CHAPTER 4

National medicine policy

SUMMARY

A national medicine policy (NMP) is a political commitment and a guide for action that shows how the government will ensure that efficacious and safe medicines of good quality are affordable, accessible, and rationally used. The NMP provides a framework for coordinating the activities of all the parties involved, such as the public and private sectors, nongovernmental organizations (NGOs), donors, and other interested stakeholders; it also defines the role that the public itself should play.

The medicine policy of one country may be similar in many ways to the medicine policies of other countries, but because their starting situations will vary, the policies will likely differ in what they emphasize and in how problems can best be tackled. A national government will be the principal agency responsible for creating the overall NMP and putting it into practice; however, collaboration will be needed with prescribers, dispensers, consumers, and those who make, market, distribute, and sell medicines. Sometimes, disagreements among the parties will be unavoidable because their interests differ, but ideally a wide partnership will develop, because an effective medicine policy is ultimately in the best interests of all.

This chapter examines the components of an NMP. Countries must choose the elements most relevant to their situation and most realistic, given their available human and financial resources. At the outset, governments will need to give priority to solving current problems, such as a lack of relevant laws and regulations and difficulty in implementing and enforcing laws and regulations that already exist; issues of finance, supply, cost, and pricing; and rational use of medicines. Less pressing matters may be addressed later.

This chapter reviews the main steps in formulating an NMP including—

- Organizing the process
- Identifying and analyzing problems
- Setting goals and objectives
- Drafting the policy
- Seeking wide agreement on the policy
- Obtaining formal endorsement of the policy
- Launching the policy

Formulating a policy is one thing; putting it into effect is another. No single, best way to implement an NMP exists, but this chapter shares the approaches that some countries have taken.

Experience shows that the essential medicines concept is central to a successful national medicine policy. The core of the concept is using an established list of essential medicines based on standard treatment guidelines, leading to a better supply of medicines, more rational prescribing, and lower costs. Finally, the success of an NMP will depend heavily on political commitment by the government and support from all stakeholders in the pharmaceutical sector.

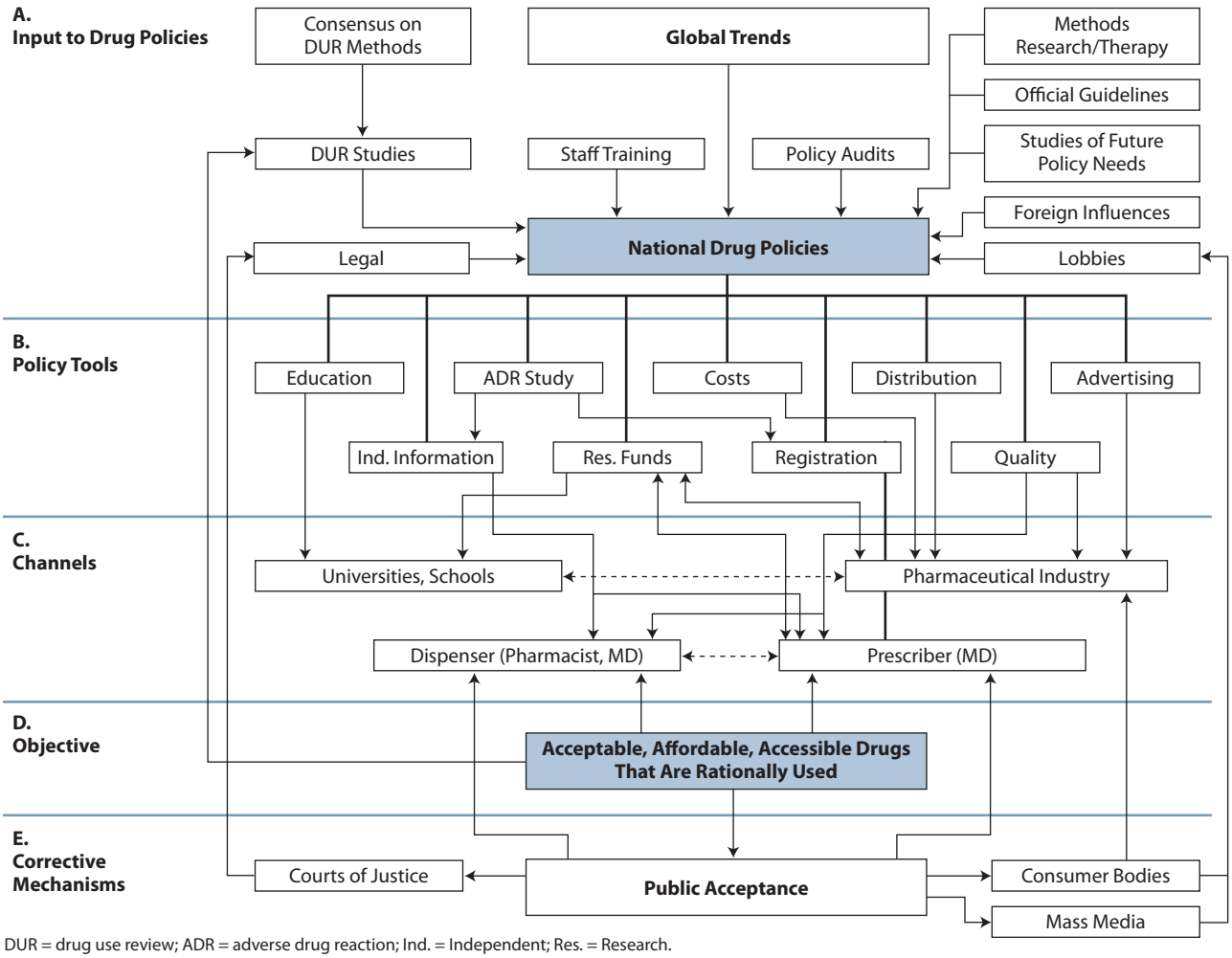
4.1 Introduction

For many decades, pharmaceutical policies were developed in a piecemeal fashion, where they existed at all. At one moment, a country may have developed a regulation on pharmaceutical advertising—at another moment, a decree on the places where medicines can be sold. One country might concentrate on sound manufacturing practice—another country on the problem of providing very poor populations with access to medicines. Only gradually did people come to realize that the issue of medicines and their proper place in society needed to be looked at as a whole. If a policy covered only select issues in the pharmaceutical sector, problems could soon arise with other issues; in fact, a one-sided approach might actually make a situation worse.

In the 1970s, for example, efforts were made in certain countries to solve problems involving pharmaceutical procurement and distribution without examining the ways in which medicines were being prescribed or used by patients. The result in some instances was that access to medicines improved, but people did not know how to use them rationally. Similarly, essential medicines policies developed for the public sector only were ineffectual because they did not address how the private and public sectors could complement each another. More recently, some East African countries' difficulties in collecting direct taxes have led to a heavier reliance on import duties and manufacturing taxes, including those from medicines. This policy makes imported pharmaceuticals more expensive and discourages local production, resulting in the availability of fewer low-cost medicines in the marketplace.

These experiences suggested that pharmaceutical problems might be better tackled within a common framework created through the development of a comprehensive national medicine policy. The overall goal of an NMP should be to promote equity and sustainability of the pharmaceutical sector (WHO 2003). Its general objectives can be simply

Figure 4-1 Structure of a complete national medicine policy



DUR = drug use review; ADR = adverse drug reaction; Ind. = Independent; Res. = Research.

This figure shows how many different elements are linked in the construction of a national medicine policy. No individual country's policy is likely to be structured in exactly the same way, and many national medicine policies are simpler. The chart can, however, be useful in analyzing the situation and looking for solutions. For example, the area of rational prescribing can be analyzed by examining the linkages illustrated. The figure shows that the prescriber is likely to receive information, advice, and persuasion from various sources: the institution where he or she was educated, the drug regulatory agency, formularies, industry representatives, and others. Can the quality of influencing sources be improved? Do they reinforce or contradict one another? Is some better form of guidance needed if the prescriber is to improve rational prescribing practices?

stated: a national medicine policy should ensure that *effective* and *safe* medicines of *good quality* are *accessible* and *affordable* to the entire population and that they are *rationally used*.

The 1980s saw the idea of an NMP emerging as a positive concept, and the World Health Organization (WHO) and World Bank became active in developing the idea further. Now the idea that every country should try to achieve optimal availability, quality, and use of medicines for patients and consumers is widely accepted. By 2007, more than 130 countries had formulated NMPs, about 60 percent of which had an updated implementation plan in place (WHO 2010).

4.2 What is a national medicine policy?

An NMP is a political commitment to a goal and a guide for action. It is a written document specifying the medium- to long-term goals set by the government for the pharmaceutical sector, their relative importance, and the main strategies for attaining them. Moreover, it provides a framework for coordinating activities of the pharmaceutical sector: the public and private sectors, NGOs, donors, and other interested parties. (Figure 4-1 illustrates the structure of a national medicine policy.) The NMP should be incorporated into the national health system to ensure that NMP goals and objectives are addressed in broad national health plans,

including disease-specific programs, and that resources are allocated efficiently. An NMP should also express the government's commitment to promoting good governance practices, including increased transparency and accountability.

In the developed world, most countries do not have written NMPs, yet many are successful in pursuing pharmaceutical sector goals. However, even in those countries, some experts advocate drawing up a document that clearly outlines the objectives of an NMP; for example, Australia launched an official NMP in 1999. In countries where resources are severely limited, an integrated approach to solving problems helps make the best use of limited resources.

What should a medicine policy accomplish?

The overall purpose of an NMP is usually expressed in general terms, without necessarily touching on every aspect of the policy. The purpose stresses the most important objectives in the simplest way. In Nigeria, the medicine policy states that the goal is "to make available at all times to the Nigerian populace adequate supplies of drugs that are effective, affordable, safe and of good quality; to ensure the rational use of such drugs; and to stimulate increased local production of essential drugs" (Federal Ministry of Health, Nigeria/WHO 2005). In Ghana, the overall goal of the policy is "to improve and sustain the health of the population of Ghana by ensuring the rational use and access to safe, effective, good quality and affordable pharmaceutical products" (Ministry of Health, Ghana, 2004).

Although specific objectives differ according to the priorities recognized by the government, the most common follow the essential medicines concept and are directly *health related—*

- To make essential medicines available and affordable to those who need them
- To ensure the safety, efficacy, and quality of all medicines provided to the public
- To improve prescribing and dispensing practices and to promote ethical practices among health professionals and the correct use of medicines by health workers and consumers

The core of the essential medicines concept is that the use of a limited number of medicines that have been carefully selected based on agreed standard treatment guidelines leads to a better supply of medicines and more rational prescribing, as well as to lower medicine costs.

The national medicine policy may also include economic goals (for example, to reduce the use of foreign exchange for pharmaceutical imports, or to provide jobs in areas such as dispensing, prepackaging, or production of pharmaceuticals) and national development goals (for example, to improve internal transportation and communication systems, develop national pharmaceutical production, or to take a stand on intellectual property rights in this particular field). Regardless of a country's specific circumstances, a comprehensive NMP should clearly specify the roles of both the public and the private sectors.

In addition, the policy should be concerned with *efficiency* (delivery of the maximum level of services given a certain level of resources); *equity* (fairness in access); *sustainability* (the ability to provide continued benefits into the future without relying on external support); and *transparency,* with clear lines of accountability. Finally, the NMP should address the issue of access to essential medicines as part of the government's obligation to fulfill its citizens' right to health (see Section 4.4).

What approaches should be used?

In addition to indicating the broad political choices that the government has made regarding the pharmaceutical sector, a general medicine policy should define some specific objectives—outcomes to achieve within a given time frame. Each objective must be linked to some clear ideas about how it will be obtained. For instance, the supply of essential medicines can be improved in the public sector by increasing the pharmaceutical budget, introducing cost-sharing mechanisms, or allocating more resources to underserved populations. Pharmaceutical supply can also be increased through the private sector by introducing economic incentives for pharmaceutical manufacturing and distribution. Some of these strategies can be introduced in the national policy document, whereas others may need to be worked out separately, after additional research and consultation. Including too much detail in the national policy may make it difficult to read and understand. The optimal solution is likely to involve applying different approaches in the private and public sectors. This combination of different approaches and strategies forms the core of an NMP.

Why do medicine policies differ by country?

Objectives and strategies may differ from country to country for various reasons. Differences may exist in the structure of the health care system, the number of trained pharmacists and physicians, the capacity of the drug regulatory authority, the way in which pharmaceuticals are distributed, or the level of funding available for pharmaceuticals. The biggest differences in the scope of medicine policies lie between industrialized countries and least developed countries.

In most industrialized countries, health care coverage is broad, and access to medicines per se is not a prominent

issue (although cost is likely to be a concern). The annual public and private expenditure on medicines is high, perhaps 500 U.S. dollars (USD) per person or more (WHO 2004b). The role of the government here is to set up rules for the operations of the private sector without becoming directly involved in medicine provision or in the pharmaceutical industry. This model requires the existence of an active private sector that is capable of developing, manufacturing, marketing, and distributing medicines to the entire population. Therefore, in these settings, pharmaceutical policies are oriented heavily toward containing costs while ensuring rational use in the interests of both public health and the economy, and the regulations should focus on the quality assurance of pharmaceutical products and services as well as on cost containment.

Although many middle-income countries have experienced improvements in indicators that measure pharmaceutical access, WHO estimates that almost one-quarter of the population in middle-income countries still lacks access to essential medicines (WHO 2004b). Whereas least developed countries are afforded equity pricing for some medicines, such as those for HIV/AIDS, middle-income countries that are ineligible for such discounts pay higher prices; however, in 2009, only one-third of these countries were instituting economic policies that could help make medicines more affordable (Stevens and Linfield 2010).

In the least developed countries, total spending on pharmaceuticals is less than USD 5 per person per year (WHO 2004b). The private sector has traditionally failed to supply affordable, high-quality medicines to the majority of the population. Consequently, governments have attempted to supply and distribute essential medicines through the public sector, often with donor support. In addition, policies often focus on such matters as ensuring the proper use of a basic range of essential medicines and encouraging the private sector to play a more constructive role in supplying those medicines.

Who are the main participants in developing and implementing a national medicine policy?

The national government is the essential driving force in designing and implementing medicine policies. Through its medicine policy, the state seeks to guarantee the availability and accessibility of effective, high-quality essential medicines for the population and to ensure that they are properly used. This goal holds true whether the government is directly involved in procurement and distribution of medicines, empowers parastatal or private institutions to carry out this function, or acts mainly as a regulatory authority for a largely private pharmaceutical market.

The government is not, however, the only actor involved with the NMP. A partnership is required, involving government ministries of health, finance, and industry; health professionals, including doctors and other prescribers and pharmacists; public and private wholesalers and retailers; academia; NGOs and consumer groups; and the pharmaceutical industry (national and multinational). Consulting with provincial and district personnel and traditional medicine practitioners is important. In addition, governmental agencies, such as the drug regulatory authority and government-sponsored health care and insurance schemes, must be involved. The involvement of such diverse groups and conflicting interests means that development and implementation of a sustainable NMP is not easy. Reaching full agreement with all the parties on every matter is ideal but not always possible. With patience and goodwill, however, an environment conducive to success can be created.

The ministry of health should establish a specific office that is responsible for coordinating the NMP review and implementation process. The office should arrange regular NMP stakeholder committee meetings to assess implementation and policies. Working groups may be needed to analyze the effect of the NMP on specific areas. In addition, the NMP office should be given the capacity to monitor and evaluate the implementation process and coordinate necessary action plans with stakeholders.

The consultations and national discussions that lead to the production of the medicine policy document are very important because they create a mechanism to bring all parties together and achieve a sense of collective ownership of the final policy. This "buy-in" is crucial in view of the national effort that will later be necessary to implement the policy. The policy *process* is just as important as the policy *document* (WHO 2001). (Box 4-1 lists all of the stakeholders involved with the most recent revision of Ghana's National Medicine Policy.)

The development and implementation of an NMP is a highly political process, requiring careful analysis to understand who the advocates are, who the opponents are, and what each group's strategies are. Mobilizing alliances and coalitions and creating constituents inside and outside the government are necessary to mobilize political will during the process.

4.3 Components of a national medicine policy

The areas of pharmaceutical policy unavoidably overlap, but the main components include legislation and regulation, choice of medicines, supply and financing policies, and a means of encouraging rational medicine use. Some countries also have a tradition of local production (or they have ambitions in this area), and that factor can also be a key issue in a national medicine policy. These components form the basic framework, with other components added according

Box 4-1
List of stakeholders who provided input in the 2004 revision of Ghana's National Medicine Policy

- Accra Metropolitan Health Directorate
- Association of Ghana Industries
- Customs, Excise and Preventive Service
- Dangme West District Administration, Greater Accra
- Danish International Donor Agency
- Department for International Development
- European Union, Ghana Delegation
- Faculty of Law, University of Ghana
- Faculty of Pharmacy, Kwame Nkrumah University of Science and Technology
- Food and Drugs Board
- General Practice Pharmacist Association
- Ghana Registered Nurses' Association
- Ghana Standards Board
- Government and Hospital Pharmacists Association
- Greater Accra Regional Directorate of Pharmaceutical Services
- KAMA Health Services, Accra
- Komfo Anokye Teaching Hospital
- Lady Pharmacists Association
- Ministry of Environment, Science and Technology
- National Centre for Pharmacovigilance
- National Drug Information Centre
- Pharmaceutical Manufacturers Association of Ghana
- Pharmaceutical Society of Ghana
- Pharmacy Council of Ghana
- Pharmacy Department, Korle-Bu Teaching Hospital
- Save the Children Fund, UK (Ghana Office)
- School of Medical Sciences, Kwame Nkrumah University of Science and Technology
- The World Bank, Ghana Office
- United Nations Population Fund
- University of Ghana Medical School, Korle-Bu
- Upper West Regional Directorate of Pharmaceutical Services
- Veterinary Council of Ghana
- Volta Regional Health Administration
- World Health Organization Headquarters, Geneva

to local conditions. Each component is essential but not sufficient in itself to ensure access. Box 4-2 summarizes these basic components of a national medicine policy, which are discussed further in the following sections.

Legislative and regulatory framework

The formulation of a medicine policy should be followed by the enactment of appropriate legislation and the introduction of regulations to provide a legal basis for the policy and make it enforceable. An NMP is usually a declaration of intent rather than a law, so the strategies set out in the policy may need to be supported by appropriate laws and regulations. In the Philippines, for example, one policy objective was to extend the use of generic medicines, and many activities related to that objective were reinforced by a new law on generics.

Legislation should provide the basis for ensuring that pharmaceutical products are of acceptable quality, safety, and efficacy and specify an agency to be responsible for this. Regulations, which are more flexible than legislation, should define the actors in the system and their responsibilities: regulations should state who can produce or import pharmaceuticals, who can prescribe them, and which medicines can be sold without the need for a prescription. Regulations should also state who can store and sell pharmaceuticals, and which institution is responsible for monitoring and enforcing regulations. Several legislative models and structures have been devised for the regulation of medicines, as discussed in Chapter 6.

As noted, making a policy, or even a law or regulation, provides no guarantee that it will be implemented. Too often, laws and regulations are not enforced, and the penalties and sanctions that the law provides are not imposed. Sometimes this failure results from lack of resources or lack of political will; sometimes an element of corruption exists. Although a commitment to good governance and the need to fight corruption should be included as a cross-cutting item throughout the NMP, some countries may also have a separate component that specifically defines how a good governance program will be implemented (Anello 2006). Another reason for failure may be that the government's rules are impractical or difficult to enforce. In this case, a careful review of the main regulations applying to the pharmaceutical sector may lead to proposals to amend them so that they are better adapted to local realities and can be better enforced.

Appropriate legislation and regulation should be accompanied by a functioning quality assurance system; pharmaceuticals of low quality, either imported or locally produced, should never reach the patient. Quality assurance calls for a transparent pharmaceutical registration system and a well-organized and -trained inspection administration that is independent of commercial pressures and a system of quality control backed by one or more laboratories (see Chapter 19).

Box 4-2
Components of a national medicine policy

Legislative and regulatory framework

- Legislation and regulations
- Drug regulatory authority
- Medicine registration and licensing
- Pharmaceutical quality assurance, including inspection and enforcement
- Pharmacovigilance
- Regulation of prescription and distribution
- Infrastructure for good governance in medicines

Choice of essential medicines

- Principles of essential medicine selection
- Selection process (market approval and selection based on national morbidity patterns)
- Selection criteria (sound and adequate evidence, cost-effectiveness)
- Use of essential medicines lists
- Traditional and herbal medicines

Supply

- Local production
- Supply system strategies and alternatives, including mix of public and private sectors
- Procurement mechanisms
- Inventory control, including prevention of theft and waste
- Distribution and storage
- Disposal of unwanted or expired medicines

Rational use of medicines

- Multidisciplinary national body to coordinate medicine use policies
- Standard treatment guidelines as the basis for selecting essential medicines and training health professionals
- Independent medicine information
- Rational medicine use training for health personnel
- Education about rational use of medicines for consumers
- Promotional activities

Affordability

- Taxes or tariffs on essential medicines
- Distribution margins and pricing
- Measures to encourage competition through generics and price information and negotiation
- Trade-related intellectual property mechanisms

Financial strategies for medicines

- Role of government in the pharmaceutical market
- Pharmaceutical financing mechanisms (public financing, user charges, health insurance, donor assistance)
- Measures to improve efficiency and cost-effectiveness

Human resources development

- Role of health professions
- Role of government in planning and overseeing training and development of human resources for the pharmaceutical sector
- Human resources management and development plan
- Education, training, and courses, including minimum requirements for each cadre of professional staff
- National and international collaborating networks
- Motivation and continuing education
- Ethical framework and code of conduct

Monitoring and evaluation

- Responsibilities and commitment
- Baseline survey of the whole country
- Indicators for monitoring
- Periodic monitoring
- Independent external evaluation every two to three years

Research

- Operational research
- Pharmaceutical development and clinical research

Technical cooperation among countries

- Information sharing
- Harmonization

Sources: Adapted from WHO 1995 and WHO 2003.

Choice of essential medicines

The selection of essential medicines to meet the health needs of the population and the registration of safe, high-quality, and effective medicines are important features of an NMP. Adoption of and political commitment to the essential medicines concept should guide selection and reimbursement decisions. Essential medicines are those considered most vital for saving lives and alleviating serious and common diseases in the majority of the population. WHO created the first Model List of Essential Drugs in 1977 and encouraged countries to use it as an example for making their own lists. Such national essential medicines lists have, in many countries, become the basis of public pharmaceutical supply systems. Hospital and outpatient practice formularies commonly guide prescribing in both the private and the public sectors. The principles, criteria, and process of medicine selection are described in Chapter 16.

In a wealthy country, any medicine that meets standards of quality, safety, and efficacy can be sold, and several thousand registered pharmaceutical products may be available on the market. Where resources are limited, however, an essential medicines list can limit the number of unnecessary or inappropriate purchases. For example, more than a hundred medicines are available to treat rheumatism and arthritis, but many are similar and some are unnecessarily expensive; three or four such medicines that are proven efficacious and affordable may be all that are needed to adequately treat patients. This selective approach is likely to save money and enable a resource-limited pharmaceutical management system to concentrate on essential medicines.

Medicines may also be selected using other criteria. For example, some countries have been hesitant to add fixed-dose combination products to lists that already include the individual components. Sometimes, a drug regulatory authority may be willing to accept a product only if its price is competitive with that of similar medicines already on the market. Some countries have accepted only medicines for which they believe a "medical need" exists—for example, where the medicines have special advantages over other products. This criterion is unpopular with manufacturers, and it is difficult to apply, but many insurance schemes now use the principle to determine for which medicines they are willing to make reimbursements. The NMP can define procedures to periodically update the national essential medicines list and address the selection of traditional and herbal medications.

Supply

In many developing countries, availability of essential medicines is the most pressing concern of the NMP. To ensure that high-quality medicines are available to all, governments not only need to select their priority medicines but also to define policies in production, procurement, and distribution, as well as to provide a mechanism for financing, which can be a key limitation. Such policies should take into account what is feasible in the short term and what is necessary for sustainable systems in the long term and under special circumstances, such as when transport is likely to be impeded during the rainy season.

In most countries, the private sector operates in the pharmaceutical supply system to some degree, including commercially based producers, importers, wholesalers, pharmacies, and other retail drug sellers. Private-sector products are often relatively expensive, with the costs covered either from the patient's pocket or refunded from a private or public insurance system. In less affluent countries, however, a public pharmaceutical supply system procures and distributes medicines and makes them available to consumers at either low or no cost. These public systems were set up in part because private-sector activities were concentrated in urban areas, prices put products out of reach of the poor, and no universal health insurance systems existed. The rationale for many of these state-supported systems persists, but they often require improvements in organization, management, and financing to carry out their mandate.

Another type of supply system is operated by NGOs, such as Christian or Islamic missions. Their goal is largely to supply the needs that are not met by the commercial private sector or the public sector, especially among the poor and in rural areas. Often their role is explicitly recognized by government and incorporated into the NMP and public health strategies.

Both government and NGO health services can be supplied through a variety of alternative arrangements that incorporate components of private-sector flexibility and efficiency (see Chapter 8).

Pharmaceutical production policy (see Chapter 7) is an important aspect of pharmaceutical supply. For many years, countries have been interested in developing their own local manufacturing capacity and a degree of national self-sufficiency. Unfortunately, the difficulties of local production have frequently been underestimated. Local production in developing countries is not necessarily a low-cost venture; although wages and some other costs are likely to be lower than in industrialized countries, pharmaceutical constituents and even packaging materials have to be imported, and maintenance of machinery is costly. Many factors influence the feasibility of local production, and a range of policy options exists. When formulating an NMP, the most important objective should be to get good-quality, therapeutically useful medicines to the people who need them, at prices they can afford—policies related to industrial production should not interfere with policies related to health care.

Affordability

Affordable prices are necessary to ensure access to medicines in both the public and private sectors. Newer medicines, such as those to treat HIV/AIDS and the newer artemisinin-based combination therapies for malaria, are very expensive. Possible mechanisms to increase affordability to essential medicines in all sectors include selecting cost-effective treatments, comparing price information, promoting price competition through generic substitution, regulating producer prices and retail margins (see Chapter 9, on pharmaceutical pricing policy), limiting tariffs on pharmaceuticals, and taking advantage of trade-related intellectual property measures such as compulsory licensing and parallel imports (see Chapter 3, on intellectual property and access to medicines).

Financing strategies

Ensuring stable and adequate financing for medicines is a major challenge. Public financing of medicines for government health services to increase access to medicines is accepted as a legitimate policy in most countries and by most institutions, and indeed, funding initiatives such as the Global Fund to Fight AIDS, Tuberculosis and Malaria have dramatically altered the pharmaceutical financing context in many developing countries. In addition, financing mechanisms such as user fees are used in the least developed countries to increase financial resources, but they are difficult to manage in a way that protects the poorest members of the population. Public and private health insurance schemes are becoming more common, and including reimbursement for medicines should be promoted. Financing policies should be designed to maximize resources for pharmaceuticals while keeping prices as low as possible. These issues are discussed in Chapter 11.

Rational medicine use

Medicines should be used appropriately, safely, and only when needed. Irrational medicine use includes overuse, underuse, and inappropriate use, caused by such factors as lack of adequate regulatory systems; shortages of essential medicines and availability of nonessential medicines; lack of sound, objective medicine information; and the considerable influence of medicine promotion on both prescribers and consumers.

An NMP should specify major activities and responsibilities for promoting rational prescribing, dispensing, and patient medicine use. A wide variety of approaches has been developed in an effort to promote rational prescribing and dispensing (Chapters 29 and 30). Medicine prescribing and use have been improved in certain institutional settings. Although not yet widely implemented, programs focused on rational medicine use can help improve medicine use in the public and private sectors. Pre- and in-service training can also promote rational medicine use.

Inadequate training of health professionals, lack of control of medicine promotion, and dispensing of medicines by untrained persons all promote irrational use of medicines. Strategies for public medication education should provide individuals and communities with the information, skills, and confidence necessary to use medicines in an appropriate, safe, and judicious way (see Chapter 33).

Human resources, monitoring, evaluation, and research

Implementing an NMP depends on people; they must be trained, motivated, and retained through competitive salaries and other incentives. Human resources management is therefore an important element of the policy. The roles of different health professions should be clear. The policy should lead to a human resources management plan that identifies education, training, continuing education requirements, and other elements necessary to develop and sustain an adequate supply of skilled professionals who are motivated to perform at a high level (Chapter 51).

The implementation of an NMP should be routinely monitored, and its effect should be evaluated at regular intervals. Provisions for monitoring and evaluation need to be included in the policy itself, and adequate staff and budget need to be allocated. Appropriate use of indicators helps quantify progress and needed improvements (Chapter 36).

Research is essential for health service and health care improvements. NMPs are particularly concerned with operational research aimed at constantly improving and adapting the selection, procurement, distribution, and use of existing medicines. The Lao People's Democratic Republic (P.D.R.) incorporated operational research into the monitoring and evaluation plan of its NMP (see Country Study 4-1). NMPs may also include specific provisions for clinical research and the development of new medicines, especially using local resources, such as indigenous plants.

Finally, many NMPs address technical cooperation among countries. Cooperation among countries within the same region and the same economic area has become increasingly common. There are examples of cooperation in virtually every aspect of pharmaceutical policy and management.

4.4 Setting priorities

When the basic components of a policy have been identified, choices must be made about the most appropriate strategies and activities to achieve policy objectives at each

Country Study 4-1
Using operations research to develop and implement the Lao P.D.R. National Drug Policy

The Food and Drug Department of the Ministry of Health in the Lao People's Democratic Republic introduced a National Drug Policy (NDP) in 1993 with the goal of ensuring the availability and rational use of high-quality medicines at a low cost, with a focus on vulnerable populations in remote areas. Over the initial ten years, the Food and Drug Department implemented the policy in three phases—

- Phase I (1993–95): Develop a draft NDP, train inspectors, and create an information, education, and communication strategy on the rational use of medicines
- Phase II (1996–2000): Implement the NDP in five pilot provinces, including building individual and institutional capacity, developing related laws and standard treatment guidelines (STGs), and initiating and evaluating operations research projects
- Phase III (2001–2003): Consolidate NDP achievements and revise the policy, roll out policy implementation to the rest of the country, further strengthen pharmaceutical management capacity, and continue operations research

The success of the Lao P.D.R.'s NDP implementation is due in part to the emphasis placed on health systems research, which began during Phase II. Operations research was built into the pilot program design to improve implementation by bridging the gap between policy and practice and to provide evidence for policy making. The six operations research areas included—

- Use of public health messages to reduce irrational use of antibiotics
- Use of traditional medicine in Champassack province
- Knowledge, attitudes, and perceptions about quality of drugs among customers and health care providers (including drug sellers)
- Effectiveness of "feedback" for improving treatment based on STGs
- Methods used to effectively implement the NDP
- Regulation of private pharmacies in Savannakhet province

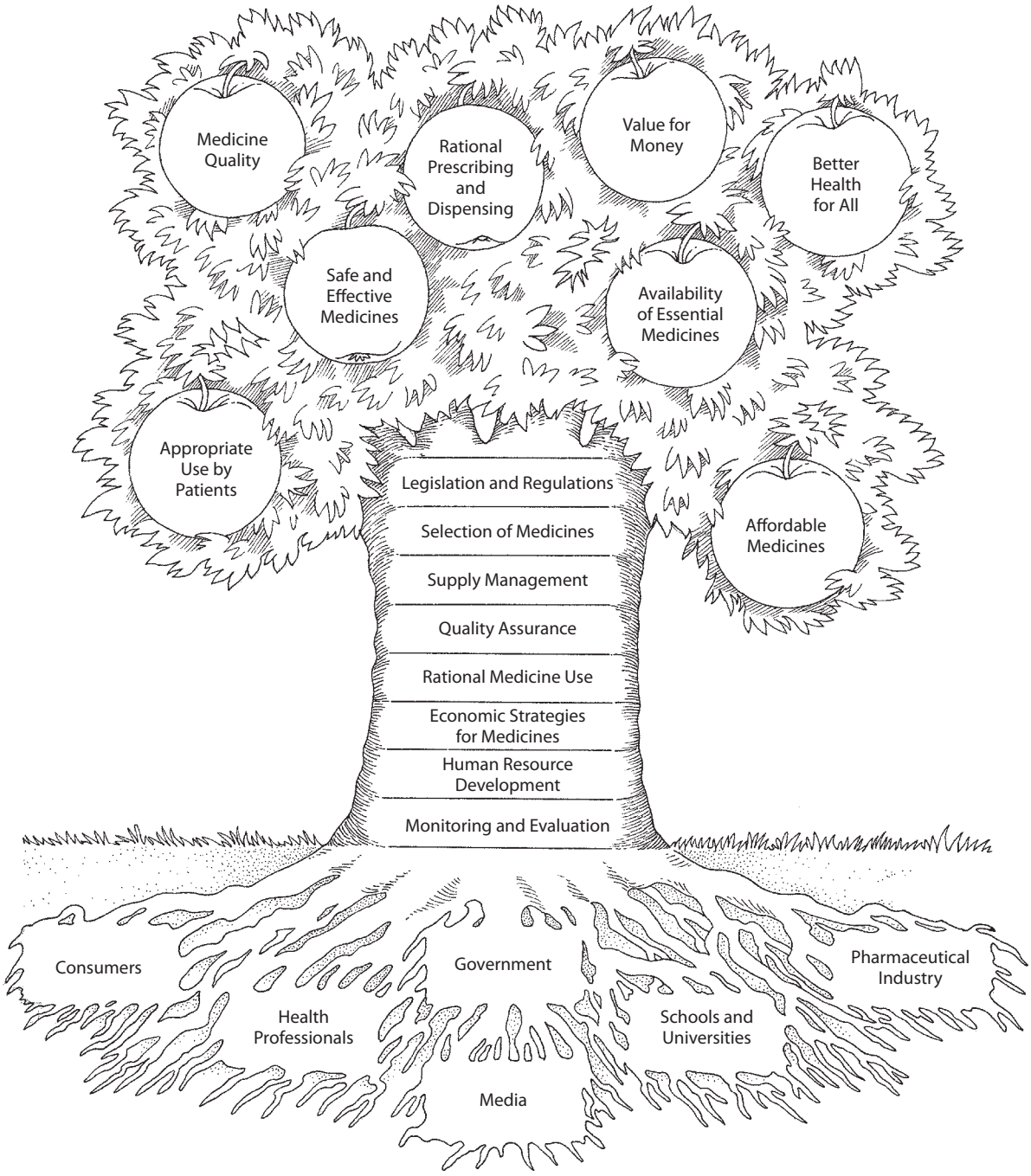
When results of a mid-program evaluation in 2000 showed the success of the NDP pilot program, policy makers revised the NDP to broaden its scope to include three new components: health systems research, human resources development, and overall management and coordination. In addition, recommendations were made to adapt the Lao NDP model for use elsewhere in the region.

Building research into the design of the Lao P.D.R.'s NDP yielded two strategic benefits. First, the results of this research guided the revision of the NDP in 2001 and showed policy makers how to more efficiently scale up the NDP nationwide. Second, building a research component into the NDP framework made monitoring and evaluation possible; the choice to pilot the implementation in only five districts made evaluating the NDP's effect by comparing pilot districts to control districts easier. In fact, research results showed that the pilot provinces performed significantly better in several aspects of quality and rational use of medicines. Research on the effectiveness of communications that promoted the rational use of medicines found that consumers still self-medicated with antibiotics, even after hearing medicines information on the radio and receiving advice from the doctor. This finding indicated that policy makers needed to adjust the information, education, and communication strategy regarding rational use of medicines.

Seeing the value of this research-based evaluation, policy makers made operations research a permanent component in the 2001 NDP. However, a solid operations research component alone is not enough to ensure a NDP's successful implementation. Research must be coupled with effective communication and dissemination of results, strong political will, and technical competence in the pharmaceutical sector.

Sources: Tomson et al. 2005; Lao P.D.R. Food and Drug Department 2003; Paphassarang et al. 2002.

level of the system. For example, to improve the supply system for essential medicines, many possible solutions exist: developing the central medical stores (CMS) further or transforming the CMS into a parastatal organization (as in Tanzania), decentralizing pharmaceutical procurement (as in Cameroon), or developing incentives for the private sector to manage supply and distribution. Activities can then be undertaken to implement the approaches selected—for example, using restrictive or competitive tenders, buying only from the essential medicines list, negotiating contracts with the private sector, and so forth. A series of interventions can be undertaken to increase rational prescribing and use of essential medicines, but depending on the country, some of these strategies will



NATIONAL MEDICINE POLICY—A TREE THAT BEARS FRUIT

be more cost-effective than others. Options may involve training medical students, providing independent medication information to all prescribers, or using programs for the ongoing review of medicine use to identify opportunities for improvement.

The range of strategies and activities that can be successfully implemented depends on the pharmaceutical situation and the socioeconomic conditions of the country. If resources are insufficient without external input, a set of priority activities should be identified that can be executed within existing means.

Initially, considering the following questions may be helpful—

- Is this approach based on scientific evidence, and has it proved to be effective in other countries?
- Is this approach or activity really needed to improve the situation in a particular area?

- Does it address the greatest needs?
- Are other approaches or activities available that might be more effective?

Policy elements may have to be set aside that—however successful they may have been in another country—would be no more than expensive luxuries in the local context, or would not work because too few technical and financial resources exist.

The combination of pharmaceutical policies that can be successfully implemented in a particular country over the short to medium term is closely linked to the structure of the pharmaceutical distribution systems, pharmaceutical spending levels, the presence or absence of health insurance schemes, the number of trained people available, and the capacity of the drug regulatory authority.

4.5 Formulating a national medicine policy

Formulating and implementing a national medicine policy are highly political processes. A policy should promote equity of access to health care by making the pharmaceutical sector more efficient, cost-effective, and responsive to health needs. Such responsiveness may involve the redistribution of goods and power, leading to increased competition among the groups affected by reform.

As mentioned, given the diverse interests and the economic importance of the issues involved, designing or revising an NMP requires complex negotiations with all stakeholders: the national and international pharmaceutical industry, the medical profession, retail drug sellers, NGOs, the government bureaucracy, and international donors. The challenge is to identify the main elements of an appropriate pharmaceutical policy and then construct a process that will bring the diverse groups together.

The pharmaceutical sector represents many varied interests that do not always run parallel; opposition to a new policy and sometimes even legal confrontations must be expected. Therefore, identifying political allies and maintaining their support throughout the process is important. Strategies to identify and deal with opponents should be developed, ways of working with them must be identified, and steps must be taken to resolve disputes. Differences may be resolved through effective communications, a collaborative approach, and careful monitoring of the policy formulation process. Decisions and priorities touching on the interests of various stakeholders must be balanced by estimating gains and losses. Nothing can be left to chance, particularly if the proposed policy seeks to change in an important way structures, historical practices, or the behavior of people. The more significant the proposed changes, the more the process of policy formulation should involve all stakeholders, taking account of their needs and fears and encouraging them to take an active part in the new policy. No simple formula exists, but political will and leadership, and effective communication and collaboration are the main components for success.

Step 1. Organize the policy process

The ministry of health (MOH) is usually the most appropriate agency to take the lead in developing an NMP. The first step is to decide how formulation of the policy will be achieved, who will be involved at the various stages, and how the necessary finances will be obtained. A plan outlining the process and the final output can be drawn up by the pharmaceutical department in the ministry, with the support of a small committee. The more changes the policy seeks to produce, the more different stakeholders will need to be involved. This factor should be considered from the beginning, because it helps to determine the resources needed. The need for external assistance from WHO or other countries with experience in developing an NMP should also be assessed at this stage.

Step 2. Identify and analyze problems

The second task when formulating a policy is performing a thorough analysis of the main problems so that attainable objectives can be set (see Chapter 36). The best way to begin is to bring together a small team of experts, including some who have performed similar studies in other countries. The national experts should not come only from the MOH; they may be from the health professions, from trade and industry, and from other agencies of government (particularly the treasury). The group's function is to examine the situation systematically, identify problems and root causes, recommend what must and can be done, and suggest approaches that might be taken. Recommendations can be formulated and discussed in a multidisciplinary workshop to prepare advice for the government. Ghana followed a similar process, which led to the drafting of an NMP in 2004 by a team of experts representing diverse interests, including consumer rights, law, traditional medicine, trade, and manufacturing.

However ambitious it may seem in the early stages of medicine policy development, the situation in the country as a whole needs to be systematically reviewed so as to identify viable reforms. This objective may be best achieved through a detailed situational analysis. For example, in countries where a poor national economic situation is a major factor leading to unsatisfactory pharmaceutical supply, basing reforms on demands for more government money makes no sense because such funds are not available. The ultimate solution must take these structural constraints into account. Not everything can be done at once, and for some urgently needed changes, reliance on donor

help may be necessary while a longer-term national solution is developed.

Step 3. Set goals and objectives

After high-priority problems and related goals have been defined, primary objectives can be identified. (See Box 4-3 for a list of the objectives of Malawi's NMP.) For instance, if one of the priority problems is the availability of poor-quality medicines, one of the primary objectives should be to ensure that they are replaced by products of good quality. The selection of the strategies or approaches is more complex and should come from the situational analysis in step 2 or perhaps in a workshop with key people asking some key questions: Where do these poor-quality medicines come from and why are they here? Would good-quality medicines necessarily be more expensive? What incentives would encourage improvements? After objectives and strategies are outlined, key participants can work out a strategy for improvement, which can then be discussed in a larger workshop to reach consensus among all the main participants.

However, not all the parties are likely to agree immediately on the strategy. Representatives of the pharmaceutical industry may be suspicious, fearing loss of profit; doctors and pharmacists may have different points of view and may worry about losing freedom; any party that feels secure in the status quo may feel threatened by change. Not uncommonly, one government agency will disagree with another on objectives, approaches, or timetables. To move forward, it is important to establish as much trust as possible, identify matters on which consensus and compromise are possible, and use those matters as the basis on which to proceed.

Step 4. Draft the policy

After a thorough analysis of the situation and an outline of the main goals, objectives, and approaches have been completed, a draft of the NMP should be written. It should state the general goal of the policy; in most countries, the goal will be to ensure that high-quality medicines are accessible and affordable to the entire population and that they are used rationally. Then the NMP should describe specific objectives and the strategy or strategies to be adopted for meeting each. For example, to ensure that essential medicines are available in health facilities (objective), the policy might propose the creation of an autonomous procurement unit and the strengthening of pharmaceutical management in health facilities (strategies).

This drafting of the policy can be done by the small committee of experts set up in step 2, with the support of the people who performed the situational analysis. The group should remain small, because a big group is difficult to manage and will have problems drafting a coherent text. The group may find that examples of NMP documents from other countries are helpful.

The draft policy should be assessed for its approach to human rights issues. Human rights concern the relationship between the state and the individual, generating individual rights and state obligations. Box 4-4 includes a list of questions to ask when assessing health programs for their attention to the right to health.

Step 5. Circulate and revise the policy

To get full support from all sectors, the document should be widely circulated for comments, first within the MOH

Box 4-3
Objectives of Malawi's 2009 National Medicine Policy

Broad objective of the NMP

To develop within the available resources the potential that medicines have to control common diseases and alleviate suffering.

Specific objectives of the NMP

- To ensure ready and constant availability (universal access) of essential medicines and medical supplies to the community
- To rationalize use of these essential medicines through the provision of improved medicine utilization information
- To educate the public on appropriate medicine use and storage
- To improve supply management, prescribing, dispensing practices, and patient adherence
- To ensure continuing education and professional development for pharmaceutical and other relevant health workers
- To institute a sustainable financing mechanism to ensure continuous availability of adequate quantities of the required essential medicines
- To ensure effective regulation of pharmaceuticals
- To strengthen partnership at the national, regional, and international levels in ensuring the full implementation of NMP through utilization of available resources, knowledge, and expertise

Source: Government of Malawi 2009.

Box 4-4
Access to essential medicines as part of the fulfillment of the right to health

The basic principles of what is called the "rights-based approach" include participation, accountability, nondiscrimination, attention to vulnerable groups, and explicit linkage to human rights instruments. Five simple questions are presented here to assess the medicines policy in a specific country or program.

1. Which essential medicines are covered by the right to health? Although WHO provides guidance on essential medicine lists, exactly which medicines are regarded as essential remains a national responsibility and, therefore, the national list of essential medicines should be used to define the minimum needs. If no such national list exists, the first step is to develop one. For situations outside the scope of national governments, such as ships and refugee camps, specific lists of essential medicines have been developed by WHO and relevant stakeholders.

2. Have all beneficiaries of the medicine program been consulted? True participation means that the beneficiaries of national medicines policies and programs are consulted in decisions that affect them. Besides the usual stakeholders, such as the government, universities, and professional associations, other important beneficiaries to be consulted are rural communities, nongovernmental organizations, patients and consumer groups, and representatives of the vulnerable groups listed in item 4.

3. Do mechanisms exist for transparency and accountability? The objectives of the medicines policy and program should be clear and include government obligations to respect, protect, and fulfill the right to health in line with any applicable international treaties. The policy should identify indicators and targets to monitor progress toward universal access to essential medicines. The national medicines policy should specify the roles and responsibilities of all stakeholders, with mechanisms in place to hold each of them accountable.

4. Do all vulnerable groups have equal access to essential medicines? How do you know? The main vulnerable groups to be considered are children (especially girls), women, people living in poverty, rural communities, indigenous populations, national (ethnic, religious, linguistic) minorities, internally displaced persons, the elderly, those with disabilities, and prisoners. Ensuring equality starts with collecting disaggregated access statistics for each of these groups. Such statistics are essential to create awareness among policy makers, to identify vulnerable groups that need special attention, and to monitor progress toward universal access. The minimum effort should consist of gender-disaggregated statistics and surveys specifically aimed at vulnerable groups.

5. Are safeguards and redress mechanisms in place in case human rights are violated? Access to essential medicines is best ensured by the development and implementation of rights-based medicines policies and programs; however, when progress is unjustifiably slow, mechanisms for redress and appeal are needed as a last resort. A WHO study has shown that targeted litigation is an additional means to encourage governments to fulfill their constitutional and international treaty obligations regarding the right to health and access to essential medicines.

Sources: Hogerzeil et al. 2006; Hogerzeil 2006.

and then in other government departments and agencies. Endorsement by ministries or departments, such as planning, finance, education, and commerce, is of particular importance, because the success of decisions regarding registration, foreign exchange allocations, and human resources development depends on the support of government officials outside the health sector. After this wide consultation is completed, the document can be finalized. Although the formulation of the policy should reflect broad participation by the community, health workers, the pharmaceutical industry, and universities, ultimate responsibility for producing the policy remains with the MOH and the government.

Step 6. Obtain formal endorsement for the policy

In some countries, the document can then go to the cabinet or parliament for formal endorsement. In others, it can be an administrative document that serves as a basis for the implementation plans and for changes in pharmaceutical laws, which are often needed. In certain cases the NMP document becomes a law—for example, in Uganda, where it was called the National Drug Policy and Authority Statute; however, the MOH found that arrangement made the implementation and revision of the NMP unwieldy, so the revised NMP was separated from the statute in 2002. Although creating a law can demonstrate strong com-

mitment on the part of the government, it is not always advantageous, because legislation is difficult to pass and difficult to change once enacted. Incorporating select components of the NMP into a law, such as was done with the Generics Act in the Philippines, may be more useful. When a national medicine policy was drafted in 2000 in newly independent East Timor, the policy was written as a simple text that could be printed in the media and posted on health facility walls for all to read, so that it became the property of the people as a nation.

Step 7. Launch the policy

Launching an NMP is a political task rather than merely a technical one. It requires as much attention as any other political campaign. Promotion should be based on good information, top-level political support, mobilization of highly qualified people, and securing of international support. The policy should be promoted through a clear and well-designed campaign that disseminates information through a variety of channels to reach different target groups. The policy needs to be explained in a way that allows the media and the public to become involved in discussions.

4.6 Implementing a national medicine policy

Policy implementation—the execution of approaches included in the policy through specific plans and programs—is a critical step; the policy itself is worthless if it is not implemented. Each NMP requires an overall implementation plan or master plan. Given the multisectoral nature of pharmaceutical issues, the MOH should develop, as early as possible, a consensus with other government agencies on action plans dealing with specific issues of economics and finance (including foreign exchange), commerce, industry, and education. The implementation plan roughly outlines for each component of the policy what needs to be done and who is responsible, estimates the budget requirement, and proposes an estimated time frame. The implementation plan allows coordination of donor input and assists in monitoring the policy implementation and intervening where necessary to keep the process moving.

The master plan should then be broken down into annual workplans, which should be carefully developed with the various agencies involved in implementation. The workplans should outline the specific approaches and activities for each component, specifying in detail who is responsible, listing the major tasks, and describing the target output, the detailed time frame, and the exact budget. (See Chapter 38 for more information on developing plans.)

Countries take different approaches to implementation (see Country Study 4-2 for Australia's approach). In all cases, if the policy is to succeed, government officials must be proactive and committed. A number of strategies are summarized below.

Use appropriate timing, and a combination of approaches and methods of implementation. Not everything can be done at the same time. In the Philippines, the rules for generic labeling and promotion had to be put in place before generic prescribing and dispensing could be implemented. In practice, a one-year interval was necessary between the issuance of the rules on generic labeling and the issuance of those on dispensing. In this way, by the time doctors and pharmacists were required to switch to generics, the products in the pharmacies had already been generically labeled.

Start implementation in relatively easy-to-change areas to ensure initial high-visibility success. Perception of success is an important consideration; if the policy is perceived to have yielded significant positive results, it is likely to continue to receive support from important sectors.

Adopt a flexible policy. In certain cases, an activity may have to be postponed because the timing is not right. If, for example, the policy proposes imposing strict rules on pricing, waiting until pharmacists have received an explanation about why the rules will be to everyone's advantage may be better than imposing the rules immediately and being met with resistance. Consensus building should always be balanced against compromising too much on key points. If the initial planning process has been carried out properly, valid objections should already have been addressed, and there should be no need to compromise later.

Use experts to vouch for the policy's technical soundness. It is important that the most qualified people in the medical and pharmaceutical fields support the policy (for example, clinical pharmacologists or specialists in the main hospitals and universities). Those who have been involved in developing the policy are likely to be its strongest advocates and its most useful allies as it is introduced and implemented.

Mobilize consumers, the media, or other key groups. Although such mobilization has been successful in the Philippines and Australia, this approach has not been common in Africa, because of the lack of a well-organized consumers' movement.

Create constituencies that support the policy both inside and outside the government. After suspicions have been allayed, such constituencies may be found in any sector. Even within the private sector, support will develop when people realize that a healthy public sector will complement rather than undermine the private sector. Having constituencies in all sectors is critical to the success of the implementation and the long-term sustainability of the policy.

Country Study 4-2
Innovative approaches in formulating and implementing a national medicine policy in Australia

In 1985, WHO called the Conference of Experts on the Rational Use of Drugs, which resulted in a document known as the *Revised Drug Strategy.* The 39th World Health Assembly, held in 1986, adopted this strategy, which calls on governments to implement a national medicinal drug policy. Australia, as a participant at this assembly, contributed to the development of this strategy. The need for a national medicine policy was further illustrated in the *Health for All Australians* document issued jointly by all Australian state and territorial health ministers in 1988.

Initially, in 1991, the government formed two advisory groups. The Australian Pharmaceutical Advisory Council (APAC) was a council of representatives from the major organizations involved, which would raise issues and make recommendations across the gamut of medicine policy. APAC represented an opportunity for all interested parties to contribute positively on a multilateral and consensus basis to the development and conduct of the policy.

The second group was the Pharmaceutical Health and Rational Use of Medicines (PHARM) working party, which advised the ministry on a policy for the use of medicines and a strategy for its implementation. PHARM drew on the best available knowledge and relevant concepts to establish a coherent framework for tackling the complex set of problems involved in the way medicines are used. The group also drew on research in behavioral change and health education; espoused principles of community ownership, participation, and consultation; and acknowledged the importance of media advocacy.

In 1992, this collaborative approach led to adoption of a draft national medicine policy. The approach was to—

- Use consumer and professional education as a primary tool
- Stimulate partnerships among the major players
- Identify—
  - What will empower consumers to use drugs well and encourage health professionals to help them do this?
  - What constitutes effective education?
  - What combination of information, skills, and motivation will be effective for different groups?
  - What will work in practice?
  - What standards should apply, and who should set them?

After policies were developed and implemented over several years, the government conducted a major review during 1999. What had evolved were four good but separate programs for improving the availability, quality, and quality use of medicines and the viability of the national pharmaceutical industry. In late 1999, the revised policy bringing these four programs together into one document was launched with government-wide support.

The 2000 National Medicines Policy has four objectives based on active partnerships, taking into account elements of social and economic policy—

- *Timely access to the medicines that Australians need, at a cost individuals and the community can afford.* The Commonwealth Government's Pharmaceutical Benefits Scheme helps improve the health of all Australian residents by ensuring they have timely access to necessary and lifesaving medicines at an affordable price.
- *Medicines meeting appropriate standards of quality, safety, and efficacy.* The Therapeutic Goods Administration provides a national framework for regulating therapeutic goods in Australia. It also ensures their quality, safety and efficacy.
- *Quality use of medicines.* Australia's National Strategy for Quality Use of Medicines (QUM) is central to the National Medicines Policy. The National Strategy for QUM is intended to assist the QUM partners, health care consumers, health practitioners and educators, health care facilities, the medicines industries, the media, health care funders and purchasers, and governments in becoming more aware of the QUM framework and approach.
- *Maintaining a responsible and viable medicines industry.* The chairs of the National Medicines Policy groups—the Pharmaceutical Health and Rational Use of Medicines Committee; the Australian Pharmaceutical Advisory Council; the Pharmaceutical Benefits Advisory Committee; and the National Prescribing Services—meet regularly to discuss issues of importance to the National Medicines Policy.

Each partner shares responsibility to various degrees for achieving each of these objectives, and all partners consider these central objectives in any relevant initiatives. The policy also recognizes the fundamental role consumers have in reaching these objectives, and all partners have committed to consult with consumer representatives. As of 2010, the policy still served as the framework for Australia's pharmaceutical sector.

Sources: Hodge 1993; Australian Government 1999.

There is no single, perfect way to implement an NMP. In most countries, the implementation process is launched and maintained directly through the pharmacy department of the MOH, as in Guinea, Tanzania, and Zimbabwe. Such a department is generally supported by committees that continue to deal with different aspects of the policy. The problem with this approach is the policy's lack of visibility; often, the limited human and financial resources of these departments prevent them from being proactive and coordinating all the actors, and physicians may not accept the promotion of rational medicine use if it comes from the MOH pharmacy department. In addition, the department may focus too much on pharmacological issues rather than on the broad public health aspects that should inform the NMP. The policy's central leadership needs to smooth out these differences and facilitate implementation; for example, by having the rational use component of the policy come from the medical department or an NGO. Country Study 4-3 illustrates how implementation can go wrong.

Regional cooperation can be useful in implementing medicine policies. Countries, institutions, and organizations can share information, expertise, skills, and facilities. Exchanging experiences helps ensure that best practices are promoted, that mistakes are not repeated, and that limited resources are used effectively. The East, Central, and Southern Africa Health Community of fourteen member countries has developed a template for a national pharmaceutical policy that its members can use as a resource for creating or revising their own national policies. The WHO Regional Office for Africa has a website with country profiles that include documents related to national medicine policy in African countries (http://www.afro.who.int/en/clusters-a-programmes/hss/essential-medicines/edm-country-profiles.html). These various documents can be used as resources and bases for comparison for any country developing or implementing an NMP.

4.7 Monitoring and evaluating a national medicine policy

Monitoring is a form of continuous review that allows senior managers to assess the progress toward achieving defined targets in each policy area and adjust strategies accordingly. It can be carried out using a combination of methods, including supervisory visits and both routine and sentinel reporting.

Evaluation is a way of analyzing progress toward meeting objectives and goals. It should build on and use monitoring systems. At the start of a program, evaluation is used to provide a clear assessment of needs. A midterm evaluation can provide valuable information about how well the program is working. Final evaluation allows a complete review of program achievements from which lessons can be drawn for the future.

A system for monitoring and evaluation serves as a management tool that enables continuous assessment of progress and helps officials make management decisions in response to problems identified. The findings, results, and recommendations of the monitoring and evaluation team should be discussed with national stakeholders and should serve as the basis for identifying problems, finding solutions, and improving performance. A monitoring and evaluation sys-

Country Study 4-3
When things go wrong with national medicine policies: The case of Yemen

From 1995 to 2002, the Republic of Yemen received technical help in developing a national medicine policy. An important element included the creation of an effective public pharmaceutical supply system to serve the 30 percent of the population unable to afford private-sector medicines.

Initially funded by donors, the system was intended to rely partly on government funding and partly on patient contributions. By late 2005, the system had virtually collapsed, and in an attempt to improve the situation, the government "nationalized" the system and declared that all medicines would be supplied free of charge from then on; however, no evident improvement occurred. By early 2006, donors were helping the government determine why the system had failed while instituting an emergency supply program.

The situational analysis showed that the revolving fund proposal had never been adequately implemented through a detailed plan of action, that expectations of patient contributions had been too optimistic in view of widespread poverty, that successive governments had shown too little commitment to funding, and that corruption had played a major role.

In such situations, bringing together the original players and seeking their views on the failure and on a recovery plan are vital. In Yemen, a small-scale emergency scheme was set up to restore faith in the system, to be followed by a longer-term (five-year) recovery plan.

tem also provides transparency and accountability and creates a standard by which comparisons can be made between countries and areas and over time. All this information may produce the necessary evidence that progress is being made (or not) to support the policy in discussions with interested parties and policy makers.

Indicators for monitoring national medicine policies have been developed by WHO and are discussed in Chapters 36 and 48. Indicators may need to be developed, adapted, or deleted to match particular national contexts. For example, countries may have additional objectives beyond those included in the WHO manual, such as development of national medicine production. In any case, a formal monitoring system is needed; ideally, this system would be integrated with the health information system. A lack of understanding about the value of monitoring and feedback can be a limitation that results in the inadequate allocation of human and budgetary resources. Therefore, this institution-building process requires the commitment of senior policy makers, but effective monitoring can be carried out even in countries with limited resources.

4.8 Constraints and facilitating factors

Formulating and implementing an NMP should be manageable, yet few countries have succeeded in implementing all aspects of their planned policies. Why? Some of the main reasons are clear—

Lack of political will: Many governments hesitate to create policies that might antagonize industry and other groups, particularly if opposition is known to exist. Building support even in potentially hostile sectors is important at the start of the process and as implementation progresses.

Lack of resources: Often, understanding or documentation of the problems, their causes, and solutions in the pharmaceutical sector is not sufficient to persuade national governments to devote scarce resources to building and implementing NMPs. The MOH will need to be persuasive in its communication with other ministries and departments to avoid these problems; the essential message is that a national medicine policy contributes to improving people's health and therefore to strengthening the economy and the nation.

Opposition: Frank opposition to medicine policies often comes from those who benefit from a laissez-faire approach. Doctors fear interference with their freedom to prescribe. Importers and manufacturers are commonly earning large profits on precisely the medicines or pharmaceutical practices that they fear would be threatened by policy changes, such as price controls or better procurement procedures. Retail pharmacists may oppose policy initiatives that would threaten their earnings.

Corruption: Corruption can be an issue in the pharmaceutical sector, where a great deal of money flows and where demand, as a rule, greatly exceeds supply. No easy solution exists; corrupt practices in a country usually extend well beyond the pharmaceutical sector. However, as the pharmaceutical sector balances the roles of public and private services, corruption is likely to decrease.

None of these impediments is easily overcome, but a number of factors can facilitate the policy process—

Support of domestic and international interest groups: Some of the domestic groups whose support is needed include political parties, industry groups, physicians and other health care professionals, consumers, and consumer activist groups. International interest groups include foreign governments, multilateral organizations, multinational corporations, and international lending agencies. Their support is required for successful policy formulation, even if it is sometimes necessary to enter into bargains and trade-offs to win such support. The consequences of each trade-off in the formulation and implementation of pharmaceutical policies should be carefully considered.

Shared values: The extent to which a congruence of interests exists among groups is another important predictor of the success of an NMP. The interests of a politically weak group (for example, poor consumers) can often be protected if its goals coincide, at least partially, with those of more powerful interest groups (for example, retail pharmacists who want to sell more medicines and are willing to handle generic products because the higher volume of sales can compensate for lower unit earnings).

The macroeconomic situation: Improvements in the efficiency of the pharmaceutical system may help countries cope with the consequences of macroeconomic shocks. For instance, the devaluation of the franc in West Africa pushed countries in the region to strengthen their essential medicines policies in the public sector and to introduce mechanisms to promote the sale of medicines under generic names in the private sector alongside more expensive branded products.

Technical expertise: The existence of technical expertise and capabilities within ministries of health, as well as access to data on patent-related issues and pharmacological, legal, and economic policy (including the policies of other countries), are key to the formulation of a sound and workable policy. WHO has a cadre of medicine advisers located in its country offices who can provide technical expertise (http://www.who.int/medicines/areas/coordination/medicinesadvisers/en/index.html). Donors and international organizations can also sup-

ASSESSMENT GUIDE

National medicine policy development and content

- Does an official NMP document exist? Has it been updated in the past ten years?
- Does the document contain objectives and strategies based on priority problems?
- Does it cover issues such as legislation, essential medicines list, registration of pharmaceuticals, supply of essential medicines, financing and pricing policies, and rational use of medicines?
- If no official NMP document exists, do any unofficial documents set objectives and strategies for the pharmaceutical sector?
- Do laws exist that specify the government's responsibility in ensuring equitable access to essential medicines?
- Does the national constitution or any other national law recognize the right of everyone to the enjoyment of the highest attainable standard of health?
- Were patients' organizations and rural communities consulted when the NMP and program were developed?

NMP implementation

- Is the NMP used as a guide for action by policy makers and senior management officers in the ministry of health?
- Does the NMP describe the obligations of the various stakeholders?
- Does the pharmaceutical legislation provide a legal basis for enforcement of the NMP?
- Does an implementation plan exist to put the policy into practice?
- Is the policy monitored regularly? If so, how is it monitored? Are baseline and target data available on access to essential medicines against which progress can be measured?
- Does any evaluation take place of the performance and outcome of the NMP in terms of attaining its objectives?
- Are legal mechanisms available to file complaints about lack of access to essential medicines? If so, have they been used?
- Is the NMP highly visible in the ministry of health and the government?

port the emergence and revision of medicine policies in developing countries through planning and technical assistance.

The presence of committed people in the MOH: In the United Kingdom in 1968, Bangladesh in 1982, the Philippines in 1986, Guinea in 1992, and Uganda in 1993, the development of these countries' first medicine policies was sustained by individuals and institutions that were persuaded of the need for it and worked toward its realization.

Each country must shape its own NMP in accordance with its needs and resources. The goals outlined at the beginning of this chapter provide a policy focus. Experiences in countries show that success in terms of public health is linked to the essential medicines concept, with an emphasis on a list of essential medicines. Strategies vary among countries, and in the end, the impact of a country's NMP depends on political commitment from the government and the support of doctors and other health professionals.■

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