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Introduction

1.1 WHY MEASURE THE PRICE AND AVAILABILITY OF MEDICINES?

One third of the global population lacks reliable access to needed medicines (1). The situation is even worse in the poorest countries of Africa and Asia, where as much as 50% of the population lacks such access. While some 10 million lives a year could be saved by improving access to essential medicines and vaccines – 4 million in Africa and South-East Asia alone (2) – a major obstacle to achieving this has been price.

Average per capita spending on pharmaceuticals in high-income countries is 100 times higher than in low-income countries – about US\$ 400 compared with US\$ 4. The World Health Organization (WHO) estimates that 15% of the world's population consumes over 90% of the global production of pharmaceuticals (by value) (3).

Access to health care is a fundamental human right, enshrined in international treaties and recognized by governments throughout the world. However, without equitable access to essential medicines for priority diseases the fundamental right to health cannot be fulfilled. Access to essential medicines is also one of the United Nations' Millennium Development Goals (MDGs) (1).

In developing countries today medicines account for 25–70% of overall health-care expenditure, compared to less than 10% in most high-income countries (1,3). The cost of newer products with proven advantage over older medicines, such as antiretrovirals, medicines for tuberculosis and new antimalarials, limits access to medicines in resource-poor settings. Moreover, up to 90% of the population in low- and middle-income countries must pay for medicines out of pocket due to lack of social insurance and inadequate publicly subsidized services (1,4). Not only are medicines unaffordable for large sectors of the global population, they are a major burden on government budgets.

In Member Countries of the Organization for Economic Co-operation and Development (OECD), many direct and indirect pharmaceutical price regulations remain in effect (5,6). However, in many low- and middle-income countries, national medicine pricing policies have been shifting from price controls to deregulation under the influence of structural adjustment and reform programmes.

Duties, taxes, mark-ups, distribution costs and dispensing fees are often high, regularly constituting between 30 to 45% of retail prices, but occasionally up to 80% or more of the total (7–9). The higher the manufacturer's selling price, the more these elements increase the final price. Prices are also influenced by factors

such as whether the country observes patents and the level of flexibility allowed under international treaties – which is eventually incorporated into national patent law; the level of domestic medicine production; national policies on protecting local industries; the level of competition between pharmaceutical manufacturers; and price regulation policies.

National policies, medicine pricing and procurement strategies are required to ensure that medicines are affordable (1). While policies are also greatly needed to improve health infrastructure and financing as well as to ensure the rational use of medicines, high medicine prices are one of the biggest obstacles to access. Nevertheless, even in the face of a weak infrastructure and poverty, improvements in access can be achieved (10).

The difficulty in finding reliable information on medicine prices and availability – and therefore in analysing their components – hinders governments in constructing sound medicine pricing policies or evaluating their impact. It also makes it difficult for them to evaluate whether their expenditure on medicines is comparable to that of other countries at a similar stage of development. Moreover, those responsible for purchasing medicines cannot negotiate cheaper deals because they have no sound basis from which to start their negotiation. Even in countries where consumers and patients have greater purchasing power, governments, insurance funds and hospitals often find it difficult to decide on the selection of medicines because they lack information.

Prices of the same medicines frequently vary between countries (11); some commonly used medicines have been found to be more expensive in developing countries than in industrialized ones (12-14); and many studies have shown that affordability is unrelated to purchasing power. The ex-manufacturer prices to countries – in particular for the private sector – are often confidential. Medicine price indicator guides¹ provide the sales prices from large wholesalers of generically equivalent medicines to governments. However, they do not give the price patients must pay in either the public or private sectors and often do not include new, essential but patented medicines. A few countries have publicly available prices, but the information's use is obstructed by the country-specifics that apply and language barriers. The monitoring of prices and cross-country comparisons are therefore important.

1.2 THE WHO/HAI PROJECT ON MEDICINE PRICES AND AVAILABILITY

1.2.1 Background and project objectives

In the mid-1990s, civil society organizations in developed and developing countries – including Health Action International (HAI), Médecins Sans Frontières (MSF), the Consumer Project on Technology and Oxfam – started drawing attention to the need for increased access to medicines as part of the fight against poverty. Unaffordable medicine prices were considered a barrier to accessing treatment, but at this time only a few small-scale studies in developing countries had been carried out to measure medicine prices and make international comparisons. Methodological difficulties left many of these studies' results open to criticism.

Study results by HAI Asia Pacific (13,14) and others were discussed with WHO at the WHO/Public Interest NGO Roundtables held in the late 1990s. While it appeared that prices were higher in low-income countries compared to some more

¹ Management Sciences for Health (MSH); the WHO Regional Office for Africa; UNICEF/UNAIDS/WHO-HTP/MSF.

wealthy nations, relatively little was known about prices in different settings in low- and middle-income countries, and about the factors that make up the final patient price. The absence of a standard methodology was seen as a stumbling block in reliable price measurement and international comparison.

Both WHO and the nongovernmental organizations (NGOs) recognized that the availability and affordability of essential medicines had to be improved through developing evidence-based national policies and programmes. To this end, the WHO/HAI Project on Medicine Prices and Availability was established in 2001 to:

- develop a reliable methodology for collecting and analysing medicine price, availability, affordability and medicine price component data across health-care sectors and regions in a country;
- publish survey data on a publicly accessible web site to improve price transparency; and
- advocate for appropriate national policies and monitor their impact.

In May 2001, delegates to the World Health Assembly endorsed and gave further support to the project. They requested WHO “to explore the feasibility and effectiveness of implementing, in collaboration with NGOs and other concerned partners, systems for voluntary monitoring [of] drug prices and reporting global drug prices with a view to improving equity in access to essential drugs” (15). A year later, the World Health Assembly called on WHO to “provide technical support, especially to developing countries, to establish drug-pricing policies” (16).

1.2.2 Development, testing and use of the manual

In Phase I of the project, WHO, HAI and a group of international experts drafted a methodology to measure medicine prices, availability, affordability and price components. Following pilot testing in Armenia, Brazil, Cameroon, Ghana, Kenya, Peru, the Philippines, South Africa and Sri Lanka, the methodology was launched at the 2003 World Health Assembly as a draft manual and Excel workbook for field testing (17). Despite considerable pilot testing, HAI and WHO viewed the first edition of the manual and workbook merely as a starting point. As more surveys were undertaken, the methodology was kept under review and further developed in collaboration with survey managers in the light of accumulating experience.

To improve price transparency, a database of survey results was established on HAI’s web site.¹ This enables international comparisons to be made, since all surveys have used the WHO/HAI standardized approach. In addition to the database, the web site also provides all survey documents, any updates to the methodology, survey reports, advocacy material as well as project and related publications.

In Phase II of the project (which began mid-2003), HAI, WHO and project members provided technical assistance to ministries of health, NGOs, university researchers and others who undertook national or provincial/state surveys using the WHO/HAI methodology. This assistance was provided through regional pre- and post-survey workshops (in anglophone and francophone Africa, Asia/Pacific, Central Asia, the Eastern Mediterranean and India), various national workshops and through online advice.

During Phase II, studies were undertaken to validate the sampling methodology, the volatility of the reference prices and to compare actual prices paid with those

¹ www.haiweb.org/medicineprices

collected by data collectors. The results confirmed the strength and appropriateness of the WHO/HAI approach.

At the request of survey managers, a system to regularly monitor medicine prices, availability and affordability was developed and piloted in various countries in Africa and Asia in Phase II of the project (see Chapter 14).

1.2.3 Survey results

By the end of 2007, over 50 surveys had been undertaken across the globe, from Cameroon and the Cook Islands to El Salvador, South Africa and the Syrian Arab Republic. They have generated reliable evidence showing, for the first time, some startling facts about the affordability and availability of medicines. The results of these surveys¹ revealed that in many low- and middle-income countries:

- medicine prices are high, especially in the private sector (e.g. over 80 times an international reference price);
- availability can be low, particularly in the public sector (including no stocks of essential medicines);
- treatments are often unaffordable (e.g. requiring over 15 days' wages to purchase 30 days' treatment);
- government procurement can be inefficient (e.g. buying expensive originator brands as well as cheaper generics);
- mark-ups in the distribution chain can be excessive; and
- numerous taxes and duties are being applied to medicines.

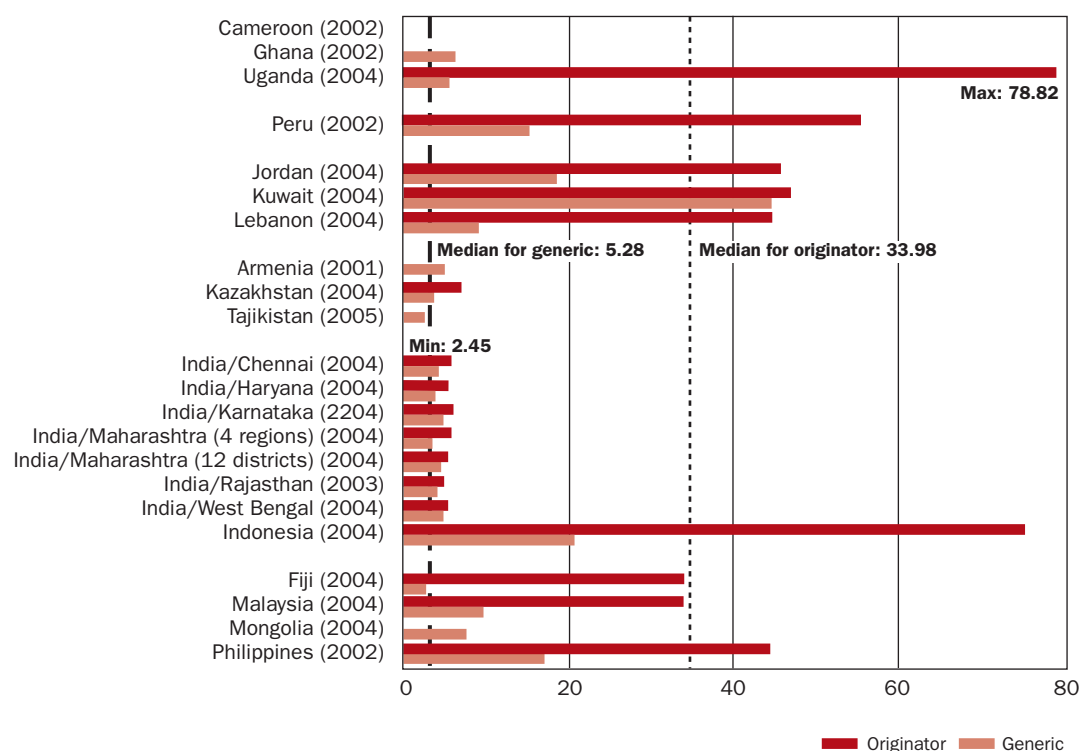
The results confirm that in many countries access to essential medicines is hindered by low availability and unaffordable prices. For example, salbutamol inhaler – an important medicine used to treat asthma – is virtually unavailable in the public sector of many countries (where medicines are generally cheaper or even free) and when purchased from the private sector, can cost the lowest-paid, unskilled government worker several days' wages (Table 1.1). As Fig. 1.1 illustrates, people are paying high prices for many medicines. The price of originator brand atenolol 50 mg tablets is over 20 times the international reference price in all the countries except India (where it is still high at 5 times the reference price) and Kazakhstan. Even the lowest-priced generic is very expensive in all countries, and there are some huge brand premiums, e.g. in Uganda the originator brand is about 13 times the price of the generic.

Table 1.1 Availability and affordability of 1 salbutamol inhaler 0.1mg/dose in selected countries^a

	Availability – public sector facilities		Affordability – private sector facilities	
	Originator	Lowest-priced generic	Originator	Lowest-priced generic
Uganda, April 2004	0%	0%	5.6 days	2.0 days
Ghana, October 2004	4%	11%	8.0 days	4.6 days
Mali, March 2004	0%	0%	4.2 days	2.7 days
Pakistan, July 2004	0%	3%	1.4 days	1.4 days
Indonesia, August 2004	13%	0%	4.1 days	-

^a Results of national medicine price and availability surveys conducted using WHO/HAI standard methodology. Data are available from <http://www.haiweb.org/medicineprices/>.

¹ <http://www.haiweb.org/medicineprices/>

Fig. 1.1 Median price ratios, atenolol 50 mg tablets, purchased from private retail pharmacies

Source: Gelders S et al. *Price, availability and affordability: an international comparison of chronic disease medicines*. Cairo, World Health Organization, 2006.

Regional analyses of data have been undertaken or are currently being drafted for surveys conducted in India (18), the WHO Eastern Mediterranean Region (19) and the WHO African Region (20), respectively, as well as Central Asia. An international comparison of prices, availability and affordability of medicines to treat chronic diseases has also been done (21), and analyses of price and availability of medicines in various therapeutic groups are underway. Reports of these analyses can be found on the HAI web site.

1.2.4 Evidence for policy development and implementation

The project's objective is to improve the availability and affordability of essential medicines through the development of evidence-based national policies and programmes. It has been encouraging, therefore, to see survey reports being disseminated and findings discussed in different national, regional and global forums.

Following the 2006 World Health Assembly, the *British Medical Journal* published an editorial drawing attention to the WHO/HAI report on prices, availability and affordability of chronic disease medicines that stated "the report's findings make explicit what has long been recognized: that the cost of medical care impoverishes or is simply beyond the reach of many people in developing countries. Amid the gloom, however, there is some light. Simply collecting data and presenting it to governments can stimulate action" (22). Indeed, some countries have acted on the evidence, among them the Government of Indonesia, which reduced the price of 458 generic medicine formulations from 5%–70% and implemented regulations to standardize prices for all public purchasing; the Government of Lebanon, which reduced the prices of a quarter of medicines on the market and introduced regressive

mark-ups; the Government of Nigeria, which is drafting a medicines policy, based on its survey findings; and the Government of Tajikistan, which abolished 20% VAT on medicines. In Phase III, the project will support countries to develop and implement policies and programmes that result in improved availability of medicines and more affordable treatments. Additionally, the project will support establishing national monitoring systems to evaluate the impact of policy changes (see Chapter 14).

Changes in national policies feature in the project's bulletin *Medicine Pricing Matters* along with publications and other interesting outcomes of pricing work being carried out worldwide. This quarterly bulletin was first published in December 2007.¹

1.2.5 Related surveys and initiatives

It has been encouraging to see other price studies utilizing the WHO/HAI survey methodology. In Nepal and Nicaragua, John Snow International and PATH conducted a survey of commodities for reproductive health (OCP, IUD, condoms, vaccines and other medicines) using an adaptation of the WHO/HAI methodology (23, 24). In 2005, WHO's Noncommunicable Diseases and Mental Health Cluster used the WHO/HAI methodology to survey the price, availability and affordability of 35 medicines used to treat chronic conditions (25). The surveys were done in Bangladesh, Brazil, Malawi, Nepal, Pakistan and Sri Lanka. More recently, the Medicines for Malaria Venture (MMV) has conducted a survey in Uganda looking at the price, availability, affordability and quality of all antimalarials on the market, using and adaptation of the WHO/HAI methodology.² MMV is planning to conduct a number of surveys in other countries.

The Medicines Transparency Alliance (MeTA) is a new initiative of the United Kingdom Department for International Development (DFID). MeTA will work with national and international partners, including WHO and the World Bank, to support national efforts to enhance transparency and build capacity in medicines policy, procurement and supply chain management. DFID envisages international actors supporting national efforts, coupled with focused technical and financial support to strengthen transparency and accountability. Such national efforts would seek to improve access to information about medicine quality, availability and pricing, with strong civil society and consumer involvement in scrutiny and debate. MeTA has identified the WHO/HAI price measurement methodology as the key tool for measuring medicine prices, availability, affordability and component costs. MeTA will be launched in May 2008, with pilots in several countries in Africa, Asia, Central Asia, the Eastern Mediterranean and Latin America.³

1.3 THE MEDICINE PRICES AND AVAILABILITY SURVEY MANUAL – SECOND EDITION

Published in 2003, the first WHO/HAI medicine prices manual *Medicine Prices – A New Approach to Measurement. Draft for field-testing* provides a draft methodology and tools to conduct national medicine prices and availability surveys. This second

¹ Contact HAI if you wish to be placed on the mailing list. WHO's *Essential Drugs Monitor* (<http://www.who.int/medicines/publications/monitor/en/index.html>) regularly features articles on medicine pricing work and the 33rd issue (<http://mednet2.who.int/edmonitor/33/mon33.html>) carried a 16-page supplement on survey findings and analyses, policy changes and advocacy. Contact edmdoccentre@who.int to receive a copy of this edition or to be placed on the mailing list.

² http://www.mmv.org/IMG/pdf/Prices_of_Antimalarials_MMV_survey_July_07_website_19_Sept.pdf

³ Additional information on MeTA can be found at <http://www.dfidhealthrc.org/MeTA/index.html>

edition of the survey manual has been updated to reflect the wealth of practical experience in conducting medicine prices and availability surveys garnered in the project's first two phases.

The new manual and accompanying tools have been developed through a consultative process with project participants, national collaborators and the WHO/HAI Project on Medicine Prices Steering and Advisory Groups. A technical meeting was held in Cairo from 27 November to 3 December 2006 with the medicine prices project management team, advisory and steering groups, selected survey managers and consultants to recommend changes to the methodology and revisions to the survey manual. This group has also been consulted throughout the manual revision process, and has contributed to sections of the manual related to their respective areas of expertise.

In the manual's second edition, the survey methodology has been refined, based on the lessons learnt in the more than 50 surveys conducted to date. New methodologies and tools have also been developed in the areas of price component surveys (Chapter 9) and routine monitoring of medicine prices and availability (Chapter 14). The revised manual also provides significantly more guidance in the areas of policy options and lines of action (Chapter 11) as well as advocacy strategies aimed at stimulating reform of medicine price policies (Chapter 13).

The second edition includes the revised survey manual along with updated versions of the automated data workbooks and survey instruments: it also includes a CD-ROM of survey tools, resources and background materials. The CD-ROM and the HAI web site¹ will be updated periodically with new materials as these become available.

Feedback on the second edition of the medicine prices and availability survey manual is welcome and encouraged.²

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¹ <http://www.haiweb.org/medicineprices/>

² Please contact HAI (info@haiweb.org) or WHO (medicineprices@who.int).

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