

Policy and legal framework

- 1 Toward sustainable access to medicines
- 2 Historical and institutional perspectives
- 3 Intellectual property and access to medicines
- 4 National medicine policy
- 5 Traditional and complementary medicine policy
- 6 Pharmaceutical legislation and regulation
- 7 Pharmaceutical production policy
- 8 Pharmaceutical supply strategies

Financing and sustainability

CHAPTER 2

Historical and institutional perspectives

Summary 2.2

- 2.1 The discovery of miracle medicines 2.2
- 2.2 The increasing gap in access to medicines 2.2
- 2.3 The rise of the essential medicines concept 2.3
UN agencies and WHO lead the way • The emergence of generic pharmaceuticals • The movement accelerates • The industry's reaction • The campaign for rational use of medicines
- 2.4 Global focus on AIDS, tuberculosis, and malaria 2.6
The role of advocacy groups and community-based organizations • Lack of systems to support access to medicines for HIV/AIDS, TB, and malaria
- 2.5 Current organizational roles in essential medicines 2.7
WHO and other UN agencies • Nongovernmental organizations • Regulatory bodies • Industry organizations
- 2.6 Clients, governments, producers, and beyond: changes in the pharmaceutical field 2.9
The evolving pharmaceutical industry • Intellectual property laws • Public-private pharmaceutical initiatives • Globalization and the Internet • Ongoing policy changes

References and further readings 2.11

ANNEX

Annex 2-1 Useful contact information 2.12

SUMMARY

Concerns about medicines—or lack of medicines—can be traced back for centuries. The discovery of “wonder drugs” about the time of World War II, however, was a milestone in pharmaceutical management. The dramatic effectiveness of some new pharmaceuticals and the intensive marketing of many others combined to catalyze widespread use of modern medicines. A rapidly growing and profitable industry, together with an enthusiastic but largely uninformed public and an often inadequately regulated marketplace, resulted in excesses of promotion and consumption, along with substantial levels of expenditure that necessitated new policy measures.

Despite the advent of wonder drugs, however, it had become clear by the 1970s that the least-advantaged nations were not even meeting the basic needs of their people for essential lifesaving and health-promoting medicines. Through the 1970s and 1980s, governments and international organizations such as the World Health Organization (WHO) began to redress this imbalance, with support from nongovernmental organizations (NGOs), largely through the promotion of essential medicines programs.

In the 1990s and 2000s, the devastation caused by the HIV/AIDS pandemic specifically helped draw atten-

tion to the plight of people living in resource-limited areas—especially sub-Saharan Africa—and the increased interest in health care and funding for treatment in developing countries spawned a number of significant global initiatives to address inequities and increase access to health care and essential medicines in the most-affected countries. As the world responds with dramatically increased financial assistance to provide affordable medicines for HIV/AIDS, tuberculosis (TB), and malaria, there has been growing recognition that the effectiveness of these multimillion-dollar initiatives is limited by the capacity of health care and pharmaceutical supply systems at the national and local levels. Constraints to improving access to medicines include inadequate infrastructure in facilities and a lack of trained staff and equipment for those facilities.

Although differences have always existed between the way pharmaceutical policies have developed in industrialized countries, on the one hand, and developing countries, on the other, many elements of pharmaceutical policy are applicable everywhere. The increasingly globalized economy is driving more uniform approaches to pharmaceutical policy, especially as the many parties engaged in the pharmaceutical arena work together in global programs for the benefit of all.

2.1 The discovery of miracle medicines

During and soon after World War II, new and powerful medicines began to emerge in rapid succession from laboratories around the world. Penicillin was isolated and first used clinically in 1941; chloroquine, first investigated in the mid-1930s, was released for trial against malaria in 1943; and streptomycin followed in 1944 as the first effective medicine for tuberculosis. Adding to the earlier benefits of smallpox and typhoid immunizations, diphtheria and tetanus toxoid vaccines were first adopted during the war for use in large military populations. Tetracycline and chloramphenicol were introduced in 1948, isoniazid in 1951, and erythromycin in 1952. Chlorpromazine signaled a new era of mental health medicine therapy in the same year. In 1954, the sulfonylureas became the first oral preparations for treating diabetes, and nystatin emerged as an antifungal agent. In 1955, field trials of oral contraceptives took place in Puerto Rico, leading to a virtual revolution that enabled women to begin to effectively control family size.

In just over a decade, the whole field of therapeutics was revolutionized, putting into the hands of practitioners and consumers new pharmaceutical compounds that could

cure or control problems in ways largely unknown in earlier times. As both scientific and anecdotal evidence spread, practitioners and patients demanded, and were willing to pay for, the innovative and powerful products that the pharmaceutical industry was patenting and producing.

2.2 The increasing gap in access to medicines

In this exciting period during the middle of the twentieth century, many authors of popular books on pharmaceuticals wrote of the revolution in medical care that modern medicines had made possible: antibiotics seemed on the verge of controlling deadly infections such as pneumonia and septicemia; cortisone had arrived to suppress painful inflammation; asthma was yielding to isoprenaline; one vaccine after another was appearing to stop fatal epidemics. *Miracle* was the word many authors used to describe these effects.

From the global perspective, however, such miracles were for the minority. Affluent countries stood in stark contrast to the rest of the world, where entire populations had little access to medicines or were struggling to cope with a maze of competitive products, many of which were obscure,

overpriced, outdated, ineffective, or, frankly, dangerous. In many countries, two contrasting problems existed side by side: no medicines at all in the countryside, but hundreds or thousands of medicines competing for prescribers' and customers' attention in the cities. Medical and nursing staff in some areas worked without the medicines they needed, while practitioners in other areas faced a flood of expensive products about which they had no reliable information or that their patients could not afford.

2.3 The rise of the essential medicines concept

An idea gradually emerged: why not concentrate first on a basic list of reliable medicines to meet the most vital needs—understanding them, finding ways to pay for them, supplying them to the people? The idea of working with a limited range of medicines had long been used in places where no alternative existed; doctors had learned to carry twenty vital medicines in their bags, oceangoing ships commonly carried 100 or fewer medicines, and in later years, some airlines designed medicine kits for use in emergencies on long-distance flights.

The idea was first applied on a national scale before World War II in Norway, which was then a poor country. Norway decided to limit its list of approved medicines to those most needed in medical practice and most affordable for the population, avoiding unnecessary duplication. In the developing world, Papua New Guinea had a policy based on “essential drugs” by the early 1950s, Sri Lanka followed in 1959, and Cuba had a list of essential medicines by 1963.

How many medicines were needed for such a list? Sri Lanka chose 500, similar in number to Norway's original list. Whatever choice was made, it provided a starting point; one day, money might be available for more. Newly independent countries, committed to providing universal health care yet desperately short of resources, saw an essential medicines policy as a means of moving ahead despite stubborn obstacles.

It became clear that focusing on an essential medicines list could also make better use of limited financial resources. The most basic medicines were often well established through longtime use, and because patents on many of them had expired, several competing manufacturers were making them and selling them at lower prices. Often, a low-cost medicine was as good as a newer product being sold at a cost ten or fifty times higher.

By the mid-1970s, the essential medicines concept had evolved into a practical policy suitable for worldwide use, with one important modification. Rather than the view that only essential medicines should be allowed on the market, the view was now that any safe and efficacious medicine should be allowed for sale, but that essential medicines

should be given priority. At this point WHO adopted the concept. In 1975, WHO's Director General defined essential medicines as “those considered to be of utmost importance and hence basic, indispensable, and necessary for the health needs of the population. They should be available at all times, in the proper dosage forms, to all segments of society.”

Two years later, WHO issued its first model list of 224 “essential drugs” (including vaccines). By then, many countries were finding the cost of medicines a concern; for example, the government of Bangladesh was spending 60 percent of its entire public health budget on medicines, yet much of the poor population could still not get access to affordable treatment. Often, pharmaceuticals and raw materials had to be imported from high-cost countries, and their prices were further inflated by substantial markups imposed by importers, wholesalers, and retailers. In addition, thousands of brand-name combination products, often of questionable efficacy and safety, were flooding the private sector. Now, realizing that a limited list of essential medicines could help solve most of those problems, public health services could base their purchasing, supply, and training primarily on items that were most needed and most affordable.

The pharmaceutical industry grew rapidly in the postwar era. Substances that cured, prevented, or ameliorated many problems were formulated into products that were protected by patents, giving producers a long period in which to establish a dominant market presence and accumulate profits. Sophisticated production and testing methods allowed the formation of efficient, largely automated, high-volume manufacturing processes, resulting in large profits that could be plowed back into new-product research and the acquisition of smaller firms. These forces created an increasingly concentrated multinational industry.

Developing countries had another reason to give priority to essential medicines. The rush to get new products to the market resulted in inadequately tested medicines and many cases of serious or fatal medicine-induced diseases. In 1960, the introduction in Europe of the sleeping aid thalidomide resulted in the birth of thousands of deformed children. In 1973, clioquinol, used to suppress diarrhea in Japan, was found to cause blindness and paralysis. Even some widely used and valuable medicines brought unexpected problems. For example, the antibiotic chloramphenicol, misused widely in Latin America, caused aplastic anemia. These examples generated a growing recognition that pharmaceuticals often brought problems as well as great promise.

UN agencies and WHO lead the way

Although WHO's role in promoting the idea of essential medicines was historic, it was only the starting point for a much broader trend involving other international organizations. By the 1970s, UN member states were urging international agencies to take up the problems of imbalances in

growth, inequities, and redistribution of resources in developing countries. In 1974, the International Labor Office adopted the idea of defining and meeting “basic needs” in the developing world as a whole, not limited to medicines alone. WHO also urged a broader approach aimed at improving the health of rural and peri-urban populations. In Alma Ata in 1978, the WHO/UN Children’s Fund (UNICEF) Conference on Primary Health Care adopted the essential medicines concept as one of its basic tools. In Geneva, the Division of Drug Policy and Management came into being to develop the concept as part of national pharmaceutical policy for member states. Important backing also came from an interagency task force set up by the United Nations (UN), which by 1979 recommended the adoption of national medicines lists using generic names.

By this time, other UN agencies were also focusing on medicines. The UN Conference on Trade and Development (UNCTAD) supported the use of generic names, competitive procurement, and cooperative purchasing arrangements. The UN Industrial Development Organization (UNIDO) emphasized local and regional cooperative production. UNICEF, long active in directly providing medicines through its supply division, embraced the essential medicines idea with WHO in the late 1970s. Finally, the mutually supportive role of such UN agencies became more visible and eventually more coherent when a series of conferences and task forces created a rough division of labor: UNICEF would concentrate on supply, WHO on health policy, UNCTAD on trade, and UNIDO on industrial development.

The emergence of generic pharmaceuticals

By the 1980s, the patents on many medicines developed in the two decades after World War II began to expire, opening the way for worldwide production and distribution. Southeast Asia, especially, had a growing number of new pharmaceutical firms with low overhead costs that began to manufacture generic versions of well-known medicines and sell them at a fraction of the original price. Because they were working in countries where foreign patents were not recognized, some of these manufacturers had long-term experience in copying pharmaceutical products; not all maintained high standards of quality, however. Nevertheless, public pharmaceutical supply systems found that they could obtain much better prices by procuring the new, low-cost generic versions of familiar medicines.

The movement accelerates

WHO’s Action Programme on Essential Drugs grew vigorously in the early 1980s. By 1984, large amounts of extra-budgetary funds from European donors were provided specifically to support projects in each region of the world

for strengthening medicine selection, procurement, and distribution. Issues of pharmaceutical financing were tackled, and standards were set for pharmaceutical information and training. In 1985, the WHO Conference of Experts in Nairobi broadened the approach with a new emphasis on the need to use medicines rationally. That same year, the *Essential Drugs Monitor*, an international newsletter advocating an essential medicines policy in all its forms, began publication. Such initiatives were heavily backed by voluntary efforts from the outside, notably by Health Action International (HAI), an international coalition of NGOs from some fifty countries with a special interest in pharmaceuticals.

The industry’s reaction

As they gained momentum, these dramatic developments provoked mixed reactions from the international pharmaceutical industry. Major multinational corporations had reaped substantial profits from selling their new products in the industrialized world. However, even given the fierce competition among multinational pharmaceutical firms, a low-cost solution to the problem of access to medicines in the developing world had not evolved. One explanation was that the industry had grown accustomed to serving affluent populations, where buyers generally accepted high prices in exchange for the newest products, which they assumed were the best. To cultivate that market, companies focused on marketing and promoting their new products. Selling a relatively small volume of pharmaceuticals to the most affluent part of the population was simpler and more profitable than trying to meet the needs of larger populations with limited ability to pay.

Despite the limited coverage of the people in the developing world by the multinational pharmaceutical industry, these countries constituted a potentially lucrative market, with promise for the future. As developed countries introduced stricter systems of pharmaceutical regulation and were forced by the economic recession of the 1970s to look critically at their own medicine costs, the largely unregulated countries of the rest of the world provided a new prospect for profitability. The fact that the UN and WHO were encouraging restrictive policies and beginning to formulate ethical criteria for pharmaceutical marketing in the developing world seemed to threaten the multinationals’ future prospects. Where the new generic manufacturers now saw an opportunity, the traditional multinationals saw a threat. One reaction of the producers of originator products was to demand better patent protection, which came to fruition with the World Trade Organization’s Agreement on Trade-Related Aspects of Intellectual Property Rights in 1994 (see Chapter 3).

The pharmaceutical industry’s direct reactions to essential medicines policies varied from hostile to mixed,

with representatives declaring on occasion that the concept was completely unacceptable. The Geneva-based International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) suggested that the adoption of an essential medicines list “would result in substandard rather than improved medical care and might well reduce health standards already attained.” The federation was heavily backed in its protests by the U.S. Pharmaceutical Manufacturers Association, which by 1985 was arguing that the imposition of additional and arbitrary criteria involving “essentiality” or “medical interest” would clearly be contrary to the public interest. In retrospect, one major problem was probably the failure to communicate to the industry and practitioners what “essential medicines” really meant. As noted, the essential medicines concept was not a question of reducing access to medicines for those who already enjoyed it, but of providing access for those who had otherwise been without.

Subsequently, having accepted that for poorer countries the essential medicines approach might be “practical, even if regrettable,” the research-based segment of the pharmaceutical industry turned to limiting its application, insisting that the concept applied only in the public sectors of the least-developed countries. This segment of the industry simultaneously discouraged WHO’s other policy initiatives, notably those involving advertising standards, and continued to promote the view that generic medicines were likely to be substandard and even dangerous.

Since 1985, however, the research-based multinational industry and the trade as a whole have largely come around to the view that they can earn a fair profit by providing low-cost medicines—whether brand-name or generic—on a large scale to essential medicines programs, with high sales volume compensating for low profit margins. On some fronts, the IFPMA has collaborated with essential medicines programs, with WHO, and with donors. Tensions between pharmaceutical manufacturers and international organizations have shifted from the essential drug concept to other issues, such as intellectual property and parallel importing.

The campaign for rational use of medicines

After access to essential medicines is addressed, proper use remains a challenge, because waste by both prescribers and users is common. The notion that if one medicine is good, two are better (and three ideal) dies hard, and both prescribers and users are prone to overuse. The quantities of medicines prescribed for a given illness are often far more than what is reasonably needed. Medicines are often prescribed when none is needed at all, because patients expect or demand a pill or an injection, or because physicians or medical assistants are anxious to be seen as doing something. In some cases, half of medicines reaching the periphery are

wasted by irrational prescribing and by inappropriate use by patients, who fail to follow the instructions given by prescribers.

The notion that all pharmaceutical policies need to promote the “rational use of medicines” was only slowly accepted. Pharmaceutical policies had always centered on medicines, not on patients. Pharmaceutical policies had been the concern largely of administrators and pharmacists, whereas medicine use was largely in the hands of physicians and paramedical staff. The medical profession in particular resented any suggestion that it might be acting irrationally as a group or that it might be in need of guidance or control. Medical personnel often insisted on the “right” to prescribe the medicine of their choice.

The rational use of medicines concept developed momentum after WHO’s 1985 Nairobi Conference of Experts used it as its central theme. The conference emphasized the need for the public to understand and use medicines better, particularly in view of all that was known about nonadherence to treatment. In many cases, neither the prescriber nor the patient was to blame for irrational use; the fault often resulted from lack of proper information and training, compounded in some cases by fear, carelessness, or misleading persuasion from the seller or others. With much of a nation’s pharmaceutical supply potentially being wasted because of irrational use, the effort to promote proper use, although time-consuming, is vital to any effective health policy and any well-managed economy.

Basic data on how medicines are actually being used in a particular country and situation, why errors are made, and the types of intervention that may improve the situation are important aids in understanding and modifying medicine use. WHO’s Collaborating Centre on Drug Utilization Research developed methods—including some that can be applied simply and quickly—for studying these matters, and those methods have now been used in many parts of the world (see WHO 2003). In 1989, the International Network for the Rational Use of Drugs (INRUD) was formed to bring together developing-country teams composed of decision makers in ministries of health, researchers, health care professionals, social scientists, and support groups. INRUD continues to serve as a forum for joint country-level efforts to investigate medicine-use problems, test strategies to change providers’ and consumers’ behavior with regard to specific problems, implement large-scale behavior-change efforts, and share national experiences internationally with colleagues. The International Conferences on Improving Use of Medicines (www.icium.org) in 1997 and 2004 have played a large role in the evolution of paradigms for promoting rational use of medicines.

In 2001, WHO launched the Global Strategy for Containment of Antimicrobial Resistance, which recognizes antimicrobial resistance as a global problem that must be addressed in all countries (WHO 2001b). No country,

however effective it is at containing resistance within its borders, can protect itself from the importation of resistant pathogens through travel and trade. Poor prescribing practices and irrational use in any country now threaten to undermine the potency of vital antimicrobials around the world. In addition, the U.S. Agency for International Development has recognized the critical importance of the issue and supports a variety of programs that help contain the spread of antimicrobial resistance.

The evolution of malaria treatment is an example of how irrational use has created major problems with drug resistance. During the past century, antimalarial drugs were used on a large scale, generally as monotherapies, introduced in sequence, and were used continually, despite unacceptably high levels of resistance. In addition, many people have typically sought care for malaria through the private sector—antimalarial medications are often available at retail drug outlets. Private prescribers and dispensers, however, are less likely to follow standard treatment guidelines, and patients will generally pay for and take only the medications needed to feel better—not necessarily what constitutes the recommended dose; for example, anecdotal evidence suggests that some people prescribed artemisinin-based combination therapy (ACT) take only the artemisinin-based drug because it is the one that makes them feel better, a practice that negates the purpose of taking a combination of medicines to slow the spread of drug resistance.

As discussed in Chapter 51, the lack of trained health professionals in many countries makes it difficult to adequately monitor rational medicine use, especially in the case of antiretrovirals (ARVs), which patients must take for the duration of their lives. This gap in human resources makes it that much more crucial to educate patients as well as the entire community about the importance of adherence and medicine use and to explore the effectiveness of community-based interventions (see Chapters 31 and 33).

2.4 Global focus on AIDS, tuberculosis, and malaria

The devastation caused by the HIV/AIDS pandemic helped draw attention to the plight of people living in resource-limited areas—especially sub-Saharan Africa. The WHO's "3x5" initiative was the first to declare a global target to provide three million people living with HIV/AIDS in low- and middle-income countries with antiretroviral therapy (ART) by the end of 2005, with the ultimate goal of making treatment accessible to all people. An additional incentive for specific action has been the establishment of the UN Millennium Development Goals; Goal 6 targets the end of the spread of HIV by 2015 and universal treatment by 2010. By 2010, however, new infections were still outstripping gains made in treatment coverage (UN 2010).

The increased interest in health care and funding for treatment in developing countries has spawned a number of significant global initiatives to address inequities and increase access to health care and essential medicines in the most-affected countries.

Large-scale funding initiatives include the following—

- *The Global Fund to Fight AIDS, Tuberculosis and Malaria* is a large multilateral funding program that approved grants for over USD 3 billion in its first two years of existence. Of that money, more than 60 percent has been distributed in Africa and almost 50 percent has gone to procure medicines and commodities.
- *The U.S. President's Emergency Plan for AIDS Relief (PEPFAR)*, announced in 2003, made a contribution of USD 19 billion to sixteen countries—including twelve in Africa. In 2009, PEPFAR became part of the Global Health Initiative, which responds to a broad range of global health needs. In response to the evolving global HIV/AIDS situation, PEPFAR now places more emphasis on overall health systems' strengthening and sustainability rather than emergency action.
- *UNITAID*, whose funding comes from taxes on airline tickets in six countries and from country and foundation contributions, was established to support the health-related Millennium Development Goals. UNITAID's model is based on long-term funding commitments and the purchase of high volumes of medicines and diagnostics used to leverage price reductions. It disburses funds to international partners working in health commodities procurement, such as the William J. Clinton Health Action Initiative and UNICEF.

Prominent partnerships and initiatives include the following—

- *The AIDS Medicines and Diagnostics Service* is a network to support increased access to good quality and effective treatments for HIV/AIDS by improving supply of ARVs and diagnostics in developing countries.
- *The Stop TB Partnership's Global Drug Facility* helps TB programs get quality-assured TB medicines at the best prices, store them properly, distribute them in a timely manner, and use them rationally.
- *The Stop TB Partnership's Green Light Committee* works to assure access to preferentially priced second-line medicines for multidrug-resistant TB.
- *The Roll Back Malaria Partnership*, established in 1998, has a goal of achieving the malaria-specific Millennium Development Goal, which is to halt and begin to reverse the incidence of malaria, by 2015, through a coordinated global approach toward prevention and treatment, including the establishment

of the Malaria Medicines and Supplies Service, which facilitates access to affordable antimalarial medicines and commodities such as insecticide-treated mosquito nets, rapid diagnostic tests, and insecticides. Also, the Global Fund's Affordable Medicines Facility–Malaria Initiative seeks to increase access to affordable ACTs subsidies. Instituting subsidies for ACTs will allow prices to be brought into line with those of cheap, yet ineffective medicines, such as sulfadoxine-pyrimethamine, eventually driving them out of the market.

The role of advocacy groups and community-based organizations

Increased advocacy from various groups, such as multi-lateral organizations, bilateral donors, nongovernmental organizations from all levels, and civil society organizations, has resulted in pressure to change policies and push pharmaceutical issues onto national and international health care agendas. Issues highlighted by these groups include the need for new health technologies and medicines for the three diseases, such as more sensitive TB diagnostics and pediatric formulations of ARVs. The response to HIV/AIDS, in particular, put into motion an advocacy movement that has profoundly influenced issues on a global scale.

The extreme impact of the AIDS pandemic fostered a unique alliance of activists and people living with the infection acting as advocates within the community. In 1983, an advocacy group in Brazil created a nongovernmental organization to fight AIDS, a year after the first case had been diagnosed there, and more groups followed. In addition to increasing prevention and treatment in poor and remote communities, Brazilian activists are credited with assuring adequate funding for ARVs and contributing to the country's successful pricing negotiations with pharmaceutical manufacturers (Homedes and Ugalde 2006). In 1987 in New York City, the AIDS Coalition to Unleash Power (ACT UP) was formed as an activist group dedicated to influencing AIDS-related policy. ACT UP was the most visible example of how involvement at the community level and from people living with HIV/AIDS could greatly affect public policy and issues such as ARV access and affordability, demonstrating an impact that ranged far beyond the group's New York roots. Since 1998, the Treatment Action Campaign and its allies in South Africa have led a lengthy and highly visible public campaign to improve access to ART through the public health sector.

Today, organizations around the world strive to mobilize community support and action not only to improve the lives of local families touched by HIV/AIDS, but to keep AIDS issues—especially access to ARVs—high on the public agenda. For example, the International HIV/AIDS Alliance (www.aidsalliance.org), which was founded in 1993, works

with community organizations in more than forty developing countries to strengthen the local response to HIV-related disease, including building community knowledge of and demand for ART. The HIV/AIDS Alliance produces a range of resources and tools to improve the effectiveness of the community effort.

Lack of systems to support access to medicines for HIV/AIDS, TB, and malaria

As the world has responded with increased financial assistance to provide affordable medicines for HIV/AIDS, TB, and malaria, there is a growing recognition that the effectiveness of these large initiatives is limited by the capacity of health and pharmaceutical supply systems at the national and local levels. Indeed, this challenge was borne out by the findings of a UN Millennium Project task force with a mandate to combat HIV/AIDS, malaria, TB, and other diseases and improve access to essential medicines. The task force concluded that attempting to address individual diseases through global programs cannot succeed without the allocation of more resources for strengthening entire health systems, noting that “existing approaches to combating AIDS, tuberculosis, and malaria, although imperfect, are adequate to greatly reduce the effect of these three diseases. However, the woeful state of health systems in most developing countries prevents these effective interventions from reaching those in greatest need, even where resources are available . . . Reliable provision of essential drugs is a strong indicator of the effectiveness of the health system” (Ruxin et al. 2005).

Although the additional financial commitment for medicines to treat these diseases is welcomed and necessary, funding is never the only constraint and is now, often, not the major constraint. Other constraints to improving access to medicines include inadequate infrastructure in facilities such as clinics, hospitals, pharmacies, and laboratories and a lack of trained staff and equipment for those facilities.

2.5 Current organizational roles in essential medicines

Organizations that are active in the essential medicines field may be useful points of contact. Numerous organizations in the public and private sectors offer a range of experience in advocacy, in public policy development, and in education and technical assistance. Several of these organizations are discussed briefly in the following sections. Organizations (such as the World Bank, the regional development banks, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and aid agencies in Europe and the United States) that primarily finance development projects, including pharmaceutical programs, are discussed in Chapter 14.

WHO and other UN agencies

WHO's Department of Essential Medicines and Pharmaceutical Policies has played a leading role in promoting the essential medicines concept. WHO publishes documents on practices and methods as well as the *Essential Medicines Monitor* newsletter on current developments around the world. It convenes expert committees, holds workshops and training sessions worldwide, and has supported some country-specific pharmaceutical management programs, largely with funds provided by interested donors.

WHO's Department of Essential Medicines and Pharmaceutical Policies is also responsible for promoting pharmaceutical quality, providing information on safety and efficacy, and convening an expert committee that revises the Model List of Essential Medicines every two to three years, and now another list specifically for children's medicines. It is responsible for the quality certification scheme and good manufacturing practices standards. In addition, its prequalification program plays a major role in promoting quality medicines through evaluation and inspection activities and by building national capacity for sustainable manufacturing and quality monitoring.

Other WHO programs dealing with specific health areas, such as diarrhea, immunizations, and HIV/AIDS, have interests in essential medicines. The WHO regional offices and individual country programs often have additional technical staff in advisory positions.

The Pan American Health Organization is WHO's regional office for the Americas. Its technical pharmaceutical management staff collaborates with ministries of health, social security agencies, and other governmental and nongovernmental institutions to strengthen national and local health systems. Other regional offices, in the Eastern Mediterranean, Africa, Europe, the Western Pacific, and South East Asia, contribute to supporting and managing essential medicines activities in their regions.

UNICEF is actively involved in program and project development internationally and at the country level. Headquarters activities include technical supervision, design, and support of country-level programs ranging from large-scale procurement (through its Supply Division, based in Copenhagen) to strategies for the purchase, distribution, and use of medical supplies. In some countries, UNICEF coordinates medicine procurement and distribution for public health programs receiving Global Fund grants.

The Interagency Pharmaceutical Coordination Group includes senior pharmaceutical advisers from WHO, the World Bank, the Joint UN Programme on HIV/AIDS (UNAIDS), the UN Population Fund (UNFPA), and UNICEF. The group, which meets every six months, coordinates the pharmaceutical policies underlying their

technical advice to partner countries and plans and coordinates the preparation of interagency statements and technical documents.

In 2002, the UN Secretary-General commissioned the UN's Millennium Project to develop an action plan for the world to achieve the Millennium Development Goals, which were established in 2000. The eight Millennium Development Goals, which have a target date of 2015, range from halving extreme poverty to promoting gender equality. The goals were agreed to by the world's countries and have formed the basis for a remarkable worldwide effort to improve the lives of those living in extreme poverty. Pharmaceutical management is a prominent component in achieving several of the goals, such as reducing child mortality, improving maternal health, and combating HIV/AIDS and other diseases.

Nongovernmental organizations

Health Action International is an association of NGOs founded in 1982 "working to increase access to essential medicines and improve their rational use." HAI and local and regional affiliates, such as Acción Internacional para la Salud, are focal points for campaigns on essential medicines action by governments and UN agencies and against industry products and practices that counter the concept.

Healthy Skepticism, previously known as the Medical Lobby for Appropriate Marketing, was formed in 1983 in Australia. The organization tracks inappropriate and misleading promotion of pharmaceutical products in developed and developing countries and encourages the use of accurate and consistent information about pharmaceuticals to improve health-related decision making. The organization's AdWatch program publicizes techniques used in pharmaceutical advertising. Healthy Skepticism has been a stimulus for other groups to monitor advertising and promotion of pharmaceuticals and other medical products. It has also influenced multinational corporations to modify their promotional practices.

The International Network for the Rational Use of Drugs works through national groups representing individuals from ministries of health, universities, NGOs, and private-sector institutions to understand local medicine-use problems and create reproducible activities that improve medicine use. INRUD's interdisciplinary focus links clinical and social sciences and emphasizes the behavioral aspects of medicine use, particularly as they concern providers and consumers, the promotion of well-designed research studies, and the sharing of experiences and technical expertise among participating individuals. INRUD also promotes cooperation among donors interested in funding activities that contribute to these objectives. The INRUD secretariat at Management Sciences for Health (MSH) is the coordinating body for the country core

groups and publishes an annual newsletter, *INRUD News* (www.inrud.org).

The International Society of Drug Bulletins (ISDB) is an association of independent and official medicine information bulletins that provides the medical community with the most current information on individual medicines free from funding and the influence of the pharmaceutical industry. ISDB helps countries develop independent, unbiased medicine information bulletins and facilitates cooperation among countries in promoting independent medicine information (see Chapter 34).

Through its Center for Pharmaceutical Management, the nonprofit organization MSH is involved in pharmaceutical sector assessments and analysis, research, technical assistance, training, and publications to improve health through the rational use of medicines. MSH staff members work with international agencies and other NGOs, as well as directly with the public and private sectors in many countries. MSH produces training materials, software for pharmaceutical management, and publications such as this manual and the widely recognized *International Drug Price Information Guide*.

The International Pharmaceutical Federation (FIP) is a global organization comprised of 122 national associations of pharmacists and pharmaceutical scientists and 4,000 individual members. FIP advocates globally on behalf of the role of the pharmacist in the health care system. FIP is active in promoting good pharmacy practice and pharmacy education and gathering and disseminating important data on the profession; a key resource is the *2009 FIP Global Pharmacy Workforce and Migration Report*.

The U.S. Pharmacopeia (USP) is the official public standards-setting authority for prescription and over-the-counter medicines manufactured or sold in the United States. USP sets standards for the quality, purity, strength, and consistency of these products, which are recognized and used in more than 130 countries. USP also works in developing countries to improve pharmaceutical quality and the information available on medicines.

Médecins Sans Frontières (MSF), the humanitarian medical organization, started its Campaign for Access to Essential Medicines in 1999 to advocate for better access and lower prices of essential medicines at the local, national, and international levels. An example of MSF's work is the annual update of *Untangling the Web of Price Reductions: A Pricing Guide for the Purchase of ARVs for Developing Countries*.

As noted in Chapter 8, missions and other NGOs provide a substantial portion of health care and pharmaceutical supply services in many countries. The Ecumenical Pharmaceutical Network (EPN) works to strengthen the medicine-related activities of faith-based health care organizations in Africa. At the international level, the EPN acts as an advocate for access to medicines and a clearinghouse for information.

Regulatory bodies

The International Conference of Drug Regulatory Authorities is a biennial forum of officials from national regulatory authorities. Its principal concerns include mechanisms to guard against substandard, counterfeit, and dangerous products. It also supports WHO's certification scheme and guiding principles for small regulatory authorities.

The International Conference on Harmonization (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use is a collaborative effort by the regulatory authorities of the European Union, the United States, and Japan to harmonize technical issues related to the registration of pharmaceuticals in these countries. The conference also makes recommendations on how to achieve greater harmonization around the world in the interpretation and application of related technical guidelines and requirements. The ICH norms do not always fully reflect the needs and capabilities of developing countries; however, WHO promotes developing-country interests by serving in an observer capacity, and the ICH Global Cooperation Group works with drug regulatory authorities in nonmember countries to facilitate the harmonization process in all countries.

Industry organizations

Most countries have individual national associations that represent manufacturers, distributors, and private pharmacies. These associations are intended primarily to protect members' interests, but they provide support to selected activities, such as training, local publications, and community medicine outlets in some countries. The IFPMA is an international advocacy group formed of many national and regional pharmaceutical manufacturers' associations and companies; it prepares position papers for the industry, testifies before international organizations, acts as a public-relations resource for the industry, and occasionally undertakes educational projects, such as quality-control training for developing-country staff. The International Federation of Pharmaceutical Wholesalers plays a similar role with respect to pharmaceutical distributors.

2.6 Clients, governments, producers, and beyond: changes in the pharmaceutical field

A review of the changes in the pharmaceutical field over the last forty years may suggest that a new symmetry among its players is on the horizon; however, a look at the future suggests a continuing process of evolution.

The evolving pharmaceutical industry

As noted previously, the multinational pharmaceutical industry has become less hostile toward some national and international pharmaceutical policy initiatives in recent decades, while focusing more on intellectual property issues. One reason for the shift in industry strategy has been the declining rate of pharmaceutical product innovation. Research-based companies are less confident that they can build their future on a regular flow of innovative new medicines; regulatory authorities have more difficulty approving new medicines to be marketed in their countries; and some medicines have been withdrawn from the market because of safety issues, such as the anti-inflammatory drug Vioxx (rofecoxib). For example, although the U.S. Food and Drug Administration (FDA) approved an average of eighty-three new medicines per year between 1998 and 2002, only one-third were new chemical entities. Over that same period, the FDA granted priority review to no more than seven medicines per year that represented a treatment advance, and the only real “breakthroughs” were usually “last-ditch treatments” for rare conditions not responding to other therapy (Angell 2004). Such medicines were likely to be used only occasionally and would not provide a significant income for the innovator company. As for safety issues, of thirteen new medicines that were removed from the U.S. market for safety reasons over a decade, not one left a significant therapeutic gap (Sigelman 2002). In the case of Vioxx, estimates are that it led to between 88,000 and 139,000 heart attacks in the United States that would not otherwise have occurred (Graham et al. 2005). With fewer new medicines emerging that carry the promise of major revenues, and with the occasional safety disaster, the industry today hesitates to rely on product innovation alone to assure a robust future as much as it once did. As a result, most major pharmaceutical developers are evaluating their research and development practices and are considering changing their current development paradigm (Kaitin 2010).

Another reason for a shift in industry policy is that developed countries have become increasingly critical of pharmaceutical prices and expenditure. Many countries have imposed rigid price controls on medicines or limits on the permitted cost of a course of treatment or instituted other interventions to control medicine prices (see Chapter 9 on pharmaceutical pricing policies). Pharmaceutical companies now must not only persuade doctors to prescribe their products but also convince critical therapeutics committees and pharmacy benefit managers that their medicines are sufficiently cost-effective to merit a place in treatment manuals and reimbursement lists—examples of the principle of essential medicines in practice.

New industry attitudes have also come as a result of structural changes in the pharmaceutical industry itself. Seeking to develop new business models to compensate for

market obstacles in industrialized countries, many companies have entered once unfamiliar areas; for example, some research-based companies have started (or restarted) producing generic medicines, either by diversifying their own activities or by acquiring established generic manufacturers.

Intellectual property laws

The issue of access to medicines for HIV/AIDS, TB, and malaria has had an impact on international trade activities. Activists working to improve affordability of ARVs in developing countries first highlighted the negative implications of the World Trade Organization’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) for access to essential medicines in developing countries, resulting in the development of the Doha Declaration, which addresses the right of all countries to protect the health of their citizens (see Chapter 3).

The TRIPS agreement may make it difficult for resource-limited countries to get access to new medicines at affordable prices. Although certain flexibilities were included in the agreement to help countries circumvent the intellectual property restrictions and accommodate their public health needs, without the necessary technical expertise, countries have found it difficult to interpret the laws and implement the appropriate policy mechanisms; however, governments are addressing this issue. For example, the regional group representing countries of East, Central, and Southern Africa created a model national pharmaceutical policy that addresses ways for member countries to incorporate these flexibilities into their policies.

Public-private pharmaceutical initiatives

For a long time, the private and public pharmaceutical sectors worked in relative isolation from each another; contact was formal, critical, and sometimes hostile. In the final years of the twentieth century, however, a number of international public-private partnerships were developed to create positive and innovative collaboration in research, development, and distribution, especially in serving the needs of developing countries. Promising advances are emerging, particularly through initiatives under the auspices of the United Nations and its specialized agencies, such as WHO. Examples include the Global Alliance for TB Drug Development and the Medicines for Malaria Venture. More time is needed to determine the long-term value of these partnerships, but increasing evidence suggests that such public-private initiatives can be productive.

Globalization and the Internet

No more than fifty years ago, the world remained rigidly divided into nation-states, each with its own specific

approach to its own specific problems; however, the process of globalization has quickly broken down that compartmentalization. Many companies now operate worldwide, developing policies and conducting activities that can only partially be controlled by national governments; in fact, some corporations have greater financial resources than many of the governments with which they do business.

The Internet is an example of a worldwide activity that largely escapes national control. On the one hand, the Internet allows users to circumvent undesirable practices such as government censorship, but on the other hand, it facilitates activities that hurt society at large, for example, the dishonest advertising and sale of ineffective and dangerous medicines. Drug regulatory authorities and others have been working to address the issue of pharmaceuticals being sold through the Internet, as well as on ways to increase access to reliable information through the Internet (for example, see WHO/IMPACT 2009; WHO 2001a, 2002).

Ongoing policy changes

The changes in the political and economic environment discussed in this chapter mean that pharmaceutical management must also adapt to new opportunities and challenges.

Of the tools and concepts described throughout MDS-3, some originated in industrialized countries, others in the developing world, and others in the international community. Many have outgrown their origins, and the ideas and experiences are increasingly becoming common ground for solving important pharmaceutical management issues throughout the world while continuing to evolve as that world changes.

Although death and disability are always tragic, the rationale for national concern and action on essential medicines is driven by the large gap remaining between what we know and what we do. We know how medicines can help eliminate unnecessary and preventable deaths and disability, yet millions continue to die of TB, which is essentially curable with medical therapy. People living with HIV/AIDS can now extend their lives with ARV medicines, but more than half of those in need of treatment do not have access (UNAIDS 2009). Malaria, pneumonia, diarrhea, and hypertension are manageable with basic medicines, yet they continue to kill millions. Children are born unwanted and into poverty merely because low-cost family-planning supplies are unavailable.

The clear public health challenge is to continue to lead public policy makers and managers toward a consistent approach to essential medicines. The primary activity is to identify and attack the major problems that are amenable to solution with available resources. The strategies of many national pharmaceutical programs in less advantaged nations, and increasingly among decision makers in more-

advantaged settings, are converging: first, to ensure that the basic medicines that save lives and improve health are available to all; second, to ensure that they are used appropriately; and third, to logically deal with the many medicines that are not essential to public health, but may play a limited or specialized role in health care. ■

References and further readings

★ = Key readings.

- Angell, M. 2004. *The Truth about the Drug Companies*. New York: Random House.
- Foster, S. D. 1991. Supply and Use of Essential Drugs in Sub-Saharan Africa: Some Issues and Possible Solutions. *Social Science and Medicine* 32:1201–18.
- Graham, D. J., D. Campen, R. Hui, M. Spence, C. Cheetham, G. Levy, S. Shoor, and W. Ray. 2005. Risk of Acute Myocardial Infarction and Sudden Cardiac Death in Patients Treated with Cyclo-oxygenase 2 Selective and Non-selective Non-steroidal Anti-inflammatory Drugs. *Lancet* 365(9458):475–81.
- Homedes, N., and A. Ugalde. 2006. Improving Access to Pharmaceuticals in Brazil and Argentina. *Health Policy and Planning* 21(2): 123–31.
- Kaitin, K. I. 2010. Deconstructing the Drug Development Process: The New Face of Innovation. *Clinical Pharmacology and Therapeutics* 87(3):356–61.
- ★ Laing R., B. Waning, A. Gray, N. Ford, and E. 't Hoen. 2003. 25 Years of the WHO Essential Medicines Lists: Progress and Challenges. *Lancet* 361:1723–9.
- Mangham, L. J., and K. Hanson. 2010. Scaling Up in International Health: What Are the Key Issues? *Health Policy and Planning* 25:85–96.
- Quick, J. D., H. V. Hogerzeil, G. Velasquez, and L. Rago. 2002. Twenty-five Years of Essential Medicines. *Bulletin of the World Health Organization* 80(11):913–4. <[http://www.who.int/bulletin/archives/80\(11\)913.pdf](http://www.who.int/bulletin/archives/80(11)913.pdf)>
- Ruxin J., J. E. Paluzzi, P. A. Wilson, Y. Tozan, M. Kruk, and A. Teklehaimanot. 2005. Emerging Consensus in HIV/AIDS, Malaria, Tuberculosis, and Access to Essential Medicines. *Lancet* 365(9459):618–21.
- Sigelman, D. W. 2002. Dangerous Medicine. *The American Prospect* (Online) 13(17). <http://www.prospect.org/cs/articles?article=dangerous_medicine>
- Smith, M. K., and S. Tickell. 2003. The Essential Drugs Concept Is Needed Now More Than Ever. *Transactions of the Royal Society of Tropical Medicine and Hygiene* 97(1):2–5.
- UN (United Nations). 2010. *The Millennium Development Goals Report 2010*. New York: UN.
- UNAIDS (Joint United Nations Programme on HIV/AIDS). 2009. *AIDS Epidemic Update 2009*. Geneva: UNAIDS. <http://data.unaids.org/pub/Report/2009/JC1700_Epi_Update_2009_en.pdf>
- ★ UN Millennium Project. 2005. *Prescription for Healthy Development: Increasing Access to Medicines. Report of the Task Force on HIV/AIDS, Malaria, TB, and Access to Essential Medicines Working Group on Access to Essential Medicines*. Sterling, Va.: Earthscan. <<http://www.unmillenniumproject.org/documents/TF5-medicines-Complete.pdf>>
- ★ WHO (World Health Organization). 2009. *Report of the 17th Expert Committee on the Selection and use of Essential Medicines: 23 to 27 March 2009*. Geneva: WHO. <http://www.who.int/selection_medicines/committees/expert/17/en/>

- . 2007. *The Selection and Use of Essential Medicines: Report of the WHO Expert Committee, 2007 (Including the 15th Model List of Essential Medicines)*. Geneva: WHO. <http://www.who.int/medicines/publications/essentialmeds_committeereports/en/>
- ★ ———. 2004a. *The World Medicines Situation*. Geneva: WHO. <http://www.searo.who.int/LinkFiles/Reports_World_Medicines_Situation.pdf>
- . 2004b. *WHO Medicines Strategy: Countries at the Core 2004–2007*. Geneva: WHO. <http://whqlibdoc.who.int/hq/2004/WHO_EDM_2004.5.pdf>
- . 2003. *Introduction to Drug Utilization Research*. Geneva: WHO. <http://www.who.int/medicines/areas/quality_safety/safety_efficacy/Drug%20utilization%20research.pdf>
- . 2002. WHO and Top Publishers Today Launch “Access to Research” Internet Initiative for Developing Countries. Press Release WHO/7. Geneva: WHO. <<https://apps.who.int/inf/en/pr-2002-07.html>>
- . 2001a. *Pharmaceuticals and the Internet: Drug Regulatory Authorities’ Perspective*. Geneva: WHO. <<http://whqlibdoc.who.int/hq/2001/a74987.pdf>>
- . 2001b. *WHO Global Strategy for Containment of Antimicrobial Resistance*. Geneva: WHO. <http://www.who.int/csr/resources/publications/drugresist/WHO_CDS_CSR_DRS_2001_2_EN/en/>
- WHO/IMPACT (World Health Organization/International Medical Products Anti-Counterfeiting Taskforce). 2009. Overview of IMPACT Working Groups’ Documents and Activities. Geneva: WHO. <<http://www.who.int/impact/activities/overviewofIMPACTworkingdocs.pdf>>

Annex 2-1 Useful contact information

Affordable Medicines Facility–Malaria

Global Fund to Fight AIDS, Tuberculosis and Malaria
Chemin de Blandonnet 8
1214 Vernier
Geneva, Switzerland
Telephone: +41 58 791 17 00
Fax: +41 58 791 17 01
E-mail: amfmconsult@theglobalfund.org
<http://www.theglobalfund.org/en/amfm>

AIDS Medicines and Diagnostics Service

HIV/AIDS Department
World Health Organization
20 Avenue Appia
CH 1211 Geneva 27 Switzerland
Telephone: +41 22 791 21 11
Fax: +41 22 791 31 11
E-mail: amds@who.int
<http://www.who.int/hiv/amds/en>

Alliance for the Prudent Use of Antibiotics

75 Kneeland Street
Boston, Massachusetts 02111 USA
Telephone: +1 617 636 0966
Fax: +1 617 636 3999
E-mail: apua@tufts.edu
<http://www.tufts.edu/med/apua>

Campaign for Access to Essential Medicines

Médecins Sans Frontières
Rue de Lausanne 78
P.O. Box 116
CH 1211 Geneva 21 Switzerland
Telephone: +41 22 849 84 05
Fax: +41 22 849 84 04
E-mail: access@msf.org
<http://www.msfaccess.org>

Clinton Health Access Initiative

William J. Clinton Foundation
55 W. 125th Street
New York, New York 10027 USA
Telephone: +1 212 348 8882
Fax: +1 212 348 5147
<http://www.clintonfoundation.org/what-we-do/clinton-hiv-aids-initiative>

Consumers International

24 Highbury Crescent
London N5 1RX United Kingdom
Telephone: +44 20 7226 6663
Fax: +44 20 7354 0607
Additional offices in Africa, Malaysia, and Chile
<http://www.consumersinternational.org>

Ecumenical Pharmaceutical Network

P.O. Box 738-00200
Nairobi, Kenya
Telephone: +254 20 444 4832/444 5020
Fax: +254 20 444 1090
Mobile: +254 72 430 1755
E-mail: info@epnetwork.org
<http://www.epnetwork.org>

Euro Health Group

Tinghøjvej 77
2860 Søborg, Denmark
Telephone: +45 3969 6888
Fax: +45 3969 5888
E-mail: eurohealth@ehg.dk
<http://ehg.dk>

Global Drug Facility Green Light Committee (Stop TB Partnership)

Stop TB Partnership Secretariat
World Health Organization
HTM/STB/TBP
20 Avenue Appia
CH 1211 Geneva 27 Switzerland
Telephone: +41 22 791 46 59
Fax: +41 22 791 48 86
E-mail: gdf@who.int
<http://www.stoptb.org/gdf>
E-mail: glc_secretariat@who.int
<http://www.who.int/tb/challenges/mdr/greenlightcommittee/en/index.html>

Global Fund to Fight AIDS, Tuberculosis and Malaria

Geneva Secretariat
Chemin de Blandonnet 8
1214 Vernier
Geneva, Switzerland
Telephone: +41 58 791 17 00
Fax: +41 58 791 17 01
E-mail: info@theglobalfund.org
<http://www.theglobalfund.org/>

Health Action International Africa

Kabernet Lane
P.O. Box 66054-00800
Nairobi, Kenya
Telephone: +254 20 386 0434/5/6
Fax: +254 20 386 0437
E-mail: info@haiafrica.org
<http://www.haiafrica.org>

Health Action International Europe

Overtoom 60/II
1054 HK Amsterdam, The Netherlands
Telephone: +31 20 683 3684
Fax: +31 20 685 5002
E-mail: info@haiweb.org
<http://www.haiweb.org>

Health Action International Latin America

(Acción Internacional para la Salud)
Apdo 41-128 Urb Javier Prado
Calle Mario Florian Mz 3 Lote 22, San Borja
Lima 41 Peru
Telephone/fax: +51 1 346 1502
E-mail: infoais@aislac.org
<http://www.aislac.org>

Healthy Skepticism

34 Methodist Street
Willunga, South Australia 5172 Australia
Telephone/fax: +61 8 8557 1040
<http://www.healthyskepticism.org>

HIV/AIDS Alliance

UK Secretariat / International HIV/AIDS Alliance
1st and 2nd Floors, Preece House
91-101 Davigdor Road
Hove BN3 1RE United Kingdom
Telephone: +44 1273 718 900
Fax: +44 1273 718 901
E-mail: mail@aidsalliance.org
<http://www.aidsalliance.org>

International Conference on Harmonization (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use

ICH Secretariat
c/o IFPMA
15 Chemin Louis-Dunant
P.O. Box 195
CH 1211 Geneva 20 Switzerland
Telephone: +41 22 338 32 06
Fax: +41 22 338 32 30
E-mail: admin@ich.org
<http://www.ich.org/index.xl>

International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)

15 Chemin Louis-Dunant
P.O. Box 195
CH 1211 Geneva 20 Switzerland
Telephone: +41 22 338 32 00
Fax: +41 22 338 32 99
E-mail: info@ifpma.org
<http://www.ifpma.org>

International Network for the Rational Use of Drugs

c/o Management Sciences for Health
4301 N. Fairfax Drive, Suite 400
Arlington, Virginia 22203 USA
Telephone: +1 703 524 6575
Fax: +1 703 524 7898
E-mail: inrud@msh.org
<http://www.inrud.org>

International Pharmaceutical Federation (FIP)

Andries Bickerweg 5
2517 JP The Hague, The Netherlands
Telephone: +31 70 302 1970
Fax: +31 70 302 1999
E-mail: fip@fip.org
<http://www.fip.org>

International Society of Drug Bulletins

103 Hertford Road
London N2 9BX United Kingdom
<http://www.isdbweb.org>

Karolinska Institutet

Department of Public Health Sciences
Division of International Health (IHCAR)
SE-17177 Stockholm, Sweden
Telephone: +46 8 524 800 00
Fax: +46 8 31 11 01
<http://www.phs.ki.se/ihcar>

Management Sciences for Health

Center for Pharmaceutical Management
4301 N. Fairfax Drive, Suite 400
Arlington, Virginia 22203 USA
Telephone: +1 703 524 6575
Fax: +1 703 524 7898
E-mail: cpm@msh.org
<http://www.msh.org>

Médecins Sans Frontières

Rue de Lausanne 78
CP 116-1211 Geneva 21 Switzerland
Telephone: +41 22 849 84 00
Fax: +41 22 849 84 04
<http://www.msf.org>

Medicus Mundi International Network

Murbacherstrasse 34
CH 4013 Basel, Switzerland
Telephone: +41 61 383 18 11 (Monday–Wednesday)
E-mail: office@medicmundi.org
<http://www.medicmundi.org>

Pan American Health Organization

WHO Regional Office for the Americas
525 23rd Street, N.W.
Washington, D.C. 20037 USA
Telephone: +1 202 974 3000
Fax: +1 202 974 3663
<http://www.paho.org>

Roll Back Malaria Partnership

(Secretariat hosted at WHO)
20 Avenue Appia
CH 1211 Geneva 27 Switzerland
Telephone: +41 22 791 58 69
Fax: +41 22 791 15 87
E-mail: inforbm@who.int
<http://www.rollbackmalaria.org>

UNAIDS

20 Avenue Appia
CH 1211 Geneva 27 Switzerland
Telephone: +41 22 791 36 66
Fax: +41 22 791 41 87
<http://www.unaids.org/en>

UNICEF

UNICEF House
Essential Drugs Unit
2 United Nations Plaza
New York, New York 10017 USA
Telephone: +1 212 326 7000
Fax: +1 212 887 7465
<http://www.unicef.org>

UNITAID

UNITAID Secretariat
World Health Organization
20 Avenue Appia
CH 1211 Geneva 27 Switzerland
Telephone: +41 22 791 55 03
Fax: +41 22 791 48 90
E-mail: unitaid@who.int
<http://www.unitaid.eu>

U.S. Pharmacopoeia

12601 Twinbrook Parkway
Rockville, Maryland 20852 USA
Telephone: +1 301 881 0666
<http://www.usp.org>

U.S. President's Emergency Plan for AIDS Relief

Office of the Global AIDS Coordinator
SA-29, 2nd Floor
2201 C Street, N.W.
Washington, D.C. 20522 USA
Telephone: +1 202 663 2440
<http://www.pepfar.gov>

World Bank's Multi-Country HIV/AIDS Program

The World Bank
1818 H Street, N.W.
Washington, D.C. 20433 USA
Telephone: +1 202 458 0606
Fax: +1 202 522 7396
E-mail: actafrica@worldbank.org
<http://go.worldbank.org/I3A0B15ZNO>

World Health Organization Collaborating Centre for Drug Statistics Methodology

Norwegian Institute of Public Health
P.O. Box 4404 Nydalen
N-0403 Oslo, Norway
Telephone: +47 21 07 81 60
Fax: +47 21 07 81 46
E-mail: whocc@fhi.no
<http://www.whocc.no>

World Health Organization Department of Essential Medicines and Pharmaceutical Policies

HSS/EMP
20 Avenue Appia
CH 1211 Geneva 27 Switzerland
Telephone: +41 22 791 21 11
Fax: +41 22 791 47 30
E-mail: empinfo@who.int
<http://www.who.int/medicines/en>

World Health Organization Eastern Mediterranean Regional Office

Abdul Razzak Al Sanhoury Street
P.O. Box 7608, Nasr City Cairo 11371 Egypt
Telephone: +20 2 2276 5000
Fax: +20 2 2670 2492
E-mail: inf@emro.who.int
<http://www.emro.who.int>

World Health Organization Regional Office for Africa

Cité du Djoué, P.O. Box 06
Brazzaville, Republic of Congo
Telephone: +47 241 39100 or +242 770 02 02
Fax: +47 241 39503
E-mail: regafro@afro.who.int
<http://www.afro.who.int>

World Health Organization Regional Office for Europe

Scherfigsvej 8
DK 2100 Copenhagen Ø Denmark
Telephone: +45 3917 1717
Fax: +45 3917 1818
E-mail: postmaster@euro.who.int
<http://www.euro.who.int>

World Health Organization Regional Office for South East Asia

World Health House
Indraprastha Estate
Mahatma Gandhi Marg
New Delhi 110 002 India
Telephone: +91 11 2337 0804
Fax: +91 11 2337 0197
E-mail: registry@searo.who.int
<http://searo.who.int>

World Health Organization Regional Office for the Western Pacific

P.O. Box 2932
1000 Manila, Philippines
Telephone: +63 2 528 8001
Fax: +63 2 521 1036
E-mail: pio@wpro.who.int
<http://www.wpro.who.int>