WHO Policy Perspectives on Medicines

8

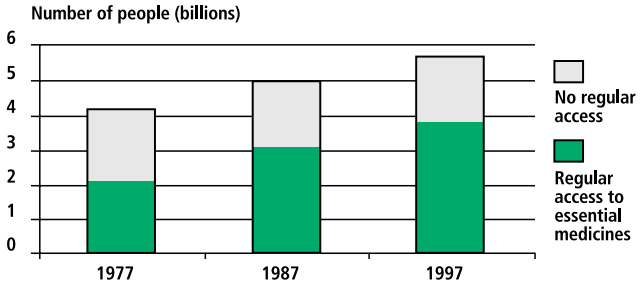
# Equitable access to essential medicines: a framework for collective action

March 2004
World Health Organization
Geneva

Essential medicines save lives and improve health when they are available, affordable, of assured quality and properly used. Still, lack of access to essential medicines remains one of the most serious global public health problems. Although considerable progress in terms of access to essential medicines has been made in the last twenty-five years since the introduction of the essential medicines concept (Figure 1) not all people have benefited equally from improvements in the provision of health care services, nor from low cost, effective treatments with essential medicines. Through a combination of public and private health systems, nearly two-thirds of the world's population are estimated to have access to full and effective treatments with the medicines they need, leaving one-thirds without regular access. It is estimated that by improving access to existing essential medicines and vaccines, about 10 million lives per year could be saved.

Essential medicines are only one element in the continuum of health care provision but they are a vital element. The major access challenges which can be obstacles for health improvement are:

**Figure 1 The total number of people with access to essential medicines has increased from around 2.1 billion in 1977 to an estimated 3.8 billion in 1997**




- **Inequitable access** - about 30% of the world's population lacks regular access to essential medicines; in the poorest parts of Africa and Asia this figure rises to over 50%.
- **Health reforms** - in many low- and middle-income countries, health sector reforms have led to insufficient public funding for health.

## Box 1 Definition of essential medicines

**"Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford. The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains a national responsibility."**

- **Medicine financing** - in many high-income countries, over 70% of pharmaceuticals are publicly funded whereas in low- and middle-income countries public medicine expenditure does not cover the basic medicine needs of the majority of the population. In these countries 50% to 90% of medicines are paid for by patients themselves.
- **Treatment costs** - high costs of treatments with new essential medicines for tuberculosis, HIV/AIDS, bacterial infections and malaria will be unaffordable for many low- and middle-income countries.
- **Globalization** - global trade agreements can threaten access to newer essential medicines in low- and middle-income countries.

### Box 2 Key points for policy makers: Access to medicines is supported by the principles of the essential medicines concept

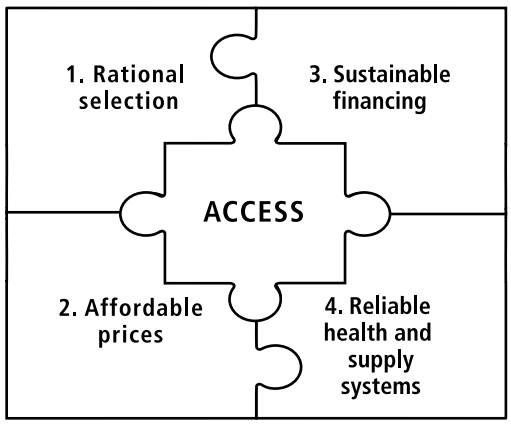
- Common health problems for the majority of the population can be treated with a small number of carefully selected medicines;
- Individual health professionals routinely use fewer than 50 different medicines; the WHO Model List of Essential Medicines contains about 300 active substances;
- Training and clinical experience should focus on the proper use of these few medicines;
- Procurement, distribution and other supply activities can be carried out most efficiently for a limited number of pharmaceutical products;
- Patients can be better informed about the effective use of medicines by health professionals.

Access to health care and therefore to essential medicines is part of the fulfilment of the fundamental right to health. All countries have to work towards the fulfilment of equitable access to health services and commodities, including essential medicines necessary for the prevention and treatment of prevalent diseases. Appropriate policies and action plans need to be put in place to achieve this aim.

## The Access Framework

Improving access to essential medicines is perhaps the most complex challenge for all actors in the public, private and NGO sectors involved in the field of medicines supply. They must all combine their efforts and expertise, and work jointly towards solutions. Many factors define the level of access, such as financing, prices, distribution systems, appropriate dispensing and use of essential medicines. WHO has formulated a four-part framework to guide and coordinate collective action on access to essential medicines (Figure 2). This framework has also been adopted by WHO's key partners.

### Figure 2 Improving access to essential medicines – a framework for collective action in line with Millennium Development Goals, Target 17




### Box 3 Key actions: check list for policy makers

**Rational selection and use of essential medicines**

- Develop national treatment guidelines based on the best available evidence concerning efficacy, safety, quality, and cost-effectiveness;
- Develop a national list of essential medicines based on national treatment guidelines;
- Use a national list of essential medicines for procurement, reimbursement, training, donations and supervision.

**Affordable prices**

- Use available and impartial price information;
- Allow price competition in the local market;
- Promote bulk procurement;
- Implement generics policies;
- Negotiate equitable pricing for newer essential medicines for priority diseases;
- Undertake price negotiation for newly registered essential medicines;
- Eliminate duties, tariffs and taxes on essential medicines;
- Reduce mark-ups through more efficient distribution and dispensing systems;
- Encourage local production of essential medicines of assured quality when appropriate and feasible;
- Include WTO/TRIPS compatible safeguards into national legislation and apply.

**Sustainable financing**

- Increase public funding for health, including for essential medicines;
- Reduce out-of-pocket spending, especially by the poor;
- Expand health insurance through national, local, and employer schemes;
- Target external funding - grants, loans, donations – at specific diseases with high public health impact;
- Explore other financing mechanisms, such as debt-relief and solidarity funds.

**Reliable supply systems**

- Integrate medicines in health sector development;
- Create efficient public-private-NGO mix approaches in supply delivery;
- Assure quality of medicines through regulatory control;
- Explore various purchasing schemes: procurement co-operatives;
- Include traditional medicines in the health care provision.

## 1 Rational selection and use of essential medicines

No health system in the world offers unlimited access to all medicines. Rational selection of essential medicines is one of the core principles of a national drug policy. It focuses therapeutic decisions, professional training, public information, financing, supply and quality assurance efforts on those medicines which will have the greatest impact in a given health care setting. It is a global concept which can be applied in any country, in both public and private sectors and at different levels of the health care system. Rational selection and use can be pursued through various tools.

**National treatment guidelines** are defined by WHO as systematically developed evidence-based statements which assist providers, patients and other stakeholders to make informed decisions about appropriate health interventions. Guidelines have mostly been used to advise practitioners on which interventions to use in their interactions with patients.

**National lists of essential medicines** should be developed for different levels of care and on the basis of standard treatment guidelines for common diseases and conditions that should be treated at each level. Careful selection of essential medicines is the first step in ensuring access.

**Rational use of essential medicines** is one of the core activities of health workers and patients. Trained and motivated health staff, and the necessary diagnostic equipment, are needed to ensure safe and effective treatments, minimizing the risks and waste linked to irrational prescribing and use of medicines.

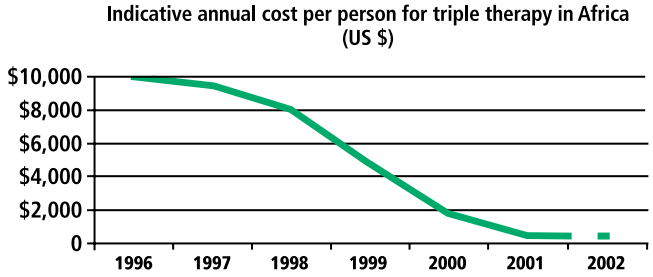
## 2 Affordable prices

With the potential cost of providing a full range of treatments for prevailing common diseases, medicine prices and financing are inescapable factors in access to essential medicines. Affordable prices can be pursued through the following mechanisms.

**Price information** is fundamental in obtaining the best price. Several international and regional price information services are made available for Member States. Price information helps in price negotiations, in locating new supply sources, and in assessing the efficiency of local procurement.

**Price competition** through tendering of generic products and therapeutic competition are powerful price-reduction tools, as evidenced by experiences from large producing countries such as Brazil and India. Through generic competition, price reductions of 75% to 95% were achieved over the initial brand prices (Figure 3 ). In addition, price reductions were also obtained through therapeutic competition - between several branded products belonging to the same therapeutic class.

### Figure 3 Advocacy, corporate responsiveness and competition have reduced antiretroviral prices by 95% in 3 years




**Bulk procurement** encompasses that medicine orders are pooled together, that the focus is on a list of priority medicines and that duplication within therapeutic categories is avoided as much as possible. This will result in larger procurement volumes and will increase purchasing power. Bulk procurement can be through cooperation of facilities in a country, but positive experience has also been reported from arrangements between states.

**Generics policies** are effective instruments when a patent expires. In the United States of America the average wholesale price falls to 60% of the price of the branded medicine when one generic competitor enters the market, and to 29% with 10 competitors. To introduce and expand the use of generic medicine products, it is important that 1) supportive regulations exist; 2) reliable quality assurance is in place; 3) professional and public acceptance is obtained; and 4) financial incentives are in place.

**Equitable pricing** is especially important for newer essential medicines that are still protected by patents or other instruments that provide market exclusivity. Equitable pricing is explained as the adaptation of prices which are charged by the manufacturer or seller to countries with different purchasing power. Widespread equitable pricing is economically feasible provided that low-priced medicines do not leak back to high-income countries.

**Reduction or elimination of duties and taxes** for both generic and patented essential medicines contribute to price reduction. In developing countries, the final price of a medicine may be two to five times the

## Box 4 WHO medicines price information services

WHO works with several partners to make price information easily accessible to governments, nongovernmental organizations, donor agencies and any institution involved in medicines procurement.

*International Drug Price Indicator Guide:* Details 350 active ingredients in 750 dosage forms from 17 sources. Indicative prices of generic products on the international market and selected tender prices. Produced by Management Sciences for Health and WHO.

*Sources and Prices of Selected Medicines and Diagnostics for People Living With HIV/AIDS:* Details 59 active ingredients in 100 dosage forms. Issued by UNICEF, UNAIDS, Médecins Sans Frontières and WHO. Covers antiretroviral (ARV) medicines, HIV/AIDS test kits for diagnosis and ongoing monitoring, and medicines for treating opportunistic infections, for pain relief, for use in palliative care, for the treatment of HIV/AIDS-related cancers, and for managing drug dependence.

*Pharmaceutical Starting Materials/Essential Drugs Report:* Details over 273 active ingredients. Issued by WHO and the International Trade Centre, a joint WTO–UNCTAD centre.

*AFRO Essential Drugs Price Indicator:* Nearly 300 essential medicines and dosage forms listed – details provided by Member States and international low-cost essential drugs suppliers. Published by the Regional Office for Africa and the WHO Collaborating Centre for the Quality Assurance of Medicines, University of Potchefstroom, South Africa.

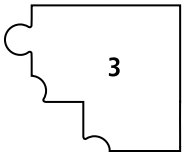
*AMRO: AIDS and STI - Average Prices of a One Year Treatment with Antiretrovirals in Countries of Latin America and the Caribbean:* Survey by Pan American Health Organization of ARV therapy in Latin American countries.

**http://www.who.int/medicines/organization/par/ipc/drugpriceinfo.shtml**

producer or importer price. This reflects the effects of multiple middlemen, taxes of over 20% in some countries, pharmaceutical import duties of up to 65%, high distribution costs, and pharmacy and drug seller charges.

**Local production of assured quality** when economically feasible and where it follows good manufacturing practices (GMP) can result in lower medicine prices. This can be facilitated by transfer of technology, GMP inspections, and other arrangements. Generic companies in India, Brazil and Thailand have offered their help to low- and middle-income countries to produce antiretrovirals locally through technology transfer through South-South collaboration.

**The WTO/TRIPS Agreement defines** minimum requirements for intellectual property rights that are applicable to all WTO members. Studies predict significantly higher medicine prices with full implementation of TRIPS requirements in low- and middle-income countries. National patent and related legislation should include standards of patentability that take health into account, promote generic competition, incorporate provisions for TRIPS compatible safeguards such as compulsory licensing and parallel import.




## Sustainable financing

Sustainable financing for essential medicines must be viewed in the context of overall health care financing. Most low- and middle-income countries rely on a diverse set of health and drug financing mechanisms which can contribute in the payment of medicines. Nevertheless there are still opportunities in many low- and middle-income countries for both *better* and *more* public spending on health and essential medicines.

## Box 5

"The inequities are striking. In developed countries, a course of antibiotics to cure pneumonia can be bought for the equivalent of 2 or 3 hours' wages. One-year's treatment for HIV infection consumes the equivalent of four to six months' salary. And the majority of drug costs are reimbursed. In developing countries, a full course of antibiotics to cure a common pneumonia may cost one months' wages. In many countries one-year's HIV treatment - if it were purchased - would consume 30 years' income. And the majority of households must buy their medicines with money from their own pockets."

*WHO Press Release WHA/13, 22 May 1999*

**Increased public funding** for health and medicines is important for high public health impact and strong potential for equity and solidarity, and for support to the disadvantaged. It does not mean that low- and middle-income countries should reallocate funds from prevention or other health priorities - but that additional new public funding should be brought to the health sector. One example is the Global Fund to fight AIDS, Tuberculosis and Malaria that offers an opportunity of additional new public funding to those countries where public funding is increasing very slowly or not at all.

**Out-of-pocket spending** is a result of failure by the government to allocate sufficient financial resources for medicine supplies essential for treating prevailing diseases for the majority of the population. Patients therefore have to buy all medicines they need from the private sector.

**Cost sharing with patients** should be seen only as a transitional measure towards long-term aims, such as universal health insurance. User charges or

co-payments for medicines in public health services do not always lead to increased supply of medicines and can result in decreased utilization of public health services. In addition they can further impoverish already disadvantaged populations. User charges should complement rather than replace government allocations for curative health services and essential medicines provision.

While virtually 100% of the population has **health insurance** of some form in most high-income countries, median coverage is 35% in Latin America, 10% in Asia, and less than 8% in Africa. Additionally the inclusion of medicine reimbursement in health insurance varies greatly. Coverage of newer and high-cost essential medicines through well developed social security schemes is necessary. Advantages of pre-payment are that the healthy part of the population subsidizes the sick and, through income-related premiums, the wealthy citizens can subsidize the poor. It reflects the solidarity principle that health care should be provided according to need and financed according to the ability to pay.

**Donor assistance and development loans** such as bilateral aid and development loans/grants from development banks continue to provide for many countries sources of health sector financing, which can include funding for essential medicines, such as HIV/AIDS-related therapies and combination treatments for medicine resistant malaria. Yet it is debatable whether development loans should be used for consumables, such as medicines.

**Donor funding for and donations of medicines** can have an impact on health progress in low-and middle-income countries in the short-term. In the medium-term these donations should be targeted at specific diseases and planned as additional supplies integrated into the national medicine supply system. But in the long-term, self-sufficiency is the only viable means to tackle increasing disease burdens.

Other financing mechanisms which are being pursued include targeted use of debt relief funds, tax incentives in high-income countries, in-kind funding in the form of medicine donations, and solidarity funds.

## 4 Reliable health and supply systems

Rapid assessment of health care and supply systems is essential for identifying the major weaknesses and initiating corrective actions. Among the many elements of an effective health care system, those most important in supporting access to essential medicines are as follows.

**Health sector development** is a vital government obligation. In a national health system, proper use of well-known and newer essential medicines for priority health problems depends on a certain minimal level of medical and pharmaceutical services. This includes inexpensive diagnostic tests to confirm diagnosis, and well-informed trained clinicians, pharmacists, nurses and other health staff to help patients, especially those with chronic illnesses, to adhere to their treatments. An overall capacity strengthening of the health and supply systems is a prerequisite to respond adequately to the increased medical and pharmaceutical needs of populations.

**Public-private-NGO mix** approaches are being pursued to ensure timely availability of medicine supplies of assured quality in the health care system. These vary considerably with respect to the role of the government, the role of the private sector (non-profit and for-profit), and the incentives for efficiency. Many countries struggle with the unfortunate combination of an inefficient public medicines supply system meant for the entire country and various private supply systems serving mostly urban areas. Increasingly, an effective medicines supply system is seen to depend on an appropriate mix of public, private, and NGO procurement, storage and distribution services.

### Box 6 Four types of medicines supply strategies in addition to central medical stores

- **Central medical stores**
  Centralized, fully public management, warehousing and delivery system.
- **(Semi-) autonomous supply agency**
  Centralized, (semi-) private management and warehousing system.
- **Direct delivery system**
  Centralized decision-making but decentralized, private direct-delivery system.
- **Prime distributor**
  Centralized decision-making but decentralized, private warehousing and delivery system.
- **Fully private supply**
  Decentralized decision-making, fully private wholesalers and pharmacies system.

**Regulatory control** is a shared responsibility of the national regulatory authorities, pharmaceutical producers, distributors, and other actors active in medicines management. Effective medicines regulation is a public service necessary to ensure the quality of pharmaceutical products, that producers fully implement good manufacturing practices to combat counterfeit and substandard medicines, and to contain drug resistance resulting from uncontrolled supply and use of antibiotics and other essential medicines in both public and private sectors.

**Procurement co-operatives** increase efficiency. Regional and sub-regional procurement schemes can become a credible option for ensuring reliable medicine supplies. The Gulf Cooperation Council (GCC) and the Organization of Eastern Caribbean States Pharmaceutical Procurement Service (OECS/PPS) sucessfully organize pooled procurement for six and eight countries respectively.

**Traditional and complementary medicines** are increasingly used in many parts of the world and play a major role in the health care system. In many low- and middle-income countries, greater accessibility to and confidence in traditional medicine practitioners, especially in rural and remote areas, may explain why most patients consult them. Traditional practitioners can therefore play a considerable role in the health care system for some aspects of health care.

## Key documents

*World Health Organization. *Traditional Medicine - Growing Needs and Potential*. Geneva: WHO, 2002 (WHO Policy Perspectives on Medicines n°2) (WHO/EDM/2002.4).

* World Health Organization. *Globalization, TRIPS and Access to Pharmaceuticals*. Geneva: WHO, 2001 (WHO Policy Perspectives on Medicines n°3) (WHO/EDM/2001.2).

* World Health Organization. *The Selection of Essential Medicines*. Geneva: WHO, 2002 (WHO Policy Perspectives on Medicines n°4) (WHO/EDM/2002.2).

* World Health Organization. *Promoting Rational Use of Medicines: Core Components*. Geneva: WHO, 2002 (WHO Policy Perspectives on Medicines n°5) (WHO/EDM/2002.3).

* World Health Organization. *How to Develop and Implement a National Drug Policy*. Geneva: WHO, 2003 (WHO Policy Perspective on Medicines n°6) (WHO/EDM/2002.5).

* World Health Organization. *Effective Medicines Regulation: ensuring safety, efficacy and quality*, Geneva: WHO, 2003 (WHO Policy Perspective on Medicines n°7) (WHO/EDM/2003.2).

Management Sciences for Health/World Health Organization. *Managing Drug Supply*. 2nd edition revised and expanded. West Hartford, CT: Kumarian Press, 1997.

*World Health Organization. *Public-Private Roles in the Pharmaceutical Sector. Implications for Equitable Access and Rational Drug Use*. Health Economics and Drugs, DAP Series No. 5. Geneva: WHO, 1997 (WHO/DAP/97.12).

* World Health Organization. *Health Reform and Drug Financing: Selected Topics*. Health Economics and Drugs. DAP Series No. 6. Geneva: WHO, 1998 (WHO/DAP/98.3).

*World Health Organization. Web site: *"Fact Sheet on: Drug Price information Services. What is WHO doing to improve drug prices?"* http://www.who.int/medicines/organization/par/ipc/drugpriceinfo.shtml

World Health Organization. *World Pharmaceutical Situation*. Geneva: WHO, 2003 (forthcoming).

*The documents marked with * are also available on http:www.who.int/medicines/*

## Contacts at WHO Regional Offices:

**Regional Office for Africa:**
Dr Jean-Marie Trapsida
Coordinator, Essential Drugs and Medicines Policy
Tel: +263 4 742829 E-mail: trapsidaj@afro.who.int

**Regional Office for the Americas:**
Dr Rosario D'Alessio
Regional Adviser for Pharmaceuticals
Tel: +1 202 974 3282 E-mail: dalessir@paho.org

**Regional Office for the Eastern Mediterranean:**
Mr Mohamed Bin Shahna
Acting Regional Adviser, Pharmaceuticals
Tel: +20 2 276 5303 E-mail: binshahnam@emro.who.int

**Regional Office for Europe:**
Mr Kees de Joncheere
Pharmaceuticals
Tel: +45 3 917 14 32 E-mail: cjo@who.dk

**Regional Office for South-East Asia:**
Dr Krisantha Weerasuriya
Regional Adviser, Essential Drugs and Medicines Policy
Tel: +91 11 331 7804 E-mail: weerasuriyak@whosea.org

**Regional Office for the Western Pacific:**
Dr Budiono Santoso
Regional Adviser
Tel: +63 2 528 9848 E-mail: santosob@wpro.who.int

## Contacts at WHO Headquarters:

**Essential Drugs and Medicines Policy**
**Health Technology and Pharmaceuticals Cluster**
**WHO Headquarters, Geneva, Switzerland:**

Director a.i.
Essential Drugs and Medicines Policy Department
Tel: +41 22 791 4443 E-mail: edmdirector@who.int

Dr Hans Hogerzeil
Team Coordinator, Policy, Access and Rational Use
Tel: +41 22 791 3528 E-mail: hogerzeilh@who.int

Dr Lembit Rägo
Team Coordinator, Quality and Safety: Medicines
Tel: +41 22 791 4420 E-mail: ragol@who.int

Dr Germán Velásquez
Team Coordinator, Drug Action Programme
Tel: +41 22 791 3509 E-mail: velasquezg@who.int

Dr Xiaorui Zhang
Team Coordinator, Traditional Medicine
Tel: +41 22 791 3639 E-mail: zhangx@who.int