
Notes

Executive summary

1. In this report, the terms *medicines* and *pharmaceuticals* will be regarded as equivalent, referring both to therapeutic agents and to vaccines. The term *drugs* is ambiguous since it is often applied to substances causing addiction and prone to misuse, many with little or no significance in medical treatment; it will be generally avoided in the present report except in direct quotation. The Working Group on Access to Essential Medicines has noted that certain other products are closely analogous to medicines and deserve similar approaches, for example, the intrauterine contraceptive device.

2. The working group's framework is in part based on WHO's four-part framework to describe the main elements that affect access to essential medicines:

- Rational selection and use.
- Affordable prices.
- Sustainable financing.
- Reliable health and supply systems.

It is the basis for the development and implementation of WHO's Department of Essential Drugs and Medicines Policy (EDM) work to increase access to medicines. This framework has been adopted by WHO's main partners (WHO 2004a). The working group, in carrying out its analysis, dealt with these elements in detail.

3. Equity pricing is a concept launched by the WHO in the late 1990s. It is based on the ethical notion that developing countries should not be asked to pay for medicine development costs, marketing, and shareholder returns. This is a much wider concept than differential pricing and encompasses all the active policy and administrative measures a government or procurement organization can take to achieve differential pricing related to purchasing power. These measures include price information and transparency, pooled procurement, reduction of taxes and margins, price negotiations, voluntary licensing agreements, and, as an ultimate measure, compulsory licensing. Equity pricing is the political choice and action, differential pricing is the result. Equity pricing has been successfully practiced for more than 30 years for children's vaccines and reproductive health commodities.

Chapter 1

1. In this report, the terms *medicines* and *pharmaceuticals* will be regarded as equivalent, referring both to therapeutic agents and to vaccines. The term *drugs* is ambiguous since it is often applied to substances causing addiction and prone to misuse, many with little or no significance in medical treatment; it will be generally avoided in the present report except in direct quotation. The Working Group on Access to Essential Medicines has noted that certain other products are closely analogous to medicines and deserve similar approaches, for example, the intrauterine contraceptive device.

2. The working group also relied on the Essential Medicines Concept, which is defined as follows:

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 (WHO 2004a).

3. See also the Global Alliance for TB Drug Development for additional information on MDR-TB, [www.tballiance.org/2_1_2_MDR_TB.asp].

4. Writing in January 2001, Attaran and Sachs concluded that, in order to contain AIDS, aid would need to be increased within the succeeding three years to a minimum of \$7.5 billion or more; they pointed out that this sum could easily be afforded by the OECD donor countries.

5. For an authoritative definition of a generic medicine, see Laurence and Carpenter (1998). Essentially the term is applied to a medicine that is not (or is no longer) protected by patent and is being supplied by a manufacturer other than the originator, generally under an international nonproprietary name. Usage differs somewhat: some definitions limit use of the term to those products that have been certified by national regulatory agencies as being fully bioequivalent to the original patented product. Others apply the term to medicines that are shown to be essentially equivalent, but for which testing for bioequivalence has not been done.

6. It is useful to review the definitions and difference between the terms *gender* and *sex*. They are not synonyms, and using them interchangeably obscures the problem and limits the scope of response. The term *gender* is used to describe those characteristics of women and men that are socially constructed; the term *sex* refers to those that are biologically determined. People are born female or male but learn to be girls and boys who grow into women and men. This learned behavior contributes to defining gender identity and will largely determine gender roles in any specific time and cultural setting. This in turn will be evident across the range of human experience including, for example, how medicines are accessed and used differently by men and women.

7. The program to eradicate smallpox, primarily based on vaccination, cost more than \$300 million over the whole of its 12-year life but saved hundreds of millions of dollars per year in directly measurable costs.

8. Brazil's ambitious program to counter AIDS has had striking economic results. The investments made have paid off in terms of savings, such as in the costs of hospitalization and in the purchase of patented medicines at world prices. The Ministry of Health has

estimated that the universal free provision of AIDS medicines prevented 234,000 AIDS-related hospital admissions during the period 1997–2000, saving \$677 million for the country's health system.

9. It has been estimated that about a third of the rural poverty in China is caused by catastrophic medical spending; the majority of medical expenses in China relate to medicines (Evidence provided by Dr. Yuanli Liu to the working group during 2003 meeting in Geneva).

10. A 1992 study showed that per capita expenditure on medicines at that time ranged from \$412 in Japan to \$2 or less in Bangladesh and parts of Sub-Saharan Africa. At the middle of the range, per capita expenditure was \$97 in the United Kingdom and \$89 in Norway (Ballance and others 1992). At the end of the century these discrepancies had still not been reduced (Bannenberg 2000; Scrip 2000; WHO 2000b, 2000d).

11. A long-term research program maintained in India by the Ciba-Geigy company was abandoned some 20 years ago. A more recent effort is covered by an agreement between Merck Inc. and the Costa Rican Biodiversity Institute (InBIO) in 1994.

12. The current definition reads: "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" (WHO 2004a).

13. More information is available on the prequalification website (<http://mednet3.who.int/prequal/>).

14. The "3 by 5" goal represents a commitment by WHO. It is not a separate program or fund, but an objective that it hopes to attain through a series of mutually complementary measures (WHO 2003a). It must be borne in mind that the total number of individuals infected is currently estimated at 42 million, though not all require intensive medicinal treatment.

15. In a suitably competitive market, generic medicines are as a rule much less expensive than their originator counterparts. Researchers from the Hudson Institute have countered that generics AIDS medicines are more expensive (Adelman, Norris, and Weicher 2004). It would appear that the authors misinterpreted MSF data; at the least, more research is needed. Clearly prices are very dynamic, so it entirely possible that a certain group of medicines, in a certain context, will be priced differently than the general rule.

16. See also www.haiweb.org/medicinesprices for pricing data being generated by country studies using the WHO and HAI pricing survey methodology. These findings also tend to support the general view that generics are less expensive.

17. Manufacturing in these countries is often severely hampered by the fact that virtually all starting materials and equipment have to be imported and that their turnover is small; as a result they can have difficulty in competing in terms of cost and quality with generics manufacturers abroad. The future significance of national manufacturing in low-income countries will need to be carefully considered. Arguments for maintaining at least some of these facilities include the following advantages:

- The ability to produce simple bulk products (such as intravenous fluids) where international transport costs can be prohibitive.
- The ability to produce traditional medicines.
- The value of a production plant as an educational and research center, such as to facilitate pharmacy training.

Chapter 2

1. The working group's framework is in part based on WHO's four-part framework to describe the main elements that affect access to essential medicines:

1. Rational selection and use.
2. Affordable prices.
3. Sustainable financing.
4. Reliable health and supply systems.

It is the basis for the development and implementation of WHO's Department of Essential Drugs and Medicines Policy work to increase access to medicines. This framework has been adopted by WHO's main partners. The working group, in carrying out its analysis, dealt with these elements in detail.

2. The mainstays of malaria treatment have been chloroquine and sulfadoxine-pyrimethamine, both of which are available at negligible cost. The former is no longer effective against *Plasmodium falciparum* in most tropical areas, however, and resistance to the latter is now widespread. There are certain alternative drugs, but they are currently too expensive for entire populations (see White 1999).

3. Sleeping sickness, after markedly decreased incidence in the 1960s, is becoming increasingly more prevalent in many Sub-Saharan African countries. The disease causes at least 40,000 deaths annually. Armed conflicts in many of the endemic areas, as well as the focused international attention on other major infectious diseases has contributed to this resurgence. An overview compiled by MSF in 1999 found that the supply of all four applicable medicines had either ceased (eflorinthine Hcl) or become insecure (suramin Na, melarsoprol, and pentamidine isethionate) because of lack of commercial interest in production (Pécoul and others 1999).

4. The fact that these wealthy nations are themselves increasingly challenging the prices of medicines and seeking lower cost solutions for their domestic markets must be noted, but falls outside the scope of the present report.

5. This is currently the situation in Afghanistan, where the Avicenna Institute was re-equipped for large-scale medicine production in order to ensure national self-sufficiency. Production has largely ceased and the future of the institute as a manufacturing center is under review (Graham Dukes, personal communication, 2003). A former Western pharmaceutical factory (built by the Hoechst company of Germany) is still mothballed, but the Business Humanitarian Forum, a partnership founded in collaboration with research-based companies, and partnered with the European Generics Association, hopes to reestablish production in the country.

6. In Viet Nam alone, it is estimated that 3 million people fall below the poverty line each year because of health-related expenditure (see Wagstaff and van Doorslaer 2003).

7. It is important to emphasize that the discussions of intellectual property rights for medicines in this report are not an attack on the entire patent system. The challenge is to ensure that patents are not a barrier in increasing access to affordable essential medicines for the poor in developing countries. Prices afforded by patent protection should not be a barrier to affordability and availability in these countries. To this end, certain TRIPS flexibilities exist, and other alternatives—such as how to promote voluntary licensing and technology transfer—need to be discussed constructively.

8. An example of the governmental use clause in practice is provided by Cameroon, a developing country member of the African Intellectual Property Organization (OAPI). The organization grants regional patents that are valid in all OAPI member states, and a significant number of antiretrovirals are currently protected by OAPI patents. Some of the patented agents are, however, available at lower prices from generic sources. In order to make the best possible use of its limited resources, the Ministry of Health of Cameroon

authorized the public procurement agency in 2000 to buy antiretrovirals from generic sources.

9. The governments of Kenya and Brazil, in announcing programs to supply generic medicines for the treatment of AIDS, have referred to the epidemic as a national emergency in their countries.

10. There is a clear market failure for medicines in developing countries. The hope that [intellectual property] protection would provide a financial incentive to drug firms to invest in drugs for tropical diseases has not materialized; during the last decade, research and development for developing country diseases has declined rather than increased. In 1975–99 only 1 percent of 1,191 new medicines approved for marketing were specifically indicated for a tropical disease. Poor countries do not constitute a market capable of inducing patent-driven investment (Lehman 2002). The global market for pharmaceuticals was estimated at \$406 billion in 2002, with the US, EU, and Japan accounting for 80 percent of this market and the rest of the world combined for only 20 percent (IMS Health 2001).

11. As part of a three-pronged approach to AIDS, the Brazilian government decided in 1996 to make the necessary medicines available free of charge to those who needed them. (Brazil, Ministry of Health 2001: Law 9,313 of 13 November 1996). Fourteen anti-retroviral drugs are currently available in this way. This has been possible because of the other aspects of the national medicines policy involving price negotiations with the suppliers, the threat of compulsory licensing, and training in medicines use. It is notable that Brazil has used the threat of compulsory license successfully in price negotiations but has never actually needed to issue a compulsory license. The Brazilian AIDS program is heavily subsidized by the government in terms of finance and staffing, and this model would be difficult to transfer to poorer countries with higher AIDS burdens without additional and long-term donor support.

12. The two leading guides on pricing are the MSH–WHO International Drug Price Indicator Guide and the UNICEF–MSF–WHO list of sources and prices of selected medicines and diagnostics for HIV/AIDS.

13. Reductions of 35 percent or more are often cited, but much greater reductions are sometimes achieved. In mid-2003, the pool representing the countries of the Andean region agreed with producers of antiretroviral medicines on drastically reduced prices; the price for one three-component product, which had been as high as \$5,000 per person per year in one participating country, fell to \$365 for all 10 countries.

14. In Argentina and Brazil, for example, the agencies for a long period accepted so-called *similares*—that is, secondary versions of medicines for which equivalence with the original product had been demonstrated only in vitro (such as in disintegration testing of tablets).

15. A broadly constituted meeting convened by MSF and the Drugs for Neglected Diseases Initiative in Geneva in July 2003 concluded, “There are substantial fears that some ICH guidelines might have a negative impact on access to essential medicines in developing countries. Specifically, new stringent requirements for raw materials may raise drug prices without offering any discernible public health benefit in exchange. Some medicines that are badly needed in developing countries may not be granted regulatory approval, since risk/benefit calculations are necessarily made differently in non-ICH and ICH countries. In addition, the existing governance structure excludes many of the stakeholders affected by the process, including developing countries, consumers, and health professionals. . . . the motivation behind extending the guidelines beyond ICH countries is not clear. Higher standards for the quality of raw materials and drugs may allow ICH countries to protect themselves from lower-priced (generic) imports from other markets that do not hold to

ICH quality standards, while at the same time ensuring continued access to high quality raw materials from non-ICH countries for their domestic manufacturers” (MSF 2001).

16. There are a small number of medicines for which the toxic dose is only slightly higher than the dose normally used in treatment (such as digitalis, which is used for heart disorders). For these substances and their pharmaceutical forms, exceptionally high standards have to be maintained.

17. For example, many developing countries import generic products from India. At their best, Indian medicines have been found to be of a standard at least equivalent to that of the equivalent originator medicines. A persistent problem is the complex and inadequate system of official inspection of manufacturing plants, partly as a consequence of the division of responsibility between the federal and state authorities. As a result, some manufacturing sources remain well below acceptable standards of quality assurance (Dukes 2001). Many developing countries therefore find it necessary to apply strict batch quality control to products of Indian origin, or prefer to purchase such medicines through a nonprofit intermediary capable of exercising its own quality control procedures.

18. The problem of substandard antimalarials has been particularly well documented in western Kenya.

19. During an epidemic of meningitis involving 41,000 cases in Niger in 1995, the country was promised a donation of 88,000 vaccine doses from Nigeria, with Pasteur Mérieux and SmithKline Beecham as manufacturers. In fact the vaccines were found to have been replaced on the way with spurious copies containing no active ingredient but with labeling meticulously copied from the original (Pinel and others 1997).

20. See examples from the Philippines, Pakistan, and Nigeria cited by Velásquez, Madrid, and Quick (1998).

21. The handbook of guidelines is available on multiple sites, including www.med.rug.nl/pharma/who-cc/ggp/homepage.htm.

22. http://dcc2.bumc.bu.edu/prdu/HTML_DOCS_TOC.htm.

23. http://dcc2.bumc.bu.edu/prdu/Session_Guides/effective_public_education.htm.

Chapter 3

1. A notable example cited to the working group is the long-term success of the national Essential Drugs Programme in Bhutan, dating from 1987. Whereas medicines access was earlier very limited, it is estimated that 90 percent of the population now enjoys access to high-quality essential medicines. In 1995, retail prices were on average 6 percent lower than in 1985, and the prices paid by the program in the course of procurement are currently some 50 percent below world market prices. Monitoring is intensive, with facilities reporting twice yearly on their stocks and use of medicines; only 0.75 percent of the overall budget was wasted as a result of medicines expiry (Stapleton 2000).

2. The case of Chad illustrates both successes and failures. Under a national medicines policy adopted in 1998, the proportion of the population with access to essential medicines rose from 46 percent in 1999 to 60 percent in 2001, and annual public expenditure on medicines was trebled over a six-year period, though it still amounted to only \$0.12 per capita. The average percentage of essential medicines available in health facilities fell from 80 to 70 percent over the same period, while the average duration of stock-outs increased from 41 to 59 days. Standard treatment guidelines were updated, but no improvements were recorded in the use of antibiotics or in the (excessive) use of injections (WHO 2001).

3. The rapid flow of donor funds for health and medicines into Uganda after the fall of the Amin regime and the restoration of a democratic regime with which donors could

work constructively provides a classic example. The results can now be assessed after 15 years of experience (DMFA 1995).

4. In Timor-Leste shortly after independence, the number of physicians available to serve a population of 800,000 was negligible. Practical nurses with elementary training were handling both diagnosis and treatment. A specially adapted handbook was therefore devised to assist them in performing this task as well as possible without the need for frequent referral (Dukes, field report 2001).

In many developing countries, poorly paid health workers earn money by levying charges on the medicines they issue to patients. Rather than attempting to prohibit this practice, it sometimes proves better to regularize it so that modest fixed charges (insufficient in themselves to constitute a barrier to access) can be made in order to provide the health worker with a living wage.

5. Good examples of successful handbooks of this type include those from Ghana, Uganda, and Zimbabwe.

6. In one African state in 2003, a delegation from a Western aid foundation proposed that it provide a massive sum of money from Western countries to be used for the purchase of AIDS medicines. Consultation led to the conclusion that the population would be better served if the proposed supply were somewhat reduced and a fair proportion of the total sum were used instead to provide training in the management, diagnosis, and treatment of the disorder. Medicines would otherwise not be used to the best advantage (Dukes, personal communication 2003).

Chapter 4

1. Equity pricing is a concept launched by WHO in the late 1990s. It is based on the ethical notion that developing countries should not be asked to pay for medicine development cost, marketing, and shareholder returns. This is a much wider concept than differential pricing and encompasses all the active policy and administrative measures a government or procurement organization can take to achieve differential pricing related to purchasing power. These measures include price information and transparency, pooled procurement, reduction of taxes and margins, price negotiations, voluntary licensing agreements, and, as an ultimate measure, compulsory licensing. Equity pricing is the political choice and action; differential pricing is the result. It has been successfully practiced for more than 30 years for children's vaccines and reproductive health commodities.

Appendix 1

1. Diseases associated with widespread changes in eating and exercise patterns, such as those associated with migration from rural to urban settings.

2. www.health.go.ug and www.cdc.gov.

3. www.health.go.ug/health_units.htm.

4. Every year, in order to estimate the level of access to essential medicines, the WHO Action Programme on Essential Drugs interviews relevant experts in each country about the pharmaceutical situation. The interviewees can choose from four levels of access to essential medicines by the population: less than 50 percent, 50–80 percent, 80–95 percent, and above 95 percent. They indicate which category is most appropriate for their country. Essential medicines are those that satisfy the healthcare needs of the majority of the population.

5. www.kaisernetnetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=24203.

6. www.uppap.or.ug/.

Appendix 2

1. World Health Organization. 2004. "Access to HIV/AIDS Drugs and Diagnostics of Acceptable Quality: Procurement Quality and Sourcing Project." Geneva. Available online at <http://mednet3.who.int/prequal/>.
2. "HHS Proposes Rapid Process for Review of Fixed Dose Combination and Co-Packaged Products." May 16, 2004. [www.hhs.gov/news/press/2004pres/20040516.html].

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