

Prescription for healthy development: increasing access to medicines

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Foreword

The world has an unprecedented opportunity to improve the lives of billions of people by adopting practical approaches to meeting the Millennium Development Goals. At the request of UN Secretary-General Kofi Annan, the UN Millennium Project has identified practical strategies to eradicate poverty by scaling up investments in infrastructure and human capital while promoting gender equality and environmental sustainability. These strategies are described in the UN Millennium Project's report *Investing in Development: A Practical Plan to Achieve the Millennium Development Goals*, which was coauthored by the coordinators of the UN Millennium Project task forces.

In *Prescription for Healthy Development: Increasing Access to Medicines*, the Working Group on Access to Essential Medicines of the Task Force on AIDS, Malaria, TB, and Access to Essential Medicines underscores the vital need to increase the availability, affordability, and appropriate use of medicines in developing countries. The working group proposes concrete and practical steps to increase incentives for research for priority diseases of developing countries, improve procurement and distribution, strengthen primary health systems, develop more human resources, and increase health funding. These are all necessary components of a comprehensive strategy to improve access to essential medicine in developing countries.

The working group benefited from the contributions of experts from academia and nongovernmental organizations, practitioners in the field, and members of the pharmaceutical industry. This diverse and accomplished group was able to reach consensus on most of the substantive recommendations, but ultimately, because of differences in perspective in a few areas, the representatives of the research-based pharmaceutical industry decided to withdraw their support for the report. In an appendix to the report, industry representatives explain these specific points of contention.

I am grateful for the thorough and skilled efforts of the entire working group. The practical options for action in this report should make an important contribution to achieving all the Millennium Development Goals. I strongly recommend it as required reading for anyone interested in how the world can ensure access to essential medicines in developing countries.

Jeffrey D. Sachs
New York
January 17, 2005

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Preface

It is estimated that between 1.7 and 2 billion people worldwide have inadequate or no access to life-saving essential medicines. The vast majority of these people live in developing countries. After the presence of trained health professionals, medicines are the single most critical element in the maintenance of health and the successful treatment of disease and illness. Shortages of essential medicines undermine the ability of healthcare workers to respond appropriately to patient needs and this in turn often erodes the confidence and trust patients and their families have in local health systems.

The sequence of steps required from the conceptualization and production of medicines to the dispensing of them are numerous and, at times, complex. Medicines, seen as marketable commodities by many, are subject to trade and commerce policies and regulations on both national and international levels.

Underlying the specific constraints to access to medicines are the social and cultural conventions that can disproportionately prevent women, children, ethnic minorities, and other marginalized populations from gaining access not just to medicines but to the larger health system.

The Working Group on Access to Medicines of the Task Force on HIV/AIDS, Malaria, TB, and Access to Essential Medicines is composed of respected individuals who bring an impressive range of public and private experience in the many and complex local, national, and international issues that, along with availability of human and fiscal resources in any given setting, will ultimately determine access to essential medicines.

Acknowledgments

As with any large group effort, the final report remains the product and responsibility of the entire group. However, it is important to acknowledge the roles and contributions of individuals. Working group members would like to thank Alec Irwin and Eva Ombaka for the tremendously helpful background paper that launched the project and effectively got members thinking and contributing from the first meeting. William Haddad offered valuable contributions to ensure the voice of the generics industry had full hearing in the process. Ellen 't Hoen provided important information in many areas of this report; the extensive and all-important on-the-ground experience and expertise of Médecins Sans Frontières informed the report in valuable ways.

A special thanks is due Graham Dukes, who served as the main writer and editor of the interim report, much of which remained the basis of the final report. A sincere thanks is owed to Hans Hogerzeil and Margaret Kruk, who worked diligently under very challenging circumstances to help compile the final report. Detailed written reviews of the penultimate draft by Henk den Besten, David Lee, Yuanli Liu, and Eva Ombaka were extremely helpful.

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Uganda, for his inputs during our June 2004 meeting in Kampala and for his detailed, patient, and informed responses to our many inquiries throughout the development of the Uganda case study found in appendix 1. We are grateful to Kevin Burns who conducted in-depth research for and contributed to the development of the Uganda case study during his internship at Partners In Health.

Partners In Health served as the secretariat for the task force since the onset of the Project, and we thank them for their helpful and efficient logistical and administrative support.

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Abbreviations

AIDS	acquired immunodeficiency syndrome
CMH	Commission on Macroeconomics and Health
DFID	Department for International Development (UK)
DOTS	recommended control strategy for tuberculosis
DNDi	Drugs for Neglected Diseases initiative
GATB	Global Alliance for TB Drug Development
GAVI	Global Alliance for Vaccines and Immunizations
GDF	Global Drug Facility
GDP	gross domestic product
GFATM	Global Fund to Fight AIDS, Tuberculosis, and Malaria
GMP	Good Manufacturing Practice (WHO requirements)
HAI	Health Action International
HIV	human immunodeficiency virus
IAVI	International AIDS Vaccine Initiative
ICH	International Conference on Harmonization (of Technical Requirements for Registration of Pharmaceuticals for Human Use)
IMF	International Monetary Fund
MAP	Multi-Country AIDS Program (World Bank)
MDR-TB	multidrug-resistant tuberculosis
MMV	Medicines for Malaria Venture
MSF	Médecins Sans Frontières
MSH	Management Sciences for Health
NGO	nongovernmental organization
PEPFAR	President's Emergency Plan for AIDS Relief (US)
PRSP	Poverty Reduction Strategy Paper
R&D	research and development
TB	tuberculosis

TDR	Programme for Research and Training in Tropical Diseases
TRIPS	Trade-Related Aspects of Intellectual Property Rights agreement
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Program
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
UNIDO	United Nations Industrial Development Organization
USAID	United States Agency for International Development
VAT	value-added tax
WHO	World Health Organization
WTO	World Trade Organization

goals

Millennium Development Goals

Goal 1

**Eradicate
extreme poverty
and hunger**

Target 1.

Halve, between 1990 and 2015, the proportion of people whose income is less than \$1 a day

Target 2.

Halve, between 1990 and 2015, the proportion of people who suffer from hunger

Goal 2

**Achieve
universal primary
education**

Target 3.

Ensure that, by 2015, children everywhere, boys and girls alike, will be able to complete a full course of primary schooling

Goal 3

**Promote gender
equality and
empower women**

Target 4.

Eliminate gender disparity in primary and secondary education, preferably by 2005, and in all levels of education no later than 2015

Goal 4

**Reduce child
mortality**

Target 5.

Reduce by two-thirds, between 1990 and 2015, the under-five mortality rate

Goal 5

**Improve
maternal health**

Target 6.

Reduce by three-quarters, between 1990 and 2015, the maternal mortality ratio

Goal 6

**Combat
HIV/AIDS,
malaria, and
other diseases**

Target 7.

Have halted by 2015 and begun to reverse the spread of HIV/AIDS

Target 8.

Have halted by 2015 and begun to reverse the incidence of malaria and other major diseases

Goal 7**Ensure
environmental
sustainability****Target 9.**

Integrate the principles of sustainable development into country policies and programs and reverse the loss of environmental resources

Target 10.

Halve, by 2015, the proportion of people without sustainable access to safe drinking water and basic sanitation

Target 11.

Have achieved by 2020 a significant improvement in the lives of at least 100 million slum dwellers

Goal 8**Develop a global
partnership for
development****Target 12.**

Develop further an open, rule-based, predictable, nondiscriminatory trading and financial system (includes a commitment to good governance, development, and poverty reduction—both nationally and internationally)

Target 13.

Address the special needs of the Least Developed Countries (includes tariff- and quota-free access for Least Developed Countries' exports, enhanced program of debt relief for heavily indebted poor countries [HIPCs] and cancellation of official bilateral debt, and more generous official development assistance for countries committed to poverty reduction)

Target 14.

Address the special needs of landlocked developing countries and small island developing states (through the Program of Action for the Sustainable Development of Small Island Developing States and 22nd General Assembly provisions)

Target 15.

Deal comprehensively with the debt problems of developing countries through national and international measures in order to make debt sustainable in the long term

Some of the indicators are monitored separately for the least developed countries, Africa, landlocked developing countries, and small island developing states

Target 16.

In cooperation with developing countries, develop and implement strategies for decent and productive work for youth

Target 17.

In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries

Target 18.

In cooperation with the private sector, make available the benefits of new technologies, especially information and communications technologies

Executive summary

Medicines are the most significant tool that society possesses to prevent, alleviate, and cure disease.¹ Most illnesses, especially infectious diseases, are either preventable or to some extent treatable with a relatively small number of existing medicines. Combined with appropriate public health interventions, appropriately prescribed essential medicines and vaccines could, in principle, massively reduce the impact of disease on communities, especially children (WHO 2004a).

The problem

A very large part of the world's population has inadequate or no access to essential and life-saving medicines. According to one study, more than 10 million children die unnecessarily each year, almost all in low-income or poor areas of middle-income countries, mostly from a short list of preventable diseases such as acute respiratory diseases, diarrhea, malaria, measles, and causes related to malnutrition (Black 2003).

The lack of access to life-saving and health-supporting medicines for an estimated 2 billion poor people stands as a direct contradiction to the fundamental principle of health as a human right. Poverty and illness create a vicious cycle. Poverty is at the source of major health risks, such as insufficient and improper nutrition, poor sanitation and hygiene, toxic indoor smoke, and extremely limited access to health education and services, all of which determine almost 45 percent of the disease burden in Least Developed Countries (WHO 2002g). Illness is a major reason that the nearly poor slip into poverty. Illness decreases people's ability to work (be it remunerative or nonremunerative). Illness prevents children from getting the education they need. Women and children make up the majority of the poor, and their low status in many societies often means that they have even less access to medicines. Improving access to medicines must be a key component of strategies to strengthen healthcare.

Increasing access to medicines, especially for the poor, offers many challenges

The knowledge and medicines are available to reduce the incidence of death and suffering greatly; what is still needed is clear priority setting and the provision of adequate resources. Resolving some of the greatest health crises in human history will not be the sole responsibility of any single actor or sector of society. These challenges come at a time when an unprecedented number of the world's population is also living (and dying) in extreme poverty. Public, private, and nongovernmental organizations (NGOs) and institutions must work together.

Increasing access to medicines in developing countries, especially for the poor, offers many challenges. These can be crystallized into two main areas:

- How to increase access to affordable existing medicines in resource-poor settings, which countries can do by improving the selection and use of essential medicines, taking steps to ensure affordable prices, increasing sustainable financing, and strengthening reliable supply systems.
- How to find new ways to promote the development of new medicines and vaccines to treat diseases of poverty.

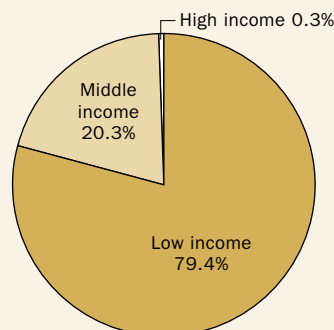
The World Health Organization (WHO) estimates that nearly a third of the world's population lacks access to the most basic essential medicines, while in the poorest parts of Africa and Asia this figure climbs to a half (WHO 2000a; WHO 2003f). WHO has also estimated that in Africa and South-east Asia, prompt diagnosis and treatment with appropriate medicines could save approximately 4 million lives annually (DFID 2004b). Moreover, it is often the poorest people who are paying the highest out-of-pocket expenses for medicines because the public sector in developing countries fails to provide affordable medicines reliably. Medical insurance schemes cover less than 8 percent of the population in Africa, and these schemes may not cover prescription medicines on an outpatient basis. Participatory assessments during national poverty reduction strategy processes often elicit the availability of medicines as a primary indicator of the effectiveness of healthcare delivery.

Though access to essential medicines has improved in recent years, WHO reports that delivering “the right medicines to the people who need them at the time they need them remains a major challenge” (WHO 2004a, p. 61).

Figure 1

Distribution by country income group of people without access to essential medicines, 1999

Source: WHO 2004a.



**Increasing
access to
affordable
medicines
requires
improving
selection,
prices, and
supply**

The analysis contained in WHO's 1999 *World Medicines Situation* shows that roughly two-thirds of the world's population now have regular access to essential medicines, up significantly from 1975 when this proportion was just under one-half (WHO 2004a). However, global population growth has meant that the absolute number of people without access has remained nearly constant, at approximately 1.7 billion.

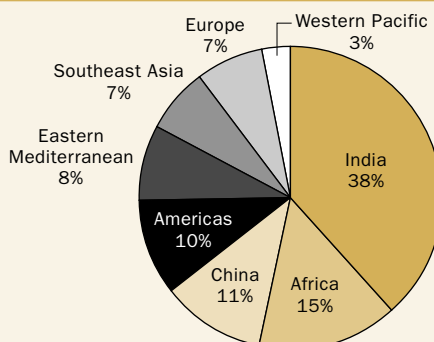
Despite the progress made in the last decades, the likelihood of an individual having access to essential medicines is still greatly affected by income level. The *World Medicines Situation* analysis found that people in poorer countries were much less likely to have access to these medicines (WHO 2004a). According to WHO, in 1999, roughly 80 percent of the global population without access to essential medicines was living in low-income countries (figure 1). This is a disproportionate share of the global burden, given their estimates that low-income countries account for approximately 60 percent of the world's population (WHO 2004a). In contrast, only 0.3 percent of those lacking access to essential medicines lived in high-income countries, which account collectively for about 15 percent of the world's population. In a global context, 15 percent of the world's population consumes 91 percent of the medicines produced (WHO 2000a). Of people living in low-income countries, nearly 40 percent did not have access to essential medicines in 1999 (WHO 2004a).

Geographically, the lack of access to essential medicines is especially severe and concentrated in Africa and India (figure 2). In fact, 38 percent of the people without access to essential medicines live in India, and 15 percent live in Africa (WHO 2004a). Together, India and Africa account for 53 percent of the world's population without access to essential medicines (WHO 2004a). Although the disease burden and mortality from preventable or curable illness is highest in Africa, pervasive poverty means that the continent's share of the global pharmaceutical market is only slightly more than 1 percent.

India's and Africa's inordinate share of the global population without access is not entirely a function of population. India accounts for 17 percent of the world's population, while Africa accounts for roughly 10 percent of the world's population. This translates to very high absolute numbers of people without

Figure 2
**Distribution by region
of people without
access to essential
medicines, 1999**

Source: WHO 2004a.



Increasing access also requires promoting the development of new medicines and vaccines

access in these two regions. Sixty-five percent of Indians and 47 percent of Africans lack access to essential medicines (figure 3). In Europe that share is 14 percent and in the Americas 22 percent (WHO 2004a).

The lack of access to medicines in most developing countries reflects the lack of sufficient incentives for developing new medicines to target those communicable diseases that disproportionately afflict the poorest countries, and also their inability to pay for and effectively distribute those that do exist. The result is what the government of the United Kingdom has called a “mismatch between pharmaceutical needs in developing countries and the current nature of the global pharmaceutical market” (DFID 2004a, p. 14).

When examining access to essential medicines for the poor, the Working Group on Access to Essential Medicines identified a number of fundamental problems common to many countries. What is very clear, however, is that the basic knowledge and technical information already exist to increase access to all segments of a population. Furthermore, the world possesses the resources to fund adequate access to essential medicines and functioning health systems in the developing world.

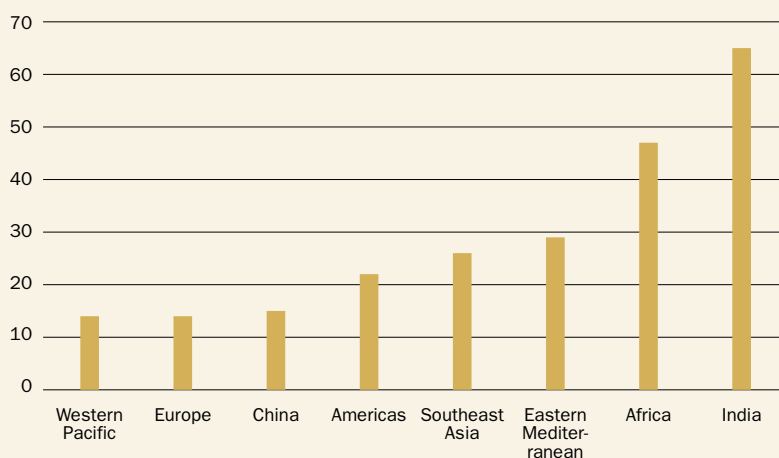
Ideally, the working group would have wished to propose a simple approach to improving access to medicines. Because obstacles to access are many and diverse, and because they differ in nature and degree from one country to another, this is not possible. The issues surrounding access are complex, at times culturally specific, and often fluid; the solutions can be no less. Some will need to be applied at the global level, while others need to be selectively employed in particular countries or regions depending on the situation and its context.

Overarching barriers

At the risk of overshadowing the other vital issues presented in this report, the Working Group on Access to Essential Medicines points to six of the most

Figure 3
Share of people without access to essential medicines by region, 1999

Source: WHO 2004a.



**Inadequate
human
resources
threatens to
undermine
all efforts to
strengthen
health systems
and improve
healthcare**

important barriers to access that merit special attention and action at this time. The first four relate to barriers to existing medicines; the last two constitute barriers to the development of affordable and available new medicines and vaccines.

Barriers to existing medicines

1. *Inadequate national commitment* to making healthcare a priority from the national to the local levels remains one of the greatest barriers to increasing access to existing medicines. There are many reasons for this lack of prioritization. Key among them are a lack of political will by policymakers to make the needs of the poor a priority; donor programs that can skew or limit national governments' abilities to set health policy; debt servicing and conditionality for loans from international financial institutions that can further limit government responsiveness to basic social service needs of citizens; and, unfortunately, the threat of corruption that continues in the healthcare sector at all levels.
2. *Inadequate human resources* for health, including pharmacists and pharmacy technicians, is a growing problem that, if unaddressed, threatens to undermine all efforts to strengthen health systems and improve healthcare in much of the developing world. Education, information, and in-service training remain potent tools to change that situation. More needs to be done to identify what is needed to retain skilled workers, especially in the face of mounting demands for health workers, such as nurses and pharmacists, in developed countries. Retention plans and compensation schemes for countries that lose health workers should be investigated.
3. The *international community has not provided adequate finance nor consistently fulfilled its existing promises to developing countries*. Some proposed actions have not been carried out at all and others have not been carried out effectively. To achieve progress, there will be a need for political will, in both industrialized and developing countries, as well as a need for transparency on all fronts. Above all, there will be a need for increased levels of long-term financial support from the world community. It remains an unfortunate ongoing reality that some of the world's wealthiest countries remain the farthest from achieving their longstanding commitment to the international development assistance target of 0.7 percent of gross domestic product (GDP).
4. A persistent *lack of coordination of international aid* reduces access to medicines. Most poor countries will require significant donor funding to achieve universal access to essential medicines. They will also need much better aid coordination to avoid unnecessarily heavy reporting requirements and to avoid resource-wasting duplication of efforts. Sector-wide approaches should be used to promote improved coordination.

**A need exists
for a great
deal more
transparency
and coordination
of effort**

Donors should commit aid that strengthens existing systems, that proactively targets the poorest and rural areas, and that avoids vertical programming by disease or by a given donor. A need exists at both the international and national levels for a great deal more transparency and coordination of effort between the large number of organizations that have already become involved in one way or another in this field. The involvement of so many bodies can and does lead to duplication of effort and to waste, and both are unacceptable. In some situations, there is every reason to merge complementary ventures. Pharmaceutical companies can and should contribute in their own way to the advancement of national medicines policies and the development of capacity in this field.

Barriers to the development of affordable new medicines

5. *The Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement may block access to affordable new medicines and vaccines.* After January 2005, generic production in India, the source of many vital existing medicines for developing countries without productive capabilities, will be fully subject to TRIPS provisions (WTO 1994). Concerns also exist that the August 30, 2003, decision reached by the WTO General Council concerning a waiver for TRIPS Article 31(f) (which would allow a compulsory license to be issued by the country in need and by the country that can produce the medicine for export) will be too cumbersome for developing countries to exploit (WTO 2003). Finally, the growing number of bilateral and regional trade agreements with major trading partners, such as the United States and the European Union, may often contain provisions that limit developing countries' use of existing flexibilities under TRIPS to protect public health (such as restrictive compulsory licensing conditions and parallel importation provisions, extended data protection, and requiring medicines regulatory agencies to take on national patent office oversight duties).

A major recommendation of this working group is for the WHO to be mandated, perhaps in coordination with the WTO or other trade bodies, to monitor the impact of TRIPS compliance by major developing country exporters and, in particular, to monitor the use of the August 30 decision over the coming two years as it concerns access to medicines. A report to the World Health Assembly and the WTO General Council, with recommendations, should be delivered no later than the end of 2007.

6. *The current incentive structure is inadequate to promote research and development of medicines and vaccines to address priority health problems of developing countries.* For a number of the most neglected diseases (such as African trypanosomiasis, Chagas disease, leishmaniasis, and dengue fever), which

Every developing country should have an overall national medicines policy and strategy founded on the essential medicines concept

occur primarily in developing countries, new medicines need to be developed (WHO and IFPMA 2001). For others, new medicines are needed to address shortcomings of existing treatments, such as safety, efficacy, appropriate dosing, length of treatment, and the ongoing threat of drug resistance. Despite progress in funding research and development (R&D) for new medicines for neglected diseases, with notable contributions from philanthropic foundations and some governments and pharmaceutical companies, more financial resources need to be mobilized in a sustainable way to create a strong pipeline of new medicines. New thinking, different means of financing and organizing medicines development, and other reforms are needed. For example, the WHO Commission on Intellectual Property Rights, Innovation, and Public Health should examine alternative international models to the current patent-based system for priority setting and financing of health R&D.

Since the problem of access has many causes, a single solution to improve the provision of medicines cannot be expected to succeed alone; it must be complemented by others. What this means is that every developing country should have an overall national medicines policy and strategy founded on the essential medicines concept:

A national drug policy is a commitment to a goal and a guide for action. It expresses and prioritizes the medium- to long-term goals set by the government for the pharmaceutical sector, and identifies the main strategies for attaining them. It provides a framework within which the activities of the pharmaceutical sector can be coordinated. It covers both the public and the private sectors, and involves all the main actors in the pharmaceutical field. (WHO 2003a, p. 19)

The most important step is to develop a model that meets national needs and to employ it as a basis for developing and managing the system as a whole.

National medicines policy cannot succeed in isolation from broader health policies and government policies in general. A ministry of health is unlikely to succeed in this area unless it has clear and acceptable understandings reached with other government departments dealing with such matters as finance; the training curricula for health professionals; the salaries of public employees; and practices regarding trade, taxation, and customs duties, all of which are likely to impinge on the supply of medicines.

Health sector strengthening and development to reach the Millennium Development Goals should be done in coordination with national poverty reduction strategic planning being adopted in poor, indebted countries. A recent WHO review of some national Poverty Reduction Strategy Papers (PRSPs) and health pointed out that much good information is being generated about health system needs, including access to medicines, in analytical phases of the poverty reduction strategy process (WHO 2004e). However,

**Achieving
universal access
to affordable
essential
medicines
requires
developing and
strengthening
primary health
systems**

it would appear that when government responses were formulated, there was a tendency to rely on existing health policy approaches and budgets, which rarely included any community or civil society participatory processes. Instead, they tended to reflect top-down prioritization shaped by international financial institution conditions and a lack of political commitment to reorient government focus more toward the social sector. A need exists, therefore, to examine how health sector and other social sector needs can be better addressed in the poverty reduction processes, including how information and needs assessments gained in participatory analysis can be better translated into government planning and budgets.

Reaching the goal of achieving universal access to affordable essential medicines in developing countries will require the development and strengthening of primary health systems, along with the myriad specialized administrative and functional features necessary to maintain a sustainable supply of all essential medicines. Firm priorities must be set, including an urgent need to reassess the importance of health sector investments by donors and recipient governments and to increase resources substantially through greater political will on both sides.

Summary of main recommendations

The Working Group on Access to Essential Medicines has organized its analysis and recommendations into three main categories: availability, affordability, and appropriateness. The group also identified basic principles and crosscutting issues.²

Expanding access to essential medicines requires attention to a diverse set of policy challenges. National health policies and systems are not always fully attuned to ensuring that medicines are available, affordable, or appropriate. Solutions must begin with an understanding of local health conditions in their broadest epidemiological, economic, regulatory, and even cultural contexts. Increasing access must be seen as a process requiring ongoing support from a range of stakeholders. Reforms are most effective when they focus on the most critical access problems, rather than attempting to address all barriers simultaneously. Countries need adequate data collection and analysis to assess and set priorities in problem areas.

Access to medicines cannot be addressed in isolation either from the rest of the health system or from the overall health situation in a given country. Access to medicines is not an issue that exists in a vacuum: it is an integral part of healthcare, the various components of which are mutually supportive. Measures in all of these areas will need to be backed by the systematic and ongoing assessment of the needs of a particular country or population. On all levels there will be a need for institutional development and a sustainable expansion of human resources. Although the access to medicines issue ultimately is a global one, the working group, in keeping with the UN Millennium Project's

**Women's
inequality
and gender
disparities
contribute to
institutionalized
inequalities
within
educational and
health systems**

mandate, has focused its main efforts on addressing how to increase access to medicines in developing countries that have the greatest need for concerted, coordinated, and effective mobilization of resources to break the cycle of ill health, poverty, and declining economies.

The working group addressed its recommendations on two main levels: national and international. Especially at the national level, an attempt was made to be as operational as possible. This division into national and international levels, however, should be viewed with caution, since increasing access will ultimately involve a complex interplay of many actors operating at many levels concurrently and dynamically.

General principles

The working group found that certain basic principles underpinned approaches to the issues of and solutions to increasing access to medicines. These general principles include the human right to health codified in the UN Declaration of Human Rights (UN 1948); the right to treatment codified in Article 12 of the International Covenant on Economic, Social, and Cultural Rights, which was clarified in 2000 to include the right to essential medicines (WHO 2002a; Hogerzeil 2003); and the right to medical treatment, including access to medicines, found in the International Guidelines on HIV/AIDS and Human Rights (OHCHR/UNAIDS 2002). However, the enforcement of these rights is not evident in the current global situation, where entire populations, particularly the poor and underprivileged, commonly have little or no access to essential medicines.

The working group also found that women's inequality and gender disparities contribute to institutionalized inequalities within educational and health systems. These inequalities limit women's and girls' access to healthcare and to needed medicines more than men's and boys'. Profound, incremental, and societywide changes must occur to eliminate these forms of discrimination. Health systems will need to be strengthened to deliver quality essential services while maintaining equity of access. Equity of access should be a cornerstone in thinking and policymaking. Simply put, the most marginalized should receive healthcare and services at the same or greater rate than more economically franchised in any program. In the case of AIDS treatment, an equitable approach would target populations that live in the most resource-challenged areas first. An equitable approach to pro-poor healthcare, would be, by definition, a bottom-up approach.

The working group in general also recognized the need to find new ways for the main actors involved in the supply of pharmaceuticals to interact to ensure that needed medicines are available. Indeed the group's discourse on the means to ensure supply was vibrant and robust. Members did agree on the fundamental point that market competition is an essential driver for innovation, supply, and affordable prices.

**Medicines
research must
become better
attuned to the
needs of the
world as a whole**

Improving the availability of medicines

Availability of medicines is affected by many factors. The main ones that need to be tackled include ensuring that needed medicines are developed and brought to market, and that supply and distribution systems are adequate to deliver them to the people who need them.

Improving the rate and relevance of innovation. Treating priority diseases of the poor is greatly hindered by a fundamental problem: the medicines required for some of the diseases and illnesses most prevalent in developing countries do not exist because of a lack of therapeutic innovation (MSF 2001). Another critical need is for new medicines to supplement or replace those to which microorganisms have become resistant, as is notably the case for malaria and tuberculosis.

A reorientation of medicines research, better attuned to the needs of the poor, is necessary. This will require creative new research, development, and financing mechanisms. The for-profit private sector is not going to take up needed innovation for major infectious diseases of poverty without major involvement and subsidy from the public sector and an appropriate and supportive policy environment. The public sector is also going to have to remain a vital force. An equitable approach globally would have these innovation costs borne primarily by the nations with the broadest shoulders: heavily industrialized countries with strong economies that are capable of sustaining relatively high prices for the medicines they require.

Public-private initiatives, such as the Medicines for Malaria Venture, the International AIDS Vaccine Initiative, and the Global Alliance for TB Drug Development, appear to be offering useful models for new medicines and vaccines development, and they should be supported. However, some questions remain about governance, adequate participation by experts from affected countries, and adequate focus on priority medicines for the poor. These aspects need to be monitored.

Successful innovation to help meet the Goals will require greater cooperation among all sectors (such as the public and private sectors, academia, foundations, and the United Nations), substantially more financing from multiple sources, clear priorities for research efforts, effective management, and technology and knowledge transfer. WHO should take a leading role in promoting R&D that meets the public health priorities of developing countries. Medicines regulatory process reforms and harmonization need to better reflect and serve the needs of developing countries. Traditional knowledge and medicines continue to be marginalized, to the detriment of consumers. Vigilance surrounding all aspects of pharmacological practice in developing countries needs to be strengthened.

All of these issues point to the need for considerable change, which will take considerable time to implement and to produce results. Taking new steps must start now.

International standards for ethical research should be applied in all countries

At the national level:

- Governments should determine priorities in medicinal innovation in accordance with the most basic and unfulfilled needs of their populations, and bring these priorities to the fore both in their domestic policies (such as through their national medicines policies, essential medicines lists, procurement strategies and budgets, and public R&D policy priority setting) and in the global forums in which they participate.
- Developing countries should be more confident about negotiating for technology transfer and more national capacity building to participate directly in R&D. Examples of innovative approaches include the Drugs for Neglected Diseases initiative (DNDi) approach to partnering with research institutes in developing countries, the cooperative effort between the Universities of Nairobi and Oxford on AIDS vaccines trials, the Kenya Medical Research Institute's partnering with GlaxoSmithKline and the University of Liverpool on the development of a new antimalarial, the Merck Vaccine Network Africa training center at Moi University in Kenya, Merck's partnership with Harvard University's AIDS Program in the Enhancing Care Initiative to build infrastructure for vaccine delivery, and the Pfizer partnership with Makerere University in Uganda and the University of Utah. Even in countries with very limited resources, some steps can and must be taken to formulate a national research policy and provide the funding and infrastructure needed to implement it, either independently or in collaboration with foreign, regional, or global institutions.
- The regulatory environment should reward sound research into priority diseases. For example, a country could devise a fast-track system for priority medicines, based on national health priorities.

At the international level:

- Public investment in medicinal research should be expanded to meet the most pressing needs of developing countries and poor populations, including developing knowledge on the basis of indigenous medicines. The international community should not rely on the research-based pharmaceutical industry to be the primary vehicle for developing medicines needed in developing regions. New ways of approaching innovation should be considered and pursued with some urgency (Folb 2004). The WHO Commission on Intellectual Property Rights, Innovation, and Public Health should examine alternative international models to the current patent-based system for priority setting and financing of health R&D. Recent papers commissioned by DFID also support the value of taking new approaches to technology transfer, patent regimes, intellectual property management, and local production as ways of meeting the demand for increased access to medicines (see, for example, Hill and Johnson 2004; Lewis-Lettington and Banda 2004).

National regulatory bodies need strengthening, and the judicial system needs the human and material resources to enforce regulations and eliminate abuses

- International standards for ethical research such as those elaborated by the Declaration of Helsinki should be applied in all countries.

Developing more reliable procurement and supply systems. Many national procurement and supply systems for medicines, whether public or private, are inefficient or poorly attuned to current needs. Procurement is not always in line with what is needed, funds are not optimally used, and medicines are commonly out of stock in both urban and rural areas. Procurement and supply systems in developing countries need to be more effective and reliable, making the best possible use of public, private, and nonprofit channels and ensuring that a reliable supply system is extended to rural areas. Each country should develop and keep an updated list of essential medicines that reflects its priority health needs and that is used as a basis for procurement and supply decisions.

At the national level:

- All potentially efficient systems for the procurement and distribution of supplies of medicines, whether public, private, or maintained by NGOs, should be encouraged and assisted to develop. This will require country-level, ongoing capacity building. Low-income countries especially need ongoing technical assistance to build expertise in effective procurement, quality control, and quality assurance systems. National regulatory bodies need strengthening urgently in developing countries, and the judicial system should be provided with the human and material resources to enforce these regulations and eliminate abuses that can lead to waste and loss.
- The advent of the Global Fund to Fight AIDS, Tuberculosis, and Malaria (GFATM) in recent years and the World Bank Multi-Country HIV/AIDS Program (MAP) provide developing countries with valuable resources and incentives to improve their procurement and medicines management systems. Both organizations promote an assured quality and lowest price approach. The GFATM asks recipient countries that receive funds for medicines purchases to demonstrate that they have a competent national system for selection, procurement, quality assurance, supply, and distribution. Initial concerns that the fund would prompt parallel procurement and supply systems are being allayed. The fund has emphasized that national systems should be strengthened, not replaced nor sidelined. The World Bank published a detailed technical guide in early 2004 that should be very helpful at the country level in addressing these systems challenges (World Bank 2004a).
- The WHO prequalification project to identify good-quality products for HIV/AIDS, tuberculosis, and malaria medicines for procurement by UN agencies is also helping low-income countries that have very limited quality assurance capacities to improve procurement by providing key quality indicators for suppliers and products. The working

Technical assistance should strengthen national systems to be able to protect and promote public health for all

group endorses the WHO prequalification project for use by developing countries and supports its expansion.

- Pooled procurement schemes remain a tantalizing, yet still underused, avenue for improved procurement. No one model for pooled procurement exists. The degree of cooperation and shared or combined systems depend on the participants, local and regional characteristics, and purchasing needs. Other examples of pooled procurements include disease-specific international initiatives such as the Global Drug Facility for TB and the Medicines for Malaria Venture. All of these strategies should be explored by developing countries. Countries pursuing these strategies should take care that a minimum number of qualified suppliers participate in these schemes to ensure a competitive market.
- Procurement should be only from suppliers that have complied with the WHO Good Manufacturing Practice (GMP) requirements.

At the international level:

- The exchange of information and advice on successes and failures of national or pooled procurement systems, routinely updated price lists, and systems of distribution and supply will be valuable in establishing new agencies or reforming those that already exist. Bringing together data from many countries on current and anticipated needs and priorities will create a basis for producers to provide appropriate supplies. International standards for operating procurement agencies are needed, and ways to prequalify procurement agencies that attain these standards should be developed.
- WHO, the GFATM, and the World Bank should provide leadership in meeting capacity-building demands. WHO, the World Intellectual Property Organization, WTO, and especially competent nongovernmental experts should provide country-level guidance on the effects of intellectual property regulation on access to medicines. The goal of all technical assistance should be to strengthen national systems to be able to protect and promote public health, particularly for the poor and marginalized. Countries that do not have sufficient regulatory capacity in the short or medium term should have access to international bodies, norms, and standards to help them make efficient decisions about quality assurance, quality control, and registration.

Promoting the safety of medicines. Substandard medicines (genuine products that do not conform to the pharmacopeial standards set for them) present a real problem, especially in developing countries that have limited regulatory and enforcement capacities. Use of these medicines endangers lives, wastes scarce resources, and contributes to development of resistance to anti-infectives. WHO estimates that as many as 200,000 of the more than 1 million deaths from malaria each year could be avoided if medicines were effective, of good quality, and used correctly.

Registration procedures should be simple, straightforward, and equitably applied

WHO also reports that the US Food and Drug Administration estimates that more than 10 percent of medicines in circulation in both developed and developing countries is counterfeit (products that are deliberately and fraudulently mislabeled with respect to identity or source). A WHO survey of counterfeit medicines reports from 20 countries showed that 60 percent of counterfeits were found in poor countries and 40 percent in industrialized countries (WHO 2003d). A recent report from the United States Pharmacopeia and Drug Quality and Information programs on the quality of anti-infectives in Asia indicates that the availability of substandard and counterfeit drugs has reached a disturbing proportion in resource-poor settings (USP and DQI 2004). This report identified gaps and weaknesses:

- Weak national medicines regulatory authority and weak enforcement of relevant laws.
- Little or no GMP compliance by manufacturers.
- Limited laboratory capacity in terms of qualified staff and equipment.
- Lack of competent inspectors.
- Lack of inexpensive, quality-assured medicines (USP and DQI 2004).

At the national level:

- Countries can combat the sale and use of poor-quality medicines by raising public knowledge and empowering consumers to demand quality assurances, conducting additional inspections of companies suspected of producing or importing substandard or counterfeit drugs, strengthening medicines laws, imposing stiffer penalties for offenders, increasing postmarketing surveillance, and restructuring the regulatory system. However, governments that rely on donor funding find themselves constrained in calling for system strengthening and increased staffing, given externally imposed conditionalities that can limit social sector spending, especially on government staffing.
- National systems that monitor suspected adverse reactions to medicines need to become more effective. They should be capable of defining the overall pattern of unwanted reactions in the population (and in particularly susceptible groups) and also cases of frank injury due to medicines. Independent drug information centers should be supported as part of improving information exchange—nationally and across borders—on medicines quality and safety. These centers must include data on benefit-risk assessment of particular agents or products, regulatory decisions involving safety issues (such as the withdrawal of disproportionately risky medicines), and reliable information on poor-quality products and producers.
- Work should be undertaken to institute no-fault systems for redressing injury from medicines.
- National registration should require bioequivalency information for both originator and generic medicines, to be provided and financed by the company seeking registration.

The drug supply systems in many developing countries are seriously underfinanced

- Registration in most developing countries takes too long for reasons that are not always clear. Registration procedures should be simple, straightforward, and equitably applied. When possible, fast-track processes should be available for medicines for national priority health needs, especially those prequalified by the WHO.

At the international level:

- International agencies and donors need to make safety and quality of medicines a higher priority by supporting regulatory strengthening and the timely exchange among countries, whether importing or exporting, of information relating to the safety of medicines. They should also enforce compliance with international GMP.
- The WHO prequalification project should be strengthened, expanded, and made a permanent and well funded function of WHO.
- Recent WHO initiatives to prequalify both individual products for high-priority diseases and the factories producing these products need to be vigorously pursued and extended.
- International organizations should share information about poor-quality products and producers based on reliable and accurate data and strengthen systems for sharing information on benefit-risk assessment and regulatory decisions (such as withdrawals). International organizations should also support existing adverse event monitoring systems.
- International organizations should work to strengthen national regulatory capacity through training, capacity building, information sharing, evaluation of best practices, and sustained funding.

Increasing the affordability of medicines

The medicines supply systems in many developing countries are seriously underfinanced. It would be unrealistic to imagine that developing countries will succeed in correcting this situation on their own during the coming 15–20 years, especially in light of growing disease burdens from major pandemics. Donor support for low-income countries should therefore be designed with a 20-year horizon at the levels needed to meet national public health goals. This support should be coordinated through sectorwide approaches.

Adequate and fair financing. Financing strategies should promote health system strengthening and progress toward national self-reliance over time.

At the national level:

- There must be a progressive increase in the public sector budget for essential medicines, particularly in order to ensure improved access for the poor; this is likely to require a shift in the allocation of government resources. Political will must exist, and government allocation decisions should be made using accurate data (such as such as those from national pharmaceutical sector baseline surveys). Governments need to

Low-income countries need long-term financial support to strengthen their systems and procure medicines

understand the importance of guaranteeing financing for procurement arrangements. User fees act as an economic barrier to healthcare for the poor. They do not provide an adequate nor long-term solution to the problem and they should be phased out wherever they exist.

- Essential medicines, along with other essential health services, should be provided at no cost to the end user in developing countries. For the poorest countries, financing in the short to medium term must come from wealthy countries, which have repeatedly committed to spending 0.7 percent of their national GDP on official development assistance and, in most cases, have fallen short. Community financing, while a useful complement to government-financed healthcare, cannot be, in the short term, a viable option for sustainable financing of primary healthcare in low-income countries.
- Payments made to providers at all levels—importers, wholesalers, and retailers—should be commensurate with the degree of service which they provide, as determined by appropriate national authorities.
- The acceptance of public or private donations of medicines should strictly follow *Guidelines for Drug Donations* (WHO 1999a).

At the international level:

- The donor community needs to accept the fact that low-income countries will need substantial additional financing per capita to meet even the most basic primary healthcare (including medicines) packages. In Uganda, for example, the spending shortfall on medicines alone is stark (\$1.20 allocated per person versus an estimated need of \$3.50 per person). It is cruelly cynical to suggest to poor countries that they need to prioritize healthcare for sustainable social and economic development and then not deliver the financing required. Low-income countries need long-term, sustained financial support to strengthen their health systems and procure needed medicines. In many cases, they will also require debt relief.
- Health sector budgets should be privileged in programs supervised by the international financial institutions, and levels of donor assistance should be adequate to support levels of service needed to achieve the Millennium Development Goals.
- Donors should fund recurrent costs, such as salaries, in the poorest countries for the short to medium term to enable health systems to function.
- In low-income countries, loans will occasionally be justified in order to provide acute relief, but in principle, funding should be in the form of financial grants, preferably provided without ties. Where loans are made, they should be earmarked for health systems development and not for the purchase of consumables, such as medicines. The world community can also provide valuable support in acquiring, analyzing, and disseminating

If a price is set at a level that a consumer cannot afford, the medicine will not be bought and used

comparative financial data on drug supply and the flow of finance both between and within countries; this will form a valuable basis for policies designed to ensure sufficient and equitable financing. Financing should promote integrating medicines procurement and supply with wider health policies and systems. Middle-income countries should be given incentives to allocate more of their available national budget for healthcare and medicines, with some international support being an option as needed.

- Innovative new global mechanisms to promote pharmaceutical R&D for urgent health problems of the developing world should be a priority. Although the total amount required is not clear, assessing current international funding flows and existing R&D needs is urgently required to identify the magnitude of funding required.

Countering high prices. Prices matter. If a price is set at a level that a consumer cannot afford, the medicine will not be bought and used. In developing countries, the overwhelming burden of poverty means that most essential medicines are not affordable. Yet every day, poor people risk their tenuous economic security to purchase medicines. Too often, the decision is a brutal tradeoff: food, housing, and children's education or the purchase of needed medicines. Sometimes drugs are unavoidably costly, but in a great many instances they are disproportionately expensive. The reasons for high prices are multiple, and the problem therefore has to be tackled vigorously at various levels. Market competition remains the most potent way to affect and lower prices. Additionally, the presence of an effective and efficient procurement and distribution system cannot be overemphasized.

At the national level:

- Governments have a range of tools available to help manage and lower medicines prices: use available and impartial price information; have and use an updated essential medicines list; have a pro-generics approach in policy (including mandatory substitution), planning, and procurement; promote price competition in the local market; promote bulk or pooled procurement (while taking care to maintain adequate numbers of qualified suppliers to supply the market); negotiate equitable prices for patented essential medicines; eliminate taxes (such as the value-added tax), duties, and tariffs on essential medicines; minimize mark-up; encourage local production of essential medicines where feasible; and ensure TRIPS public health safeguards are in national legislation and the expertise and will exist to use them.
- Prices for medicines should be transparent because information asymmetries are a main source of procurement inefficiencies that can result in higher prices. Medicines price lists, such as those published by WHO and Management Sciences for Health, can be a valuable tool for countries.

**Strategies
are needed
to permit
continued
production
and supply of
low-cost generic
drugs for poor
populations**

- Prices of medicines in developing countries must be reduced to the minimum sustainable level, which in many developing countries means that industry needs to provide these medicines at production cost (“no profit, no loss”) to national health systems. In middle-income countries, differential pricing should be pursued, although the prices will not be at marginal cost.
- Governments should recognize that guarantees of timely payment and financial credibility with suppliers are extremely effective in lowering prices. Suppliers, above all, want to know that they will be paid, and that it will be in a timely manner.

At the international level:

- There is the need to identify and adopt strategies that will permit continued production and supply of low-cost generic medicines for poor populations after January 2005. This is likely to involve providing new options, beyond those already incorporated in TRIPS. Of key concern will be the impact of TRIPS compliance by India, a major source of low-cost generic essential medicines in developing countries, and overall use of the WTO August 30 decision, which may prove too cumbersome to be considered a real solution (see figures 2.1 and 2.2 for details of how Least Developed Countries and developing countries can use it). Regional and bilateral trade agreements should not compromise the ability of developing countries to invoke the flexibilities provided in TRIPS (see, for example, Vivas Eugui 2003). The impact of TRIPS compliance and the August 30 decision on access to medicines in developing countries should be monitored by competent authorities, such as WHO, and findings to date and recommendations should be reported by the end of 2007.
- Pharmaceutical companies should be willing to negotiate medicines prices based on a concept of equity.³ Differential pricing negotiations should be simplified and transparency should be assured.
- All efforts must be made to continue and strengthen best price, assured quality procurement policies in the GFATM and the World Bank MAPs. Bilateral programs that restrict procurement only to originator medicines limit the impact of such aid to populations in great need, and such restrictions should be avoided.
- Both within exporting states and in international consultation, policies should favor international competition in the pharmaceutical field, including unhampered competition between individual firms and between originator companies on the one hand and generics producers on the other.
- Much benefit will be gained by sharing information between countries and agencies on producer prices, mark-ups and profits, tariffs, taxes, and other charges, so that successful approaches to the reduction of consumer prices in one country can be emulated in others.

**Consumers
often judge
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care by whether
they received
a prescription**

Promoting the appropriate use of medicines

Medicines are not fully available to a population unless the treatment in which they are used is provided in such a way that the patient is most likely to benefit. In many situations, inappropriate prescribing, dispensing, and consumption of medicines means that this aim is not achieved.

Better prescribing and dispensing. In too many cases, prescribers write too many prescriptions, and they do so for many reasons. For example, quick and affordable testing for an acute respiratory infection may not be available, so a clinician will presume the worst and prescribe an antibiotic—just in case. Consumers often judge the quality of care by whether or not they received a prescription. In some developing countries, the average number of prescriptions per visit can exceed three. Multiple prescribing is not advisable in most cases. It can put the burden on consumers to decide, on their own, which of the multiple items they can afford to purchase. Prescribing inessential or ineffective medicines (such as cough syrups) is also a problem.

At the national level:

- A coordinated policy should be devised and introduced to promote the appropriate use of medicines. There should be an essential medicines list, developed according to established international practice and reflecting the health needs and priorities of a given country. The essential medicines list should also be in line with evidence-based standard treatment guidelines. The standard treatment guidelines should also provide the basis for practice, as well as for teaching and evaluating health professionals.
- Hospitals should set up medicines and therapeutics committees.
- The essential medicines list and standard treatment guidelines should be the basis for ongoing monitoring of the manner in which medicines are used. Appropriate and regular development and modification of the standards should reflect current knowledge and country-specific challenges and responses. Similarly, dispensers need to be trained according to these standards and their performance needs to be monitored.
- It is vital to provide reliable information on medicines and their use, both during the education of professionals and on an ongoing basis during their professional careers (such as through the publication of formularies, standard treatment guidelines, and regular prescribing bulletins). The information provided by manufacturers and importers may supplement this, but measures should be taken to ensure that it adheres, at a minimum, to *WHO Ethical Criteria for Medicinal Drug Promotion* (WHO 1988).
- The processes of prescribing and dispensing should, whenever possible, be separated to avoid overprescribing because of financial incentives to the prescriber.

Use in the household must be understood from economic, social, cultural, and gender perspectives

- Patients should always be given basic information about the medications that are prescribed for them (including name, dosage, clear use instructions, and possible side effects). This approach will require sensitivity to patient population characteristics, such as accommodating different dialects and meeting the needs of largely illiterate populations.

At the international level:

- Donors and global agencies engaged in the health field need to work together to promote the appropriate use of drugs. The *WHO Ethical Criteria for Medicinal Drug Promotion* (WHO 1988) should be updated and extended to deal with newer issues, including the trend toward direct-to-consumer advertising and the increasing use of the Internet to promote medicines.
- WHO should also ensure the worldwide sharing and dissemination of authoritative texts on the best means of treating major and epidemic conditions, so that these can form the basis for national guidelines.

Better use of medicines in the home. To ensure the well informed use of medicines in the home, long-term and incremental behavior change is needed. Education and culturally appropriate information on the use of medicines must be made available through appropriate channels, with special consideration for illiterate and minority-language populations. It is often the case that even medicines that have been appropriately prescribed and dispensed are still improperly used in the home. For example, the consumer may not have received adequate information about the treatment and the labeling could be inadequate. She or he may not be able to read instructions. Consumers may seek a savings, by stopping treatment when they feel better because they believe that the saved doses can then be available for use in future illness. A need exists to understand use in the household from economic, social, cultural, and gender perspectives. Information that is primarily technical in nature could be missing the point of why inappropriate use is taking place and consequently could be of little use in changing behavior.

At the national level:

- Governments should seek to educate the public on priority health issues, including the proper use of medicines. This general information should be supplemented by medicine-specific information, disseminated to households or patients in a culturally appropriate manner. This should not be a unilateral task for the authorities: community mobilization around issues of health and education is common. Forming alliances with community groups will be a valuable way of disseminating important information.
- As is the case with commercial promotion to professionals, pharmaceutical advertising directed to the general public should adhere to accepted standards and be responsive to local concerns.

Curricula for all workers who prescribe and dispense should be progressively upgraded

At the international level:

- International health organizations and NGOs should continue to develop and disseminate health literacy information related to appropriate use of medicines for use in developing countries.

Crosscutting issues

The Working Group on Access to Essential Medicines identified two key crosscutting issues:

- The persistent and often worsening loss of skilled health workers is a threat to all efforts to improve health systems, including access to medicines.
- Gender is a key determinant in who gets access to medicines, why, and how. The extent to which gender considerations are integrated in policies and programs affects their success.

Human resources. Needed improvements in medicines supply, distribution, prescribing, and dispensing are not going to be realized if the entire underlying issue of human resource requirements is not adequately and urgently addressed. At its simplest, many more skilled workers need to be trained, deployed, and retained in the healthcare system. However, as studies of human resource issues in developing countries show, the problems are daunting and complex. New approaches and substantial resources will be required.

At the national level:

- Healthcare workers need to be paid wages that will ensure they can work in the field of their training.
- Governments should develop programs that will increase the sheer numbers of qualified workers and also ensure improved distribution, especially to poorer and rural areas. In many indebted developing countries, social sector spending limits continue to impede the country's ability to be responsive to health staffing needs.
- Curricula for all healthcare workers involved in prescribing and dispensing should be progressively upgraded and continuing education provided.
- The community's own resource persons should be mobilized to participate in healthcare planning and delivery of large-scale treatment programs (such as vaccines programs).

At the international level:

- Important support can be provided for training professionals, using internationally tested curricula.
- Donor financing should be available to subsidize staff wages in critical need areas.
- The brain drain of all types of health professionals from developing to developed countries is becoming a real crisis in some countries, such as Ghana, South Africa, and Zimbabwe. The international community needs to highlight the problem and reach consensus about how to

**Medicines
information
should be
gender
responsive and
made available
in ways that
are useful to
women, who
are often the
primary care
providers**

reduce and manage the impact of this migration on developing countries. Possible solutions include banning active recruitment of health workers from developing countries or reimbursing training costs to the country that is losing that worker.

- International financing agencies, such as the World Bank and the GFATM, and major bilateral donors should focus on training and building capacity for a substantial number of supply chain managers and other essential health workers in developing countries.

Gender. Gender discrimination in all facets of women's and girls' lives has devastating consequences for their health and mortality. However, merely focusing on gender in isolation as a health issue will not succeed. The broader fundamental social, cultural, political, and economic interlocking roots of women's inequality in all societies must be tackled. Priority areas should include eliminating all forms of violence against women, especially sexual violence; improving economic security; removing discriminatory inheritance laws; and ensuring access to education for all girls.

At the national level:

- In health systems, policies and plans should mainstream gender considerations. This can be done only if women's participation increases and it is valued in decisionmaking.
- Governments should collect sex- and gender-disaggregated data on healthcare access and use, which, in combination with adequate gender analysis, should inform policies, plans, and budgets.
- National essential medicines lists should contain the core medicines and devices for sexual and reproductive health recommended by the United Nations Population Fund and WHO (see box 1.1).
- Access to healthcare and treatment must be significantly increased for women and girls if the Millennium Development Goals are to be on track.
- Policymakers and planners would benefit from having more research done on the gendered aspects of medicines access and use by women and girls and men and boys. Medicines information should be gender responsive and made available in ways that are useful to women, who are most often the primary care providers in families.

At the international level:

- UN agencies and the GFATM should adopt policies and approaches that ensure that gender considerations are adequately integrated into all aspects of their planning, activities, and budgets.

Conclusion

Access to medicines has always been an important concern in health development policymaking and programming. But it was WHO's call for "Health for All by 2000" in the 1977 Alma Ata Declaration that launched what has been

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an ongoing effort to examine and eliminate barriers to access, especially for the poor. Both the frameworks and the expertise exist to understand, in complexity and scale, how to address all of the major obstacles. However, to date, the world remains a long way from attaining equitable access within developing countries, let alone across regions.

Thirty years ago, medicines policy was a technical discourse mainly among UN agencies, ministries of health, and international experts. However, the growing AIDS pandemic has galvanized discussions about access to treatment. The United Nations, donors, recipient governments, and suppliers are being pressured by a growing global network of public interest NGOs and civil society groups that need medicines and are not able to get them. New bodies, such as the GFATM, have been founded to provide financing for national programs to tackle three of the major diseases of poverty. Existing organizations, both public and private, have become increasingly engaged in finding new ways to increase access to medicines. But more needs to be done, and it will require new thinking and new approaches.

In the last decade, most developing countries have undertaken measures to improve access to medicines, with varying degrees of success. Even where there have been setbacks, the experience gained strongly indicates that progress is possible. Where both the initiatives and the results have been monitored, lessons emerge that can be adapted to local conditions and applied elsewhere. A key finding is the need to involve the community in developing health system policies and programming.

Not all trends are developing satisfactorily. Finance is still seriously insufficient, and the overall health sector situation in developing countries remains extremely complex. In addition, the continued advance of AIDS in all of the poorest countries threatens to overwhelm already weakened, limited, and inequitable health systems.

According to WHO, access to essential medicines worldwide increased from roughly 2.4 billion to 4.3 billion between 1975 and 1999 (WHO 2004a). A closer look at the numbers, however, shows that the overall number of those without access remains relatively unchanged and that these people are primarily the poorest and most marginalized. Consequently, it remains to be seen if current knowledge about access and current approaches to increasing access adequately reflect a truly pro-poor framework from the global level (especially international financial institutions, UN agencies, and development strategies of major donor countries) to the local level (including real commitment by national governments to tackle poverty and take steps to improve national economic development).