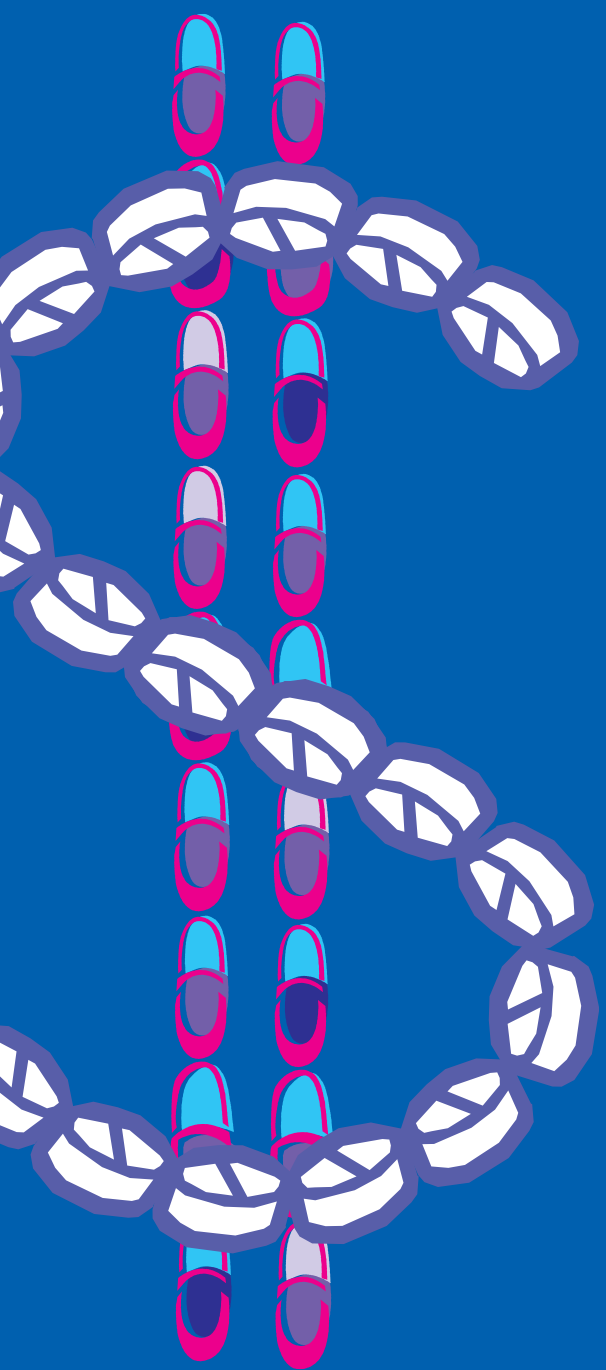
WHO-EM/EDB/068/E



Price, availability and affordability

An international comparison of chronic disease medicines

Background report prepared for the WHO Planning Meeting on the Global Initiative for Treatment of Chronic Diseases, Cairo, December 2005

World Health Organization
REGIONAL OFFICE FOR THE Eastern Mediterranean

HAI
Health Action International

WHO-EM/EDB/068/E

Price, availability and affordability
An international comparison of chronic disease medicines

Background report prepared for the WHO Planning Meeting on the Global Initiative for Treatment of Chronic Diseases held in Cairo in December 2005

Susanne Gelders, Margaret Ewen, Nakae Noguchi, Richard Laing

World Health Organization
REGIONAL OFFICE FOR THE Eastern Mediterranean

HAI
Health Action International

Cairo
2006

This document has been produced with the financial assistance of the European Community. The views expressed herein are those of the authors and can therefore in no way be taken to reflect the official opinion of the European Community.

European Community

Cover design by Ahmed Salah Mostafa
Printed by Metropole, Cairo

Document WHO-EM/EDB/068/E/05.06/3000

Contents

Contents of CD-ROM

Summary dataset. Asthma: beclometasone and salbutamol

Summary dataset. Diabetes: glibenclamide and metformin

Summary dataset. Hypertension: atenolol, captopril, hydrochlorothiazide, losartan and nifedipine retard

Summary dataset. Epilepsy: carbamazepine and phenytoin

Summary dataset. Psychiatric disorders: amitriptyline, fluoxetine and fluphenazine decanoate

Originator brand names and manufacturers of medicines surveyed

Foreword

Hussein A. Gezairy, MD, FRCS

The idea of a global initiative for the treatment of chronic diseases started here at WHO's Regional Office for the Eastern Mediterranean, when I sent a memorandum to Dr LEE Jong-Wook, Director-General of the World Health Organization. In this memorandum, I said, "As we go through the 21st century with its spectacular advances in science and technology, we also carry with us an ever-increasing burden of chronic diseases. Chronic diseases now pose the biggest public health problem of our times, affecting our lives and those of our younger generation, rich and poor both."

There is strong scientific evidence that cost-effective medications can contribute to substantial individual and public health benefits in this respect. For cardiovascular disease, each of the medicine categories of aspirin, beta-blockers, angiotensin-converting enzyme (ACE)-inhibitors and lipid-lowering therapies lower the risk of future vascular events by about a quarter each in high-risk patients, including patients with diabetes. The benefits of these medicines are largely independent, so that when used in combination, two-thirds to three-quarters of future vascular events could be prevented. Similarly, making medications affordable and accessible to all patients with asthma and diabetes can lead to a substantial reduction in morbidity and mortality from these conditions. In this respect, I would also refer to the recent publication of the Disease Control Priorities Project (DCCP), which gives evidence-based data for the cost effective pharmacological and non-pharmacological interventions for acute and long-term management of cardiovascular diseases.

Large-scale surveys conducted in high-income countries have demonstrated the existence of large gaps between clinical recommendations and treatment:

- The ASPIRE (action on secondary prevention through intervention to reduce events) study enrolled 2538 patients with coronary disease from 24 hospitals in the United Kingdom. For patients diagnosed with high serum cholesterol, 50% received therapeutic intervention. Among patients who were receiving lipid-lowering drugs, most (57%–69%) remained hypercholesterolaemic six months after being hospitalized for coronary heart disease.[1]

- EUROASPIRE extended this research to 10 European countries, and found a similarly large gap between clinical recommendations and practice.[2]
- The WHO-PREMISE study (WHO Study on Prevention of Recurrences of Myocardial Infarction and Stroke) was conducted in 2002 and 2003.[3] This was a health care facility-based study in defined areas in 10 low-income and middle-income countries to investigate the current patterns of practice relating to secondary prevention of cardiovascular diseases. Data from this study demonstrated that the percentages of patients with coronary heart disease who received medication were: aspirin 81.2%; beta blockers 48.1%; ACE inhibitors 39.8%, and statins 29.8%. World Health Survey data derived from household surveys also indicate that a very high proportion of patients with major chronic conditions are not receiving cost-effective essential medications.
- A study by Beran published in 2005 found that insulin was only available at all times in 20% of the hospitals and none of the health centres in Mozambique. In Zambia, insulin was found in 100% of the hospitals and 42% of the health centres.[4]

While these large-scale surveys provide useful information about the current standard of care, it is nonetheless necessary to probe further to understand and address the factors that contribute to major treatment gaps. I feel that the time has now come for WHO once again to take the lead in introducing a global effort wherein all partners are engaged in a concerted effort to make good quality medicines for chronic, or noncommunicable, diseases affordable and available to the poor and needy suffering from these diseases – an initiative that will help to lift the poor out of the devastating spiral of poverty and chronic disease. WHO's successes in establishing Public–Private Partnerships for the Control of Onchocerciasis, the Global Drug Facility for Tuberculosis Control, the Global Alliance to Eradicate Leprosy, and the recent plan to make antiretroviral medicines for HIV/AIDS control more widely available through the framework of the 3 by 5 Initiative are models that we can emulate.

In May 2000, the World Health Assembly adopted resolution WHA 53.17 endorsing a WHO global strategy for the prevention and control of noncommunicable diseases. The global strategy urges the Member States to promote the effectiveness of secondary prevention and to ensure that the management of major noncommunicable diseases (cardiovascular diseases, cancer, diabetes and chronic respiratory diseases) is based on cost-effective interventions and equitable access. These indeed should be the major objectives of the proposed initiative.

A WHO global initiative for the treatment of chronic diseases should recognize the need to improve health outcomes by making evidence-based non-pharmacological and pharmacological interventions available to populations in low- and middle-income countries. It should also seek to provide guidance to policy-makers to respond to the legitimate needs of those suffering from chronic disease, within the overall context of national health system development.

Finally, such a global initiative should set a framework for:

- identification of gaps in access and availability of cost-effective medicines for chronic diseases;
- identification of innovative strategies for influencing and managing the price and availability of these medicines;
- development of models to improve access and affordability of medicines for noncommunicable diseases;
- addressing treatment needs of patients with major chronic diseases through national programmes that ensure equitable access;
- WHO to lead a global effort involving all partners to make good quality medicines for chronic diseases available and affordable.

This report, on the prices, availability and affordability of chronic disease medicines, was prepared for the WHO Planning Meeting on the Global Initiative for Treatment of Chronic Diseases held in Cairo in December 2005. The report documents the situation in 30 countries covering all six WHO Regions. It identifies serious gaps in availability in the public sector, and high prices, and thus poor affordability, in the private sector in most countries.

I urge anyone interested in improving the quality of care for patients with chronic diseases and access to medicines for chronic disease patients to study this report carefully, and take the key lessons for their national health systems and government responsibilities.

Hussein A. Gezairy, MD, FRCS
WHO Regional Director for the Eastern Mediterranean

Acknowledgements

This report was prepared using data collected with World Health Organization/Health Action International medicine prices surveys. Its authors, Susanne Gelders[*], Margaret Ewen[†], Nakae Noguchi[‡] and Richard Laing[§] acknowledge that the report could not have been written without the help of the many people involved in developing the WHO/HAI medicine price survey methodology, the survey managers of the 30 surveys included in this report and the reviewers. We would like to thank them all for their patience and efforts, and hope that this new analysis will further enrich their work. We also wish to thank all the national and state governments, universities, and civil society groups which support price transparency and gave permission for their data to be publicly accessible on the HAI web site and in this report.

Survey managers

Armenia: Movses Aristakesyan, Armenian Drug and Medical Technology Agency; *Brazil/Rio de Janeiro state*: André Luis de Almeida dos Reis, National School of Public Health – Oswaldo Cruz Foundation; *Cameroon*: Meinolf Kuper, The German Agency for Technical Cooperation; *Chad*: Zarana Bandiang, Ministry of Health; *China/Shandong Province*: Sun Qiang, Centre for Health Management and Policy, Shandong University; *Fiji*: Murray Bailey, Fiji School of Medicine; *Ghana*: Charles Allotey, National Catholic Secretariat; *India/Chennai*: Shobha Iyer, Citizen, Consumer and Civic Action Group (CAG); *India/Haryana*: G.L. Singal, Ministry of Health and Family Welfare, Government of Haryana; *India/Karnataka*: P.K. Lakshmi, Drug Information Centre, Karnataka State Pharmacy Council; *India/Maharashtra (12 districts)*: Kannamma Raman, Association for Consumers Action on Safety and Health (ACASH) Mumbai; *India/Maharashtra (four regions)*: Archana Patel, Department of Paediatrics and Clinical Epidemiology Unit, Indira Gandhi Medical College, Nagpur and Vijay Thawani, Department of Pharmacology, Government Medical College, Nagpur; *India/Rajasthan*: Anita Kotwani, Vallabhbhai Patel Chest Institute, University of Delhi; *India/West Bengal*: Dalia Dey, Consumer Unity and Trust Society (CUTS) Kolkata and Santanu Kumar Tripathi, Community Development Medicinal Unit (CDMU) Kolkata; *Indonesia*: Martuti Budiharto and Selma Siahaan, National Institute of Health R&D; *Jordan*: Laila Jarrar, Pricing Department, Jordan Food and Drug Administration; *Kazakhstan*: Talgat Nurgozhin and Yermekbaeva Bakytgul Abkenovna, Drug Information Centre, Karaganda; *Kenya*: Isaac Ongubo Kibwage, College of Health Sciences, University of Nairobi; *Kuwait*: Douglas Ball, Faculty of Pharmacy, Kuwait University; *Lebanon*: Rita Karam, Import/Export & Drug Registration Department, Ministry of Public Health; *Malaysia*: Zaheer Ud-Din-Babar, School of Pharmacy, University College Sedaya International; *Mali*: Ouattara Oumar, Directeur Général Union Technique Mutualité Malienne; *Mongolia*: Ch. Munkhdelger, Pharmaceutical

[*] Independent consultant, e-mail: Susanne@Gelders.net

[†] Health Action International price survey coordinator, e-mail: marg@haiweb.org

[‡] Japan International Cooperation Agency Fellow, e-mail: nakaenoguchi@yahoo.co.jp

[§] World Health Organization medical officer, e-mail: laingr@who.int (corresponding author)

and Health Devices Department, Ministry of Health; *Morocco*: Dr A. Agoumi, Director, Pharmaceutical Department, Ministry of Health; *Peru*: Javier Olivas, Asociación Internacional para la Salud; *Philippines*: Aldrin Santiago, Health Action Information Network, Manila; *South Africa/KwaZulu-Natal*: Aarti Patel, Public Health Consultant Pharmacist, South Africa; *Sri Lanka*: Rajitha Wickremasinghe, Department of Community Medicine and Family Medicine, University of Sri Jayawardenapura; *Tajikistan*: Jamila Anvarova, Drug Information Centre, Dushanbe; *Uganda*: Patrick Mubangizi, Coalition for Health Promotion and Social Development (HEPS Uganda) and HAI Africa.

See the survey report on HAI's web site (**http://www.haiweb.org/medicineprices**) for a full list of all those who contributed to the national surveys.

Sponsors of the WHO/HAI Project on Medicine Prices

Ministry of Foreign Affairs, the Netherlands; The Rockefeller Foundation; Swedish International Development Cooperation Agency; Department for International Development, United Kingdom; European Union DG Development and the World Health Organization.

Members of the WHO/HAI Project on Medicine Prices

Management: Margaret Ewen, Health Action International (HAI) Europe; Richard Laing, Department of Medicines Policy and Standards, World Health Organization, and Gilles Forte, Department of Technical Cooperation for Essential Drugs and Traditional Medicine, World Health Organization.

Advisory group: Kumaraiah Balasubramaniam, HAI Asia Pacific, Sri Lanka; Jorge Bermudez, Pan American Health Organization, USA; Dennis Ross-Degnan, Harvard Medical School, USA; Jerôme Dumoulin, University of Grenoble, France; Yves-Antoine Flori, University of Bordeaux, France; David Henry, University of Newcastle, Australia; Jeanne Madden, Harvard Medical School, USA; Barbara McPake, London School of Hygiene and Tropical Medicine, England; Elias Mossialos, London School of Economics, England; Kirsten Myhr, Ullevål University Hospital, Norway; Carmen Perez Casas, Médecins Sans Frontières; Aarti Patel, University of Otago, New Zealand; and Anthony So, Duke University, USA.

Steering committee: Daphne Fresle, World Health Organization, Ellen 't Hoen, Médecins Sans Frontières, France; Zafar Mirza, World Health Organization Regional Office for the Eastern Mediterranean, Egypt; Lander van Ommen, Ministry of Foreign Affairs, the Netherlands; Raffaella Ravinetto, Médecins Sans Frontières; Harry van Schooten, Ministry of Foreign Affairs, the Netherlands, and Mohga Kamal Smith, Oxfam, England.

Consultants: Martin Auton, South Africa; Douglas Ball, Kuwait; Simona Chorliet, Mali; Andrew Creese, France; Jan Fordham, England; Pierrick Gonnet, Switzerland; Anita Kotwani, India; Libby Levison, USA; Sadara, the Netherlands; and Klara Tisocki, Kuwait.

Reviewers of this report

Nadia Ait-Khaled; Murray Bailey; Douglas Ball; Amitava Banerjee; David Beran; Kees de Joncheere; Peter Graaff; Hilbrand Haak; Anita Kotwani; Jeanne Madden; Barbara McPake; Zafar Mirza; Kirsten Myhr; Aarti Patel; Carmen Perez; Abdel Aziz Saleh, Willem Scholten; Ellen 't Hoen and Jun Yoshida.

Editors and layout

Susan Kaplan, Kathleen Hurst, Lisa Greenough and Monique Renevier.

Acronyms

ACE-inhibitor	angiotensin-converting enzyme inhibitor
BP	*British Pharmacopoeia*
EU	European Union
GDP	gross domestic product
GST	goods and services tax
HAI	Health Action International
HIV/AIDS	human immunodeficiency virus/acquired immunodeficiency syndrome
INN	International Nonproprietary Name
IRP	international reference price
JICA	Japan International Cooperation Agency
MPR	median price ratio
MSH	Management Sciences for Health
NGO	nongovernmental organization
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UNICEF	United Nations Children's Fund
USP	*United States Pharmacopeia*
VAT	value added tax
WHO	World Health Organization
WTO	World Trade Organization

Executive summary

Chronic diseases are a serious public health issue, particularly because they require long-term therapy. Ensuring access to medicines for treating chronic disease, however, remains neglected. Generally, efforts to improve access to medicines focus on medicines for treating infectious diseases, in the context of a programme addressing the specific disease or disease group. The priority in most programmes that address chronic diseases is prevention. However, it is well established that in addition to prevention, treatment of chronic diseases is an essential component of a comprehensive public health care programme.

In May 2001, the World Health Assembly adopted a resolution stating that WHO should explore systems for monitoring medicine prices with a view to improving access to essential drugs. WHO and Health Action International, in collaboration with a panel of experts, developed a methodology for surveying the prices, availability, affordability and components of medicine prices in developing and transitional countries. This report presents the synthesis data of 14 chronic disease medicines collected in 30 surveys that were undertaken using this methodology between 2001 and 2005.

The key findings of the report can be summarized as follows:

- Government procurement systems are generally efficient in obtaining *prices* similar to the international reference prices when procuring for their own supply systems (for example, generic glibenclamide with a median value of 0.82 times the international reference price; generic metformin with a median value of 0.46 times the international reference price). However, the procurement prices of some individual medicines can be high. In addition, government or public systems tend to be unable to ensure adequate availability of medicines for chronic diseases (for example, generic glibenclamide: median availability 42%; generic metformin 16%), with a few notable exceptions. Where the public sector provides medicines free to the patient, the medicines are often not available. If patients have to pay for their medicines in the public sector, the prices tend to be high compared to the procurement prices (for instance, generic glibenclamide procurement median value was 0.82 times the international reference price while the median public sector patient price ratio was 4.49).
- The private sector generally has better *availability* of medicines, but prices are much higher, ranging from three times the international reference price to peaks of one hundred times the international reference price at country level (for instance, the median value of originator captopril was 14.54 times the international reference price; that of originator hydrochlorothiazide 49.48 times higher; and that of generic atenolol 5.46 times higher).
- For *affordability*, the price of the medicine related to the wage of the lowest paid unskilled government worker in each country has been determined and expressed as the number of days this person would have to work to buy predetermined regimens

of treatment for selected chronic conditions. In some countries where wages are low, medicines may be affordable because of their low prices; in others either wages are too low or prices too high for medicines to be affordable. In countries with high prices, even if they earn average wages, patients face serious difficulties in affording treatment for a chronic disease. (For example, the treatment of asthma with one beclometasone and one salbutamol inhaler per month would "cost" the lowest paid unskilled government worker, as a median value over the 30 countries, 1.8 working days for the lowest priced generic and 5.5 days for the originator versions).

One major finding of the surveys was that taxes and duties levied on medicines, as well as the mark-ups applied, frequently contribute more to the final price than the actual manufacturers' price does. Government intervention can potentially be applied to all these additional costs. If interventions are applied to reduce prices to patients, care should be taken to ensure that there is no distortion when price controls are applied incorrectly. One such distortion occurs when the policy is to price generic medicines down from the price of originator medicines, rather than up from the actual procurement price.

No single policy approach is applicable in every country; case studies at country level will be required to define optimal policies. For originator medicines for which no therapeutic equivalents exist, price controls are likely to be necessary. Excessive mark-ups by pharmacies, and particularly by dispensing doctors, will also require regulatory controls. However, for multisource generic medicines, governments should promote competition through appropriate pricing policy. Measures could include waiving or reducing registration fees, as happens in the USA, providing a fast-track registration process, and encouraging or requiring generic substitution, as happens in a number of European countries. There seems to be no public policy basis for levying duties or charging taxes on chronic disease medicines. It is equivalent to a government choosing to tax the sick. Consumers should play a more significant role in becoming well-informed purchasers. This can only happen if prices are monitored and price data are widely disseminated to the public.

The key recommendation of this report is that to improve access to medicines for chronic diseases, governments should measure and continuously monitor the prices, availability and affordability of medicines and price components. They should also develop, implement and enforce policy options addressing these issues in order to reduce prices and make medicines affordable and available to their citizens.

1. Introduction

In low- and middle-income countries, large proportions of the population have limited access to medicines, either because of poor availability or because patients must pay for their prescriptions and are not able to do so.[5] Although research has been undertaken on medicine prices, there has so far been insufficient progress in improving medicine affordability and availability for individual patients in many countries. For chronic diseases, research on financial aspects has been limited to the large-scale economic consequences of treatment and prevention for society at large, rather than focusing on individuals in a particular society.

In this report, we describe the prices, availability and affordability of 14 medicines for chronic diseases for patients with specific diseases in a number of countries. It is hoped that the report will stimulate dialogue among policy-makers, civil society, the pharmaceutical industry and health care workers on finding ways to improve availability, prices and affordability. This report does not address the important diagnostic and care aspects of chronic diseases. The "core" list of medicines WHO and HAI recommend for inclusion in a price survey includes three antiretrovirals, but regrettably in most surveys availability was so poor that analysis of their price and affordability was rarely possible. Pricing information about HIV/AIDS medicines from other data sources is available at: **http://www.who.int/3by5/amds/price/hdd/**.

The WHO/HAI Medicine Prices survey methodology is described, followed by a review of current developments in the area of chronic disease management and a description of the methodology applied for the secondary analysis of price survey data is provided. Data have been collected in both the private and public sectors. In addition to price information, availability data were collected. Affordability has been calculated based on the daily wage of the lowest paid unskilled government worker in the survey country.

A full list of the 30 surveys, and the medicines surveyed, is included. For a number of diseases, "typical" treatments have been used to demonstrate the actual affordability for individual patients in a number of settings. The methodology for secondary analysis of the data collected has been developed for this report and is described in detail, together with all additional data sources and an explanation of the selection criteria. All summary datasets are included on the CD-ROM that accompanies this report. The following chapters discuss the survey results and policy issues, conclusions are drawn, and further investigations and general recommendations are proposed.

This report contains an analysis of the data collected in recent surveys of originator and generic medicines used to treat chronic diseases, and demonstrates that the price, availability and affordability are optimal for neither product types in most of the countries surveyed. The report is intended to be used by policy-makers and programme managers responsible for pricing, price regulation, procurement and other regulatory affairs related to chronic diseases. The data can also be used by civil society groups concerned about access to essential medicines to advocate for pricing policies that make medicines more affordable and

available. In addition, this report is intended to serve as a resource for WHO regional and country advisers on chronic diseases and essential medicines. It is also intended to be a basis for planning further surveys, either in other countries applying the same survey methodology, or in some of the countries already surveyed, where more detailed case-studies are being undertaken. The data provided in this report may also be used to suggest how medicines for treating chronic diseases could be made more available at more affordable prices, either for the individual or for the government providing care to the population.

2. Background

2.1 Medicine prices in developing countries: literature review

In 1996, Balasubramaniam reported that retail medicine prices in developing countries in the Asia Pacific Region, and in selected developed countries, varied dramatically, with percentage differences varying from several hundreds to several thousands, with extremely large ranges for the developing countries (minimal difference 233%; maximum 32,757%).[6] Comparison of the medicine prices with economic indicators (minimum daily wage and real per capita gross domestic product (GDP)) and common food items (rice, sugar, milk and eggs), showed that it was rarely possible to pay for a treatment course by leaving out a meal, as again, the ranges for medicine prices were staggering in comparison with the economic or household references (range for price of 1 kg rice US$ 0.39–0.80; range for price of 100 Zantac tablets US$ 3–250) (Note: Zantac is ranitidine as marketed by GlaxoSmithKline, 150 mg). This collection of papers and further work by the same and other authors highlighted the issue of medicine pricing in the context of equitable health care.[7]

In 2000, Myhr published a study comparing the prices and availability of a selected number of essential medicines in different sectors of the health care system in four East African countries, Ethiopia, Kenya, Uganda and the United Republic of Tanzania.[8] A basket of 15 different essential medicines was developed on the basis of essential needs for medicines for prevailing diseases (tropical diseases, HIV/AIDS and opportunistic infectious diseases), as well as patent status. Prices were collected from different sectors in rural and urban areas in each country. Information on official duties, taxes and mark-ups was also collected. The data collection was done in a few randomly selected facilities in May 2000. International reference price (IRP) data were taken from the Norwegian official price list, as being representative of typical European prices.

The results of this survey showed that both Ethiopia and the United Republic of Tanzania had low- or non-availability of many of the observed medicines, whereas Kenya had high availability. The lowest availability was generally found in the public sector. In the private not-for-profit sector, the availability was almost the same as in the private sector. Private hospitals in Ethiopia and the United Republic of Tanzania were poorly stocked with the indicator medicines. Looking at the range and the difference between originator medicines and generics, generics were generally found to be significantly cheaper than the originator medicines. It was also observed that the more generics were available, the larger the spread in prices between the cheapest generic and the originator brand.

The data confirmed earlier findings that pharmaceutical pricing is, according to the authors, about the ”law of the jungle, where might is right and medicines are very far from being equity priced”. The wide variation in prices of originator medicines in developing countries suggested that the guiding principle that the pharmaceutical industry seems to apply when fixing prices is to set the upper limits according to what the market can bear. The results further confirmed that high retail prices of originator medicines in developing countries were often double those in European countries. The impact of generic competition on prices

of generics was that these products were often priced at less than one tenth of the price of the originator's brand. There were large differences in medicine prices between the four countries surveyed.

Following the study in East Africa, a methodology was developed by HAI and WHO for the systematic collection of medicine prices, availability and affordability data, resulting in a first draft manual that was published in 2003.[9] The results of the pilot studies using the methodology can be consulted on **http://mednet2.who.int/edmonitor/33/mon33.html** and **http://www.haiweb.org/medicineprices/articles/Synthesis_paper_20031100.pdf**. For a brief description of the methodology see chapter 3.

Recently surveys of prices, availability and affordability of medicines for chronic disease have been completed by WHO in five countries; Bangladesh, Malawi, Nepal, Pakistan and Sri Lanka. These surveys are based on a longer list of chronic disease medicines than in previous surveys. The report in its present form provides only aggregate basket data and not comparative results on specific individual medicines. However the general results, as yet unpublished, are consistent with the specific findings reported in this paper.[10]

2.2 Chronic diseases

As countries undergo epidemiological transformation chronic diseases are rapidly becoming more important determinants of national disease burdens. Although the causes, effects, and options for prevention of the most important of these diseases are well-known, the demand for medical treatment continues to increase.

In a study by Barcelo et al on the cost of diabetes in Latin America and the Caribbean, prevalence estimates of diabetes from 2000 were used to calculate direct and indirect costs of diabetes mellitus.[11] The cost was expressed in loss of years of productive life from disability and premature mortality, or direct costs such as hospitalization or medication. The authors estimated that 80% of the total population with type 2 diabetes used oral medication, that 97.5% of the cases of diabetes mellitus were of type 2, and that the total direct costs of oral medication were 59% of the total costs of medicines, or 26% of the total estimated direct costs of diabetes. The overall conclusion of the study was that diabetes imposed a high economic burden on individuals and society in all of the countries studied. The gap between health expenditures in the region and the cost of diabetes care, might lead to adverse outcomes such as a high frequency of complications, disabilities and premature mortality.

The PREMISE study by Mendis et al. in 2002–2003 determined the extent of secondary prevention of coronary vascular disease and cerebral vascular disease in low- and middle-income countries and concluded that a significant proportion of the coronary heart disease patients who took part in the survey (one tenth) were not on any medication, not even the inexpensive and widely available aspirin or beta-blockers.[3] Aspirin was used more widely (81.2%) than beta-blockers (51.9%), angiotensin converting enzyme (ACE)-inhibitors (38.8%) or statins (20.8%). One of the explanations suggested for the treatment gaps was non-affordability and unavailability of the medication, as well as inequitable prescribing behaviour.

In October 2005, the Lancet opened its 'Chronic Diseases' series with the statement by Horton that "without concerted and coordinated political action, the gains achieved in reducing the burden of infectious disease will be washed away as a new wave of preventable illness engulfs those least able to protect themselves. Let this series be part of a new international commitment to deny that outcome".[12] The first paper in the series, by Strong et al., revealed that, globally, around 58 million people would die in 2005; and that 35 million of these deaths would be from chronic diseases.[13] By 2015, 36 million lives could have been saved worldwide if deaths from chronic diseases, such as heart disease, stroke and cancer were reduced by 2% annually. In the second paper, by Epping-Jordan et al., a public health approach for reducing the burden of chronic diseases in low- and middle-income countries was described.[14] Their framework takes into consideration the limited resources as well as the double burden of infectious and chronic diseases that occurs in many low- and middle-income countries. The third paper, by Srinath Reddy et al. outlined actions that might curb the rising burden of chronic diseases in India, estimated to account for 53% of all deaths in the country.[15] Tobacco consumption, for example, is especially common among the poor and rural population and accounts for a large proportion of deaths from cancer. The final paper in the series, by Wang et al., focused on the prevention of chronic diseases in India and the People's Republic of China.[16] Regrettably there is a lack of data on the prevalence and treatment of chronic diseases in other parts of the world, including many African countries.

The recently published WHO global report entitled *Preventing chronic diseases: a vital investment* dispels the long-held misunderstandings about heart disease, stroke, cancer and other chronic diseases that have contributed to their global neglect.[17] The reality is that 80% of this year's 35 million chronic disease-related deaths will occur in low- and middle-income countries, where they affect men and women at younger ages than in high-income countries. Premature deaths in countries such as India, the People's Republic of China and the Russian Federation are projected to cost billions of dollars over the next 10 years. The report gives practical advice for reducing numbers of deaths and improving the lives of millions of people by underlining preventive measures, disease management and other interventions in an integrated, comprehensive approach. Emphasis is put on leadership and effective and low-cost interventions.

From 11 to 13 December 2005, WHO organized the WHO Planning Meeting on the Global Initiative for Treatment of Chronic Diseases in the WHO Regional Office for the Eastern Mediterranean, Cairo, Egypt. The programme for this meeting included sessions on the initiative, on regional perspectives on the topic, on potential links between current activities and the proposed initiative, on affordability of treatment, equitability of access, quality of medicines, and using the lessons learned. The participants at the meeting developed a framework for action which can be found in Annex 1.

3. Methodology: World Health Organization / Health Action International Medicine Price survey

The WHO Essential Drugs and Medicines Policy Department (WHO/EDM) and Health Action International (HAI) developed the WHO/HAI manual *Medicine Prices, a new approach to measurement* (2003).[9] This manual is the outcome of a technical project of the WHO/Public Interest Nongovernmental Organizations Roundtable on Pharmaceuticals, which was established in 1998 to strengthen collaboration between WHO and civil society. Coordination of the roundtable and of this project is undertaken by HAI Europe. Details of pricing project are available on the HAI web site (**www.haiweb.org/medicineprices**).

After reviewing experiences gained in monitoring the prices of medicines, the need for the development of a standardized method for the collection and analysis of medicine prices and price composition within a country at a specific point in time and over time was identified by the roundtable group. A panel of highly experienced and widely recognized experts assisted with the work. The outcome is an approach for measuring the prices that people pay for a selection of important medicines across all pharmaceutical sectors in each country, including the public sector, private retail pharmacies and "other" medicine outlets. In addition, the manual outlines how to collect information on elements of price composition, such as taxes, mark-ups and fees, and how to assess the affordability and availability of medicines. To facilitate data analysis, a software application is available which accompanies the printed manual, and can also be accessed via the HAI web site (see above). The manual is available in several languages, including Arabic, English, French, Russian and Spanish. Users of the manual are encouraged to submit their data so that after revision they can be compiled in one general, publicly accessible database on the same web site.

The survey approach involves the use of a systematic survey to collect accurate data and reliable information on the price, availability and affordability of a selected number of medicines, and provides guidance on reporting as well as on formulating policies aimed at rectifying the diagnosed problems. During 2001 and 2002 the manual was field-tested in nine countries (Armenia, Brazil, Cameroon, Ghana, Kenya, Peru, Philippines, South Africa and Sri Lanka) over four continents. Results from these surveys have been included in the secondary analysis presented in this report. Since then, over 40 surveys have been completed or are nearing completion. The methodology manual and accompanying workbook can be downloaded from the HAI web site. Key features from the manual are described below.

3.1 Methodology

The methodology requires a systematic survey of the prices of a core list of medicines and allows for a supplementary list of medicines that are selected by each country on the basis of their importance in treating major national health problems.

Selection of survey facilities, for generating data on prices to patients in both the private and public sectors, uses a sampling approach which selects one central area, the major urban centre (usually the capital of the geographical area (e.g. country, province or state), combined

with three other administrative areas chosen randomly from a list of areas that can be reached within one day's travel from the central area. In each of the four identified areas, at least five public health facilities are selected, including the main public hospital. The choice of private sector pharmacies sampled should be based on their proximity to the public health facilities surveyed; at least five pharmacies per survey area should be included. Private sector not-for-profit facilities (e.g. a nongovernmental organization) should be selected if they are present, applying the same methodology. The procurement prices for the public sector can be collected in the administrative centre (procurement offices or central medical stores).

Data entry and analysis generally take place at the central level. A standardized computerized workbook is used to double enter the data collected in the field. The workbook allows rapid entry, verification and analysis of the data. Data analysis, using the same software application, generates information on the prices in different sectors, geographical areas, health facilities and pharmacies; on the components of medicine prices; the affordability of the medicines; and on the availability of the medicines. Pricing information is expressed as median price ratios (MPRs), i.e. median prices from the survey, compared with international reference prices (IRPs).

3.2 Medicines

In countries undertaking surveys many different medicines are registered and available. A national essential medicines list, which is often applied only in the public sector, normally contains between 250 and 500 formulations, including different dosage forms and strengths of the same active ingredients. In the private sector, however, several thousand products may be available. In order to make the survey manageable and to enable comparability, a core list of 30 medicines has been selected as the basis for data collection and analysis. For each medicine, the core list contains one dosage form, one strength, one recommended pack size and up to three products to be measured: the originator brand, the most sold generic equivalent (MSG) and the lowest price generic (LPG) equivalent. Recently the methodology has been modified because of problems with the collection of data on the two different generic products. Users are now advised to collect only prices for the originator brand and lowest price generic medicines. The list of core medicines can be found in Table 3.1.

The 30 medicines contained in the core list have been selected because they meet the following criteria:

- ***Global burden of disease*:** the products are all used to treat common conditions, both acute and chronic, that cause significant morbidity and mortality, including cardiovascular diseases, diabetes, asthma, respiratory tract infections and mental health disorders.
- ***Availability*:** the products are available in standard formulations and are widely used in many countries.
- ***Importance*:** the majority of the products are included in the *WHO Model List of Essential Medicines*.
- ***Patent status*:** they represent both medicines that are new (and hence probably still patent protected in some countries) and older medicines. In some instances, both new

and older products for the treatment of the same condition have been included. In this case the availability of generic versions of the newer patented medicines is not considered.

The medicines that are included in the surveys must be registered in the country where the survey is undertaken. The only known exception to have been made was in Fiji, where, at the time of survey, there was no operational medicine registration system in place. In order to assure the quality of the medicines included in the Fiji survey, only those medicines listed in the *British Pharmacopoeia* (BP) or the *United States Pharmacopeia* (USP) were included.

In addition to surveying the prices of core list medicines, up to 20 additional supplementary medicines that are commonly used in the treatment of important national health problems can be added. The supplementary list could also include medicines that are pharmaceutically equivalent to ones on the core list but that are more frequently used in the area surveyed, such as a different ACE inhibitor, antidiabetic or antacid medicine, or medicines on the core list, but that are more frequently used in a different strength or dosage form in the country surveyed.

Table 3.1: Core list of survey medicines, World Health Organization / Health Action International medicine prices methodology

Medicine category	Generic name	Dose	Dosage form
Antacid	*omeprazole*	*20 mg*	*tablet/capsule*
	ranitidine	*150 mg*	*tablet/capsule*
Antiasthmatic	*beclometasone*	*50 mcg/dose*	*inhaler*
	salbutamol	*0.1 mg/dose*	*inhaler*
Antibacterial	*amoxicillin*	*250 mg*	*tablet/capsule*
	ceftriaxone	*1 g*	*powder for injection*
	ciprofloxacin	*500 mg*	*tablet*
	co-trimoxazole	*8 + 40 mg/ml*	*paediatric suspension*
Antidepressant	*amitriptyline*	*25 mg*	*tablet/capsule*
	fluoxetine	*20 mg*	*tablet/capsule*
Antidiabetic	*glibenclamide*	*5 mg*	*tablet/capsule*
	metformin	*500 mg*	*tablet/capsule*
Antiepileptic	*carbamazepine*	*200 mg*	*tablet/capsule*
	phenytoin	*100 mg*	*tablet/capsule*
Antifungal	*fluconazole*	*200 mg*	*tablet/capsule*
Antihypertensive	*atenolol*	*50 mg*	*tablet/capsule*
	captopril	*25 mg*	*tablet/capsule*
	hydrochlorothiazide	*25 mg*	*tablet/capsule*
	losartan	*50 mg*	*tablet/capsule*
	nifedipine retard	*20 mg*	*retard tablet*
Anti-inflammatory	*diclofenac*	*25 mg*	*tablet/capsule*
Antimalarial	*artesunate*	*100 mg*	*tablet/capsule*
	pyrimethamine with sulfadoxine	*500+25 mg*	*tablet/capsule*
Antipsychotic	*fluphenazine decanoate*	*25 mg/ml*	*injection*
Antiviral	*aciclovir*	*200 mg*	*tablet/capsule*
	indinavir	*400 mg*	*tablet/capsule*
	nevirapine	*200 mg*	*tablet/capsule*
	zidovudine	*100 mg*	*tablet/capsule*
Anxiolytic	*diazepam*	*5 mg*	*tablet/capsule*
Serum lipid reducing	*lovastatin*	*20 mg*	*tablet/capsule*

3.3 International reference prices (IRP) and median price ratios

Reference prices are used to facilitate national and international comparisons. Summary measures of the medicine prices noted during the survey are expressed as ratios relative to a standard set of reference prices. The reference prices from the Management Sciences for Health (MSH) International Drug Price Indicator Guide[18] have been selected as the most useful standard, because they are recognized internationally and updated annually. These IRPs are the medians of recent procurement prices offered by international suppliers to developing countries for multisource generically equivalent products. These prices are available on the Internet at **http://erc.msh.org**.

MPRs are calculated by dividing the median price of each medicine in the survey by the IRP. The ratio indicates how many times more or less the MPR is than the IRP, a method that permits easy international comparison of surveyed price information. The reason for using median rather than mean values is that the price ranges observed often showed peak values for prices that were very high, and that distorted the price information if mean values were used. A median value is the middle value of a set of numerically ordered values, or the average of the middle two in the case of an even number of values.

The workbook for data entry automatically generates summary tables, which compare the median prices from the survey with IRPs.

3.4 Sectors

The survey measures medicine prices at central public procurement level, as well as prices to patients in three sectors: public, private and "other".

Procurement prices are the prices that the government and other purchasers pay to procure medicines, generally through a tendering process. Data on tenders or orders tend to be collected at central stores or facility level. In a few situations the procurement prices included local taxes and handling charges.

Public sector prices are those prices patients must pay in government, municipality or other local authority health facilities, including clinics and hospitals, health centres and pharmacies, irrespective of whether these will be reimbursed or not. These are not the prices patients would pay in co-payment schemes. In countries where medicines are provided free in public facilities, most surveys have only examined the availability of the target medicines in the public sector.

Private sector prices are those prices patients pay in retail pharmacies and pharmacies in private clinics and hospitals. Health facilities operated by private companies (i.e. mining companies) have been excluded from the analysis.

Other sector prices are those prices paid by the patients for medicines in "other" health facilities as defined according to local circumstances, for instance health facilities run by NGOs including religious organizations, such as church missions, charitable organizations, relief or development agencies, dispensing doctors, as in Malaysia, or other non-pharmacy private medicine outlets that stock a reasonable range of products.

3.5 Availability

Availability was noted in all facilities surveyed, and expressed as the percentage of facilities in which the medicine concerned was available at the time of survey.

3.6 Affordability

One of the best ways of illustrating the impact of medicine prices on the cost of health care for individual patients and society is to compare the cost of treatment with people's actual incomes. For the WHO/HAI survey, the daily wage of the lowest paid unskilled government worker in each country is used for comparison, and affordability is expressed as the number of days the lowest paid unskilled government worker would have to work in order to afford the cost of 30 days of treatment for the chronic condition being analysed.

3.7 Price comparisons

Comparisons of medicine prices with those in other countries can provide powerful tools for advocacy and help to identify possible policy changes and lines of action to reduce high prices. The web site database containing price data collected using the WHO/HAI methodology can be used for comparisons of prices and price composition of a medicine between and within countries.

3.8 Analysis

After analysis of the data with the software available in the electronic workbook, the manual describes methods for generating data charts and tables of the various aspects of the results, with the aim of making the information generated accessible. Reports are written by the survey teams at country level, and both reports and data are made available on the HAI web site. A number of reports are posted on the web site (**www.haiweg.org/medicineprices**).

4. Secondary analysis methods

The secondary analysis of the survey data as developed for this report utilizes the data collected in surveys at the national level using the WHO/HAI methodology.

4.1 Data sources

The survey data available on the HAI web site, together with the completed and verified workbooks, have been used to collate data for secondary analysis. For each of the medicines included, the data on the price ratios obtained from surveys that were conducted in different years have all been adjusted to the MSH reference prices of 2003.

4.2 Disease selection

The chronic diseases identified are basically defined by the medicine data available on the core list. Only those medicines that tend to be prescribed for long periods of time for the treatment of chronic diseases such as asthma, diabetes, epilepsy, hypertension and psychiatric disorders are chosen.

4.3 Medicine selection

The medicines that are included in the secondary analysis are represented both as originator and generic equivalent medicines. A full list of the medicines included in the secondary analysis can be found in Table 4.1. Lovastatin, for reducing serum lipid concentrations, has not been included since very few data were available.

In the surveys, the identification of the originator brand is done centrally rather than at each facility. For each medicine, the originator brand product and the name of the manufacturer, are listed in the WHO/HAI survey manual. However, the trade name of the product may vary across countries and in some cases the licence to manufacture the product is transferred to another company so the manufacturer's name can also vary. The generic medicines are the "lowest price generic equivalent" of that medicine identified at the facility.

The name of the originator brand product surveyed, and the manufacturer's name, are listed in a table on the CD-ROM that accompanies this report. At the time of printing most survey managers were able to provide this information. The lowest priced generics are not listed as there can be as many as the number of facilities surveyed.

Table 4.1: Chronic disease medicines selected

Medicine category	Generic name	Dose	Dosage form
Asthma	*beclometasone*	*50 mcg/dose*	*inhaler, 200 doses*
	salbutamol	*0.1 mg/dose*	*inhaler, 200 doses*
Diabetes	*glibenclamide*	*5 mg*	*tablet/capsule*
	metformin	*500 mg*	*tablet/capsule*
Epilepsy	*carbamazepine*	*200 mg*	*tablet/capsule*
	phenytoin	*100 mg*	*tablet/capsule*
Hypertension	*atenolol*	*50 mg*	*tablet/capsule*
	captopril	*25 mg*	*tablet/capsule*
	hydrochlorothiazide	*25 mg*	*tablet/capsule*
	losartan	*50 mg*	*tablet/capsule*
	nifedipine retard	*20 mg*	*retard tablet*
Psychiatric disorders	*amitriptyline*	*25 mg*	*tablet/capsule*
	fluoxetine	*20 mg*	*tablet/capsule*
	fluphenazine decanoate	*25 mg/ml*	*injection*

4.4 Countries

The surveys included in the secondary analysis are those for which at the time of analysis (October–November 2005) complete and verified workbooks were available. These surveys were in the following countries or provinces: Armenia; Brazil, Rio de Janeiro state; Cameroon; Chad; China, Shandong Province; Fiji; Ghana; India, Chennai; India, Haryana; India, Karnataka; India, Maharashtra (12 districts); India, Maharashtra, (4 regions); India, Rajasthan; India, West Bengal; Indonesia; Jordan; Kazakhstan; Kenya; Kuwait; Lebanon; Malaysia; Mali; Mongolia; Morocco; Peru; Philippines; South Africa, KwaZulu-Natal Province; Sri Lanka; Tajikistan and Uganda. It should be noted that two surveys were undertaken in Maharashtra, India – one over 12 districts, and one over 4 regions. A complete list of the countries, the year the survey was done and their WHO Region can be found in Table 4.2.

In many countries, patients do not pay for their medicines in the public sector facilities. For such countries only availability data in the public sector is reported. The countries in which this is the case are the surveyed states in India, and Kuwait, Lebanon, Malaysia, Morocco and Uganda.

Table 4.2: Countries/surveys included in secondary analysis

WHO region*	Country/Region	Year of survey
AF	Cameroon	2002
AF	Chad	2004
AF	Ghana	2002
AF	Kenya	2001
AF	Mali	2004
AF	South Africa/KwaZulu-Natal	2001
AF	Uganda	2004
AM/PAHO	Brazil/ Rio de Janeiro State	2001
AM/PAHO	Peru	2002
EM	Jordan	2004
EM	Kuwait	2004
EM	Lebanon	2004
EM	Morocco	2004
EU	Armenia	2001
EU	Kazakhstan	2004
EU	Tajikistan	2005
SEA	India/Chennai	2004
SEA	India/Haryana	2004
SEA	India/Karnataka	2004
SEA	India/Maharashtra (12 districts)	2004
SEA	India/Maharashtra (4 regions)	2005
SEA	India/Rajasthan	2003
SEA	India/West Bengal	2004
SEA	Indonesia	2004
SEA	Sri Lanka	2001
WP	China/Shandong Province	2004
WP	Fiji	2004
WP	Malaysia	2004
WP	Mongolia	2004
WP	Philippines	2002

* AF, WHO African Region; AM/PAHO, WHO Region of the Americas/Pan American Health Organization; EM, WHO Eastern Mediterranean Region; EU, WHO European Region; SEA, WHO South-East Asia Region; WP, WHO Western Pacific Region.

4.5 Sectors

The sectors included in the secondary analysis are government procurement, private and public facilities. The "other" sector data were generally few, and therefore have not been included.

4.6 Inclusion/exclusion criteria

Median Price Ratios: Public sector procurement data was obtained from a variety of sources depending on the method of procurement. These included the Ministry of Health, central and/or regional stores, wholesalers (tender prices), or public sector facilities. In general, all procurement data were included in the analysis except where data were obtained from public sector facilities. In this case, prices were generally only included in the analysis if a minimum of four were collected.

Note: for the India surveys, public sector procurement prices are those paid by the public sector facilities. In some states these prices included taxes and/or handling charges.

For inclusion in the analysis, the minimum number of public sector patient prices was four for all surveys except Kazakhstan where only one public sector facility was surveyed. The minimum number of private pharmacy patient prices for inclusion in the analysis was 4 for all surveys.

See Table 4.3 for the number of facilities surveyed per sector for each of the 30 surveys, and the minimum number of public sector procurement prices for inclusion in the analysis.

Table 4.3: Survey sampling and the minimum number of public sector procurement prices in the analysis.

Surveys	Public sector procurement prices		Public sector patient prices	Private sector patient prices
	Number of orders or facilities	Minimum number of prices in analysis	Number of public facilities surveyed	Number of private pharmacies surveyed
Armenia	not surveyed		not surveyed	40
Brazil/Rio de Janeiro State	9	1	not surveyed	20
Cameroon	not surveyed		13	9
Chad	1	1	24	11
China/Shandong Province	7	1	20	20
Fiji	1	1	not surveyed	36
Ghana	not surveyed		19	33
India/Chennai	20	4	20 (availability only)	40
India/Haryana	30	4	30 (availability only)	30
India/Karnataka	24	4	24 (availability only)	40
India/Maharashtra (12 districts)	60	4	60 (availability only)	60
India/Maharashtra (4 regions)	20	4	20 (availability only)	48
India/Rajasthan	20	1	20 (availability only)	20
India/West Bengal	26	4	26 (availability only)	35
Indonesia	16	4	15	58
Jordan	1	1	18	20
Kazakhstan	2	1	1	20
Kenya	3	1	not surveyed	26
Kuwait	1	1	25 (availability only)	25
Lebanon	2	1	20 (availability only)	40
Malaysia	20	4	20 (availability only)	32
Mali	1	1	21	20
Mongolia	8	1	4	25
Morocco	2	1	20 (availability only)	20
Peru	not surveyed		26	43
Philippines	not surveyed		25	77
South Africa/KwaZulu-Natal	1	1	not surveyed	20
Sri Lanka	not surveyed		not surveyed	43
Tajikistan	not surveyed		20	20
Uganda	2	1	20 (availability only)	20

4.7 Adjusting price information for secondary analysis methods

The price data as collected in the original survey were represented as MPRs. The MPR, calculated at the time of the survey, is the ratio of median prices to the IRP at that time. In the secondary analysis presented in this report, in order to enable the comparison of MPR values calculated at different times in the various surveys, the MPR has been adjusted to a single reference point, the IRP of 2003. The 2003 reference prices for the medicines included in the report are shown in Table 4.4, together with the changes in percentages in the years before and after 2003. The average percentage changes versus the 2003 IRP are also indicated in Table 4.4. The base year of 2003 was chosen because this was the reference year most frequently used in the different surveys.

Table 4.4: Fluctuations in percentages and international reference prices (IRPs) for 2003

	2001 per cent fluctuation versus 2003	2002 per cent fluctuation versus 2003	2003 IRP* (US$)	2004 per cent fluctuation versus 2003
amitriptyline	25.00	–7.89	0.0076	–21.05
atenolol	22.58	–11.83	0.0093	–6.45
beclometasone	–13.61	–3.55	0.0169	0.00
captopril	–11.74	0.00	0.0264	–14.02
carbamazepine	20.60	–3.02	0.0199	2.51
fluoxetine	16.61	–6.44	0.0295	–16.61
fluphenazine	28.07	–22.07	0.4866	36.09
glibenclamide	19.51	19.51	0.0041	4.88
hydrochlorothiazide	25.71	–2.86	0.0035	–31.43
losartan	–6.17	6.17	0.9449	–0.92
metformin	34.27	–4.49	0.0178	–8.99
nifedipine	1.39	10.65	0.0216	–14.81
phenytoin	18.31	–1.41	0.0071	–19.72
salbutamol	37.11	–12.37	0.0097	5.15
Average fluctuation	**15.55**	**–2.83**		**–6.10**

* ***Source:*** MSH International Drug Price Indicator Guide (2000–2005).

The data were collected on master sheets, which formed the basis for the adjustment calculation, and eventually provided the adjusted MPR data, as well as availability and affordability data, for producing the tables and charts for each of the individual medicines (see accompanying CD-ROM).

4.8 Affordability of treatment and combination therapy

A number of combined treatments have been studied. The affordability of the treatment with an individual or a combination of medicines for patients with asthma, depression, epilepsy, type 2 diabetes and hypertension was calculated.

Table 4.5: Treatment schedules for calculation of affordability

Medicine	Strength	Dosage form	Treatment schedule
amitriptyline	25 mg	cap/tab	1 tab 3 times / day / 30 days
atenolol	50 mg	cap/tab	1 tab / day / 30 days
beclometasone	0.05 mg/dose	inhaler	200 doses / 30 days
captopril	25 mg	cap/tab	2 tab / day / 30 days
carbamazepine	200 mg	cap/tab	1 tab 2 times / day / 30 days
fluoxetine	20 mg	cap/tab	2 tabs / day / 30 days
fluphenazine	25 mg/ml	injection	1 injection / 30 days
glibenclamide	5 mg	cap/tab	1 tab 2 times / day / 30 days
hydrochlorothiazide	25 mg	cap/tab	1 tab / day / 30 days
losartan	50 mg	cap/tab	1 tab / day / 30 days
metformin	500 mg	cap/tab	1 tab / day / 30 days
nifedipine retard	20 mg	retard tab	1 tab / day / 30 days
phenytoin	100 mg	cap/tab	1 tab 3 times / day / 30 days
salbutamol	0.1 mg/dose	inhaler	200 doses / 30 days

5. Results

5.1 General overview

For each of the disease categories, summary results for price (MPR), availability (percentage of facilities with stock of the required medicines on the day survey data were collected) and affordability (in terms of number of days' wages for the lowest paid unskilled government worker) for each of the medicines are presented. Selected tables or charts are included where appropriate. Readers are encouraged to review the complete set of summary datasets included in the CD-ROM that accompanies this report.

Some of the values presented below (e.g. ranges and medians) refer to inter-country data whereas others, such as MPRs and number of days worked to afford a treatment, are specific to a national or state survey.

In order to enable discussion, we have used the following cut-off points of MPRs to represent acceptable local price ratios:

- public sector – procurement price: MPR ≤ 1
- public sector – patient price: MPR ≤ 1.5
- private retail pharmacy – patient price: MPR ≤ 2.5

We consider MPRs above these values to represent excessive local prices.

The following ranges have been used for describing availability:

- < 30% very low
- 30–49% low
- 50–80% fairly high
- >80% high

Low availability should not be overemphasized because countries may have other strengths or dosage forms of the particular medicine available.

Note: to assist readability, all surveys are referred to in this section as "country surveys". As shown in Table 4.2 some surveys were undertaken at the state level (e.g. the surveys in India) rather than nationally.

5.2 Asthma: beclometasone and salbutamol

5.2.1 Prices

***Private sector retail pharmacies*:** In the private sector, information on the MPRs of beclometasone inhalers was available for 21 countries. The originator medicine showed a wider price range (1.08–5.59) than did the generic medicines (0.87–2.62). Some surveys in India (Karnataka, both surveys in Maharashtra and Rajasthan) had only data on generic products available. The surveys in Fiji, India/Chennai, Jordan, Lebanon, Malaysia, South Africa and Sri Lanka had MPR data available on both originator and generic beclometasone.

Private sector data on MPRs for salbutamol inhalers showed a wider range for the originator medicine (0.86–6.89) as well as for the generic medicines (0.30–3.25) than beclometasone. Data on MPRs for salbutamol in the private sector were available for 29 out of 30 countries. Twenty-three of the 30 countries had data on MPR for both originator and generic medicines. Apart from the survey in Kazakhstan and all those in India, where the MPRs for the originator and generic products were only slightly different, all MPR values in other surveys (Armenia, China, Fiji, Ghana, Jordan, Kenya, Lebanon, Malaysia, Mali, Morocco, Peru, Philippines, South Africa, Sri Lanka and Uganda) indicated that a brand premium was being levied.

***Public sector facilities*:** Because medicines are provided free in the public sector in most of the countries that included either beclometasone or salbutamol in their surveys, too few data on prices of either of these medicines in the public sector were available for analysis.

***Public sector procurement prices*:** The public procurement data presented a slightly different picture for beclometasone: only 10 out of 30 countries had data available on either originator or generic products, and the price ranges were rather narrow (originator1.25–2.34; generic 0.23–1.71). The survey data from China showed that the MPR for generic products was actually higher than that for the originator product (generic 1.71; originator 1.25). For Morocco, the only other survey with data available on both originator and generic products, the reverse was the case, indicating a brand premium (originator 2.34; generic 0.73).

MPR data on salbutamol were available for 15 of 30 countries. The surveys in Kenya and Morocco had data on both the originator brand and generic products. Again, Morocco had a higher MPR for the originator product (originator 2.33; generic 1.55). In Kenya the opposite was true (originator 0.84; generic 1.44). The range of MPRs for generic products (0.44–2.48) was wider than that for originator brands (0.84–2.33).

5.2.2 Availability

***Private sector retail pharmacies*:** No country had 100% availability for beclometasone and there were only five countries in which availability of both the originator brand and generic products was over 30% (Jordan: originator 75%, generics 35%; Lebanon: originator 85%, generics 98%; India/Chennai: originator 55%, generics 90%; South Africa: originator 80%, generics 90%; Sri Lanka: originator 74%, generics 40%). In seven countries no generic beclometasone was found in the pharmacies surveyed and a further 12 countries had availability of generic beclometasone of less than 30%.

The data indicated that the availability of salbutamol in private retail pharmacies was generally fairly high, with median values of 64% for the originator product and 78% for generics. Neither originator nor generic products were available in Cameroon. In two other countries (Chad and Indonesia), no generic products were available and the availability of the originator brand was 73% and 57%, respectively.

***Public sector facilities*:** The range of availability of the originator brand of beclometasone was narrow (0%–30%) compared to that of the generics (0%–92%). Over the 27 surveys, the availability of beclometasone in public sector facilities was extremely poor (median: originator 0%; generic 0%).

The availability of salbutamol in public sector facilities was very low – the median values were 0% for the originator brand product and 5% for the generics. Neither African countries nor Indian states had good availability for salbutamol in this sector. Five countries (of 30) had both originator brand and generic salbutamol available: namely, China, Ghana, Morocco, Peru and Tajikistan. A further 10 countries had either originator or generic salbutamol available: Chad, Jordan, Lebanon, Kuwait, India/Maharashtra (4 regions), India/Rajasthan, Indonesia, Malaysia, Mongolia and the Philippines. The availability of generic medicines was high (> 80%) in three countries (Tajikistan 85%, Morocco 95% and Mongolia 100%).

5.2.3 Affordability

***Private sector retail pharmacies*:** The affordability of beclometasone ranged from 1.0–9.6 days for one month's treatment (one inhaler, 200 doses) for the originator and 0.5–5.3 days for the generic products. The originator data indicated a high median (3.3 days). Cameroon (originator 8.9 days) and Kenya (9.6 days) showed particularly high values, thus very poor affordability. The affordability of generic beclometasone was very poor in Armenia (5.3 days) and in Sri Lanka (2.8 days). The affordability was also poor in Jordan, Kazakhstan, both surveys in Maharashtra and Malaysia (range 1.6–1.9 days).

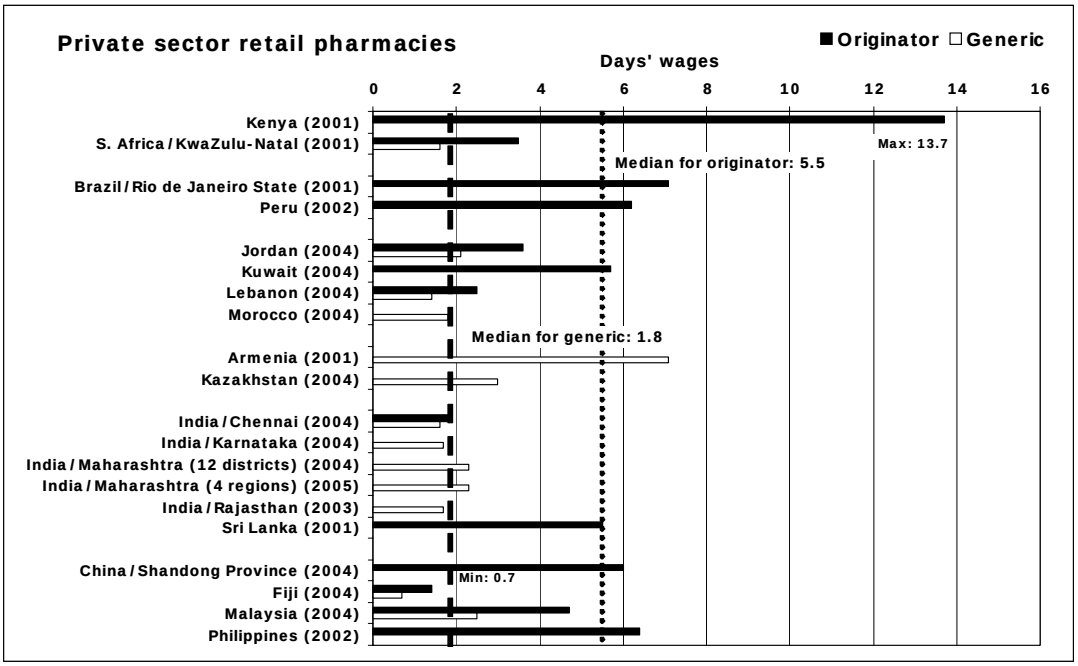
The affordability of one month of treatment with salbutamol (one inhaler, 200 doses) varied greatly, both for originator and generic medicines (originator 0.4–5.8 days; generic 0.2–15 days); however, the median values of the data ranges were relatively low (originator 1.2 days; generic 0.7 days). Some of the African countries showed very poor affordability: Ghana (originator 5.8 days; generics 3.5 days), Uganda (originator 5.6 days; generics 2 days), Chad (originator 4.1 days), Kenya (originator 4.1 days; generic 2.2 days) and Mali (originator 4.2 days; generics 2.7 days).

***Public sector facilities*:** Too few data were available for any conclusions to be drawn. The poor affordability of salbutamol inhalers in Tajikistan (15.0 days for generic products in both the private and the public sector) can be explained by the very low salary of the lowest paid unskilled government worker, which is the reference used for the calculations of affordability.

5.2.4 Affordability of treatment with combination of beclometasone and salbutamol

By combining the affordability data for beclometasone and salbutamol, a theoretical treatment schedule of one inhaler of each per month for an asthma patient is calculated in terms of affordability in number of days' salary for the lowest paid unskilled government worker in the countries surveyed. The "average" patient would use beclometasone three times daily taking two puffs (i.e. 100 micrograms), and salbutamol when required. The assumption is made that the salbutamol inhaler will be finished within one month. Results show a wide range of affordability for both originator and generic medicines (originator 1.4–13.7 days; generic 0.7–7.1 days), and a particularly high median value for the originator medicine (originator 5.5; generic 1.8). These high combined values, as shown in Figure 5.1, show that in many countries asthma patients will not be able to afford treatment considering the additional constraint that availability in the public sector tends to be very low to low. These findings confirm those of Aït-Khaled et al. from a study undertaken in some developing countries in 1998.[19] Their conclusion was that the cost and availability of asthma medications vary widely and may represent an important barrier to effective management of this disease in low- and middle-income countries.

Figure 5.1: Affordability of asthma treatment in private retail pharmacies
Affordability of beclometasone inhaler 50 mcg/dose (200 doses or 1 inhaler per month) + salbutamol inhaler 0.1 mg/dose (200 doses or 1 inhaler per month)



5.3 Diabetes: glibenclamide and metformin

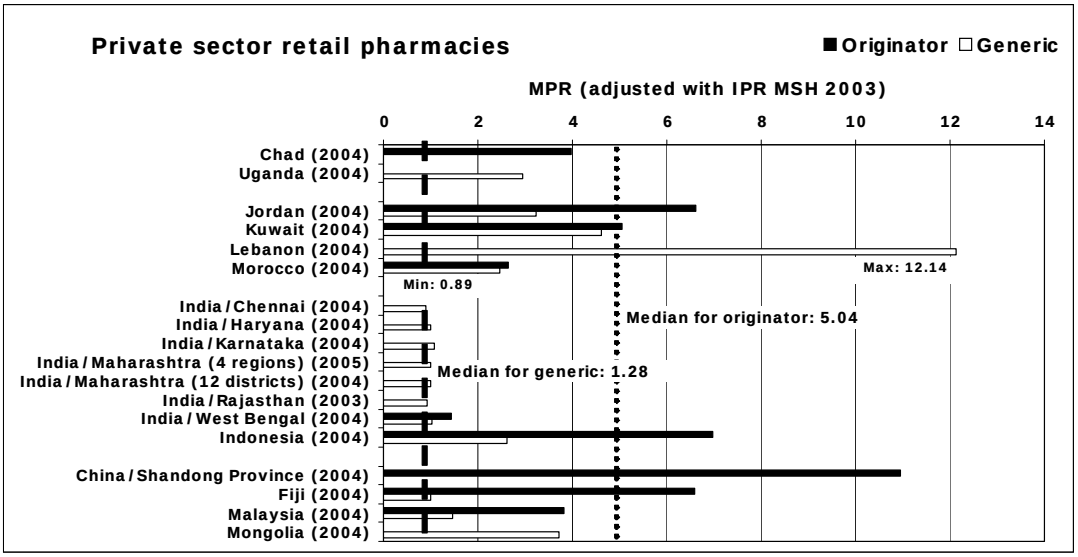
5.3.1 Prices

***Private sector retail pharmacies*:** The median of the MPRs of glibenclamide was very high in private pharmacies (generic 6.06; originator 32.09). The fact that the median value of MPR for

generic products in private retail pharmacies is much higher than the procurement price for public facilities (median 0.82) may indicate large profit margins in the private sector. MPR data from Ghana suggest a large brand premium (originator 32.09; generic 6.41), as do those for Jordan (originator 38.87; generic 18.45), Lebanon (originator 34.97; generic 7.16), Morocco (originator 39.71; generic 16.66), Indonesia (originator 79.45 generic 5.74), Fiji (originator 17.18; generic 2.86) and Malaysia (originator 35.12; generic 6.38). In Kuwait, the MPR for the generic was similar to the MPR for the originator (originator 66.27, generic 60.66).

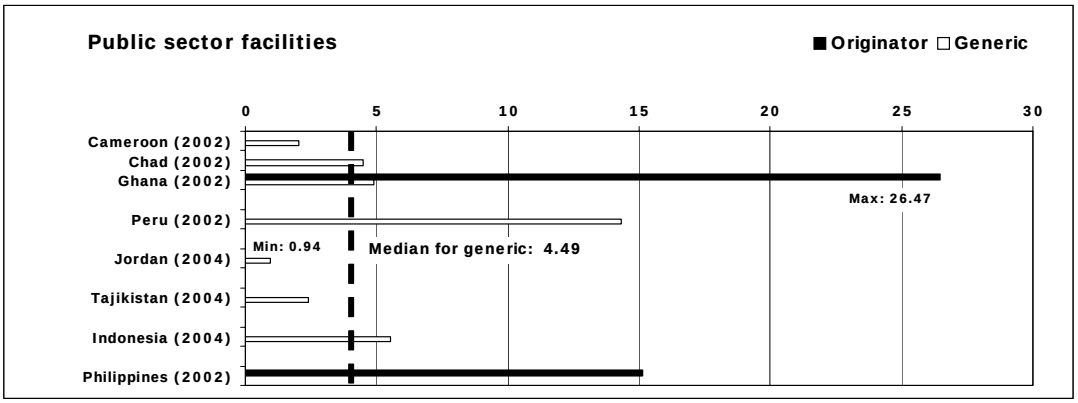
The MPR of generic products of metformin was reasonable in the Indian states (MPR ranges 0.89–1.08). In Lebanon, however, the price of generic products was 12 times higher than the IRP. The price of generic metformin was also high in Indonesia, Jordan, Kuwait, Mongolia, and Uganda, as shown in Figure 5.2.

Figure 5.2: Median price ratios (MPRs) of metformin 500 mg tablets



***Public sector facilities*:** Because medicines are provided free in many countries, and data on the price in the public sector are available for only a few countries, few conclusions can be drawn. From the data available, the median price of generic glibenclamide in the public sector (MPR 4.49) was slightly lower than that in the private sector (6.06), but much higher than the international reference. Originator products were very expensive in public facilities in Ghana (26.47) and in the Philippines (15.12).

Figure 5.3: Median price ratios (MPRs), glibenclamide 5 mg tablets



Data on prices to patients for metformin in the public sector are available only from Indonesia. The values are only slightly lower than those in the private sector (public originator 6.15, generic 2.54; private originator 6.97, generic 2.62).

Public procurement: The MPR of generic glibenclamide for public procurement varies (0.27–5.15) with a median of 0.82. The MPR is especially low in China, Fiji, Malaysia and most Indian states. In Mongolia, Kuwait, India/Rajasthan, Indonesia and Kazakhstan the MPRs are high (5.15, 4.96, 3.82, 4.56 and 3.85, respectively).

Across the 13 countries for which procurement data for the public sector are available, the median MPR of generic metformin is 0.46 but the range is wide (0.17–8.23). In China, the public procurement price is much higher than the IRP (8.23 for generic and 9.61 for originator product). In Mongolia, the MPR for the generic products was also high (2.93).

5.3.2 Availability

***Private sector retail pharmacies*:** Generic glibenclamide products are generally less available than originator products in private pharmacies (median originator 83%; generics 67%). The availability of generic products is higher than that of originator products in only 11 of 25 countries (Fiji, Ghana, Jordan, Kazakhstan, India/Chennai, China, Indonesia, Mongolia, Peru, Tajikistan and Uganda). No generics were found in Cameroon and Chad but there was 100% availability in Morocco and India/Chennai. Availability was extremely low in China for both the originator brand (0%) and generic products (5%).

Median availability of metformin was 82% for generic and 8% for originator medicines. In Chad and China, generic products were not available in private pharmacies. Availability of generics was less than 30% in Chad, China, Kuwait, Kazakhstan, Tajikistan and Mongolia, whereas in Fiji, India/Chennai and India/Rajasthan, availability of generic products was 100%.

***Public sector facilities*:** There was great variation in the availability of glibenclamide in the public sector, particularly of generic products, but in general the availability was very low (median originator 0%; generic 42%). Only three countries (India/Karnataka, Malaysia and Morocco) achieved 100% availability of generics in their public facilities. In China, Chad, India/Rajasthan, India/Maharashtra (12 districts), India/West Bengal, Lebanon, Mali,

Philippines and Uganda, the availability of the generic products was very low (less than 30%). The availability of the originator brand was 0% in all 23 countries for which data were available except Ghana (21%), Indonesia (20%), Kuwait (4%) and the Philippines (45%).

The availability of metformin in the public sector was extremely low in many countries (median originator 0%; generic 16%). The medicine was not available at all (neither generic nor originator brand) in public facilities in Chad, Jordan, Lebanon, Tajikistan, India/Maharashtra (12 districts) and India/West Bengal.

Table 5.1: Percentage availability of metformin 500 mg tablets public and private sectors

Countries by WHO Region	Availability (in %)*			
	Private		Public	
	Originator	Generic	Originator	Generic
Chad (2004)	36%	0%	0%	0%
Uganda (2004)	0%	85%	0%	25%
Jordan (2004)	90%	80%	0%	0%
Kuwait (2004)	72%	28%	52%	36%
Lebanon (2004)	0%	83%	0%	0%
Morocco (2004)	100%	45%	25%	5%
Kazakhstan (2004)	10%	15%		
Tajikistan (2005)	0%	5%	0%	0%
India/Chennai (2004)	0%	100%	0%	100%
India/Haryana (2004)	0%	63%	0%	10%
India/Karnataka (2004)	3%	90%	0%	83%
India/Maharashtra (4 regions) (2005)	2%	85%	0%	21%
India/Maharashtra (12 districts) (2004)	5%	88%	0%	0%
India/Rajasthan (2003)	0%	100%	0%	40%
India/West Bengal (2004)	11%	97%	0%	0%
Indonesia (2004)	71%	50%	33%	47%
China/Shandong Province (2004)	20%	0%	15%	10%
Fiji (2004)	75%	100%		
Malaysia (2004)	84%	88%	0%	90%
Mongolia (2004)	0%	20%	0%	50%
Min	**0%**	**0%**	**0%**	**0%**
Max	**100%**	**100%**	**52%**	**100%**
Median	**8%**	**82%**	**0%**	**16%**

* In percentage of surveyed facilities with medicine available versus total number of facilities surveyed.
0% Indicates that the drug was not available at any survey points.
Italics For MSGs (Most Sold Generics) if no LPG (Lowest Price Generic) available.

5.3.3 Affordability

***Private sector retail pharmacies*:** For glibenclamide, affordability of the originator brand is extremely poor in all African countries and Indonesia (range 7.5–8.3 days' wages for one month of treatment). In Indian states affordability values for both originator and generic products were reasonable (range 0.2–0.4 days' wages); thus affordability was good. In Fiji, Kazakhstan, Lebanon and Malaysia, the affordability of the generic products was also less than 0.4 days' wages, but in some of the other countries the affordability of the generics was poor especially in Kuwait, Mali, Peru, the Philippines and Tajikistan.

The median affordability value of generic metformin was slightly higher than that of glibenclamide (0.6 versus 0.5 days). The generic product was more affordable in Fiji, the Indian states, Malaysia and Morocco (0.1–0.6 days' wages) than in other countries. In China, the cost of treatment was 10.8 days' wages for the originator – outstandingly high. In Uganda, Mongolia and Lebanon it requires 3.6, 3.1 and 2.9 days wages, respectively to purchase a month of treatment with generic metformin from private retail pharmacies.

***Public sector facilities*:** Data on affordability in the public sector are limited, because medicines are provided free in this sector in many countries. For glibenclamide, median affordability for generic products was 0.7 days' wages. In Tajikistan generic glibenclamide was not affordable in the public sector (4.5 days' wages).

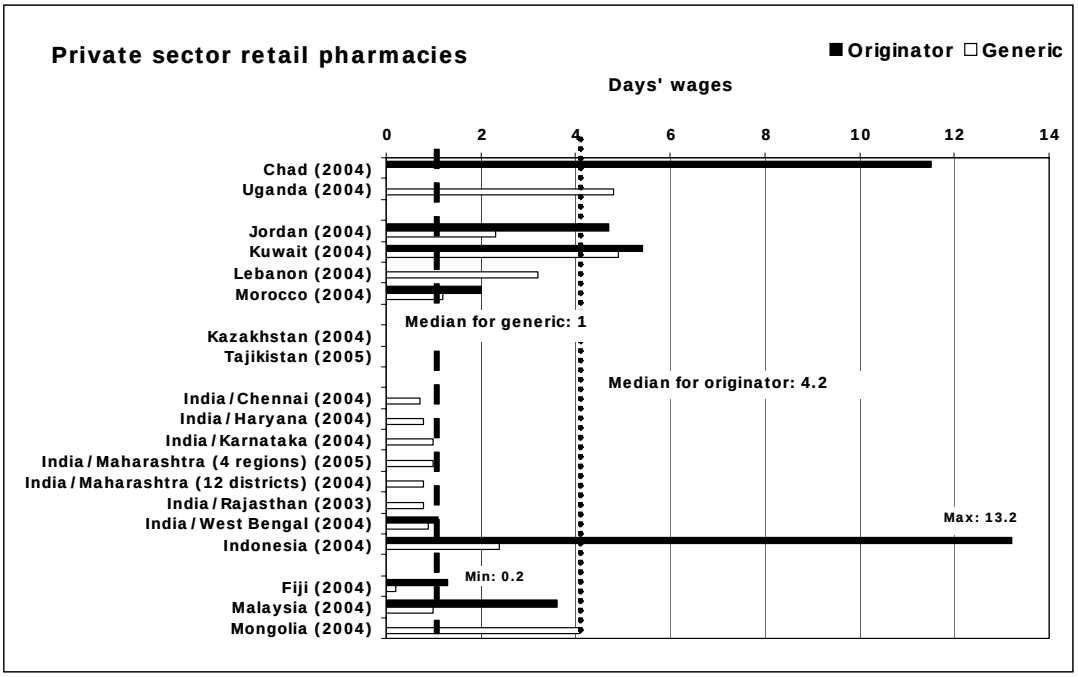
For the affordability of metformin in the public sector, the only data available were from Indonesia where affordability values were slightly lower than in the private sector (private originator 4.8, public originator 4.2; private generic 1.8, public generic 1.7).

5.3.4 Affordability of treatment with combination of glibenclamide and metformin

A combination of the two medicines, glibenclamide and metformin, can be used to treat type 2 diabetes. Affordability of the combination therapy has been calculated based on a treatment schedule of glibenclamide, 5 mg twice daily, and metformin, 500 mg three times daily, both for 30 days, and purchased from private retail pharmacies.

There was a large variation in affordability of the combination therapy (range 0.2–13.2 days' wages). In Chad affordability was very poor for the originator combination (11.5 days' wages). Generic products were not available in private pharmacies in Chad. In Indonesia, Jordan, Kuwait, Lebanon, Mongolia and Uganda, combination treatment with generics was not affordable (range 2.3–4.9 days' wages). In contrast, affordability of generic products was acceptable in Fiji, the Indian states and Malaysia, with a combined affordability of one day or less. Data from Indonesia on the affordability of treatment with the combination of medicines indicated a large brand premium (originator 13.2 days' wages; generic 2.4 days) (Figure 5.4).

Figure 5.4: Affordability of diabetes therapy with glibenclamide and metformin for 30 days (glibenclamide, 5 mg tablet twice a day + metformin 500 mg tablet three times a day expressed in days' wages of the lowest paid unskilled government worker to pay for treatment)



5.4 Hypertension: atenolol, captopril, hydrochlorothiazide, losartan and nifedipine retard

The anti-hypertension medicines atenolol (50 mg), captopril (25 mg), hydrochlorothiazide (25 mg), losartan (50 mg) and nifedipine retard (20 mg) were included in the secondary analysis.

5.4.1 Prices

***Private sector retail pharmacies*:** The MPR of atenolol was high for both originator and generic products (median originator 24.99; generic 5.46). Large brand premiums were noted in Fiji, Indonesia, Jordan, Lebanon, Malaysia, Peru, the Philippines and Uganda. MPRs were high for generic atenolol in all countries particularly in Kuwait (44.31), Indonesia (20.44), Jordan (18.39), the Philippines (16.99) and Peru (15.23).

The combined range of MPR values for captopril, was wide (originator and generic combined range 0.15–22.78). Large brand name premiums were noted in Fiji, Indonesia and Sri Lanka. China had the lowest price for generic atenolol (MPR 0.15). In Kuwait the price of the originator brand was slightly lower than that of the generic products (MPR originator 15.25; generics 16.0).

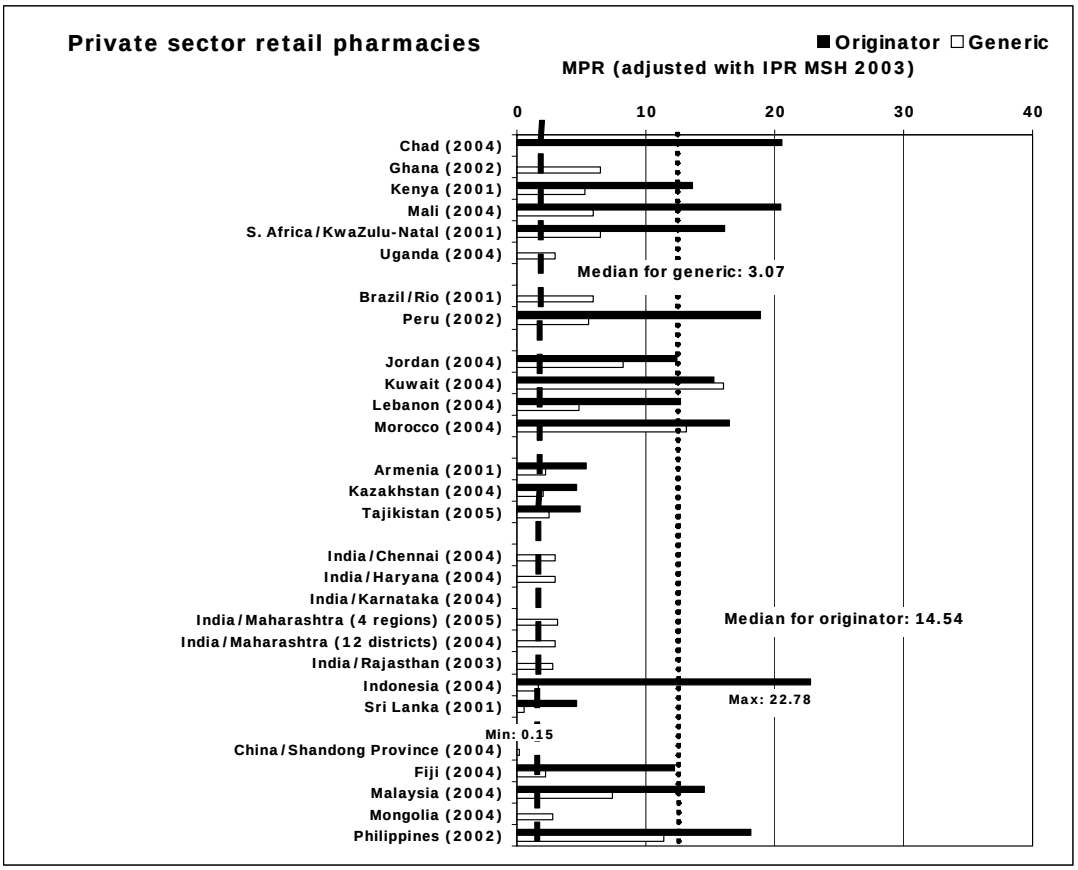
The combined price range is also extremely wide for hydrochlorothiazide (originator and generic combined range 0.52–58.89). In general the MPR is extremely high compared to that of the other anti-hypertensive medicines included in the surveys. Only in China and Indonesia was the MPR for hydrochlorothiazide below 1 for the generic products. In the

other countries, the generic MPRs were very high, ranging from 3.35 to 50.27. The MPR for generic products was extremely high in Peru (50.27), Jordan (49.5), Tajikistan (37.23), South Africa (35.99), Mongolia (30.77) and Lebanon (29.15). Prices were also very high for the originator brands, with MPRs ranging from 22.37 in Chad to 58.89 in Kazakhstan.

Price data on losartan are limited; information was available on the originator brand for only eight countries and on generics for 12 countries. The median values are reasonable (MPR originator 1.35; generic 0.11), as are the combined ranges (range originator and generic combined 0.06–1.57). Losartan was a patented medicine at the time of the survey, and was included to have some patented medicines on the list. It is often used in the private sector.

The MPR range for nifedipine retard is wide for both originator and generic medicines (originator 1.84–31.4; generic 1.21–13.1). A large brand premium was noted in Fiji, Lebanon, Malaysia, Mali and Morocco. No generic price data were available for Kuwait and Indonesia, where originator products were respectively, 29.01 and 23.34 times higher than IRP. The highest MPR values for both originator and generic products were reported in Morocco (originator 31.40; generic 13.10).

Figure 5.5: Median price ratios (MPRs) for captopril 25 mg tablets, private sector retail pharmacies corrected with IPR MSH 2003



***Public sector facilities*:** In general, data for prices in the public sector are limited because of the free provision of medicines in many countries. In Ghana, Indonesia, Mongolia and Tajikistan, the MPR for the generic version of atenolol was lower than that in private retail pharmacies, but still the median is 4.79 and the range 2.33–18.58. The MPR for generic atenolol was very high in Indonesia at 18.58.

The MPRs for generic captopril were lower in the public sector than the private sector in Indonesia, Jordan, Peru and the Philippines, and higher in China and Mongolia. For generic products, the median MPR was slightly lower than in the private sector (public sector median MPR 1.96 versus private sector median MPR 3.07). There was a large brand premium in Indonesia for captopril (originator 21.8; generics 1.69).

The MPR for originator hydrochlorothiazide was not available for any of the countries surveyed. The MPR for generic products in the public sector was lower than that in the private sector in Ghana, Indonesia and Tajikistan, and slightly higher in China. The MPR of generic hydrochlorothiazide in Tajikistan was 33.5.

Only two values were available for losartan; the MPR for the generic product in Indonesia was 0.95 (slightly less than in the private sector) and the MPR for the originator brand in China was 0.98 (slightly higher than in the private sector).

Data on MPR for generic nifedipine retard in the public sector were available only for Jordan (0.33) and China (4.51). In China, the price to patients in the public sector for the generics was slightly higher than that in the private sector (public 4.51; private 4.13).

Public sector procurement prices: The median MPR for atenolol was 0.98. The price in Indian states was low (MPRs ranged from 0.21–0.98). In contrast, in Kazakhstan, Kenya, Kuwait, Lebanon, Mongolia and Uganda, the MPR was more than 2 for generic atenolol. In Mongolia the procurement price for the generic product (4.29) was higher than the price to patients in the public sector (3.93).

For captopril, the median MPR was 1.07. The price for generic versions in Brazil, China, Jordan, Kuwait, South Africa and Uganda was less than 1. On the other hand, the MRP values in Morocco were very high (originator 37.65; generic 12.8), similar to those in the private sector data. Procurement prices in Kenya were also high (originator 12.0; generics 4.17).

Compared to other hypertensive medicines the public procurement MPRs for hydrochlorothiazide were generally high (median 2.74). Similar to the results for the private sector, the MPRs for generic products were low in Indonesia and China (0.57 and 0.43, respectively), but very high in Kazakhstan and Mongolia (25.63 and 24.14, respectively). Data on procurement prices and public sector patient prices were available for generics in only three countries. In Chad the price ratio for patients was 2.63 compared to 1.22 for the procurement price, in Indonesia the two ratios were 0.70 and 0.57 and in China the ratios were 0.77 and 0.43, respectively.

Few data on MPRs were available for losartan (Kazakhstan and China – originator brand, Jordan – generic). All MPRs were low (range 0.13–0.82).

For nifedipine retard, MPR values for generics in Fiji, Jordan, India/Rajasthan and Kazakhstan were less than 1 and those for China and Lebanon were more than 3. The MPR for originator nifedipine retard was available from Kuwait (5.5) and Morocco (19.06) – neither had data for generic nifedipine retard.

5.4.2 Availability

***Private sector retail pharmacies*:** The median availability of atenolol in the private sector was 36% for originator and 81% for generic products. The availability of generic medicines in the Indian states surveyed was high (87–100%), in contrast with nil availability of generics in Cameroon, Kenya and South Africa and only 5% in China.

The median availability for captopril, was 47% for originator and 55% for generic products. In eight of the 29 countries that had captopril on the core list, the availability of the generic products was lower than that of the originator medicine. Five countries had no originator brand available and less than 30% availability of the generic products (Ghana, India/Karnataka, both India/Maharashtra surveys and India/Rajasthan). China, Lebanon and Mongolia had 100% availability of generic captopril in the private retail pharmacies.

Availability of hydrochlorothiazide was generally very low (median originator 0%; generic 41%). In Brazil, Chad, Kuwait, India/Maharashtra (4 regions) and Morocco the generic product was not available. No country surveyed had 100% availability of hydrochlorothiazide (generic or originator).

The data for losartan show that the availability of the originator product was poor (median 8%) although Morocco had 100% availability. Apart from China, Kazakhstan, Lebanon, Malaysia and Morocco, all the other countries surveyed had fairly high availability of generic medicines (50–95%).

The median percentage availability of nifedipine retard was low for the originator brand in comparison with that for the generics (originator 7%; generics 75%). However, in Mali, Morocco and Indonesia, the availability of generics was lower than that of the much more expensive originator brand. In Kuwait no generic products were available, and the originator brand was expensive (MPR 29.01) (Figure 5.6).

***Public sector facilities*:** The availability of atenolol was low (median originator 0%; generic 15%) in the public sector. One hundred per cent availability of the generics was achieved only in India/Chennai, India/Rajasthan and Mongolia. In Cameroon, Kazakhstan and China the medicine was not available, and in India/Karnataka, Lebanon, Malaysia, Peru and Uganda, the availability was 10% or less for both generics and the originator brand product.

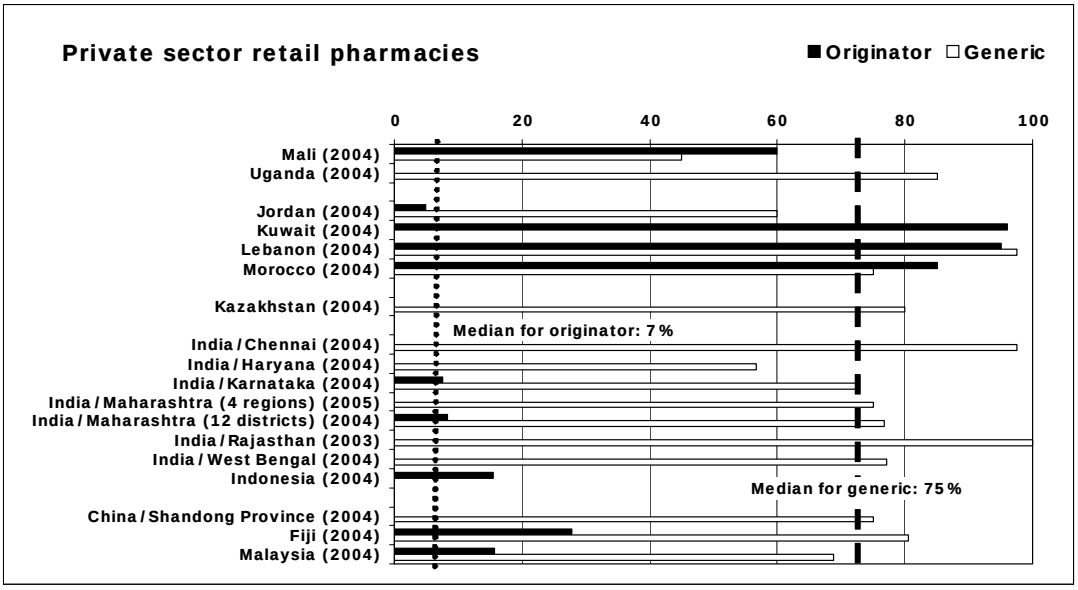
The availability of captopril was extremely low in general (median originator 0%; generic 8%). In 10 out of the 11 countries where medicines are provided free in the public sector, the availability of the generic products in the public system was 20% or less. In Cameroon, Chad, Malaysia, Morocco and the Indian states the generic version was not available at all.

The availability of hydrochlorothiazide was also low in the public sector (median originator 0%; generic 0%). None of the surveyed countries achieved 100% availability for either originator or generic medicines. In Cameroon, India/Chennai, both Maharashtra surveys, India/Rajasthan, India/West Bengal and India/Haryana, Lebanon, Malaysia and Morocco, neither originator nor generic products were available.

The availability of losartan was poor (median originator 0%; generic 0%). In Jordan, Lebanon, Morocco, Uganda and five of the Indian surveys no losartan was available (neither generic nor originator brand). In contrast, there was 90% availability of originator brand losartan in Malaysia.

The availability of nifedipine retard was also extremely low (median for both originator and generic was 0%) in the public sector. In Kuwait and Morocco the availability of the originator brand was high (80% and 75%, respectively) but no generic products were available.

Figure 5.6: Private sector retail pharmacies percentage availability of nifedipine retard 20 mg tablets



5.4.3 Affordability

***Private sector retail pharmacies*:** In the Indian states, atenolol treatment was affordable (median affordability originator 1.35 days and generic 0.85 days). A reason for the poor affordability noted in Tajikistan (5.3 days for generics) may be the low wages, although the MPR for generics was quite high (MPR 2.45). In spite of a very high price for the originator medicine in Peru (MPR 55.18), its affordability (3.8 days) is reasonable if compared with that of Uganda (MPR 78.82; affordability 16.8 days), and Indonesia (MPR 75.07; affordability 9 days). However, treatment with originator brand atenolol was clearly not affordable in Indonesia, Peru or Uganda. All of these countries required more than 1 day's wages to purchase one month's supply of generic atenolol.

For captopril, both originator and generic products showed a wide range in the number of days needed to purchase a month's treatment (originator 1.7–60 days; generic 0.1–30 days). The median values (median originator 5.5 days; generic 2.3 days) were higher than those for other anti-hypertensive medicines. Affordability was poor in all African countries surveyed (e.g. Mali 20.3 days for originator, 5.9 for generics; Kenya 15.5 days for originator, 6 days for generics). Affordability was also very poor in the Philippines (originator 10.3 days; generics 6.4 days) and Tajikistan (originator 60 days; generic 30 days). In Ghana, where only generics were available, captopril was not affordable (9.8 days). Conversely, affordability was acceptable in China (0.1 days).

The range of affordability for generic products of hydrochlorothiazide was wide, when compared with that for the originator brand (range for generics 0.03–30 days; originator 0.6–2.7 days). The affordability of generics was generally reasonable (median 0.5 days), but the originator brand was less affordable (median for originator 1.5 days). In Tajikistan, treatment with hydrochlorothiazide was totally unaffordable (30 days) in the private sector.

Losartan treatment was generally unaffordable. The innovator brand was much more expensive than the generic product (median originator 6.7 days; generic 1.1 days). However, even for the generic products the range was extremely wide (0.6–17.7 days). In Kazakhstan it required 17.7 days' wages to purchase treatment with generics, and in Indonesia 12.1 days. In China, where only data on the originator brand were available, 16.4 days' wages were required to purchase a month's treatment. For nifedipine retard, the affordability in Fiji and the Indian states was reasonable (range for generic products in these countries 0.2–0.4 days). In Indonesia and Kuwait, treatment with the originator was not affordable (6.5 days and 4.2 days, respectively); generic products were not found in these countries.

***Public sector facilities*:** As for the price information, very few data on affordability were available for the public sector.

For atenolol, affordability for generic products was poorer in the public sector than in the private sector (median for generics in the public sector 1.85 days; private sector 0.85 days). Similar to the pattern in the private sector, affordability was poor Tajikistan (5.0 days) and Indonesia (2.2) days.

The median value for affordability of generic captopril products was lower than that in the private sector (median in the public sector 1; private sector 2.3 days), but in China the affordability value for generic captopril was twice that in the private sector, although the difference was small (generic: private 0.1 days; public 0.2 days). There was a large difference between affordability of the originator product and that of generics in Indonesia (14.8 days originator; 1.1 generics). Affordability of the originator in Tajikistan was 52 days. No public sector affordability data were available for captopril in any of the African countries surveyed.

The generic products of hydrochlorothiazide were affordable in the public sector in those countries where they were available (range 0.031–0.5 days), except for Tajikistan (27 days).

In Indonesia, affordability of generic losartan in the public sector was similar to that in the private sector (public 11.5; private 12.1 days). In China the affordability of the originator

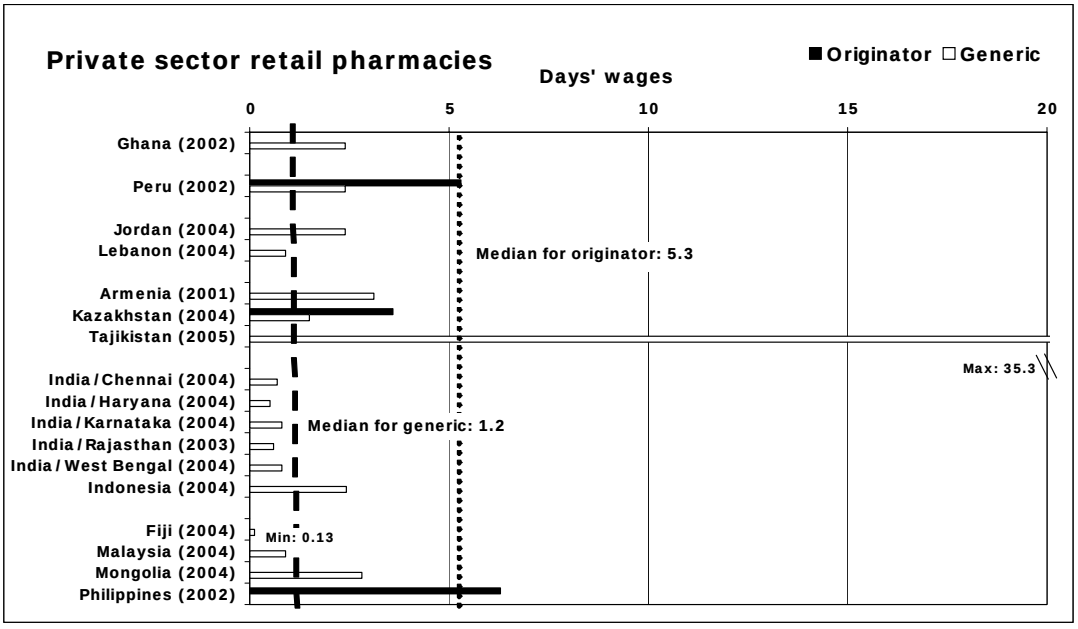
brand was similar in the public and private sectors (public 17.1; private 16.4 days). Clearly, treatment with this medicine is unaffordable in both countries.

For nifedipine retard, data on affordability of generic products in the public sector were available only for China and Jordan. In China the affordability in the public sector (1.8 days) was similar to that in the private sector (1.7 days) but in Jordan, treatment with generic products in the private sector was much less affordable (1.7 days) than treatment in the public sector (0.1days).

5.4.4 Affordability of treatment with a combination of medicines

Since many patients use two or more anti-hypertensive medicines to control blood pressure, we examined the affordability of a combination of medicines. The combination considered was atenolol 50 mg and hydrochlorothiazide 25 mg, one tablet of each per day for 30 days. Affordability has been calculated for the combination therapy. The median affordability values are 5.3 days' wages for originator brand and 1.2 days for generic products. The therapy was less affordable in Armenia, Ghana, Indonesia, Jordan, Kazakhstan, Mongolia, Morocco, Peru, Tajikistan and the Philippines (all more than 2 days), mostly for generic products. Tajikistan once again had poor affordability, the cost of a combination of generic products would require 35.3 days' wages (see Figure 5.7).

Figure 5.7: Affordability of combination therapy with atenolol and hydrochlorothiazide – 30 days supply expressed in days' wages of the lowest paid unskilled government worker, private sector retail pharmacies



5.5 Epilepsy: carbamazepine and phenytoin

5.5.1 Prices

***Private sector retail pharmacies*:** Prices of carbamazepine in general were high, although in the Indian states they were lower than the other countries surveyed (range in India for MPR generic and originator combined 1.64–1.94). Overall the innovator brand had a wider range as well as a higher median value (originator range 1.71–19.73; median 7.97) than the generic medicines (generic range 1.64–5.78; median 2.63). In many countries both the originator and generics had high prices, e.g. Uganda (originator 19.73; generics 2.63), Jordan (originator 11.68; generics 5.78), Lebanon (originator 10.02; generics 4.88), Kazakhstan (originator 7.67; generics 4.45), Indonesia (originator 18.92; generics 2.81), Fiji (originator 8.26; generics 2.95) and Malaysia (originator 17.76; generics 5.26). Prices were high in the four countries for which data were available only for the originator brand (Chad, China, Kuwait and Morocco).

Price information for the originator brand of phenytoin in the private sector were available only from Fiji, Jordan, Kuwait, Lebanon, Malaysia, Morocco and India/Maharashtra (4 regions) which all showed high values (median 9.92; range 4.38–23.78). Generic medicines in the Indian states were expensive (MPR range 3.30–4.23). MPRs for generic medicines in Fiji, Indonesia and Malaysia were very high (9.22, 24.12 and 7.83 respectively). Only China had an MPR below 1 (MPR for generic products 0.72).

***Public sector facilities*:** Carbamazepine is dispensed free in many of the countries surveyed. MPRs for generic carbamazepine were 0.85 in Jordan, 1.92 in Mongolia and 2.84 in Indonesia.

Phenytoin is supplied free of charge in the public sector in most of the countries surveyed. A very high MPR for generic phenytoin was noted in Indonesia (21.46). In Jordan, where no generic phenytoin was found in the public sector, the MPR for the originator brand was high (5.95).

***Public sector procurement prices*:** The range of MPRs for generic carbamazepine was 0.47–5.22 (median 0.99). Morocco and Kazakhstan had very high MPRs for generic carbamazepine (5.22 and 4.1, respectively). The median MPR for the originator brand was 6.3 (range 3.2–9.01). In China, Kuwait and Malaysia data were available only for the originator brand.

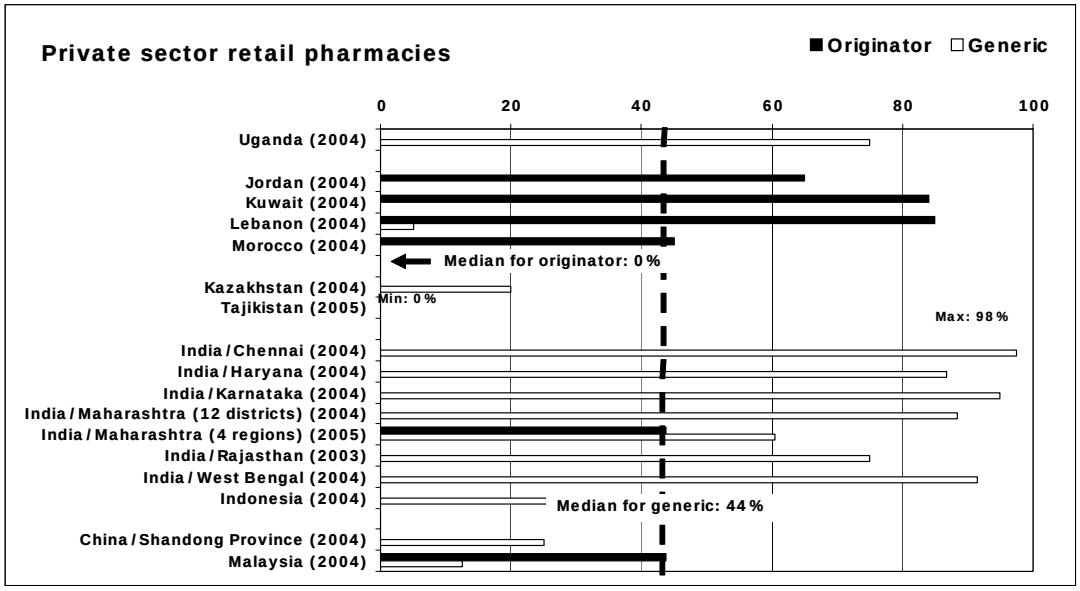
MPRs for generic phenytoin were below 1 for all surveys except those from India/Rajasthan (3.05) and Indonesia (2.19). In Jordan, Kuwait, Lebanon and Malaysia data were available only for the originator brand. The median MPR for these four countries was 5.55.

5.5.2 Availability

***Private sector retail pharmacies*:** In the private sector, originator brand carbamazepine was more widely available than the generic products (range for originator 0–100%; generic 0–93%; median originator 79%; median generic 55%). In Chad, China, Morocco and Kuwait, no generic product was found in the private retail pharmacies surveyed. Conversely, in Mongolia only generics were found (80% availability).

Overall, the data on phenytoin show a low availability for generic medicines and very low availability for originator products (median originator 0%; generic 44%). The Indian states had good availability of generics with a small range and values all more than 60% (Figure 5.8). Conversely, no generic was found in Jordan, Kuwait or Morocco, and availability in Lebanon was only 5%. No phenytoin (neither generics nor originator brand) was found in Tajikistan and availability was less than 30% in China and Kazakhstan (generics).

Figure 5.8: Percentage availability of phenytoin 100 mg capsules/tablets, private sector retail pharmacies



***Public sector facilities*:** The overall availability of carbamazepine was low. Chad, China, India/Haryana, India/West Bengal, Lebanon and Tajikistan had a combined availability of less than 10% (generic and originator brand). However, 100% availability for generic carbamazepine was noted in India/Chennai and Mongolia. For originator medicines, availability was poor, with a median value of 0%.

Phenytoin, as either originator brand or generic product, was unavailable in five of the countries surveyed (Lebanon, Morocco Kazakhstan, Tajikistan and India/West Bengal). Median values for availability were very low for both originator and generic products (originator 0%; generic 20%).

5.5.3 Affordability

***Private sector retail pharmacies*:** The data for carbamazepine showed reasonable affordability for the generic product, but poorer affordability for the originator (median originator 1.7 days; generic 0.8 days), but the range was rather wide for the originator brand (0.7–18 days). In Chad the affordability for the originator was very poor (8.8 days) (no generic was found in the private sector). In Uganda both the originator and generic were unaffordable (originator 18 days; generic 2.4 days). In Mongolia, where only the generic was available, it would take 2.1 days' work to afford a month of treatment in the private sector.

Phenytoin was reasonably affordable in the Indian states, with a value ranging from 0.8 to 1 days' wages required to pay for generic products. Treatment with generic medicine in Indonesia was very expensive (6.6 days' wages for a month of therapy).

***Public sector patient outlets*:** Data on the affordability of carbamazepine or phenytoin are limited in this sector; however, Indonesia had very poor affordability for generic phenytoin (5.9 days).

5.6 Psychiatric disorders: amitriptyline, fluoxetine and fluphenazine decanoate

Amitriptyline was on the core list of 29 of the countries in which surveys were undertaken, fluoxetine on 26 and fluphenazine decanoate injection on only 14.

5.6.1 Prices

***Private sector retail pharmacies*:** Amitriptyline prices were generally high, with exceptionally high values for originator medicines in South Africa, Brazil, Peru and Kuwait (MPR originator 52.88, 23.61, 37.43, 13.47, respectively). The generic values for MPR were lower than for the originator brand (median originator 7.16; generic 3.93) but still very high compared to the IRP (generics ranged from 0.64–22.16). In a number of countries where only generics were found, the MPRs were very high e.g. Chad (15.31), Jordan (8.65), Mongolia (7.63) and Malaysia (6.89).

Table 5.2: Median price ratios, amitriptyline 25 mg tablet/capsule

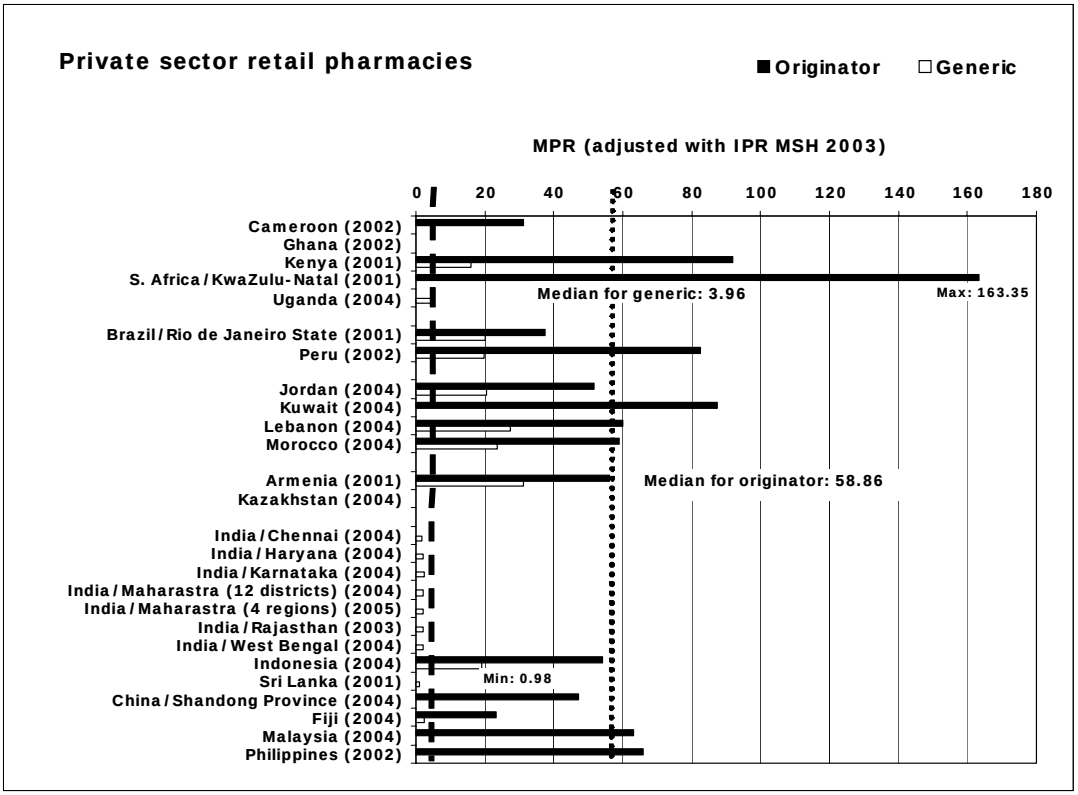
Countries by WHO Region	Median price ratio (MPR)*					
	Private		Public		Procurement	
	Originator	Generic	Originator	Generic	Originator	Generic
Cameroon (2002)						
Chad (2004)		15.31				
Ghana (2002)		3.47				
Kenya (2001)	11.67	1.67				1.42
S. Africa/KwaZulu-Natal (2001)	52.88	*22.16*				1.43
Uganda (2004)		3.44	#	#		0.82
Brazil/Rio de Janeiro State (2001)	23.61	*19.60*				1.62
Peru (2002)	37.43					
Jordan (2004)		8.65			3.42	
Kuwait (2004)	13.47		#	#		3.12
Lebanon (2004)	8.52		#	#		4.48
Morocco (2004)	9.62		#	#	6.77	
Armenia (2001)		2.35				
Kazakhstan (2004)		4.42				3.42
Tajikistan (2005)						
India/Chennai (2004)	5.20	4.99	#	#		0.35
India/Haryana (2004)	5.24	3.89	#	#		
India/Karnataka (2004)	5.81	4.88	#	#		0.45
India/Maharashtra (12 districts) (2004)	5.20	3.89	#	#		0.53
India/Maharashtra (4 regions) (2005)	5.81	4.35	#	#		
India/Rajasthan (2003)	4.93	3.93	#	#		1.39
India/West Bengal (2004)	5.40	3.89	#	#		0.59
Indonesia (2004)		2.23		2.15		1.55
Sri Lanka (2001)	4.69	0.64				
China/Shandong Province (2004)						
Fiji (2004)	8.50	3.86				0.53
Malaysia (2004)		6.89	#	#		1.24
Mongolia (2004)		7.63		5.52		5.24
Philippines (2002)						

Min	**4.69**	**0.64**				**0.35**
Max	**52.88**	**22.16**				**5.24**
Median	**7.16**	**3.93**				**1.41**

* MPRs express the price of the product and dosage compared to the MSH Drug Price Indicator median values. MPR is adjusted with International Reference Price MSH 2003.
Italics For MSGs (Most Sold Generics) if no LPG (Lowest Price Generic) available.
\# Medicines are provided free in public facilities.

Price data on fluoxetine showed a large difference between originator and generic medicines: the median value for the latter was less than one tenth of the value of the former (originator 58.86; generic 3.96). However, the range for generic products was wider than that for the originator product (originator 23.08–163.35; generic 0.98–31.13) and some of the prices of the generic alternatives were extremely high compared to the IRP. The prices of both generic products and the originator brand were extremely high in many countries including Armenia, Brazil, Indonesia, Jordan, Kenya, Peru and South Africa.

Figure 5.9: Median price ratios of fluoxetine tablet/capsule, 20 mg



Price information on fluphenazine decanoate was scarce. All MPR values for the originator product were high: Indonesia (19.79), Lebanon (11.88) and Morocco (5.94).

***Public sector facilities*:** Amitriptyline, fluoxetine and fluphenazine decanoate were dispensed free of charge in most of the public sector facilities surveyed. Only two of the 28 entries for amitriptyline (originator and generic combined) were not "free", namely, those for generic products in Indonesia and Mongolia, (MPR 2.15 and 5.52 respectively). Similarly, price information for fluoxetine was available for generic products only in Jordan (1.72), China (a very high 21.28) and the originator product in the Philippines (also very high – 46.85).

***Public sector procurement prices*:** Two countries, Morocco and Jordan, were purchasing originator brand amitriptyline rather than the generic version. The MPRs were 6.77 and 3.42, respectively. The range of prices for generics was wide (0.35–5.24) and prices were particularly high in Mongolia (MPR 5.24), Lebanon (4.48), Kazakhstan (3.42) and Kuwait

(3.12) in comparison to the IRP. In Mongolia the price for generic amitryptiline to patients in the public sector was only slightly higher than the procurement price (5.52 patient price; 5.24 procurement price). In Indonesia, the patient MPR was 2.15 whereas the procurement price ratio was 1.55.

Procurement prices for the originator brand of fluoxetine were high in China (MPR 39.14) and Malaysia (31.06) but acceptable in Jordan (0.58). Prices for generic fluoxetine were reasonable except in Kenya (MPR13.16), Lebanon (13.51), China (11.85) and Kuwait (7.48). In China the price to patients in the public sector for generic fluoxetine was slightly less than twice the procurement price (21.28 patient price; 11.85 procurement price).

The MPRs for generic fluphenazine injection were less than 1 in the three countries where data was available (Fiji, India/Karnataka and Malaysia). The originator MPRs were higher – Morocco (3.71) and Jordan (2.03).

5.6.2 Availability

***Private sector retail pharmacies*:** The availability of both originator and generic amitriptyline was rather poor, with wide ranges but low median values (range for originator brand 0–98%, generic 0–100%; median for originator 16%, generic 36%). The availability for the originator brand and generics (combined) was below 16% in Cameroon, China, Kuwait, the Philippines and Tajikistan.

Fluoxetine was "available" in all of the countries surveyed. However the lowest combined value for originator and generic medicines was only 3% (for Ghana). Availability was less than 30% in a number of other countries (Peru, Armenia, Philippines, Sri Lanka, Kazakhstan and China). Originator medicine was relatively poorly available, with a median availability of 16%. Generics showed a higher median availability of 43%. The availability of generics was 80% or more in India/Chennai, India/Haryana, Lebanon, Morocco, India/Rajasthan and South Africa.

Data on the availability of fluphenazine decanoate showed a very poor situation, with a similar range for originator and generic products (0–65%) and similar, extremely low median values for both (originator 0%; generic 0%). Only in Lebanon and Morocco was the originator medicine available in fairly reasonable amounts (65% and 55%, respectively), and India/Chennai had reasonable availability for the generic products (65%). For the remaining nine countries surveyed none had availability figures of more than 15% .

***Public sector facilities*:** The availability of amitriptyline was poor: of the 29 surveys, five had no availability (0%) for either the originator or the generic medicine in the public sector (Chad, Cameroon, Kazakhstan, Philippines and Peru). In only five countries was availability for originator and generic products combined 40% or more (India/Chennai, Indonesia, Kuwait, Malaysia and Mongolia).

The data on the availability of fluoxetine were equally limited, but showed poor availability: of the 26 surveyed countries, seven had no availability (0%) for originator or generic products (Cameroon, Ghana, India/Maharashtra (4 regions) Kazakhstan, India/West Bengal, Lebanon, Morocco and Peru) and a further ten had a total combined value of less than 30%.

The median values for both the originator and generic product are low, and for the generic product, the range was narrow (median for originator 0%, generic 2%, range generic 0–22%).

Fluphenazine decanoate was rarely available in the public sector except in Morocco (80% originator brand) and Malaysia (70% generics).

5.6.3 Affordability

***Private sector retail pharmacies*:** In spite of the wide range for both originator and generic products (range for originator 0.5–7.2 days' wages; generic 0.2–6.7 days), the affordability of amitriptyline seems more acceptable if the median values for both products are considered (median originator 1.3 days; generic 1.1 days). The African and South American countries surveyed all had poor affordability, and with the exception of generic products in Kenya (0.8 days), all values were high. Mongolia also has a high value for generic amitriptyline (2.7 days).

The affordability of fluoxetine showed extremely wide ranges (range originator 3.5–117.3 days; generic 0.4-53.3 days). Affordability was very poor for instance in Kenya, where both originator and generic medicines were unaffordable (originator 117.3 days, generic 20.2 days). All other countries apart from Fiji, Sri Lanka and the Indian states show very poor affordability.

Data on the affordability of fluphenazine decanoate in the private sector were too few for a full analysis: however, in Indonesia one ampoule would cost 4.1 days' wages, whereas in Lebanon, Morocco, India/Chennai and India/Maharashtra it would cost less than 1 day's wages.

***Public sector facilities*:** Data on the affordability of amitriptyline were very limited, with only two values for affordability of generic products (2 days' wages in Mongolia and 0.6 day in Indonesia).

Data on the affordability of fluoxetine in the public sector were also limited and were available for only three countries. In the Philippines, 34 days' wages would be required to purchase a month of treatment with originator's brand fluoxetine purchased in the public sector, and in China 23.2 days' wages would be needed to pay for treatment with the generic product.

6. Price components

The price ratios that are reported in Chapter 5 reveal the gross disparities in prices for the medicines surveyed between as well as within countries. In some cases, the prices of originator medicines are many times higher than those of their generic equivalents, in others they are similar. Prices charged in different sectors may also vary dramatically for the same products. *Before effective policy actions can be initiated, the exact reasons for these price disparities must be understood*. The final price paid for a medicine is the sum of the manufacturers' price and many different additional charges. In some cases, the manufacturers' price is the major determinant of the final price, whereas in others these additional charges may be the major factor determining the final charge. As part of the WHO/HAI project, work has been undertaken to systematize the process of analysing these additional costs. In 2003, Levison and Laing wrote on the hidden cost of medicines in the *Essential Drugs Monitor*.[20] On the basis of a survey of eight countries they observed that additional costs in pharmaceutical procurement varied from 48% in Nepal to 88% in Armenia.

6.1 Structure of additional costs

The WHO/HAI manual proposed a simple framework for the collection of data on cumulative mark-ups and price components which was used in surveys undertaken in most of the countries surveyed. The cumulative mark-ups included taxes, duties and fees, together with wholesale and retail mark-ups. Such a simple analysis failed however to reflect the complexity of the situation. Levison[21] developed a more sophisticated analytical tool, which was field-tested in several countries. Additional charges were broken down as occurring in five different stages. These stages were:

Stage 0: manufacturer's selling price (MSP);

Stage 1: stage 0 plus insurance and freight;

Stage 2: customs, port and quarantine charges (after the arrival of medicines in the country). Letter of credit charges are included in the finance and banking fees;

Stage 3: distributor/wholesaler's mark-up;

Stage 4: retailers' or dispensing doctors' mark-ups;

Stage 5: other charges such as value added tax (VAT), general sales tax (GST) or dispensing fees.

6.2 Price components results of country surveys

A selection of results from different country surveys is included in this chapter. More detailed reports will be produced soon for all medicines.

6.2.1 Mongolia

A study was undertaken in Mongolia, using the original simpler method. The results are shown in Table 6.1. Prices in Mongolia were generally competitive by international standards. However it is clear from this simple analysis that government charges in the form of customs duties, stamp duties and VAT added over 21% to the cost of imported generics in the private sector.

Table 6.1: Price components and cumulative mark-up, Mongolia 2004

Price component	Imported generic product, private sector		Locally produced generic equivalent, public sector tender	
	percentage	cumulative mark-up	percentage	cumulative mark-up
Import price		100.00		100.00
Customs	5	105.00		
Stamp duty	1	106.05		
Wholesale mark-up	25	132.56	15	115.00
Retail mark-up	30	172.33		
Value added tax (VAT)	15	198.41	15	132.25
Sales price		***198.41***		***132.25***
Total add-ons		**98.41**		**32.25**

6.2.2 Tajikistan

A similar survey in Tajikistan again demonstrated the impact of government charges on the final costs paid by consumers. For imported medical products (except for humanitarian aid), according to current legislation, suppliers pay the following additional costs:

- VAT: 20%;
- transportation expenses: varying from 6% to 20%, depending on the country in which the medicines are purchased, the manufacturer and the type of transport (e.g. road, sea or air);
- customs duties: 5%;
- customs procedures: 0.15%;
- tax if sold outside Dushanbe city: 4%–5 %;
- tax from sales in Dushanbe city: 1%;
- wholesale and retail mark-up: 15%–30%.

The additional charges could amount to a mark-up of over 80% on the original price. Some of these charges are unavoidable, such as transport and profit margin for the wholesaler or retailer. But taxes and duties could amount to 30%, and if these were removed the mark-up would be slightly more than 50%.

6.2.3 Malaysia*

In Malaysia an extensive survey investigated price components in three sectors, government, private for-profit facilities and private dispensing doctors.[24] This study used the "five stages" analysis developed by Levison (see section 6.1).

***Public sector procurement*:** Figure 6.1 illustrates the relationship between the different stages of the cost for generic and originator atenolol in the public sector. For generic atenolol, stage 1 includes the manufacturers' sales price, insurance and freight, which constituted 68% of the total cost. In contrast, for originator brand atenolol, the manufacturers' sales price, insurance and freight, contributed 79%, while add-ons made up the remaining 21% of the total price. The wholesale mark-up (Stage 3) was 17% of the final price for both the generic and the originator medicine. Actual figures are presented in Tables 6.2 and 6.3.

Component costs in the private sector retail pharmacies: The private retail pharmacies surveyed procured generic atenolol, 50 mg, from a local supplier known as a "runner", a supplier who tends to operate without a wholesale licence, and who purchases items in bulk from the sole distributor to re-sell them to retailers. Bulk purchases often mean lower prices, giving the "runner" a larger profit margin even if there is no big mark-up. Figure 6.2 shows the component costs for originator and generic atenolol. The retailer's mark-up, 100% of the wholesale price, is the largest component of the 149.48% add-on costs for generic atenolol. The distributors', or runners', mark-up is stage 3. In comparison to generic atenolol, the originator medicine has a lower percentage of add-on costs and the price components are more evenly distributed – including between the wholesaler and the retailer. Tables 6.4 and 6.5 show the actual mark-ups for generic and originator atenolol.

Component costs in the dispensing doctors' sector: Dispensing doctors often procure directly from the sole distributor, and bypass the wholesaler. The dispensing doctors procured generic atenolol, 50 mg, from the sole distributor, but procured the originator brand from a wholesaler. Table 6.6 shows stage 4 mark-ups of 146% for generic atenolol while a mark-up of 76% for originator medicine can be seen in Table 6.7.

As shown by this analysis, total mark-ups in the public procurement sector varied from 27% for the originator to 47% for the generic medicine. In the private retail sector mark-ups varied from 80% for originator to 150% for generic products. For the dispensing doctors even greater mark-ups were noted – 129% for the originator and 234% for the generic medicines. As the base price for the originator was substantially higher, the end price for the generic product is still lower, but the profit that has been made is large.

* *Note*: Text from the Malaysia report has been copied into this section to demonstrate the use and application of price component information in setting pricing policies and regulation. Although the authors reported on three medicines, we use only the example of atenolol in this report.

Figure 6.1: Share of component costs (as percentages of the total cost) across stages in public sector procurement for imported generic and originator atenolol (50 mg tablets, pack size 60)

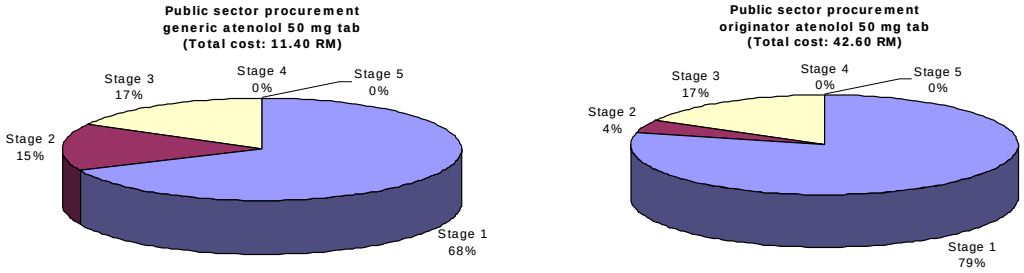


Table 6.2: Actual price and percentage mark-up in public sector for generic atenolol (50 mg tablets, pack size 60)

Stage	% mark-up	Value of charges (RM)	Cost (RM)
Stage 1 MSP + Insurance & transport			7.78
Stage 2 Customs & port clearing	22.2%	1.72	9.50
Stage 3 Distributor Wholesale mark-up	20%	1.90	11.40
Stage 4 Retailer or dispensing doc mark-up	N/A		11.40
Stage 5 Other charges incl. VAT, GST etc	N/A		11.40
Total % mark-up and price	**46.52%**	**3.62**	**11.40**

Table 6.3: Actual price and percentage mark-up in public sector for originator atenolol (50 mg tablets, pack size 60)

Stage	% mark-up	Value of charges (RM)	Cost (RM)
Stage 1 MSP + Insurance & ransport			33.63
Stage 2 Customs & port clearing	5.6%	1.87	35.5
Stage 3 Distributor wholesale mark-up	20%	7.10	42.60
Stage 4 Retailer or dispensing doc mark-up	N/A		42.60
Stage 5 Other charges incl. VAT, GST etc	N/A		42.60
Final % mark-up and price	**26.7%**	**8.97**	**42.60**

Figure 6.2: Component costs across stages in private sector retail pharmacies: generic and originator brand atenolol (50 mg tablet, pack size: 60)

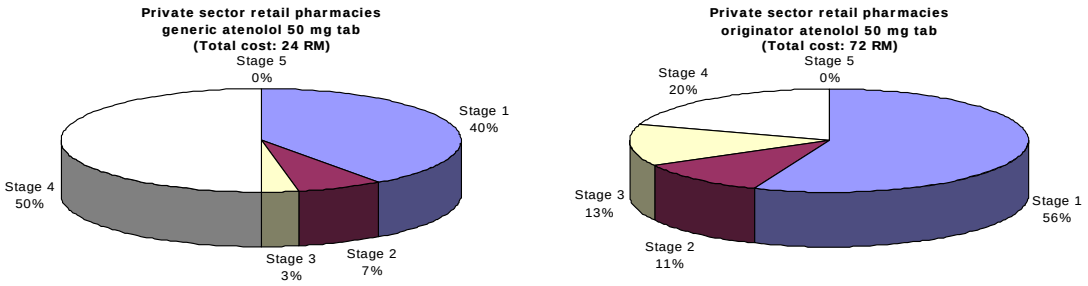


Table 6.4: Actual price and percentage mark-up in private sector retail pharmacies for generic atenolol (50 mg tablets, pack size 60)

Stage	% mark-up	Value of charges (RM)	Cost (RM)
Stage 1 MSP + Insurance & transport			9.62
Stage 2 Customs & port clearing	17.87%	1.72	11.34
Stage 3 Distributor wholesale mark-up	5.82%	0.66	12.00
Stage 4 Retailer or dispensing doctor mark-up	100%	12.00	24.00
Stage 5 Other charges incl. VAT, GST etc	N/A		24.00
Final % mark-up and price	**149.48%**	**14.38**	**24.00**

Table 6.5: Actual price and percentage mark-up in private sector retail pharmacies for originator atenolol (50 mg tablets, pack size 60)

Stage	% mark-up	Value of charges (RM)	Cost (RM)
Stage 1 MSP + Insurance &transport			40.05
Stage 2 Customs & port clearing	20.37%	8.16	48.21
Stage 3 Distributor wholesale mark-up	19.12%	9.22	57.43
Stage 4 Retailer or dispensing doctor mark-up	25.37%	14.57	72.00
Stage 5 Other charges incl. VAT, GST etc	N/A		72.00
Final % mark-up and price	**79.77%**	**31.95**	**72.00**

Figure 6.3: Component costs across stages in dispensing doctors' sector for imported generic and originator atenolol (50 mg tablet, pack size: 60)

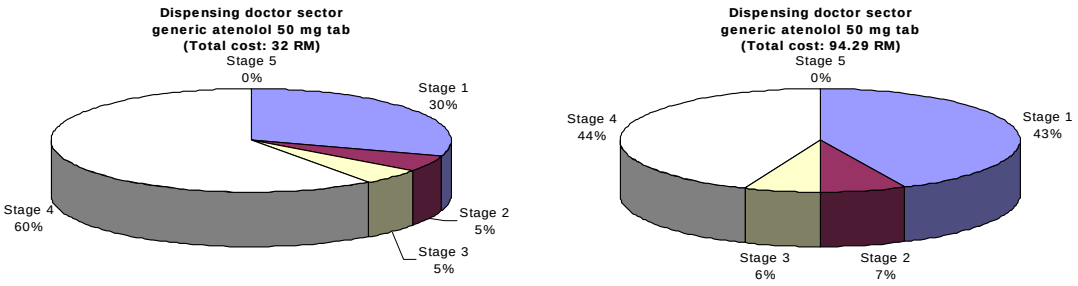


Table 6.6: Actual cost and percentage mark-up in dispensing doctor sector for generic atenolol (50 mg tablets, pack size 60)

Stage	% mark-up	Value of charges (RM)	Cost (RM)
Stage 1 MSP + Insurance &transport			9.58
Stage 2 Customs & port clearing	17.95%	1.72	11.30
Stage 3 Distributor wholesale mark-up	15.04%	1.70	13.00
Stage 4 Retailer or dispensing doctor mark-up	146.15%	19.00	32.00
Stage 5 Other charges incl. VAT, GST etc	N/A		32.00
Final % mark-up and price	**234%**	**22.42**	**32.00**

Table 6.7: Actual cost and percentage mark-up in dispensing doctor sector for originator atenolol (50 mg tablets, pack size 60)

Stage	% mark-up	Value of charges (RM)	Cost (RM)
Stage 1 MSP +Insurance & transport			41.17
Stage 2 Customs & port clearing	17.09%	7.04	48.21
Stage 3 Distributor wholesale mark-up	11.11%	5.36	53.57
Stage 4 Retailer or dispensing doctor mark-up	76.02%	40.72	94.29
Stage 5 Other charges incl. VAT, GST etc	N/A		94.29
Final % mark-up and price	**129.02%**	**53.12**	**94.29**

7. Discussion

7.1 Background

This report has been written as a background document for the aforementioned Cairo meeting on the "Global Initiative for Treatment of Chronic Diseases". It aims to bring together the available information on prices, availability and affordability of selected chronic disease medicines from 30 countries. Focusing on chronic diseases at this time is necessary as the burden of disease is increasing and treatment has become more possible. This initiative is being taken against the background of effective campaigns for improving access to and/or prices of medicines for HIV/AIDS, tuberculosis and malaria, together with other efforts focused on other infectious diseases. Other diseases especially chronic diseases have been neglected in these access campaigns and the time has come to correct this imbalance.

The methods used in the more than 40 surveys using the WHO/HAI methodology have been shown to be reliable and practical. Only a limited number of chronic disease medicines have so far been surveyed, and some data are missing from those surveys that have already been undertaken. Reports of the country surveys are available on the HAI web site.

The secondary analysis that has been undertaken has both strengths and weaknesses. The major strengths include the fact that the survey data have been adjusted to ensure that the price data are compared to a common reference point and that the availability and affordability of the 14 medicines (see Table 4.1) were examined in 30 countries. In addition, this report has compared the prices, availability and affordability of individual medicines rather that aggregating medicines into a basket. Such comparisons may be valid when the baskets are identical, but when different baskets are aggregated and compared, as often is the case, the comparison is clearly invalid.

Of particular concern is the fact that we have not undertaken price component analysis in many countries. We have included some price component data from Mongolia, Tajikistan and Malaysia (see Chapter 6), but this aspect of the survey methodology will need to be strengthened in the future.

7.2 Results

The results reported here are interesting, and provide a good basis for further action. Although some general findings are clear across all countries, there is also substantial variation between individual countries. This demonstrates a need for more in-depth national-level surveys to determine the situation in *each* country. By pooling such surveys, further analysis, similar to that reported here, can be undertaken to assess the global situation. In addition, the impact of interventions can be evaluated and trends over time assessed.

***Price*:** As would be expected, prices are generally lower in the public sector than they are in the private sector. However exceptions to this general rule do occur in countries where a supplier who has a monopoly on the supplies to public sector facilities competes with a competitive private sector, as for instance is the case in Tajikistan. Prices to patients in the public sector are often higher than public procurement prices, even in countries where prices are low. The large margins may suggest that many public facilities are generating income through selling medicines. Clearly there are distribution and storage costs, which have to be covered, but the many-fold differences raise questions as to whether the public facilities are committed to providing medicines to the patients at the lowest possible prices.

In the private sector, brand name premiums are often very high. For instance, the nifedipine retard median MPR for originator medicine is eight times higher than that for generic products. For countries where this is the case, requiring or at least promoting generic substitution may be necessary. In other countries, the brand name premiums may be very low. In these circumstances the price must be compared to the IRP. In India for example, the originator and generic MPRs are low, close to the IPR. In other countries, such as Kuwait, there seems to be a low brand name premium but generally very high prices. In these situations the generic price might have been set to be discounted down from the originator rather than up from the procurement price. In India the brand-name product is priced down to the price of the generic. But in other countries such as Kuwait or for some medicines in Peru, the generic product is priced up to be a high proportion of the originator brand price. Clearly where price control regulations for generic products exist these should be set up from the international procurement price, rather than down from the originator brand price.

Some countries, such as Morocco, have high procurement prices. This may relate to local purchasing arrangements or to the failure to use international competitive tendering. Local regulations to limit importation to only those companies that can manufacture products may dramatically increase prices because of a lack of local competition.

Availability: As would be expected, the availability of generic medicines is generally better in public than in private sector facilities. In some countries, for instance Ghana and the Philippines, both originator and generic products are available in the same public sector facilities. While this may give consumers choice it would not appear to promote access to quality assured generics at the lowest possible price. In some countries where prices are low in public sector facilities, availability may also be low, forcing patients to go to high-cost private outlets to obtain their medicines, as is the case for beclometasone in a number of Indian states.

***Affordability*:** In general, medicines are less affordable in African countries because of low wages and higher prices. In Indian states, where wages are also low, the low prices make most products more affordable. In Tajikistan the very low wages make many medicines unaffordable, in spite of their low prices.

7.3 Chronic diseases

7.3.1 Asthma

***Prices*:** The price ratios for beclometasone, when available, tend to be slightly higher than those of salbutamol. The median MPR values for beclometasone in the private sector were 3.32 and 1.43 for originator and generic products, respectively versus 2.7 and 1.2 for originator and generic salbutamol, respectively. It should be noted that the MPR ranges for salbutamol are wider, and the minimum and maximum values in various countries were unexpected, with an MPR of 0.3 for the generic version in China versus the lowest MPR in an African country of 1.35 (for Uganda).

***Availability*:** The availability of beclometasone was generally poor: the median value for availability of the originator product in the private sector was 14% and that for the generic product 12%. Salbutamol, on the other hand, was available in most countries. The only exceptions were Cameroon, where neither the originator brand nor the generic product was available (public or private sector), and Chad and Indonesia where no generic version was available. The median availability of the generic product was 78% versus 64% for the originator product.

***Affordability*:** The generic products of salbutamol are fairly affordable with a median affordability value of 0.7 days' wages in the private sector. This combined with the good availability of the generic product means that symptomatic treatment of asthma is fairly assured. Even the median affordability value of the originator is reasonable, at 1.2 days' wages. However, continuous treatment with beclometasone is heavily compromised by poor availability combined with poor affordability: 3.3 days' wages for the originator and 1.4 days' wages for the generic product in the private sector.

7.3.2 Diabetes

***Prices*:** The price ratios for glibenclamide were much higher than those for metformin. The public procurement price was close to the IRP for generic glibenclamide, and 50% of IRP for generic metformin. This, combined with the fact that the IRP for metformin is much lower than that for glibenclamide, makes the price situation of glibenclamide even worse. Why this should be the case for these widely used "old" medicines is open to question.

***Availability*:** The median availability of generic versions of glibenclamide in the public sector was 42%, that of metformin only 16%. However, in the private sector availability of glibenclamide was 83% (originator) and 67% (generic), compared to 8% (originator) and 82% (generic) for metformin. This may signal a reality that in many countries type 2 diabetes is treated with medicines procured from the private sector!

***Affordability*:** In most countries the affordability of generic glibenclamide and metformin is reasonable, being less than 1 days' wages except in countries where only the originator is available (e.g. metformin in China (10.8 days), glibenclamide in Cameroon (8.1 days) and Chad (7.4 days)). The affordability of the originator versions of glibenclamide is also poor in Indonesia, Cameroon and Mali, and policies to promote the use of generic medicines should be encouraged. This includes requiring generic substitution in addition to other measures related to facilitating registration and ensuring availability.

Diabetes is a disease that is likely to increase dramatically in prevalence in the near future. Although this disease may initially affect the affluent, many poor people will also be affected. Governments need to ensure that these poor people have access to effective generic medications ideally through public facilities at low or no cost.

7.3.3 Hypertension

Prices: The availability of hydrochlorothiazide was limited and the prices high (median MPR for public procurement was 2.74). Atenolol was more available and the median MPR for the generic in public procurement was 0.98. The procurement price of generic captopril was generally fair when compared to IRP and availability in the private sector was generally reasonable.

The MPR of hydrochlorothiazide in the private sector was high in most countries (median 11.22), but was low in China and Indonesia. This demonstrates that this product could be procured at far lower prices in most countries. The MPR for the generic version of nifedipine retard was 2.71, and the medicine was more widely available than the originator product. The median MPRs of generic atenolol and captopril were 5.46 and 3.07, respectively, in the private sectors of the countries surveyed.

Availability: Public sector availability for products for treating hypertension was generally very low. The median availability of generic versions of these products in the private sector was 41% for hydrochlorothiazide, 55% for captopril, 75% for nifedipine retard and 81% for atenolol.

Affordability: The affordability of each generic product for treating hypertension was about 0.5 day's wages except for captopril, which was 2.3 days' wages. The exception was Tajikistan where the wages were very low.

7.3.4 Epilepsy

Of particular note from this secondary analysis exercise was the scarcity of data on medicines for treating epilepsy. Many country surveys did not include epilepsy medicines. The availability of these products in the private sector was reasonable but the medicines were expensive. Availability in the public sector was poor to very poor. Too few data are available to enable an assessment of affordability in the public sector but affordability in the private sector was acceptable for generic products.

7.3.5 Psychiatric disorders

Prices: The prices of medicines for treating psychiatric disorders were surprisingly high especially in the Indian states. The median MPR for amitriptyline was 7.16 for originator and 3.93 for generic products. Fluoxetine, which came off patent during the period when these surveys were being done, demonstrated some of the largest brand-name premiums in the private sector, especially in the early surveys. Overall the brand-name premium was a factor of ten. In Fiji the MPR for the originator was 23.08 while that for the generic was 2.59.

***Availability*:** Amitriptyline was included on 28 of the 29 core lists and fluoxetine on 25 of the 29 lists. Fluphenazine decanoate, which in some health systems is dispensed only in hospitals, was on 13 of the 29 lists. Generic amitriptyline, in particular, was generally poorly available in both sectors. Availability of fluoxetine was better in the private sector except for the Indian states where this was usually the generic version.

***Affordability*:** With median affordability values of 1.3 and 1.1 days' wages for originator and generic products, respectively, amitriptyline treatment is fairly affordable in the private sector. This is in stark contrast to the situation with fluoxetine, which is barely affordable as a generic product (median 5.9 days' wages) and beyond reach, as an originator product (median 36.4 days' wages), for the lowest paid unskilled government workers.

7.3.6 Price components

Prices for identical products vary greatly between countries. For example, the MPR of originator brand atenolol purchased in private pharmacies ranged from 5.06 in Rajasthan to 78.82 in Uganda. The MPR for originator brand glibenclamide ranged from 3.37 in Rajasthan to 79.45 in Indonesia.

Two factors make up the final price: the manufacturer's price, and the local add-on costs, such as taxes and mark-ups. These factors also vary considerably between countries. In India the manufacturer's price is often the predominant component, with add-ons accounting for less than 40% of the final price. The pricing authority in India allows 100% of the manufacturers' price as maximum mark-up on retail prices for those medicines that are under price control. In other countries, such as Uganda and Malaysia, pharmacy mark-ups alone can be more than 100%; these additional costs contribute significantly to the final retail price.

Taxes and tariffs add to the price the patient pays. Due to the cumulative nature of price components, a small tax applied early in the distribution chain (such as an import tax) can have a significantly larger impact on the final price. Some governments apply several taxes on essential medicines e.g. in Peru an import tax of 12% is applied as well as 18% VAT.

7.4 Conclusion

In summary, the medicines for epilepsy and psychiatry were less available and more expensive than medicines for treating other chronic diseases. As chronic diseases may adversely affect income-generating capabilities, governments need to pay particular attention to the fate of people who are chronically ill.

8. Policy options

This section addresses price, availability, affordability and price component issues in the treatment of chronic diseases, on the basis of the survey data presented in this report. Policies and actions are proposed to address these issues with the purpose of making essential medicines more accessible.

8.1 Medicine prices

8.1.1 Government procurement prices

Some governments procure medicines efficiently, but others do not. Older products that have been off patent for many years, and of which many low priced generic versions of assured quality are available on the world market, are sometimes purchased at extremely high prices. Nifedipine retard tablets are being procured at acceptable prices in many countries, but not in Lebanon (generic MPR 3.32), China/Shandong Province (generic MPR 3.48), Kuwait (originator MPR 5.50) and Morocco (originator MPR a massive 19.06 times the IRP). Government procurement of glibenclamide showed similar price variations: from an efficient MPR of 0.27 in India/Chennai to an MPR of 5.15 in Mongolia for the lowest priced generic.

It might be expected that, for off-patent medicines, only generic versions would be available in the public sector, as they are known to be cheaper, but this is not always the case. In Malaysia, many medicines on the National Essential Drugs List that were off-patent long ago, were available only as originator brands, for instance beclometasone inhaler, phenytoin and prazosin. In a few countries, public sector facilities stocked both the originator brand and generic versions of a medicine, as was the case in Indonesia, where both the originator brand and generics of captopril and metformin were stocked in public sector facilities. The price of the originator brand was 13 times that of the lowest priced generic for captopril; and for metformin the factor was 2.42. For newer products there are a number of options available for acquiring the best priced generic products, which are applicable even if the products are protected by a patent in the country concerned.

The efficiency of the public sector procurement system should be constantly monitored. Adequate price information must be available to procurement officers so that they can take into account this information. In addition to national price information, procurement officers should consult international price reference sources.

8.1.2 Prices to patients in the public sector

There is evidence that some governments procure medicines efficiently, but charge markedly higher prices to patients. In Shandong Province, patients purchasing phenytoin in the public sector paid 2.5 times the government procurement price. In the public sector in Indonesia, patients paid 11 times the procurement price for this medicine.

Most countries charge patients for medicines in the public sector. Prices vary considerably, even for generics. In some countries they are generally acceptable in international terms, in

others they are not. The MPR for the lowest priced generic atenolol tablets in the public sector ranged from 2.45 in Tajikistan to a massive 18.6 in Indonesia. The MPR for hydrochlorothiazide, also used to treat cardiovascular disease, ranged from an acceptable value of about 0.7 in Indonesia and Shandong Province China, to 7.52 in Ghana, and 37.23 in Tajikistan. There can be no justification for generics being so expensive. These high prices may be due to inefficiencies in the supply system or to governments choosing to fund their health system with the profits from the sales of medicines. The two situations need to be addressed differently.

Treatments vary in price. For example, in the public sector in Indonesia it is significantly cheaper to treat hypertension with generic hydrochlorothiazide than with captopril or atenolol using standard regimens. Countries need to develop and use standard treatment guidelines and provide cost-effective treatment taking into account current medicine prices. To do this, prices must be regularly monitored.

8.1.3 Patient prices in private retail pharmacies

Huge differences in price between the originator brand and the lowest priced generic equivalent, known as the "brand premium", were noted in many countries. In Indonesia, the price of the originator brand of glibenclamide was 13.8 times that of the lowest priced generic. In Fiji, Ghana and Lebanon, the brand name premium factor was 5 to 6. This is not an issue if the generic is widely available and dispensed, but regrettably this is not always the case.

In some countries, the prices of the lowest priced generics were excessive. In Morocco the prices of some individual generic preparations were very high: fluoxetine was 23.48 times the reference price and glibenclamide was 16.66 times higher. Even factoring in local distribution costs, these prices are excessive and limit treatment options for patients. In the Philippines, the lowest priced generic of glibenclamide was more expensive than the originator brand, and both were at least 38 times more expensive than the reference price. In Kuwait, the MPR for the originator brand of glibenclamide was 66.27 and that for the lowest priced generic was 60.66. For atenolol, the MPRs were 46.98 and 44.31, respectively. It seems from these figures that the practice in Kuwait is to base the price of generics on that of the expensive originator brand, rather than on procurement prices.

8.1.4 Patient prices in the dispensing doctor sector

A survey of prices charged for medicines by dispensing doctors was undertaken in Malaysia.[22] The lowest priced generics were 18% more expensive when purchased from dispensing doctors than when purchased from private retail pharmacies; prices of originator brands were about the same. In Malaysia, dispensing doctors often procure directly from the distributor, bypassing the wholesaler so distribution costs are less. In this way they profit not only by charging more, but also by procuring at lower prices.

8.1.5 Policy proposals

Before embarking on policy change it is vital to ascertain the contributing causes of high prices. Invariably there are several causes. Undertaking price surveys will expose issues to be addressed.

If all people are to benefit from treatment with medicines, governments must establish essential medicines lists and purchase low-priced quality generics, and not expensive originator brands. In the first instance, governments should always press for equitable prices. In the face of inequitable prices for patented medicines, governments should issue compulsory licenses or invoke government use of local patent law as confirmed in the WTO Doha Declaration on TRIPS and Public Health.

To ensure the availability of more affordable generic medicines, governments need to protect and encourage their manufacture. In particular, in countries with manufacturers who produce and export medicines in large quantities, governments should allow the production of generic medicines using the flexibilities in patent law to set aside patents as necessary.[23]

Generic competition is the key, and governments should do all they can to increase the use of quality assured, low-priced generics. Fast-tracking of the regulatory approval of generic medicines is needed, together with waiver of registration fees, as occurs in the US; registration of producers of quality generics; encouraging prescribing by International Non-proprietary Name (INN) rather than by brand name; and permitting generic substitution, are proven policy options. Where generic competition is lacking, price regulation could be considered. Generally, manufacturers of originator brands are not affected by generic competition. The value of generics is lost if they are not used. Policy-makers and health professionals as well as consumers need to be educated about the availability and acceptability of generics.

To aid procurement, greater price transparency is needed so that informed choices can be made. Ultimately, the power to ensure patient access to affordable essential medicines resides with national governments that can negotiate prices based on comparative data.

To increase access to treatment for chronic diseases, governments must either supply medicines free of charge or pass low procurement prices on to patients with minimal additional charges. Patients will benefit from the development and use of standard treatment guidelines and cost-effective treatments that have been developed taking into account current costs of medicines.

Regulatory authorities also need to provide a regulatory and enforcement mechanism in which cheaper alternative medicines are more often prescribed, dispensed and used than newer, more expensive medicines. Prescribing a new expensive treatment, despite the availability of proven cheaper alternatives, is not cost-effective and wastes the scarce resources of governments and patients. There is clearly a conflict of interests when doctors both prescribe and dispense – and it is the patient who pays the price when profits come before ethics. There can be no justification for doctors being authorized to dispense unless there are no public or private pharmacies nearby – in which case governments need to regulate the prices charged by doctors to remove any incentives for expensive prescribing.
Regular monitoring of prices to patients is needed so that the impact of pricing policies can be assessed, and action taken when needed. It is vital that patients are informed of current prices, for instance through regular publication in newspapers, so that they know what is an acceptable price for a medicine when entering a pharmacy.

8.2 Availability of medicines

The concept of supplying medicines free or at low cost in the public sector is a praiseworthy aim, but the medicines need to be available. In Uganda, the median availability of the Essential Drugs List medicines surveyed was 55%. In Malaysia, it was 65% and some of the essential medicines were available in only a few facilities e.g. beclometasone inhaler was found in only three of the 20 public facilities surveyed, and atenolol tablets in two facilities. In China/Shandong Province, many of the medicines on China's Essential Drug List were available in only a few facilities: the median availability of generic glibenclamide in the public and private sectors was 5%.

In India, the six states surveyed had very poor availability for a number of medicines in both the public and private sectors. Captopril was not available in the public sector, and only in Chennai was its availability in private retail pharmacies more than 33%. Hydrochlorothiazide was only available in the public sector in Karnataka, and then in only 8% of the facilities surveyed. In the private sector, the availability of any generic hydrochlorothiazide product ranged from 0% in Maharashtra (4 regions) to 75% in Chennai. Fortunately for patients with hypertension, the availability of generic atenolol in the private sector was more than 85% in all six states surveyed.

8.2.1 Policy proposals

Using the procurement methods discussed earlier, governments must improve the availability of essential medicines in the public sector. It is not enough to rely on the private sector. Even if they stock the needed medicines, the higher prices can tip the balance from affordable treatment to having to go without it.

8.3 Affordability of treatment for chronic diseases

If you are a diabetic needing metformin, your chances of long-term survival are much better if you live in a country where this essential medicine is affordable. Metformin is the most prescribed medicine for lowering blood sugar levels in people with type 2 diabetes in the US. In the surveys presented in this report, metformin is provided free in the public sector (to all or to certain categories of patients) in a number of countries. In some countries, treatment with metformin is not an option because of its high price. For in example, in Shandong Province in China, the lowest paid unskilled government employee would have to work for nearly 11 days to afford to purchase a month's therapy from a private pharmacy. The figure is 4.1 days in Chad and 3.1 days in Mongolia. In these countries, treatment with metformin is clearly not affordable in the private sector, and in addition, the availability of this medicine in the public sector was found to be extremely low.

The reality in many countries is actually much worse. In Lebanon, where metformin is provided free of charge in the public sector, the medicine was not found in any of the 20 public facilities surveyed. Therefore, people with diabetes are forced to purchase metformin in the private sector where treatment is expensive: 2.9 days' wages are required to pay for a month of therapy. Likewise, in Uganda, the availability of generic metformin in the public sector was only 25%, meaning that many diabetics would be forced to purchase the medicine in private pharmacies, where it is available (85%) but unaffordable at 3.6 days' wages.

Chronic diseases seldom affect only one person in a household. In Indonesia and Uganda it takes nearly 6 days' wages to pay for a month's therapy with metformin for a parent with diabetes, and one salbutamol inhaler for a child with asthma, if medicines are purchased from a private retail pharmacy. A chronic disease can also be a risk factor for another condition, which also requires treatment. Diabetes, for instance, is a strong risk factor for cardiovascular disease. While treatment for one condition may be affordable, the added burden of a second condition can result in treatment being prohibitively expensive. Clearly, in both these situations, difficult choices about treatments have to be made. For acute illnesses, a family might manage to pay for expensive courses of treatment by taking out loans or finding other ad hoc solutions. But for patients with chronic conditions, such solutions are unsustainable and therefore not a realistic option.

In Tajikistan a different affordability issue was noted. Whereas the prices of some medicines were acceptable by international standards, the daily wage of the lowest paid unskilled government worker was so low that most standard treatments were not affordable. For example, one salbutamol inhaler "costs" 15 days' wages. In many countries, the wage of the lowest paid unskilled government employee is considered high. Therefore, a course of treatment barely affordable to this person will be unaffordable for large proportions of that country's population.

8.3.1 Policy proposals

High medicine prices and low wages are major barriers to the affordability of treatments for chronic diseases. The ability of the poor to afford treatments must be regularly monitored by governments to detect access problems and enable them to take corrective measures. In addition to the method used in these surveys, simple questions will highlight problems, such as:

- Are some treatments taking a disproportionate amount of family budgets?
- Are diseases left untreated because the treatment is unaffordable?

Policies must be implemented to lower prices in both the private and public sectors and to increase the availability of medicines in the public sector. In cases of extreme poverty, the only solution is free provision of essential medicines in the public sector. When the budget of the ministry of health is clearly insufficient to provide essential medicines free of charge, priorities will need to be set, e.g. by medical condition and/or categories of patients. In addition improvements in the efficiency of the procurement of medicines in the public sector to obtain the lowest possible prices for products of assured quality to enable a maximum number of patients to be treated becomes an urgent priority.

8.4 Price components

Because the situation of price components varies between countries, studying these components is particularly important. Although this may be challenging, key individuals within the pharmaceuticals distribution chain frequently know exactly where the additional charges are occurring. Individual patients are very unlikely to have access to such

information and so the government has a responsibility for obtaining this information and sharing it widely. Often policy actions will be required to address specific areas of abuse.

8.4.1 Policy proposals

Once the details of price components become known, various policy options can be considered. In some cases, taxes and duties add significantly to the end price of the medicines. Because the sick, particularly those with chronic diseases, who need these medicines are often the least able to afford such taxes, there can be no public policy purpose to be served by taxing or levying duties on medicines.

Promoting a policy that would require compulsory generic substitution makes sense only in countries in which there is a substantial brand-name, or originator, premium. This is the case in many countries. In those countries in which mark-ups are excessive, mark-up controls may be required. If these can be implemented with the use of a fixed professional or dispensing fee this would create an incentive for the retailer to promote lower cost generic items rather than the higher cost originator products.

Dispensing doctors have consistently been shown to provide a more expensive dispensing service than other dispensing outlets. There are strong policy reasons for separating the prescribing and dispensing functions whenever there are financial incentives that may affect prescribing decisions. Many other health professionals also appear to be gaining from dispensing as well as prescribing. While they need to be adequately remunerated for professional services, huge mark-ups are unacceptable. This incentive for expensive prescribing should be removed.

Many other options may be possible depending on the circumstances revealed by a price components survey. However, suggesting that price regulation will always be necessary may not be an appropriate response when the local market for generic products functions efficiently.

Governments are mandated to care about the health of their people. Therefore, amassing revenue by taxing people who are ill is not acceptable. It is even worse if that money is being diverted from funding health care in the country. Adequate means of financing hospitals or other public health facilities that do not rely on the sale of essential medicines must be found.

If local add-on costs are less important contributors to the final price, but prices are high by international standards, the procurement process needs to be examined to ensure the best possible prices, for instance, by purchasing the best priced generic through international bid or from international procurement agencies. Where products are protected by patent, compulsory licences or government use provisions may be needed to ensure availability of affordable medicines for treating chronic disease. Where local factors such as taxes, including VAT, and mark-ups contribute significantly to the final price, a review of the local distribution process is needed, together with a revision of the local policies on taxes on raw materials imported for local production of medicines.

The revenue of all those in the distribution chain needs to be reviewed. In some settings, the mark-ups applied by importers, wholesalers and pharmacists will need to be regulated. In

other situations, competition may be more effective. Pharmacists provide a valuable service so remuneration should be based on the service provided using fixed professional fees, which are not linked to the value of the medicine dispensed. The exact nature of these professional fees should be studied at the national level, and experiences gained in other countries carefully considered. If mark-ups are needed, these should differentially favour the dispensing of cheaper quality assured generics. In the situation where prescription medicines are available through the informal sector, regulation should be enforced

8.5 Conclusion

There are many policy options to address the problems of high prices, low availability, poor affordability and excessive mark-ups. By studying the price, availability and affordability data available from a range of diverse countries and regions, policy-makers will be able to undertake surveys and develop policy interventions.

It is important to identify and assess the contributing causes before opting for and embarking on any policy change. Once a new policy is adopted, education will smooth the process of implementation but enforcement will also be needed. Most importantly, the impact of policy changes must be assessed, for instance by regular price monitoring and increased price transparency at all levels.

9. Recommendations

For those countries in which no survey of availability and affordability of medicines for chronic diseases has yet been done, such a survey should be undertaken soon. It is impossible to propose policies without having accurate data to serve as the basis for policy recommendations. In countries in which surveys have already been done, further work, particularly in relation to price components, may be required. Both survey data and further study data should be reported to HAI so that the results can be posted on the international web site, and secondary analysis undertaken.

In addition to surveys on medicine prices, availability and affordability, studies of actual practices in prescribing and dispensing medicines for chronic diseases are required.

In order to improve the price, availability and affordability of medicines, i.e. accessibility of medicines:

Governments should:

- exempt all essential medicines, especially those for the treatment of chronic diseases, from all duties and taxes (both central and local);
- where patents are an obstacle to access, use compulsory licensing and government use rules under local patent law as confirmed in the WTO Doha Declaration on TRIPS and Public Health;
- promote policies on generic substitution where brand-name premiums exist, and avoid the use of originator products in the public sector if cheaper generic products of assured quality are available;
- stimulate competition or enforce price regulations to ensure that generic products are available at prices close to international prices, especially if the prices of generics are high;
- ensure that patients with chronic diseases obtain their medicines at the lowest possible prices, especially where large differences exist between government procurement prices and government facility prices;
- make chronic disease medicines available to registered patients either through special outlets or through special schemes within private sector facilities where large differences exist between government procurement prices and facility prices or private sector prices. Such schemes were successful in Iraq, and still exist in Jamaica and the Eastern Caribbean;
- investigate the prescribing and pricing practices of dispensing doctors, to remove dispensing income incentives which will affect prescribing;
- extend current funding mechanisms, or establish a comprehensive mechanism, to cover unaffordable or unavailable medicines for treating chronic diseases, particularly those for asthma, epilepsy and psychiatric disorders;

- develop funding schemes to generate revenue to pay the salaries of those who work in the health system, and other expenses, without depending on revenue generated through the sale of medicines;
- monitor prices, availability and affordability of chronic disease medicines with transparent publication to their citizens.

International institutions should:

- support countries to monitor the medicine prices situation, diagnose the problems and implement corrective measures;
- fund capacity building activities, especially on procurement and good prescribing practices;
- avoid linking the funding of medicines to measures that increase medicine prices or compromise the continuous provision of medicines.

The World Health Organization should:

- continue to provide information on medicine prices and other data relevant for the development of pharmaceutical policy at the global, regional and national levels;
- assist countries in reducing the price of medicines and encourage the availability of generic products;
- encourage the development of a system for the continuous monitoring of the prices, availability, affordability and price structures of medicines for chronic diseases based on the WHO Model List of Essential Medicines and the WHO/HAI price survey methodology;
- provide evidence based policy advice to Member States to ensure national policy-makers are aware of their options for controlling prices while ensuring availability.

References

1. Bowker TJ, et al. A British Cardiac Society survey of the potential for the secondary prevention of coronary disease: ASPIRE (action on secondary prevention through intervention to reduce events). *Heart* 1996, 75:334–342.
2. EUROASPIRE Study Group. A European Society of Cardiology survey on secondary prevention of coronary heart disease. Principal results. *European Heart Journal*, 1997, 18:1569–1582.
3. Mendis S, et.al. WHO study on Prevention of Recurrences of Myocardial Infarction and Stroke (WHO-PREMISE). Bulletin of the World Health Organization, 2005, 83:820–828.
4. Beran D, Yudkin JS, de Courten M, Access to care for patients with insulin-requiring diabetes in developing countries. Diabetes Care, 2005, 28 2136–2140.
5. *The world medicines situation*. Geneva, World Health Organization, 2004.
6. Balasubramaniam K. *Health and pharmaceuticals in developing countries: towards social justice and equity.* Penang, Malaysia, Consumers International-Regional Office for Asia and the Pacific, 1996.
7. Balasubramaniam K. Is equitable pricing the answer? *HAI NEWS*, July-September 2001, No. 118 (available at **http://www.haiweb.org/pubs/hainews/200107_1.html**, accessed November 2005).
8. Myhr K. Comparing prices of essential drugs between four countries in East Africa and with international prices. *MSF Conference, Nairobi 2000* (available at: **http://www.accessmed-msf.org/upload/ReportsandPublications/3920012349208/East%20Africa.pdf**, accessed November 2005).
9. *Medicine prices, a new approach to measurement, working draft for field-testing and revision.* World Health Organization and Health Action International, 2003 (available at: **http://www.haiweb.org/medicineprices/**, accessed November 2005).
10. S. Mendis, K, et al. The availability and affordability of selected essential medicines for major chronic diseases in Bangladesh, Brazil, Malawi, Nepal, Pakistan and Sri Lanka. (Forthcoming.)
11. Barcelo A, et. al. The cost of diabetes in Latin America and the Caribbean. *Bulletin of the World Health Organization,* 2003, 81:19–27.
12. Horton R. The neglected epidemic of chronic disease *Lancet*, 2005, 366:1514.
13. Strong K, Mathers C, Leeder S, Beaglehole R. Preventing chronic diseases: how many lives can we save? *Lancet*, 2005, 366:1578–1582.
14. Epping-Jordan JE, Galea G, Tukuitonga C, Beaglehole R. Preventing chronic diseases: taking stepwise action. *Lancet*, 2005, 366:1667–1671.
15. Srinath Reddy K, Shah B, Varghese C, Ramadoss A. Responding to the threat of chronic diseases in India. *Lancet*, 2005, 366:1744–1749.

16. Wang L, Kong L, Wu F, Bai Y, Burton R. Preventing chronic diseases in China, *Lancet*, 2005, 366:1821–1824.

17. *Preventing chronic diseases, a vital investment, WHO global repor*t, 2005. Geneva, World Health Organization, 2005 (available at: **www.who.int/chp/chronic_disease_report/en**, accessed November 2005).

18. *International drug price indicator guide, 2004 edition*. Washington, DC, Management Sciences for Health, 2005.

19. Aït-Khaled N, et al. Affordability of inhaled corticosteroids as a potential barrier to treatment of asthma in some developing countries. *International Journal of Tuberculosis and Lung Disease*, 2000, 4:268–271.

20. Levison L, Laing R. The hidden cost of medicines. *Essential Drugs Monitor*, 2003, 33:20–21.

21. Levison L. Investigating price components: Tracking medicine costs between procurement and point of delivery. Report to WHO HAI 2006 Amsterdam.

22. Zaheer UDB, Ibrahim MIM, Singh H, Bukhari NI. A survey of medicine prices, availability, affordability and price components using the WHO/HAI methodology (available at: **http://www.haiweb.org/medicineprices/surveys/200410MY/survey_report.pdf**, accessed November 2005).

23. *TRIPS, R&D and access to medicines: a guide to the post 2005 world. External briefing document.* Geneva, Médecins Sans Frontières (MSF) Campaign for Access to Essential Medicines, 2005.

Annex 1

Strategic framework of the Global Initiative for Scaling Up the Care for Major Noncommunicable Diseases
(outcomes of the Cairo meeting)

Goal

To improve health outcomes by ensuring effective, evidence-based care for individuals with, or at high risk of developing, major chronic diseases.

Main objectives

1. Assess population health needs for addressing major chronic diseases in the locality/country.
2. Document and evaluate the current situation with respect to the provision of care for major chronic diseases.
    - Identify barriers to access, availability and affordability of diagnostic technologies and medicines.
    - Assess quality of care and utilization of effective interventions for the treatment of chronic diseases.
    - Document other activities coordinated by WHO and other major international agencies which are relevant to the goals of the initiative.
3. Develop, validate and implement an evidence-based, affordable "core package" of integrated interventions at all levels of care.
4. Support countries to bridge gaps in care through affordable strategies.
5. Promote patient autonomy, and the role of the family and community, in decision-making related to both clinical management and programme implementation.
6. Stimulate and foster effective global, regional and national partnerships between public and private sectors, civil society and other stakeholders to improve access to treatments, diagnostics, and information and communication technologies.
7. Support research and development related to innovative intervention strategies and ensure the dissemination of findings.
8. Monitor and evaluate all aspects, ensuring timely feedback to relevant stakeholders.

Added value of the Global Initiative

The initiative has added value in that it will:

- give visibility to the need to improve the management of chronic diseases;
- define public health priorities in chronic diseases;
- integrate the management of chronic diseases into primary health care;
- unify existing approaches to the care of patients with chronic diseases;
- improve the quality of care of patients with chronic diseases;
- involve patients, families and communities;
- mitigate the socioeconomic impacts of chronic diseases;
- be linked to policy at every stage;
- be linked to the critical components of the health system at all levels;
- create links between the Millennium Development Goals and chronic diseases by addressing health care inequalities associated with poverty.

Target diseases

The initiative should target a core list of chronic diseases, with the addition of supplementary chronic diseases based on local or regional need and availability of resources. The selection of diseases for inclusion in the initiative should be based on the following criteria:

- Burden of disease data (morbidity and mortality) which show that the disease is a major public health issue.
- Effective evidence-based interventions exist for both the disease and its risk factors.

The core chronic diseases and conditions targeted by the initiative will be:

- cardiovascular disease (coronary heart disease, cerebrovascular disease, rheumatic heart diseases, high cardiovascular risk);
- type 1 and type 2 diabetes;
- asthma.

Chronic diseases which may be added to this list are:

- epilepsy;
- depression;
- cancer;
- glaucoma.

Cancer represents a special case for which prevention and treatment are more difficult to incorporate into an integrated approach to chronic disease. In this respect, palliative care represents an opportunity for intervention that should be acted upon, particularly with regard to improving access to morphine.

Implementation

The initiative should encompass various aspects of the management of chronic diseases across the continuum of care, from diagnosis to treatment and follow-up. A step-wise approach should be applied to the implementation of interventions. In light of their high potential impact, particular emphasis should be placed on strategies for improving access to affordable medicines.

Phase 1: baseline situation analyses

In Phase 1, situation analyses will be conducted to assess the current status of chronic disease care at the country level. The situation analyses will include the assessment of the following:

- health facilities including risk assessment, diagnostic facilities, treatment, patient education and counselling;
- availability, affordability and cost of medicines;
- record-keeping and follow-up, including outcomes;
- stakeholder analysis;
- community perception.

Phase 2: intervention

Phase 2 will consist of a matrix of issues to be tackled at the global, regional and local levels. Country-level interventions will be selected on the basis of the results of the Phase 1 situation analysis.

Core areas are likely to include the following:

- policy reforms;
- development of guidelines and protocols;
- education and counselling of patient and family;
- training and involvement of health workers and pharmacists;
- medicine procurement and supply management;
- community empowerment;
- advocacy.

Supplementary activities may consist of:

- resource mobilization;
- establishment of partnerships;
- local production of medicines;
- establishment of a supply facility for chronic disease medicines.

Partnerships

The development and implementation of the initiative requires partnerships with various stakeholders, including:

- international organizations;
- professional and patient associations;
- nongovernmental organizations and civil society;
- the private sector;
- donors.

The structure of the partnerships is to be determined.

Short-term recommendations

All regional advisers and experts unanimously agreed that the initiative is worthwhile and recommended to the Assistant Director-General that:

- Financial and human resource support should be mobilized for further development of the initiative.
- The initiative should be officially launched and operationalized in 2006, beginning with country situation assessments.

Operational strategy 2006

Agreed next steps, targets and time lines

- Collection of existing resources, methodologies and tools for country situation assessments by 1 April 2006 (approximate cost US$ 30 000).
- Package of tools for country assessment developed, adapted and translated as required and ready for implementation in countries by May 2006 (approximate cost US$ 125 000).
- Situation analysis of selected countries by December 2006 (approximate cost US$ 45 000 per country).
- Convene a follow up meeting in 2006 to facilitate progress of situation analyses and to develop tools for core areas of intervention (Box 1).

Tools and methodologies to be developed, adapted and collated

- Facility capacity assessment questionnaire.
- Population coverage questionnaire.
- PREMISE (WHO study on prevention of recurrences of myocardial infarction and stroke) protocol on practice patterns.
- Rapid Assessment Protocol.
- Patient education and counselling protocols.
- Medicine availability/affordability survey.
- Record keeping and follow-up tools.
- Stakeholder analysis.
- Community perception analysis.
- Monitoring and evaluation tools.

This report was produced with data collected by survey teams using the World Health Organization/Health Action International price survey methodology. Further information is available at http://www.haiweb.org/medicineprices/