requirements, and using a prime vendor as its principal supplier (a local wholesaler, Pyramid Pharma, in collaboration with an international supplier, the International Dispensary Association). The network of hospitals grew; as of August 2008, MEMS coordinated routine pharmaceutical and medical supply procurement for thirty faithbased hospitals serving over 4 million rural Tanzanians. In addition, through the palliative care project of Evangelical Lutheran Churches in Tanzania, Interchurch Medical Assistance, and Catholic Relief Services, MEMS extended its services of procurement coordination to thirty-seven other hospitals, including public hospitals.

Source: SEAM 2008.

8.12 POLICY AND LEGAL FRAMEWORK





Source: Dalberg Global Development Advisors/MIT-Zaragoza International Logistics Program 2008.

Potential intervention areas with private sector.

in stock. Primary distributors may maintain their own vehicle fleets or subcontract with other firms for transportation.

In some cases, a group of providers, such as hospitals, pool their resources to benefit from bulk purchasing, but instead of taking on the responsibility for selection, price negotiation, and quality assurance, the group contracts with a primary distributor that takes over these additional tasks, leaving the group to merely administer the contract.

Like other private-sector contracts, this system depends on sole-source commitment for the medicines under tender contract, although districts and health facilities may be allowed to purchase nontender medicines from any source. The system also requires the availability of good information, and performance monitoring and compliance by both health system staff and the contracted distributors.

The primary distributor is paid a fee for storage and delivery services. In some industrialized countries, this fee is typically less than 2 percent. Primary distributors are able to achieve such low margins by distributing very large volumes of goods and by generating revenue through the "float" in money markets or bank interest. This income is generated through a difference in payment terms: the primary distributor pays the supplier after thirty to sixty days but requires health facilities to pay within fifteen days, thus giving the primary distributor access to the equivalent of fifteen to forty-five days' cash turnover.

The primary distributor system may appear to add an extra intermediary and extra costs, but experience has shown that the cost of a primary distributor can be more than offset in some situations by savings from increased efficiency. Competitive awards of primary distributor contracts and enforcing contract terms are important to achieve this efficiency.

Primarily private system

National policy, insufficient financing, or management problems have led some countries to avoid taking on the responsibility for providing hospitals and health centers with even essential medicines. In some systems, commercial pharmacies are established within ministry facilities; such pharmacies may be part of a parastatal pharmaceutical enterprise, or they may be independent enterprises. In other cases, the government may contract with commercial pharmacies to provide medicines to public-sector patients. Pharmacies established in government health facilities may operate on a nonprofit or for-profit basis, depending on the arrangement with the government. Often, such pharmacies are limited to the sale of essential medicines. In some cases, private pharmacies operate in parallel with government pharmacies in the same institution.

In countries where pharmaceutical procurement has been decentralized to the regional, district, or even health facility level, procurement officers may be quick to fill their supply orders through a private wholesaler if they perceive that the public-sector supplier is undependable or slow. Not only is this practice more expensive, but also the quality of products in the private-sector supply chain is generally not monitored as closely, if at all. In addition, unreliable orders cripple the public-sector supplier by rendering forecasts useless, resulting in overstocks and expiries. Moreover, without the purchasers to make the public sector's revolving funds revolve, decapitalization results. An added complication occurs when legislation forces the public supplier to continue to ship orders to districts that do not pay or when districts allow debts to build up and then quit placing orders with the CMS rather than pay off accumulated debt, as was the case in Ghana (Seiter and Gyansa-Lutterodt 2009).

In many countries, the relative roles of the public and private sectors in public health and pharmaceutical supply are undergoing change. Changes in public and private roles must be designed to promote accessibility to medicines and rational medicine use (Figure 8-3). As with revolving drug funds operated by the government, the greatest concern with a mainly private supply system is equity of access for the poor, children, patients with communicable diseases, and other target groups.

8.4 Contracting for pharmaceutical supply services

The direct delivery system, the primary distributor system, and in some instances, the autonomous supply agency system involve management or service contracts (see Chapter 39). Important differences exist between contracting for pharmaceutical products and contracting for services. Contract terms are different, and a different approach is needed for monitoring.

Contracting out or outsourcing in health care has most commonly been used for nonclinical services such as equipment maintenance, laundry, and food services. Contracting out services is common in the private sector. Often, companies find that outside contractors who specialize in specific services such as managing cafeterias or repairing computers can provide those services at lower cost and higher quality than companies can provide in-house.

In pharmaceutical supply, primary distributor systems, transport contracts, port-clearing services, and other private-sector involvement require contracting for services in contrast to contracting for products (for example, medicines). However, contracting out activities requires the skills of writing, negotiating, and monitoring contracts. The contract must include specific performance indicators with a time frame for when those indicators will be met. Even experienced companies can run into problems by underestimating the necessary financial and human resources to fulfill the contract requirements. In the case of pharmaceutical supply, for example, a lack of reliable data from health facilities on medicine use and demand makes estimating order quantities difficult, resulting in overages or stockouts. All parties to the contract need to have a clear understanding of any limitations that may affect performance.

The outsourcing process functions most effectively where potential competition exists, as with any tendering process. Contracting out also demands a commitment to pay the contractors according to the terms of the contract. Government officials must develop special skills to prepare and monitor such contracts.

8.5 Comparison of basic supply systems

The five basic supply systems are compared in Table 8-2. The models vary with respect to the role of the state and the degree of private-sector involvement. The CMS approach demands the most of the central government in terms of human and physical resources, because it operates virtually the entire distribution system. With an autonomous supply agency, direct delivery system, or primary distributor system, the role of the government changes from direct operations to a combination of direct operations and contract management coordination and monitoring. Some direct delivery or primary distributor systems do not require a large central government distribution infrastructure, but depending on where the responsibility for procurement lies, such systems may require a pharmaceutical procurement office or an equivalent department with oversight responsibility to manage contracts and monitor performance effectively. A CMS or autonomous supply agency approach may be required when the local private sector is not sufficiently developed to support the efficient operation of a direct delivery or primary distributor system.

Ghana and Zambia provide examples of different types of systems in terms of the role of the private sector. In Ghana, private-sector wholesalers provide a substantial portion of sales and delivery of medicines to public regional medical stores, hospitals, and NGO facilities. In Zambia, however, almost all of the public and NGO facilities receive medicines through international suppliers and procurement agents; medicines are then distributed through the public-sector supply chain (Dalberg Global Development Advisors/MIT-Zaragoza International Logistics Program 2008).

Pharmaceutical supply systems need to achieve three main objectives: (a) high service level, as measured by low rates of shortages and stockouts; (b) efficiency, as measured by having low total costs for a given level of service; and (c) the ability to cope with disaster situations (see Chapter 15 for examples of pharmaceutical supply management issues in emergencies). Autonomous supply agencies, direct delivery contracts, and primary distributor systems offer different approaches to create the flexibility, competition, and clear performance targets that help achieve these objectives.

Historically, options for handling public supply have been presented as a choice between various stand-alone alternatives (for example, CMS, autonomous store, or primary distributor). However, with growing demand for products and services, individual organizations and companies, whether public or private, will undoubtedly struggle to satisfy all needs. Against this background, a multifaceted approach using the full range of resources, including a combination of public- and private-sector strategies that spread the burden and risk, will increasingly be required.

Some countries may choose to join forces with others in their region to increase efficiency in their pharmaceutical sectors. These regional partnerships could range from sharing information on pricing and suppliers to formal pooled procurement schemes, where one central body procures medicines and commodities for a regional group of countries (see Chapter 18 on procurement). Some countries may consider setting up similar alliances for storage and distribution or contracting with a private company to provide regionwide services to multiple countries. Some regional organizations are exploring options for collaborating in pharmaceutical supply, and experiences from the eastern Caribbean and the Gulf states demonstrate the potential savings and sustainability of such arrangements (Kanavos et al. 2010); however, strong political commitment and a shared cultural outlook and language appear to be required for success.

8.6 Vertical supply systems

Public health programs that focus on targeted interventions, such as family planning or tuberculosis control, may operate vertical pharmaceutical supply systems that are set up outside a country's regular health and pharmaceutical supply system. With the dramatic increase in global health initiatives, multiple vertical supply systems have become the norm in many countries. For donors, particularly, vertical programs can be appealing because they show quick results and they are easier to manage than inclusive, horizontal programs. However, many government and donor policy makers in developing countries see vertical programs as diverting human and financial resources from already resourceconstrained health systems and as undermining sustainability of the pharmaceutical sector in general. An analysis of the effect of global health initiatives on country health systems found that, in some places, the resulting vertical supply systems duplicated or displaced the countries' existing systems and that lack of coordination between vertical and essential medicines systems caused stock excesses and deficits (WHO Maximizing Positive Synergies Collaborative Group 2009).

International vertical supply programs include the Global TB Drug Facility, which works to provide inexpensive, quality-assured tuberculosis medicines for DOTS programs worldwide. The World Health Organization (WHO) created a similar program for HIV/AIDS-related medicines and commodities; however, unlike the Global TB Drug Facility, the AIDS Medicines and Diagnostic Service does not procure medicines directly but rather provides resources and assistance to countries in procuring quality medicines at the best prices and managing the distribution of those medicines. Other large vertical programs include the President's Malaria Initiative; the U.S. President's Emergency Plan for AIDS Relief and its supply mechanism, the Supply Chain Management System project; and the Global Fund to Fight AIDS, Tuberculosis and Malaria's procurement mechanism. Some large-scale vertical supply programs are based on donated medicines, such as the ivermectin distribution program for onchocerciasis.

Efforts are being made in some countries, such as Uganda, to integrate supply systems for vertical programs into essential medicines programs. Resource-intensive functions such as procurement, quality assurance, storage, and physical distribution may be integrated under the essential medicines program, whereas financing, quantification, and monitoring may stay under the control of the vertical program. Integration can provide savings and benefits but is reliant on strong government commitment to the process.

The initial experiences with integrating vertical program supply systems may not be a reliable guide to the potential for incorporating mature HIV/AIDS programs into broader public health supply systems-even ones that are efficient and well managed. Integrating HIV/AIDS programs into a country's general essential medicines program may be very difficult because of the sheer difference in scale compared with previously integrated programs, such as those for family planning. Typically, integrating a vertical program involves the absorption of a smaller supply system into a larger one, which can be reasonably achieved when the larger system functions well and has sufficient spare capacity. However, a supply system for a country's HIV/AIDS program may be as large as or larger than its essential medicines supply program; under such circumstances, integration of the two systems would require a strategic redesign and restructuring of the entire pharmaceutical supply system.

8.7 Meeting health needs through private channels

As mentioned, changes in national policy, declining government financial resources, or other trends may lead to an increased role for the private sector, including for-profit and not-for-profit entities, in providing access to medicines. Governments' inability to provide regular medicines and supplies may push more health facilities to purchase medicines from private wholesalers, and patients to purchase medicines from retail drug sellers.

Not-for-profit pharmaceutical services

Nonprofit health care providers, including faith-based and charitable health services and other NGOs, play an important role in the financing and provision of health services in many countries. The share of health services provided through the private nonprofit health sector varies considerably among countries, but in low-income countries it can be large, especially in rural areas; for example, the Christian Health Association of Malawi provides up to 40 percent of services in the country overall, with 90 percent of its facilities located in rural areas (UN 2007). NGOs can play an important role in promoting the concept of essential medicines and in supplying essential medicines.

To the extent that NGOs target their services to rural populations, mothers and children, the urban poor, and other underserved groups, encouraging the growth and development of such organizations can be in the government's interest. Government incentives and subsidies for NGOs may include annual lump-sum grants, temporary assignment of ministry health personnel, payment of NGO staff, permission to purchase pharmaceuticals from government stores, exemption from import duties (sometimes limited to products on the national essential medicines list), and payment of retirement benefits. Providing access to government medical stores and exemption from import duties are particularly important in encouraging NGOs to supply essential medicines for their patients. Some countries have allowed specific NGOs to purchase medicines from government medical stores—in some cases, at subsidized prices.

Beginning in the late 1970s, coincident with WHO's introduction of the essential medicines concept, mission or other nonprofit health associations in some countries began to create their own agencies to procure and distribute essential medicines. These NGOs generally develop their own essential medicines list, often based on the WHO model. NGOs obtain pharmaceutical products from the national parastatal (where one exists), local manufacturers, international nonprofit suppliers, or other foreign suppliers. Financing usually comes from a combination of external donations, local donations, and fees. Ghana, India, Kenya, Nepal, Nigeria, and Uganda are among the countries in which NGOs operate essential medicines supply services. Country Study 8-3 describes the origin and operation of Kenya's Mission for Essential Drugs (MEDS) and Uganda's Joint Medical Stores (JMS). Despite financial and organizational difficulties, some NGO essential medicines services have been very successful. Furthermore, in some countries where public-sector systems have experienced problems, demands on NGO services have increased as they try to fill service gaps.

For NGOs that lack the capital or organizational capacity required to establish their own central store, the direct delivery or primary distributor system offers a means to obtain more favorable prices on a limited range of locally procured essential medicines.

For-profit pharmaceutical services: retail pharmacies and drug sellers

On the consumer side, when public facilities are not located where people can easily access them, or if their supply of medicines is unreliable, people will turn to retail drug outlets as their first source of health care. Such outlets often offer questionable product and service quality at higher prices. In these examples, patients are left to buy virtually all medicines on their own from the private sector. This situation usually results from lack of funds within the government rather than any official pharmaceutical management plan. Private pharmacies and other private drug outlets exist in virtually every country in the world. In addition, doctors, other clinicians in private practice, and practitioners in the informal health sector commonly dispense pharmaceuticals, often deriving more income from pharmaceuticals than from consulting fees.

The percentage of total pharmaceutical expenditures that pass through the private sector varies from under 10 percent in some small, relatively isolated countries to over 90 percent in countries with a well-developed private sector and limited public-sector pharmaceutical supply. By retail value,

Country Study 8-3 NGO essential medicines services in East Africa

Two mission-run pharmaceutical supply services that are generally considered success stories are Kenya's Mission for Essential Drugs and Uganda's Joint Medical Stores. A WHO-commissioned report presented the findings of an analysis of key factors for success and obstacles faced in running NGO pharmaceutical supply systems. Both systems are now largely self-sustaining, but they required—and continue to require to some degree—an enormous amount of multidonor support. Although operating in similar environments, MEDS, established in 1986, and JMS, established in 1979, differ in where they source their products, either locally or internationally, and what clients they serve, but both have efficient systems, producing 90 percent availability rates and competitive prices. Kawasaki and Patten (2002) said in their analysis, "The most important point is that both organizations maintain high staff motivation levels, and provide a reliable pharmaceutical supply system for their customers. Both organizations voice a strong commitment to serving the poor in their respective countries, and achieve this goal through efficiency and maintaining their purpose. Both organizations are beginning to supply significant amounts of products to organizations in neighboring countries."

Although MEDS and JMS are clearly effective in contributing to increased access to medicines in their respective countries, this success evolved from and depended on decades of sustained commitment—financial, technical, and political—from supportive donors. However, as it has for other essential medicine supply services in the region, the increase in demand for products has pushed MEDS and JMS to the limit of their current capacities, which will test their ability to maintain quality services.

Source: Kawasaki and Patten 2002.

the majority of pharmaceuticals in many developing countries flow through the private sector (including the private nonprofit or faith-based sector).

For many common medical problems, such as malaria and diarrhea, a variety of factors encourage people to diagnose themselves or their children, then purchase medications from retail drug sellers before visiting a government health facility. These factors include distance to the health facility; perceived seriousness of the illness; medicine availability in the public facility; cash availability; and perceptions of privacy and quality of the health care providers, health facilities, and medicines.

Because pharmacies are mainly located in urban areas, whereas many people live in rural and peri-urban communities, these informal shops are often the most convenient retail outlet from which to buy medicines. Moreover, when public primary health care facilities have unreliable supplies of medicines, patients will turn to private shops to obtain pharmaceuticals prescribed by the government health worker.

Given the absence of pharmacy services in rural areas and the shortage in poor urban areas, retail drug outlets play an important role in providing access to essential medicines for a significant proportion of the population in many developing countries; however, experience (CPM 2003) shows that access through retail drug outlets can be characterized by a number of problems including—

- Authorization to sell only a limited list of medicines, not including basic essential prescription medicines
- Illegal availability of prescription medicines that are prohibited for sale in drug shops
- · Quality of medicines that cannot be assured
- Difficulty in finding reliable and legal sources of medicines and other health care commodities
- Lack of adequate facilities for storing medicines properly
- Dispensing staff who lack basic qualifications and training
- High prices charged to consumers
- Inadequate regulation and supervision

Because informal retail drug outlets generally operate in an uncontrolled environment, improving and monitoring the quality of products and services is a challenge; however, groundbreaking initiatives aimed at the informal private sector have been introduced successfully. Chapter 32 describes programs that have created accreditation and franchising schemes to provide incentives to drug shop owners to maintain standards of quality medicines and services. Such initiatives are innovative approaches to improving products and services in the commercial sector, but they are complex, costly, and time-consuming undertakings that require extensive commitment and resources. Other, less complex approaches aimed at improving dispensing by private-sector providers include interventions such as vendor-to-vendor education programs (Tavrow et al. 2003), face-to-face drug seller training (Ross-Degnan et al. 1996), and combined drug retailer and community education programs (Marsh et al. 2004) that often focus on one condition, such as diagnosing and treating childhood malaria. Knowledgeable dispensers are more likely to ask questions and give instructions and advice to customers rather than simply sell the medicine that the customer requests (Brieger et al. 2004).

8.8 Health systems strengthening, decentralization, and pharmaceutical supply management

The various mechanisms for buying and distributing pharmaceuticals must be couched in the context of ongoing efforts to strengthen health systems, which is a unifying theme for many global health organizations and initiatives, including WHO, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and the U.S. President's Emergency Plan for AIDS Relief. Changes to strengthen the supply system may include incorporation of competitive mechanisms within the public sector, decentralization of health service provision, contracting out specific services, and expanding the role for private or NGO sectors.

Selection, procurement, and distribution can, in principle, be effectively managed in centralized, partially decentralized, or fully decentralized systems. In a fully decentralized public-sector system, each authorized level, typically a province or a district, is responsible for independently procuring and supplying its own medicines. More commonly, in mixed systems, centers, provinces, and sometimes districts each supply a different set of medicines. Of the four main functions in the pharmaceutical management cycle, only local distribution and medicine use are, by their nature, decentralized. Most other functions could be performed at the national, provincial, district, or local level.

Much attention has been given to decentralization. But what is meant by decentralization? The term is used to describe at least three different approaches to transferring power from central authorities: delegation, devolution, and privatization. These can be described as follows—

Delegation describes the assignment of responsibility

for specific tasks to lower-level units within the health system, with overall control remaining at the central level. For example, selection and quantification can be delegated to hospitals, while tendering, compiling pharmaceutical orders, and determining final order quantities remain central functions.

Country Study 8-4 Decentralization's effect on the supply of essential medicines in Indonesia

In Indonesia, the public-sector pharmaceutical supply situation was complex before decentralization occurred. Numerous vertical programs were managing programspecific commodity and medicine supply. A centralized procurement mechanism existed, but supply was locally administered for some essential medicines. The decentralization of the health system led to disruption and confusion because traditional lines of communication and authority were dislocated, and opinions conflicted on determining levels of responsibility. The laws and regulations relating to decentralization were unclear, and program managers were making new, often inconsistent, interpretations of the existing regulations. In addition, different provinces and districts responded in different ways, developing and using differing methods and procedures, which resulted in conflicting information, sometimes even from within the same organization. The nature of the conflicting information made direct comparisons and data analysis difficult. However, even with the problems that were associated with Indonesia's decentralization process, evidence indicated that in 2004, medicine availability had not decreased.

- *Devolution* refers to the transfer of power (responsibility, authority, and accountability) to lower-level units, which are then outside the direct control of the central level.
- *Privatization* is properly defined as the transfer of ownership from the public to the private sector. But the term is also applied, less precisely, to contracting government services to the private sector (as with direct delivery contracts) or introducing private-sector features into the public sector (as with government-owned but semiautonomous supply agencies). As mentioned in Section 8.4, contracting requires skillful management and careful monitoring.

Decentralization in any of these forms is intended to improve the responsiveness, quality, and efficiency of health services. Decentralization aims to achieve these benefits through greater local involvement, more direct public accountability, increased flexibility to adjust to local circumstances, more rapid and more accurate communication, and quicker adaptation to changing conditions. Improvements are far from certain, however. The loss of scale and purchasing power and the general lack of technical and managerial skills at the regional and district levels hinder decentralized systems from achieving efficient and effective supply management. This can be seen in the example from Indonesia in Country Study 8-4. Problems that have occurred with attempts to decentralize pharmaceutical management functions include—

- *Lack of capacity:* Decentralization of pharmaceutical management responsibility may be implemented without ensuring that sufficient local staff and management capacity are present to sustain services.
- Lack of financial resources: Responsibility is sometimes decentralized without providing an adequate budget

or financing system at the levels where responsibility is placed. In this case, decentralization simply becomes abandonment of responsibility.

- *Increased corruption:* Because of the money involved, interference for personal gain is common in pharmaceutical supply systems. Although decentralization is meant to improve accountability, it sometimes creates opportunities for local officials or other special interests to profit.
- *Increased cost:* Decentralization of procurement usually means smaller order quantities. It can result in higher prices for essential medicines, although this problem can be overcome with central contracts coupled with decentralized ordering. Districts or facilities with purchasing power that choose to purchase from the private sector pay more for medicines.
- *Decreased product quality:* Selecting reliable suppliers and monitoring medicine quality are difficult at the local level if no unified national system exists or if public entities are buying from unmonitored private-sector sources.
- *Untested private-sector providers:* Private companies that have limited experience with providing large-scale health care services may underestimate the level of effort and resources necessary to fulfill the need, or the contracting authority may make the same mistake in assessing the capacity of the vendor.

In managing a pharmaceutical supply system, thinking in terms of a task-specific approach to decentralization is useful. Tasks better performed centrally include those that require specialized skills, involve economies of scale, or depend on extensive or rapidly changing technical information. Examples of such tasks include development of essential medicines lists, preparation of standard treatments, management of competitive tenders, selection and monitoring of suppliers, quality assurance, and development of training programs on rational medicine use. Tasks that can be decentralized include those that do not require uncommon technical skills and those for which local information is required. Decentralization is appropriate when local circumstances vary significantly throughout the country and local interests favor improved performance. Examples of such tasks include adaptation of medicines lists or standard treatments to local needs, quantification of medicine requirements, coordination of local distribution, training in rational medicine use, and monitoring of medicine use at health facilities.

In the Philippines, the province of Pangasinan's approach to pooled procurement by government hospitals provides an example of a task-specific approach. Procurement is based on the national medicine formulary, treatment guidelines, and morbidity and mortality data, and hospital procurement plans must be approved by the provincial therapeutic committee. Suppliers are selected from those that have been prequalified. Tendering is centralized at the level of the General Services Office to obtain lower bulk prices, and all deliveries are made directly to the hospitals. Quantification of medication requirements, budgeting, receipt and storage, and supervision of medicine quality and use are all decentralized to the level of the individual hospital.

8.9 Analyzing options for supplying essential medicines

The following considerations are important in developing an appropriate strategy for drawing on the combined strengths of both public and private pharmaceutical sectors—

- *Analysis of the national policy framework:* Within the context of economic, development, and industrial policy, what is the overall government approach to the roles of the public and private sectors? What have been the experiences in other sectors with the mix between private and public provision and financing of services?
- *Analysis of the legal framework*: Is the legislation related to pharmaceuticals up-to-date? Is the drug regulatory authority adequately staffed, financed, and equipped? Does a national commitment exist to implement the measures necessary to ensure pharmaceutical quality, safety, and efficacy?
- *Pharmaceutical-sector analysis:* What is the current status of the public pharmaceutical sector with respect to financing, human resources, physical infrastructure, management systems, and overall performance? What is the current status of the private sector with respect to these elements?
- *Comparative advantages of public and private pharmaceutical sectors:* Given the current level of development in the public and private sectors, what are the advantages of promoting one over the other? Are clear benefits likely to result from changing the status quo?

- *Costs versus benefits of expanded private-sector involvement:* Any change involves costs and benefits. Do the potential economic and health benefits of expanded private-sector involvement outweigh the costs of such expansion?
- *Phasing-in of changes in the pharmaceutical sector:* Even if good information and sound judgment lead to the conclusion that the public role in the pharmaceutical sector should change, planners should not assume that such a shift can occur immediately and in one step. Phasing-in of changes may lead to a smoother transition.
- *Monitoring of changes*: Finally, the objectives of government action must be clearly specified, and indicators need to be identified and monitored to determine whether the objectives are being met. Such monitoring is especially important if changes are being made in phases and if an opportunity exists to hasten, delay, or modify implementation based on experience.

Clarifying public-sector roles in essential medicines programs should be a central concern in the development and review of national medicine policies. From a public health perspective, the objectives for government involvement with all pharmaceutical sectors, public and private, are to provide access to medicines by ensuring—

- · Physical availability
- Affordability
- Geographical accessibility
- Acceptability (or satisfaction)
- · Quality of products and services

Chapter 36 provides information on how to assess a pharmaceutical system.

Ultimately, the role a government assumes in providing essential medicines depends on the circumstances of the individual country. The spectrum of responsibility in supplying pharmaceutical products ranges from entirely public to primarily private. Most countries operate under a paradigm somewhere in between. Generally, countries that take advantage of the capacities of both their public and private sectors have better access to medicines. As mentioned, increasing challenges to pharmaceutical supply may encourage the formation of regional partnerships to increase the resource capacity for participating countries.

8.10 Implementing sustainable changes in pharmaceutical supply systems

Pharmaceutical availability and affordability are of particular concern when government health services do not exist or are not able to provide medicines for poor, medically needy, geographically isolated, or otherwise underserved populations. In countries where a large proportion of the population is poor and government health services lack sufficient resources, ensuring universal access to medicines is particularly challenging.

These considerations must now be placed into a new and evolving context resulting from dramatic changes in public health care-especially in the pharmaceutical market—related primarily to HIV/AIDS but also to changes in treatment guidelines for malaria and other diseases. For example, from its founding in 2003 through 2010, the U.S. President's Emergency Plan for AIDS Relief is estimated to have contributed approximately 32 billion U.S. dollars (USD) through partnerships with more than 30 countries. In 2009, almost 14 percent of the budget was used to procure antiretrovirals. The Global Fund to Fight AIDS, Tuberculosis and Malaria approved grant proposals for over USD 19.2 billion through Round 9. Through Round 7, almost 60 percent of grants had been distributed in Africa, and 45 percent had gone to medicines and commodities (PEPFAR 2010; Global Fund n.d.).

For many countries, this increase in pharmaceutical funding has dramatically affected the size of their pharmaceutical market not only for these products but also for all pharmaceuticals. In addition, the high value of HIV/AIDS medicines and artemisinin-based combination therapies for malaria, as well as the sheer volume of products, will make security in the supply chain a much larger concern (see Chapter 43).

A key message is that a country cannot easily or quickly make major changes in the way it supplies medicines and health commodities; developing and implementing sustainable improvements is a complex and expensive process. A clear policy, legal, and regulatory framework must underpin planned changes, which requires the support and buyin of stakeholders at all levels of the system. Substantial and sustained investments will be needed in a range of activities and technical areas, such as advocacy, information systems, logistics, infrastructure, and human resources development. Because the time frame for implementation will be years, changes must be addressed in phases, with appropriate technical assistance throughout. In addition, efficient decision making and project management must be in place to avoid delays in implementation.

The goal should be not only a more cost-efficient and effective supply system that maximizes access to pharmaceuticals, but also a system that—once in place—is able to function with minimum external support. Technical assistance and leadership, as well as donor and government funding and private investment, will be integral in countries that are implementing changes to their pharmaceutical supply systems, but the empowerment of stakeholders from the national level down to the local levels will help foster selfreliance and reduce dependence on outside support.

Each country must assess its own situation to determine which strategies appear best suited to its circumstances. The concepts tried in other countries and their experiences of challenges and success should provide a framework for identifying options and making choices while keeping the key public health objectives in mind: increasing the availability and affordability of essential medicines, promoting rational use of medicines, and ensuring acceptable medicine quality.

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ASSESSMENT GUIDE

National pharmaceutical financing and distribution

- Which pharmaceutical financing sources are used (government budgets, private out-of-pocket purchases, insurance, other sources)?
- What is the structure of the pharmaceutical distribution system (state wholesale monopoly, private wholesale distributors, NGO pharmaceutical supply agency, centralized distribution for government facilities, other distributors)?
- What is the national health care delivery context (decentralization, rapidly expanding demand for pharmaceuticals caused by rollout of artemisinin-based combination therapy for malaria)?

Pharmaceutical supply for government health services

- What system is currently used (central medical stores, autonomous supply agency, direct delivery, primary distributor, primarily private supply)?
- Is a kit system in place? Do current plans include kits, or is the goal to shift to an ordering system?
- Which alternative supply systems were considered?
- How well is the current system performing (see notes)?

Autonomous pharmaceutical supply agency (if applicable)

- Does the agency have an independent and effective management board?
- What are the qualifications of the senior managers?
- What measures to ensure efficiency and monitor performance are in place?
- Are financing and financial controls adequate?
- How is the system performing in terms of cost and delivery (see notes)?

Direct delivery and primary distributor contracts (if applicable)

- Does the legal framework permit outsourcing of services?
- Are contracts effectively monitored?
- Is competition sufficient to ensure low prices and good service?
- Are financing and financial controls adequate?
- How is the system performing in terms of cost and delivery (see notes)?

Performance indicators for pharmaceutical supply

- Are indicator medicines currently available at health facilities?
- What is the frequency of stockouts for indicator medicines at health facilities?
- What is the average duration of stockouts for indicator medicines at health facilities?
- What is the average time between order and delivery for indicator medicines for regular orders?
- What percentage of supplier medicine prices are the average distribution costs (administration, storage, transport)?

Measures affecting private supply channels

- How mature is the commercial pharmaceutical sector (how many companies, how large, how long in business)?
- Are companies interested in expansion? Do they have access to capital for investment? Are they prepared to take risks to enlarge their business?
- What is the capacity of NGOs that are providing health care services?
- What is the geographic reach of each company or NGO? Are they limited to urban distribution?
- Would additional supply responsibilities be easily absorbed, or would such responsibilities overwhelm their capacity?
- What licensing provisions and incentives are in place to increase geographic access through private wholesalers and retailers?
- Does the law permit the sale of any essential prescription medicines in nonpharmacy drug outlets?
- Can the drug regulatory authority ensure the quality of privately sourced medicines?
- Does the current supply system result in a greater reliance on the private sector for access to medicines?
- What kind of training and certification exists for pharmacy aides and other drug sellers?
- What types of policies, legislation, and regulations on clinician dispensing exist?

Notes: Supply system performance should be measured at least annually. Most indicators can be measured at regional and other supply depots as well as at health facilities. Whenever possible, annual figures should be compared for the most recent year and two preceding years (three years total). See Chapter 48 for a discussion of indicator medicines. See assessment guides for Chapters 18 and 22 for additional procurement and distribution indicators, respectively. *Countries.* 12th ed. Geneva: Campaign for Access to Essential Medicines/MSF. Updated regularly and available online at http://utw.msfaccess.org.

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