Measuring medicine prices, availability, affordability and price components

2ND EDITION

World Health Organization

hai GLOBAL

WHO/PSM/PAR/2008.3

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CD-ROM

Please refer to the accompanying CD-ROM for the full text of the manual in .pdf format, the automated data workbooks and other survey tools, resources and background materials.

Abbreviations

ATC	Artemesinin-Based Combination Treatment
AIDS	Acquired Immunodeficiency Syndrome
ARVs	Antiretrovirals
CIF	Cost, Insurance and Freight
CMS	Central Medical Stores
CPI	Consumer Price Index
CSO	Civil Society Organization
DDU	Delivered Duty Unpaid
DFID	Department for International Development (UK)
EML	Essential Medicines List
EXW	Ex-Works
FOB	Free on Board
GDP	Gross Domestic Product
GST	Goods and Services Tax
HAI	Health Action International
HIV	Human Immunodeficiency Virus
ID	Identification
INF	Insurance and Freight
IUD	Intrauterine Device
INN	International Nonproprietary Name
IRP	International Reference Price
Km	Kilometre
LoC	Letter of Credit
LPG	Lowest-Priced Generic
MDGs	Millenium Development Goals
MPR	Median Price Ratio
MeTA	Medicines Transparency Alliance (UK)
MoH	Ministry of Health
MMV	Medicines for Malaria Venture
MRP	Maximum Retail Price
MSF	Médecins Sans Frontières
MSH	Management Sciences for Health
MSP	Manufacturer's Selling Price
NA	Not Available
NEML	National Essential Medicines List
NGO	Nongovernmental Organization
NMP	National Medicine Policy
OB	Originator Brand
OCP	Oral Contraceptive Pill
PBS	Pharmaceutical Benefits Scheme (Australia)
PHARMAC	Pharmaceutical Management Agency (New Zealand)

PPP	Purchasing Power Parity
THE	Total Health Expenditure
USD	U.S. Dollar
VAT	Value Added Tax
Vs	Versus
WHO	World Health Organization

Foreword

Access to essential medicines is part of the fulfilment of the right to the highest attainable standard of health (in short: the right to health). So why do millions of people across the globe go without the treatments they need? The reasons are now becoming clearer – and the price and availability of medicines to those who need them are crucial factors. Prices for poor people are simply too high and products are often not available. This may not be news to the sick and poor, but it has been news for those whose responsibility it is to ensure the health of citizens.

In 2001, the World Health Assembly passed resolution 54.11 which requested the Director-General "*to explore the feasibility and effectiveness of implementing, in collaboration with nongovernmental organizations and other concerned partners, systems for voluntary monitoring drug prices and reporting global drug prices with a view to improving equity in access to essential drugs in health systems, and to provide support to Member States in that regard.*"

The first edition of *Medicine prices – a new approach to measurement* was published in 2003 as a working draft for field-testing and subsequent revision. Since then, more than 50 medicine price and availability surveys have been conducted in all regions of the world, using the recommended standard method. The results have exposed many problems of poor access to medicines, for example, people having to work 15 days or more to afford one month's treatment for a chronic disease; important medicines simply not being available locally to patients; governments not passing on low procurement prices to their citizens; excessive mark-ups in the private sector, and taxes and duties being applied to essential medicines. From the evidence that has resulted from use of the WHO/HAI survey tool, medicine affordability and availability issues show no boundaries. Crucially, it is the poor who are really paying the price – both economically and with their health.

The wealth of experience gained from four years of use of the WHO/HAI survey tool has led to a number of improvements in this second edition of the manual. We believe that the method is rigorous, facilitating reliable data collection and valid analysis. With the publication of the new edition, we encourage countries and organizations to not only undertake surveys, but also to implement systems for the regular monitoring of medicine prices, availability and affordability.

Gathering evidence is, of course, only the first step – data alone cannot improve access to treatment. That takes commitment – from governments, civil society, international organizations, health professionals, industry and many others, all working together to overcome the barriers. The work of the WHO/HAI Project on Medicine Prices and Availability and the survey teams across the globe has generated an extensive network of advocates, policy-makers, academics and others who are now focusing world attention on improving medicine affordability and availability.

Producing this manual is the latest activity in the implementation of the 2001 World Health Assembly resolution. The work that has been done has resulted from the

joint efforts of the World Health Organization and Health Action International with their many partners. We hope the new edition of the manual will further encourage others to tackle this challenge of ensuring universal access to affordable medicines.

Equitable access to essential medicines is the goal – it is the people's right.

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We especially want to thank all the survey teams, and in particular the survey managers, who undertook surveys using the 2003 methodology. Your advice on how to improve the manual and workbook has been very helpful. Most importantly, it is because of your efforts that we now know much more about the price, availability and affordability of medicines across the globe.

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1

Introduction

1.1 WHY MEASURE THE PRICE AND AVAILABILITY OF MEDICINES?

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

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

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

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

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

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

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

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

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

Prices of the same medicines frequently vary between countries (*11*); some commonly used medicines have been found to be more expensive in developing countries than in industrialized ones (*12–14*); and many studies have shown that affordability is unrelated to purchasing power. The ex-manufacturer prices to countries – in particular for the private sector – are often confidential. Medicine price indicator guides[1] provide the sales prices from large wholesalers of generically equivalent medicines to governments. However, they do not give the price patients must pay in either the public or private sectors and often do not include new, essential but patented medicines. A few countries have publicly available prices, but the information's use is obstructed by the country-specifics that apply and language barriers. The monitoring of prices and cross-country comparisons are therefore important.

1.2 THE WHO/HAI PROJECT ON MEDICINE PRICES AND AVAILABILITY

1.2.1 Background and project objectives

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

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

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

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

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

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

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

1.2.2 Development, testing and use of the manual

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

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

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

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

[1] www.haiweb.org/medicineprices

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

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

1.2.3 Survey results

By the end of 2007, over 50 surveys had been undertaken across the globe, from Cameroon and the Cook Islands to El Salvador, South Africa and the Syrian Arab Republic. They have generated reliable evidence showing, for the first time, some startling facts about the affordability and availability of medicines. The results of these surveys[1] revealed that in many low- and middle-income countries:

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

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

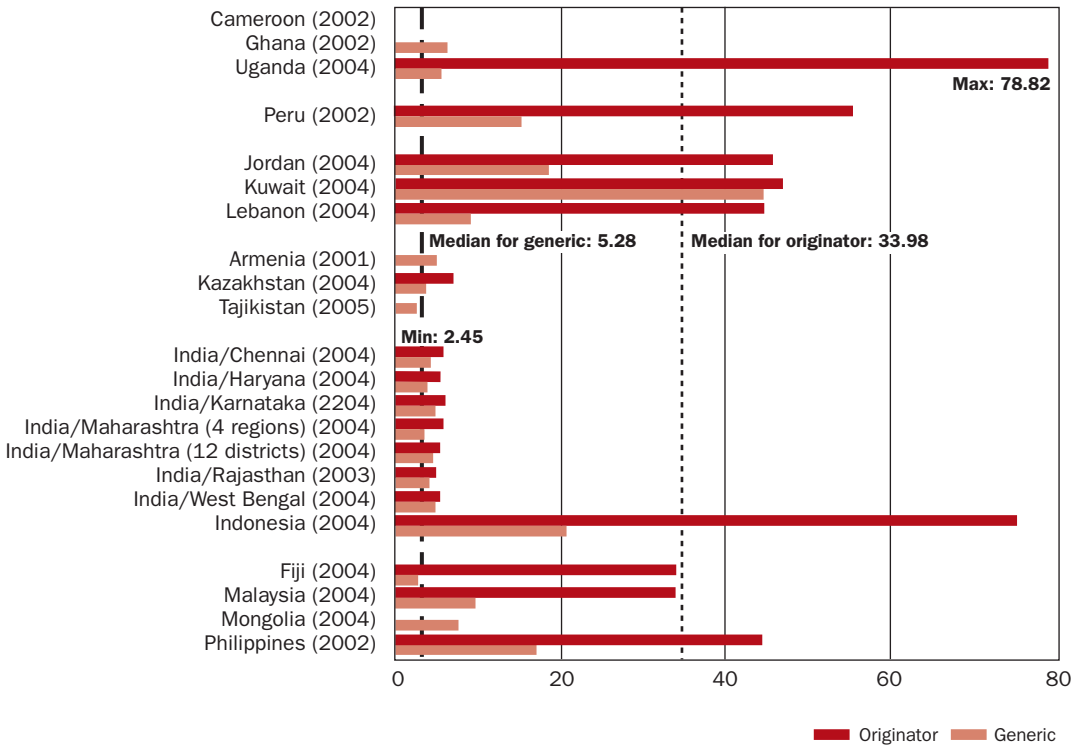
Table 1.1 Availability and affordability of 1 salbutamol inhaler 0.1mg/dose in selected countries[a]

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

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

[1] http://www.haiweb.org/medicineprices

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



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

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

1.2.4 Evidence for policy development and implementation

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

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

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

Changes in national policies feature in the project's bulletin *Medicine Pricing Matters* along with publications and other interesting outcomes of pricing work being carried out worldwide. This quarterly bulletin was first published in December 2007.[1]

1.2.5 Related surveys and initiatives

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

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

1.3 THE MEDICINE PRICES AND AVAILABILITY SURVEY MANUAL – SECOND EDITION

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

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

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

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

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

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

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

The second edition includes the revised survey manual along with updated versions of the automated data workbooks and survey instruments: it also includes a CD-ROM of survey tools, resources and background materials. The CD-ROM and the HAI web site[1] will be updated periodically with new materials as these become available.

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

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

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2

Survey overview and pre-survey planning

2.1 SURVEY OVERVIEW

2.1.1 Survey objectives

The survey's objective is to generate reliable information on the price, availability and affordability of selected important medicines and price components in the supply chain, with the ultimate goal of improving access to affordable medicines for all.

The survey enables the following questions to be answered:

- What price do people pay for key medicines?
- Do the prices and availability of the same medicines vary in different sectors (public sector, private sector and other medicine outlets)?
- Do prices and availability vary in different parts of a country?
- What is the difference in prices and availability of originator brands and generically equivalent medicines?
- Do prices vary between product types (e.g. originator brands and generics) within the same sector?
- How do government procurement prices compare with patient prices in the public sector?
- How do national prices compare with international reference prices?
- What taxes and duties are levied on medicines and what is the level of various mark-ups that contribute to their retail and public sector prices?
- How affordable are medicines for ordinary people?

The medicine price and availability study focuses on a limited number of medicines and enables their prices and availability to be investigated across health-care sectors within individual countries and also between countries. It is designed to measure medicine prices and availability at a certain point in time, but can also be used to monitor them over a period of time. The methodology facilitates rapid and reliable data collection and is easily replicable. The survey measures real paid prices, i.e. what patients pay in retail medicine outlets, and the price the government procurement agency paid; it does not rely on list prices produced by wholesalers, manufacturers and insurers, etc. A medicine price and availability study using this methodology also enables the price of selected medicines to be followed from

the point at which it leaves the manufacturer to the time it reaches the consumer's hands.

The survey identifies issues related to procurement price efficiency, public and private sector availability and prices, price structure and mark-ups, and crucially, the affordability of treatments for people with lower incomes. It is a useful tool for policy-makers and others concerned about access to medicines, and serves as an important basis for more in-depth analysis of various issues that might be identified, policy considerations and interventions.

If you are considering a medicine price and availability survey, spend some time clarifying and drafting your specific objectives. Consider the expected results and how you will use them to achieve the objectives identified, including any advocacy strategies that may be needed. Be very clear about to whom you will direct the results and recommended actions, and who else could work with you as a team to achieve the survey objectives.

This survey has been designed to provide a comprehensive picture of the prices and availability of selected medicines in a country. It should be repeated periodically to assess the impact of policy and programmatic changes on the prices of medicines.

The survey has been developed for use by governments, civil society groups, international agencies, researchers and health professional organizations. A survey manager coordinates the survey management. The survey manager is the primary audience for this manual, though the commissioning organization should also be thoroughly familiar with the survey procedures. An advisory committee should always be established to provide support and expertise throughout the survey and to initiate policy discussions based on the findings. The inclusion of prominent and respected stakeholders will enhance the credibility of the study, report and recommendations.

LESSONS FROM THE FIELD

"Undertaking such a survey is beyond the scope of an individual, and requires the commitment of a group of people. We contacted people – consumer associations, academics, pharmacists, pharmacy and medical associations and NGOs to contribute in one way or another."

Baber Z, Ibrahim M. Conducting a medicine pricing survey: experiences and challenges. *Essential Drugs Monitor*, 2005, Issue No. 34.

2.1.2 Key elements of the survey design

In the survey, data are collected on the availability and price of a selection of important medicines from a sample of medicine outlets in the public, private and other sectors (e.g. NGOs) in six regions of a country or – in the case of large countries – of a state or province. Data on medicine prices, but not availability, are also collected for government procurement; these data are usually collected at the central level (e.g. government procurement office). Most surveys are national, however in large countries it is recommended that the methodology be applied at the state or provincial level or that the number of regions surveyed be increased. Sampling is done in a systematic way to ensure that the findings are representative of the country or state/province in which the survey is being conducted.

The survey methodology also includes a process for collecting information on the add-on costs that contribute to the final price of medicines. This involves beginning with the final (patient) price of selected medicines and tracking these prices back through the distribution chain. Identifying price components is an essential part of the survey, both for understanding price results and for determining their policy implications.

It is usually not feasible to collect data from a large number of health facilities, pharmacies and other medicine outlets, so a small sample of facilities is selected in at least six geographical areas: a country's main urban centre and five other administrative areas (survey areas). In each survey area, a sample of medicine outlets are examined from each of the public sector, e.g. primary health-care centres and government hospitals, and the private sector, e.g. licensed pharmacies and licensed drug stores. Up to two 'other' sectors where medicines are commonly sold can also be surveyed, such as the mission sector and dispensing doctors. In each survey area, data are collected in at least five medicine outlets per sector, for a total of five outlets x six survey areas = 30 outlets per sector.

Up to 50 medicines are included in the survey. The list of survey medicines is generally composed of:

- 14 global core medicines;
- 16 regional core medicines; and
- 20 supplementary medicines.

- Data collection takes place in six areas of the country (survey areas)
- Medicine outlets from the public, private and up to two other sectors are surveyed. Prices are also collected for government procurement.
- Up to 50 medicines are surveyed, including core medicines that allow for global and regional comparisons, and supplementary medicines of local importance.
- Data on the price and availability of medicines in the public, private and other sectors are obtained by data collectors during visits to medicine outlets. Public procurement data are usually obtained centrally, e.g. from the office of the procurement officer or central medical stores.
- For each medicine, data are collected on the originator brand and the lowest-priced generic equivalent found at each medicine outlet.
- A second, important part of the methodology is the price components survey, where information is collected on the various charges applied to medicines as they proceed through the distribution chain.

The global and regional core medicine lists are part of the WHO/HAI standard methodology. By standardizing the medicines surveyed at the global and regional levels across surveys, countries can compare their findings with other countries and other international comparisons can be conducted. Supplementary medicines are selected at the country level for their national importance, or to collect data on a particular therapeutic class. For each medicine in the survey, data are collected for two products: the originator brand (previously called innovator brand), and the lowest-priced generic equivalent found at each medicine outlet.

In each survey area, data collection is managed by an area supervisor. Data collectors, who have received standardized training, including a data collection pilot

test, visit medicine outlets in pairs and record whether medicines are found, and if so, their price. When less than 50% of expected medicines are available at a given outlet, data collectors visit a back-up facility and repeat the data collection. This ensures that a sufficient number of medicine prices are collected to allow for robust analyses. However, the data from the original facility are also kept and used in the analysis to provide an accurate representation of medicine availability.

To ensure data quality, area supervisors check data collection forms at the end of each day of fieldwork and follow up on any incomplete, erroneous or illegible data. They also validate data collection by re-conducting the survey at 20% of the sample medicine outlets and comparing their results to those of data collectors. Once data collection is completed, verified data collection forms are sent to the survey manager at the central level. Data entry personnel enter the data into the computerized *WHO/HAI Medicine Price and Availability Workbook – Part I and Part II*, which is a customized application for Microsoft Excel®. To guard against errors, data are entered twice by separate personnel and cross-checked (double entry). The workbook's data-checker function is then used to highlight suspicious data that require verification. Ensuring the quality of the data entered into the workbook is critical to the accuracy of the survey results.

Data analysis is conducted using the electronic workbooks, which is pre-programmed to consolidate and summarize results. The availability of individual medicines is reported as the percentage (%) of medicine outlets in which the medicine was found on the day of data collection. To facilitate international comparisons, medicine prices found during the survey are expressed as ratios relative to a standard set of international reference prices, known as the median price ratio or MPR. The ratio is an expression of how much greater or less the median local medicine price is than the international reference price, e.g. an MPR of 2 would mean that the local medicine price is twice the international reference price. Management Sciences for Health (MSH) reference prices[1] are recommended as the most useful standard. These are prices offered by mostly not-for-profit suppliers to developing countries for multi-source products, and generally do not include insurance or transportation charges.

Affordability is estimated using the daily wage of the lowest-paid unskilled government worker by determining the number of days' wages required to purchase selected courses of treatment for common acute and chronic conditions.

Data collected on the components of medicine prices are analysed according to five common stages in the supply chain that all medicines go through as they move from manufacturer to patient:

Stage 1: manufacturer's selling price + insurance and freight

Stage 2: landed price

Stage 3: wholesale selling price (private sector) or
Central Medical Stores price (public sector)

Stage 4: retail price (private sector) or dispensary price (public sector)

Stage 5: dispensed price

This categorization allows comparisons both between health systems and between countries. Data on price components are also entered into the workbook, which automatically calculates the contribution of each stage of the supply chain to the

[1] http://erc.msh.org/

final price as well as the total contribution of price components to the final price of medicines.

2.1.3 The standard approach to measuring medicine prices and availability

The standard approach described in this manual involves a systematic survey to collect accurate data and reliable information on medicine prices and availability. It is characterized as follows:

- standard global and regional lists of medicines for international comparisons
- systematic sampling process
- use of international reference prices
- comparison of originator brand and generically equivalent medicines
- sector comparisons: public (patient and procurement prices), private and other sectors
- treatment affordability comparisons
- identification of price components, e.g. taxes and mark-ups, which contribute to the final patient price of medicines
- standard data entry and analysis methods using computerized workbooks
- standard report format

The standard methodology must be followed to ensure that the data are reliable and that international comparisons are possible.

2.1.4 Steps in the survey

Table 2.1 provides an overview of the survey's steps, the activities to be undertaken at each step and the chapter in the manual where detailed instructions are provided.

2.2 PRE-SURVEY PREPARATION

The following resources are provided to assist you in conducting the survey:

- Survey manual
- Survey templates, tools and supporting materials (on CD-ROM)
- Computerized workbooks for generation of survey instrument (data collection form), data entry and processing

Note that the workbook is in two parts:

Part I is used to enter the study medicines and international reference prices, generate the data collection form for the price and availability survey, enter unit prices collected in the public sector (procurement and patient prices), private sector and other sectors, analyse prices and availability, and assess affordability

Part II is for entering and analysing price component data

Table 2.1 Steps in the survey

Step	Survey activity	Chapter
Pre-survey preparation Estimated duration: two to three weeks	1. Establish an advisory committee and meet to clarify survey objectives, scope (national vs provincial survey, survey areas, sectors), medicines to be surveyed, source of procurement data, personnel and other resource needs, timelines, budget, potential donors (if needed). 2. Collect background information on the pharmaceutical sector. 3. Recruit survey personnel. 4. Secure technical and financial resources. 5. Seek endorsement for the survey. 6. Prepare a survey schedule.	2
Planning the survey Estimated duration: two to three weeks	1. Select the sample of medicine outlets. 2. Finalize list of medicines to be surveyed. 3. Develop draft survey protocol, submit to HAI or WHO for review. 4. Develop Medicine Price Data Collection form. 5. Plan and conduct training course, including data collection pilot test.	3 & 4
Preparation for data collection in the field Estimated duration: one week	1. Prepare Letter of Introduction. 2. Plan schedule of data collection visits and transport/accommodation in the field. 3. Prepare Medicine Price Data Collection forms for field visits. 4. Prepare information materials and tools for data collectors. 5. Arrange for regular communications during fieldwork.	5
Data collection in the field Estimated duration: two weeks (if three data collection teams, each surveying two areas, are used and sampling distances are adhered to)	1. Collect central government procurement data. 2. Assemble materials necessary for local data collection. 3. Confirm appointments with medicine outlets. 4. Visit medicine outlets and any regional government procurement units, collect data on medicine availability and price, and complete Medicine Price Data Collection form. 5. At the end of each day, check data collection forms and resolve missing/unreliable information. 6. Validate data collection by re-conducting survey at 20% of medicine outlets. 7. Copy and store data collection forms and, upon completion of data collection, transfer originals to survey manager for initial visual inspection.	6
Data entry, analysis and interpretation Estimated duration: three weeks	1. Enter data twice, using double-entry function and verify/correct any inconsistencies. 2. Run “data checker” and verify/correct any suspicious data. 3. Send data to HAI or WHO for a data quality review. 4. Conduct analyses of medicine availability, price and affordability, including international comparisons as appropriate. 5. Meet with advisory committee to analyse and interpret results, explore possible policy options and lines of action, and plan price components survey. The latter includes identifying key sources of information; determining priority price components to be surveyed; and selecting regions, medicine outlets and medicines for tracking medicines through the supply chain.	7, 8 & 10
Price components survey Estimated duration: three weeks	1. Recruit survey personnel as needed and conduct training. 2. Plan schedule of data collection visits and any transport/accommodation in the field. 3. Visit key informants and collect central level data on national policies related to price components. 4. Collect data on the actual charges applied to selected target medicines. Visit the dispensing point for each sector and track target medicines backwards along the supply chain to their point of origin, recording the charges incurred. 5. Enter data on the charges applied to target medicines in the workbook. 6. Conduct analysis of the contribution of price components to the final price of each target medicine, by stage and overall. 7. Prepare report on price components.	9

Table 2.1 ***Continued***

Step	Survey activity	Chapter
Using the information collected Estimated duration: one to two weeks for survey report, with advocacy and communications ongoing	1. Meet with advisory committee to analyse and interpret price components results; consolidate all survey results; and finalize recommendations. 2. Draft survey report. 3. Share preliminary findings with key stakeholders and consult on next steps. 4. Plan and implement advocacy and communications activities.	11, 12 & 13

Before starting to plan the survey, read the manual in full and familiarize yourself with the resources included on the accompanying CD-ROM. Some survey managers have said the manual needs to be read two or three times for a thorough understanding of the methodology!

Careful planning and preparation are essential before data collection begins. Experience in the surveys conducted to date shows that most errors and missed opportunities could have been avoided by better pre-survey planning.

2.2.1 Establishing an advisory committee

An advisory committee should be assembled to help plan and support the survey and promote its findings. Advisers should be involved from an early stage to ensure their support of the validity of the survey results and their assistance in promoting pricing policy changes. Involving key stakeholders and opinion leaders will also strengthen the credibility of the survey findings.

The role of the advisory committee should include:

- clarifying the survey's objectives;
- assisting in obtaining endorsement for the survey;
- identifying possible sponsors (if needed);
- supporting the survey manager in planning, preparing and conducting the study, and identifying important policy issues that should inform the survey protocol (e.g. medicine selection);
- advising on any matters that arise during survey preparation, fieldwork and data analysis;
- assisting in planning and conducting the price components survey, including identifying and contacting key informants;
- assisting in interpreting data and developing policy recommendations;
- promoting the survey's findings and advocating for appropriate policy changes; and
- assisting in carrying out a follow-on, in-depth study or intervention study.

Holding regular meetings with the advisory committee, throughout the survey process, is important. You should hold at least one meeting to support the planning and preparation of the medicine prices and availability survey and one post-survey meeting for interpreting survey results and developing recommendations. The latter meeting should also be used to plan the price components survey if it is being conducted after the general pricing survey. You should hold a second post-survey meeting following the price components survey to discuss the results and their policy implications, consolidate all survey results and finalize recommendations.

Medicine price monitoring: lessons from the field

"In Kenya, the collaboration between the Ministry of Health (MoH) pharmacy division and the WHO National Professional Officer has been instrumental in facilitating the survey. The advisory group, composed of individuals from relevant Ministry departments and NGOs, has also been extremely important. The MoH is considering institutionalizing this work as part of monitoring and evaluation and the chief pharmacist uses the reports frequently. We now have a strong team of data collectors whose capacity has been built and who are undertaking other monitoring and evaluation activities in the area of medicines."

Patrick Mubangizi, Survey Manager, Medicine Price Monitoring, Kenya

You should select the advisory committee membership carefully. It should complement the survey manager's skills and include at least one medical doctor and pharmacist, a health economist (where possible) and stakeholders such as policy-makers, relevant professional associations, public-health institutions, academic institutions and civil society groups working on health issues (preferably access to medicine issues). At least one member should be knowledgeable about the medicines supply chain in various sectors to provide support to the price components survey. If there is a market survey company active in your community, such as Intercontinental Medical Statistics (IMS) Health, you may wish to involve them in the committee. It may also be wise to include an area supervisor with an understanding of local realities. The size of the advisory committee should be kept sufficiently small to enable regular meetings, however if this is not possible, working groups can be formed to address specific topics (e.g. methodology, price components, advocacy).

2.2.2 Clarifying the specific survey objectives

The broad objective of any medicines price and availability survey is to generate reliable information on the price, availability and affordability of selected important medicines with a view to ensuring access to affordable medicines for all. However, the specific research and policy objectives of each individual survey will vary. For example, a country may wish to investigate the impact of originator brand product use on medicine affordability as a means to support introducing a generic substitution policy. Another country might want to survey prices and availability of all medicines in a particular therapeutic group (e.g. antimalarials or palliative care medicines). The commissioning organization, advisory committee and survey manager should work together to clarify the survey's research and policy objectives so that a survey design is developed according to these objectives. They should also consider whether any other research is needed to provide a broader perspective (e.g. assessing sales volume). Well-defined survey objectives will also help to guide data analysis and interpretation, as well as follow-on communication and advocacy activities.

2.2.3 Collecting information on the health system and pharmaceutical sector

A critical step in preparing for the medicines price survey is to collect background information on the pharmaceutical sector. This information is indispensable for survey planning, e.g. selection of sectors to study and medicines to survey. It will also be of critical importance in analysing the data and formulating policy recommendations.

The structure of the health-care system and the organization of the pharmaceutical sector vary widely between, and sometimes within, countries. Before beginning

the survey, it is important to have a clear understanding of how pharmaceutical services are organized, including the relative contribution of various sectors to the supply of medicines. Additionally, the main procurement and distribution channels for pharmaceuticals should be clearly identified. This will allow you to put medicine prices in a countrywide context and identify countries with similar pharmaceutical characteristics, thus enabling you to make useful comparisons. Specifically, these data will allow you to consider the relative importance of different market segments and different financing arrangements, such as social insurance, in making national and international price comparisons.

Data on the national pharmaceutical sector are collected using an abridged version of the WHO *Questionnaire on structures and processes of country pharmaceutical situations*.[1] This questionnaire measures structures and processes at the level of national governments, including policies, regulations, quality control measures, essential medicines list, supply system, financing, access, production, rational use and intellectual property rights legislation. It is a basic assessment tool that provides a rapid means of obtaining information on the existing infrastructure and key processes of each component of the pharmaceutical sector. Administered through the WHO Medicines Policy and Standards/Technical Cooperation for Essential Drugs and Traditional Medicine department, the questionnaire is distributed every four years to all Member States, most recently in 2007. WHO uses the results to assess the global pharmaceutical situation, evaluate progress achieved towards goals set in the WHO Medicines Strategy, make plans and set targets for WHO work for the next four years.

An abridged version of the questionnaire that includes only those questions relevant to medicine pricing, availability and affordability has been developed for use as part of the survey. A set of supplementary questions important to the medicine prices and availability survey has also been included.

The abridged version of WHO's *Questionnaire on structures and processes of country pharmaceutical situations*, available in Annex 1 and on the CD-ROM that accompanies this manual, should be completed before beginning to plan the survey. Survey managers should check with the WHO Department of Medicines Policy and Standards/Technical Coooperation for Essential Drugs and Traditional Medicine[2] to see if the full questionnaire has been administered recently.

In addition to completing the abridged questionnaire, survey managers should also collect as many other relevant materials as possible, such as the national medicines policy or other related policies; the essential medicines list; and the reports of medicine use studies where these have been conducted. It is useful to check with the MoH, national statistical office or WHO office to see whether any recent surveys have been undertaken as part of a national medicines or health-system policy review.

Collecting baseline information on the organization of the pharmaceutical sector is essential for appropriate survey planning and later for interpreting the survey findings and identifying policy options. Allocate sufficient time for collecting information and do not begin planning the survey until the abridged WHO *Questionnaire on structures and processes of country pharmaceutical situations* is completed.

[1] This questionnaire replaces the National Pharmaceutical Sector form used in the first edition of the survey methodology.
[2] Contact Dr Daisy Carandang at carandange@who.int

Descriptive information on your country's health-care system and pharmaceutical sector can be very valuable in explaining or interpreting the survey findings. **Data on the national pharmaceutical sector should therefore be summarized in the background section of your survey report (see Chapter 12)**. Depending on the country situation and the survey results obtained, some aspects of WHO's *Questionnaire on structures and processes of country pharmaceutical situations* may benefit from further elaboration in the survey report, particularly where they are likely to have a substantial impact on medicine prices or availability. You may also want to add additional information to your summary on topics not included in the questionnaire to help readers understand the survey setting and results.

2.2.4 Selecting survey personnel

The survey will require the involvement of the following personnel:

- the survey manager, supported by an advisory committee;
- area supervisors;
- data collectors; and
- data entry personnel.

Survey manager

The survey manager plans and coordinates the survey at the central (national) level. This includes planning the survey's technical and logistical aspects, recruiting and training survey personnel, supervising data collection and data entry, conducting data quality assurance and data analysis, interpreting results and preparing a survey report. For NGOs, this role may also include fundraising to support the survey and related follow-up activities.

Wherever possible, the survey manager should be a pharmacist with experience in conducting surveys and familiarity with the health-care system. The survey manager should be familiar with Microsoft Excel spreadsheets, basic statistics (such as ratios, medians and percentiles) and interpreting data. Successful communication of the survey results also requires an understanding of the policy-making process and different advocacy strategies. Where the survey manager does not possess all of these qualities, he or she should select the advisory committee members to ensure that the survey management team includes the necessary pharmacy, surveying, statistics, policy and advocacy skills.

Area supervisors

Area supervisors are responsible for overseeing all aspects of data collection in the survey area(s) for which they are responsible. In a small country or in a survey that is conducted in a single region of a country, it may be possible for all field work to be undertaken by a single team. Experience has shown that in larger-scale studies, however, it is advisable to designate a supervisor, preferably a pharmacist, in each of the geographical areas that will be surveyed.

Area supervisors have a crucial role to play in ensuring data quality and consistency. They should be experienced in data collection and be familiar with pharmaceutical terminology. They will also be instrumental in gaining access to facilities; if any area supervisor is unfamiliar with their designated area, a local contact may be needed to assist in identifying medicine outlets. Area supervisors may also be responsible for choosing local data collectors when they are not sent from the central level.

Area supervisors have a crucial role to play in ensuring data quality in the field.

Data collectors

Data collectors are responsible for visiting medicine outlets and recording information on medicine prices and availability with a high degree of accuracy. The survey methodology has been designed to minimize as far as possible the need for a high level of technical expertise. However, data collectors should, wherever possible, have the following skills and capabilities:

- a basic understanding of pharmaceuticals, including different formulations (strengths, dose forms, etc.) and pack sizes, in order to be able to extract the required information from both health professionals and from written material such as packs and order lists. (Ideally, data collectors should have some pharmaceutical training and/or experience since previous survey experience shows that the most effective data collectors are those with relevant knowledge and experience, e.g. pharmacists, pharmacy technicians, pharmacy students and nurses.)
- some understanding of the principles of sample surveys, ideally with some previous experience in conducting surveys;
- an appreciation of the logistical requirements for carrying out field studies;
- a minimum of post-secondary school education; and
- familiarity with the locality and local language/dialect.

Data collection can be tedious work and requires an aptitude for concentration and attention to detail. The best data collectors combine the discipline of collecting data in a standardized way with the ability to identify unusual situations that require advice from the area supervisor or survey manager.

The number of data collectors required depends on the sample size of the survey. Data collectors should work in pairs so that they can make systematic checks of entries into the Medicine Price Data Collection form. Each visit to a health facility or pharmacy is likely to require about one to two hours plus transport time. In practice, this means that a team of two data collectors can probably survey two to four facilities per day. Depending on the locations of the survey areas, travel conditions and number of medicine outlets to be surveyed, you will probably need 6–12 data collectors (1 pair per survey area or per 2 survey areas). It is better to have a smaller number of better qualified data collectors than to have a large team where some data collectors lack the necessary skills.

LESSONS FROM THE FIELD

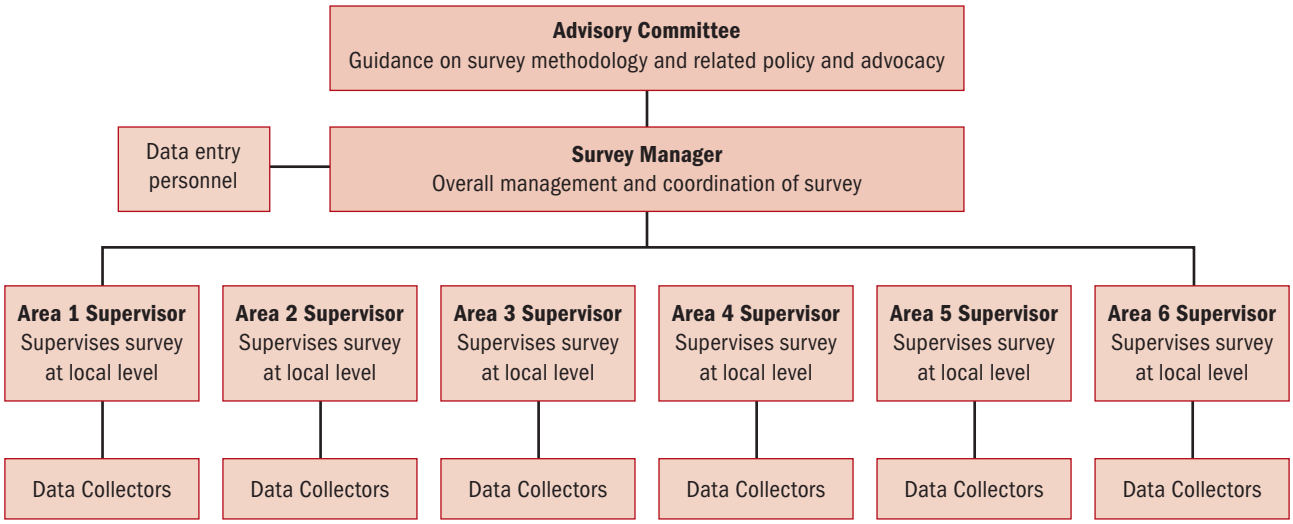
In the 2002 survey in South Africa, regional pharmacists were recruited as data collectors because they were known to the pharmacists and doctors in the area and also knew the facilities in the area.

Kishuna A. Drug Pricing Survey in KwaZulu-Natal. *Essential Drugs Monitor*, No.32, 2003. (http://mednet2.who.int/edmonitor/32/32_2.pdf, accessed 13 December 2007)

Data entry personnel

Accurate data entry is vital to ensure the reliability of the results. Two data processing personnel with experience in using Microsoft Excel are required: one to enter the data and the other to re-enter the same data to check that the entries are

Fig 2.1 Organizational structure of the survey



Note: Some area supervisors and data collectors may survey more than one survey area; six separate teams are not always required.

correct. The computerized workbook has been designed to identify any discrepancies in data entry using this "double-entry" process. Double entry is essential to ensuring the accuracy of the data entry process. In some cases, it may be possible to use the same personnel for both data collection and data entry, provided they have the necessary expertise to undertake both functions.

Fig. 2.1 illustrates the survey's organizational structure.

2.2.5 Securing the technical and financial resources required

Technical resources

The computerized workbook used for data entry and analysis is a specially designed software application for Microsoft Excel. To use it, a computer that meets the following minimum requirements will be needed:

- a personal computer (PC) with a Pentium 3 or higher processor;
- Windows operating environment;
- 48 megabytes of system memory;
- Microsoft Excel Office 97 or later version;
- a CD drive or Internet access, so that the workbook can be loaded from the CD-ROM supplied with the manual or downloaded from the HAI web site.

Very few other resources are needed to conduct the survey. Area supervisors and data collectors should be supplied with a simple calculator to determine unit prices. Paper will be needed for data collection forms. Transport will also be needed to take the data collection teams to the medicine outlet visits. If the teams are not from the local survey area, transport to and from the survey area, as well as accommodation, will also be required.

Data collection includes validation at 20% of medicine outlets, as well as potential visits to back-up facilities. These activities are integral parts of the survey methodology that should be built into the survey budget and timeline.

Financial resources

The survey methodology has been designed to be feasible and carried out easily with minimal technical and financial resources. However, when planning the survey, it is essential to ensure that there is an adequate budget for the following items:

- personnel:
  - — survey manager
  - — area supervisors
  - — data collectors
  - — data entry personnel
- training:
  - — training venue
  - — daily allowance and accommodation
  - — transport
  - — materials
  - — expenses related to pilot test
- data collection and validation, including price components:
  - — daily field allowance and accommodation for data collectors
  - — transport
  - — materials: paper, pens, calculators
  - — photocopying
  - — communication (e.g. telephone charges)
- meetings of the advisory committee
- report production and dissemination – layout, printing, postage
- advocacy and communications
- overhead
- contingency, including data collection at back-up facilities

A budget template is provided as part of the Survey Protocol template that should be completed and sent to HAI[1] or WHO[2] for review prior to the initiation of data collection. The Survey Protocol template is available on the CD-ROM that accompanies this manual.

[1] Contact info@haiweb.org
[2] Contact medicineprices@who.int

2.2.6 Seeking endorsement for the survey

A signed, official letter from the MoH or national pharmacy association endorsing the survey can be of great help when seeking funding and when collecting data in the field. If the survey manager approaches the relevant bodies with an example of the kind of letter that is sought, it may be easier for them to provide such an endorsement. A sample letter of endorsement, shown in Annex 2, is included as a Word file on the CD-ROM for modification as appropriate. WHO will also provide a letter of endorsement on request.[1]

An official letter of endorsement from the ministry of health and/or the national pharmacy association will facilitate data collection.

2.2.7 Preparing a survey schedule

The complete survey should generally take about 14 weeks to complete, including preparation, data collection, data entry and analysis and report writing. Further time should be allotted for advocacy and follow-on activities.

Given that medicine prices are subject to change based on exchange rates, market influences and other factors, it is important that data collection be conducted rapidly and the report generated within one month of completing the survey. In countries with fluctuating inflation rates, it is particularly important that the survey be completed in as short a time frame as possible.

A survey schedule should be developed and consulted regularly to ensure that activities are proceeding according to plan. A sample survey schedule is provided as part of the Survey Protocol template that should be completed and sent to HAI[2] or WHO[3] for review before initiating data collection.

The complete survey should take about 14 weeks to complete, including data collection, data entry, data analysis and report writing. Given that price data can quickly become out-of-date, it is important that the survey report be generated within one month of completing data collection.

[1] Contact you local WHO country office or WHO headquarters at medicineprices@who.int.
[2] Contact info@haiweb.org
[3] Contact medicineprices@who.int

3

Preparation

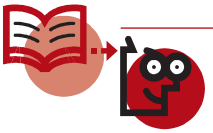
You may begin detailed planning of the survey after attaining a thorough understanding of the national pharmaceutical sector and obtaining the necessary human, technical and financial resources required to carry it out.

Chapter 3 describes the various activities required to create a country-specific survey design based on the standard methodology. This effort involves:

- identifying the regions in which to conduct the survey ('survey areas');
- identifying the sectors to include in the survey ('sectors');
- developing the sample of medicine dispensing points to survey for each sector ('medicine outlets');
- finalizing the list of medicines to be surveyed; and
- for each medicine to be surveyed, identifying the originator brand product and manufacturer (lowest-priced generic products will be identified at individual medicine outlets).

Once the various elements of the survey design have been developed, a survey protocol should be prepared and sent to HAI[1] or WHO[2] for review prior to starting the survey. The Survey Protocol template is provided on the accompanying CD-ROM.

Meaningful survey results depend on an appropriate survey design. This requires strict adherence to the medicine price survey standard methodology and process, as well as careful consideration of the national pharmaceutical situation.



It is essential to follow the survey methodology, particularly the sampling methods.

3.1 DETERMINING THE SURVEY SCOPE

3.1.1 Planning where to conduct the study – national or regional?

Most medicine price surveys will involve examining prices and price variations in an entire country. The ideal national survey would collect data from a large number of health facilities and other medicine outlets situated throughout the country.

[1] Contact info@haiweb.org
[2] Contact medicineprices@who.int

However, this would require a great deal of time and resources. To make the survey feasible, therefore, it is based on small representative samples of geographical areas and medicine outlets. Validation studies have shown that through careful selection, these study sites can represent the situation in the country as a whole adequately. **However, in large countries (e.g. large in geographical size or population or number of medicine outlets), the sample size may not be nationally representative. In these cases, it is recommended that the methodology be applied as a state or provincial survey or that the total number of survey areas be increased**. If resources allow, a series of state- or provincial-based surveys should be conducted.

For simplicity, this manual describes a national medicine prices survey. However, it can easily be applied to a state- or provincial-based survey, like those that have been conducted in Brazil, People's Republic of China, India and Sudan.[1] If you are in any doubt about the design of your survey, contact HAI[2] or WHO[3] for advice.

3.1.2 Identifying sectors to be surveyed

The next step in developing the survey design is to decide which sectors to survey. Each sector represents a different source of medicine prices and availability to be assessed and compared. In identifying sectors, consider both the structure of the health system and the relative importance of various sectors in supplying medicines.

Most surveys will examine at least three of the following sectors.

1. **Public sector procurement prices**. These are prices that the government pays to procure medicines. Unlike other sectors where data are always collected at a sample of medicine outlets, procurement data are usually collected centrally from the ministry of health (from tender or other documents) or at central or regional medical stores. However, where there is decentralized procurement or a mix of centralized and decentralized procurement, data are collected from public health facilities (see page 52). For this sector, data are only collected on medicine prices and not availability.

   Some countries have both a central store and regional medical stores. Both central and regional procurement data can be entered on the *Field Data Consolidation: Public Sector Procurement Prices* page of the workbook, but each should be clearly labelled so that separate analyses are possible (see Chapter 8, page 106).

   Medicine procurement prices from other sectors, such as the private sector, the NGO sector or mission sector, can also be collected. **Procurement prices from different sectors must always be analysed separately and should *never* be combined into one set of procurement results**. It is therefore very important to clearly label each set of procurement data according to sector. More information on entering and analysing procurement data from different sectors is provided in Chapters 7 and 8.

2. **Public sector patient prices**. Public sector patient prices can include government, municipality or other local authority health facilities, where patients receive medicines, such as hospitals, clinics and health centres. Note that for the hospitals included in the public sector sample, medicine price/availability data

[1] http://www.haiweb.org/medicineprices/surveys.php.
[2] info@haiweb.org
[3] medicineprices@who.int

Whereas in other sectors both the price and availability of medicines are measured, only medicine prices are collected for procurement.

are collected for the outpatient/primary health care service. The structure of the health system, including the expected availability of medicines at each level of care, should be considered when developing the public sector sample.

In most countries, governments supply medicines through the public sector. In some countries, medicines in the public sector are free to all, or to certain categories of people (e.g. the elderly). In other countries, patients have to pay either the full cost of the medicine or a standard (fixed) fee that may or may not include consultation costs. Where medicines are available for free or for a fixed fee, this should be described in the survey report.

Where medicines are provided free to *all patients*, or are *always* available at a standard fee irrespective of the medicine dispensed, the cost of medicines is covered by another means (e.g. social health insurance). There are therefore no patient medicine prices to measure in the public sector. **In such cases, collect data on medicine availability but not price**.

There could also be instances in which some, but not all, medicines are provided free of charge in the public sector (e.g. certain medicines are provided free through donation programmes). In such cases only availability data are collected for the free medicines, and both price and availability are collected for other medicines.

3. **Private sector patient prices**. The private sector includes licensed retail pharmacies and licensed drug stores only. Note that in some countries, drug stores may be far more prevalent than pharmacies and should not be overlooked in developing the private sector sample.

   The private sector does not include unlicensed drug stores, drug sellers in the informal sector, pharmacies in private clinics and hospitals or health facilities operated by private companies, such as mining companies. If these medicine sources are of interest, they can be considered as 'other' sectors (see below). Licensed drug stores could also be considered as an 'other' sector separate from licensed pharmacies, if regulations and/or prices are expected to vary significantly between the two.

4. **'Other' sector patient prices**. Depending on the nature of the pharmaceutical sector and the survey's policy objectives, there may be 'other' sectors you may wish to include in the survey. In general, if a sector other than the public and private sectors supplies medicines to a substantial number of patients, it should be included as an 'other' sector. The computerized workbook can accommodate up to two other sectors. Examples of other sectors include:

   — health facilities run by NGOs, such as charitable organizations;

   — health facilities run by religious organizations, such as church missions;

   — private hospitals; and

   — dispensing doctors.

   Some of these facilities and sectors may not exist in your country. In some countries, there may be no 'other' sectors that supply medicines; in such cases the survey is limited to the public and private sectors.

If specialized or hospital-only medicines are of particular interest, for example in surveying a particular therapeutic group, public hospitals can also be included as an 'other' sector. Although hospitals are included as part of the public sector sample, this sector is focused on medicines available through the outpatient/primary health-care services of district or regional hospitals. You may wish to survey basic inpatient care or tertiary care services as an 'other' sector to capture data on the medicines available through these services.

Different sources of medicines (e.g. mission hospitals, dispensing doctors) should always be considered separately and never be combined into one 'other' sector.

BOX 3.1

Selecting sectors – special cases

Private pharmacies in public hospitals
Private pharmacies operating in public hospitals may have different medicine availability and prices than both public pharmacies in public hospitals and private retailers in the community. They should not be included in either the public or private sector samples, but rather should be surveyed as an 'other' sector.

Pharmacies with both public and private counters or mixed public/private counters
In pharmacies where both public and private services co-exist, these should be treated as two separate sectors. In cases where public and private counters co-exist, these should also be surveyed separately, i.e. as two different sectors.

Vertical health programmes as an 'other' sector
A vertical health programme is a package of activities designed to deal with a single health problem (e.g. tuberculosis, HIV/AIDS) or a group of linked health problems (e.g. reproductive health). The programme may be located in hospitals – sometimes with independent staffing, infrastructure and logistic systems – or in the community. In vertical programmes, any core or supplementary medicines that are not relevant to the target health problem will usually not be available; similarly, medicines available through the vertical programme may not be available in any other sectors. This reduces the number of medicines upon which price analyses are based, thereby weakening summary data. As a result, if a vertical health programme is selected as an 'other' sector, it is recommended that a set of medicines specific to the target programme be surveyed *in addition* to the 20 supplementary medicines.

Note that to obtain an accurate estimate of availability, medicines only available through vertical programmes will need to be excluded from the availability analysis in other sectors. Similarly, core or supplementary medicines that are not available through vertical programmes will need to be excluded from the availability analysis in this sector. Chapter 8 (page 123) provides further information on excluding individual medicines from summary results.

The computerized workbook is designed to measure prices, availability and affordability in up to five sectors: public sector procurement prices, public sector patient prices, private retail patient prices and two 'other' sectors. In a survey that includes more than five sectors, data for the additional sectors can be entered into a second workbook. However, this will limit the ability to conduct comparative analyses between sectors in different workbooks. Consideration should also be given to the additional time and resources required to survey multiple other sectors. In general, it is recommended that the survey be limited to a maximum of five sectors.

3.1.3 Identifying survey areas

Survey areas are administrative areas (e.g. districts, municipalities, counties) in your country, where data will be collected from medicine outlets. Most countries will have multiple administrative divisions that could be used as survey areas. When deciding which administrative division to use, the following criteria should serve as a guide:

- Each survey area should cover a population of about 100 000 to 250 000 (in small countries a lower population coverage may be appropriate).
- All survey areas should be reachable within one day's travel from the country's main urban centre.
- The six survey areas in the sample should be large enough to represent the country (for a national survey) and contain the requisite number of health facilities (see below).

Six survey areas should be selected for data collection:

Choose the country's *major urban centre* (usually the capital city) as one area.

Choose *an additional five survey areas* randomly from all the administrative areas that can be reached *within one day* from the major urban centre using the most appropriate means of transportation, usually car, bus or train (see Fig. 3.1).

- If your country has another important major urban centre (e.g. provincial or business capital), choose this as a survey area. Then choose *four more areas* randomly from all the administrative areas that can be reached within one day from the major urban centre.
- If your country does not have another important major urban centre, choose *five more areas* randomly from all the administrative areas that can be reached within one day from the major urban centre.

In some cases, there may be a valid reason for excluding an area from the random sample, e.g. political instability or risk of cross-border trade/smuggling. Decisions to exclude certain areas from the survey should be made prior to sampling and should be justified in the survey report.

The geographical distribution of population should be considered in selecting survey areas to ensure that both urban and rural areas are surveyed. If there are large differences in the population densities of administrative areas:

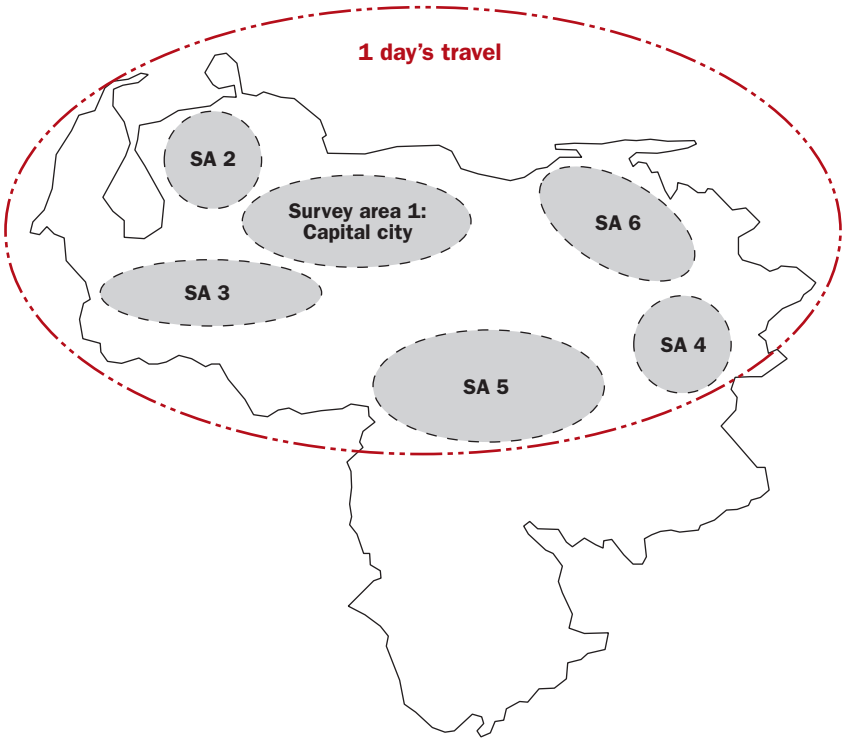
- Divide the administrative areas that can be reached within one day from the major urban centre into groups according to population density (e.g. urban, rural, periurban).
- Randomly select survey areas from each group, allocating the number of survey areas to each group roughly according to the proportion of population it represents.

Alternatively, it would also be possible to stratify the selection of survey areas by socioeconomic status:

- Divide the administrative areas that can be reached within one day from the major urban centre into groups according to their socioeconomic status (e.g. low-, medium- or high-income).
- Randomly select survey areas from each group, allocating the number of survey areas to each group roughly according to the proportion of population it represents.

To facilitate data collection, all survey areas should be reachable within one day's travel from the urban centre using the most appropriate means of transportation, usually car, bus or train.

Fig. 3.1 Six survey areas: the capital city plus five areas reachable within one day's travel



3.2 SELECTING THE SAMPLE

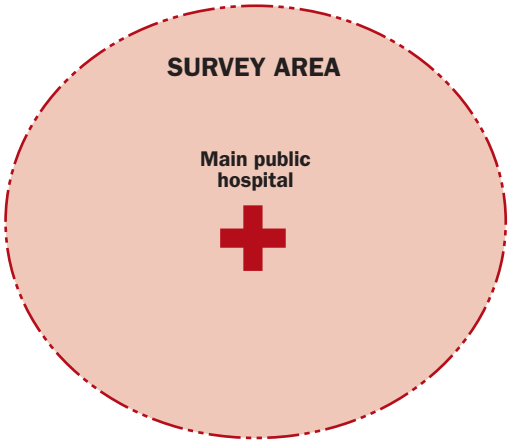
Once the geographical survey areas have been chosen, the sample of medicine outlets in which to gather data will need to be identified in each of the public, private and 'other' sectors (note that public procurement data are usually collected centrally). For convenience, public medicine outlets are used to anchor the sample, with other types of medicine outlets chosen by their proximity to these facilities.

Experience from over 50 studies confirms the importance of following the recommendations on survey design and sampling carefully. Selecting a smaller sample size severely weakens the data's reliability.

Increasing the numbers of medicine outlets above the minimum numbers recommended below will increase the survey's accuracy. In increasing the sample size, it is recommended that the number of survey areas be increased to provide a more representative sample, rather than increasing the number of medicine outlets surveyed in each survey area.

STEP 1: In each survey area, choose the main public hospital (generally district or regional hospital, though it could be a tertiary hospital).

These hospitals will be part of the sample of medicine outlets that you will survey. Data are collected for each hospital's outpatient/primary health-care services.



STEP 2: Create a list of public sector medicine outlets in each survey area.

For each survey area, create a complete list of all public health facilities that have pharmacies or dispensaries that are *within three hours' travel* from the main hospital selected in Step 1. Note that for hospitals, only those with outpatient/primary health-care services should be included. Lists of public health facilities are generally available at the ministry of health. Some survey managers have found central lists to be somewhat out-of-date, with the regional ministry offices able to provide more up-to-date lists.

Most countries have several levels of facilities, from hospitals down to health centres or dispensaries. Include all types of facilities that are expected to stock most of the medicines included in the study. Rural health posts or village health workers may only stock a small number of emergency medicines, in which case these facilities should be excluded from the sample. If certain levels of health facilities are excluded from the sample frame, it should be noted in the survey report.

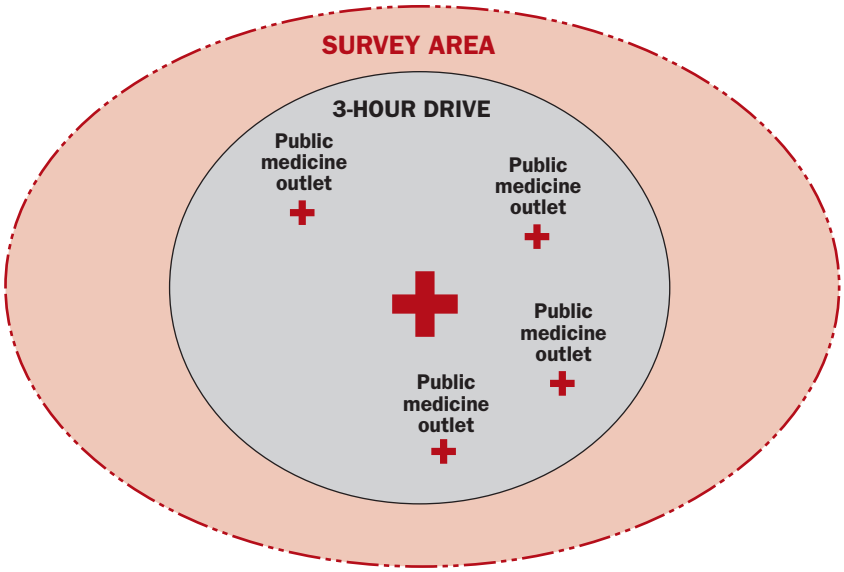
- If there are fewer than five medicine outlets within three hours' travel distance from the main hospital, extend the perimeter until you have at least five medicine outlets on your list.
- If there are fewer than five medicine outlets in the whole survey area, include the closest medicine outlets from a neighbouring area.

To facilitate data collection visits, all medicine outlets should be within three hours' travel of the main public hospital in each survey area. However, if travel conditions significantly limit the distance that can be covered in that time, the limitations on maximum travel time can be relaxed, resources and time allowing, to increase the level of representation.

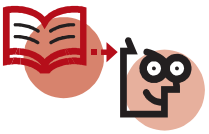
STEP 3: Select four public sector outlets in each survey area.

For each survey area, randomly select four public sector medicine outlets from the lists you created in Step 2.

- If there is only one level of health facility on the list (e.g. only primary health-care centres), choose four at random.
- If there are two or more levels on the list (e.g. primary health-care centres and district hospitals):
  - — Divide the list by level.
  - — Randomly select an equal number of medicine outlets for each level (e.g. two district hospitals plus two health centres).
  - — If there are fewer than two medicine outlets in any level, increase the number selected from the other level accordingly (e.g. one district hospital plus three health centres).



You should now have five public medicine outlets (main public hospital plus four public medicine outlets) selected for each survey area.



If a survey area includes a mix of urban, peri-urban and/or rural areas, the sample can reflect this distribution by dividing the list of public medicine outlets by rural/urban/peri-urban breakdown, and then randomly selecting outlets from each list according to the proportion of the population it represents.

STEP 4: Select an additional four public medicine outlets in each survey area, as back-up outlets.

In addition to the public sector outlets selected for the survey, a set of back-up medicine outlets should be identified. Data collectors will survey a pre-selected, back-up outlet if less than 50% of the medicines on the Medicine Price Data Collection form are available at a medicine outlet in the primary sample. Surveying back-up outlets will ensure that a sufficient quantity of price data is collected to allow for robust analyses. However, the data from the original outlet are still entered in the workbook to provide an accurate representation of availability.

For each public medicine outlet in the sample (i.e. selected in Steps 1 and 3 above), select the nearest public medicine outlet for use as a back-up outlet. To the extent possible, back-up outlets should represent the same level of care as sample outlets.

Back-up outlets can also be visited if managers from medicine outlets in the primary sample will not give permission for data collection, even after being shown the letter of introduction and being assured of anonymity. However, experience from previous surveys has shown this to be uncommon.

For each medicine outlet in the sample, only one back-up should be identified. If less than 50% of the medicines on the Medicine Price Data Collection form are available at the back-up outlet, then these data would be entered and analysed, but no additional back-up outlets would be visited.

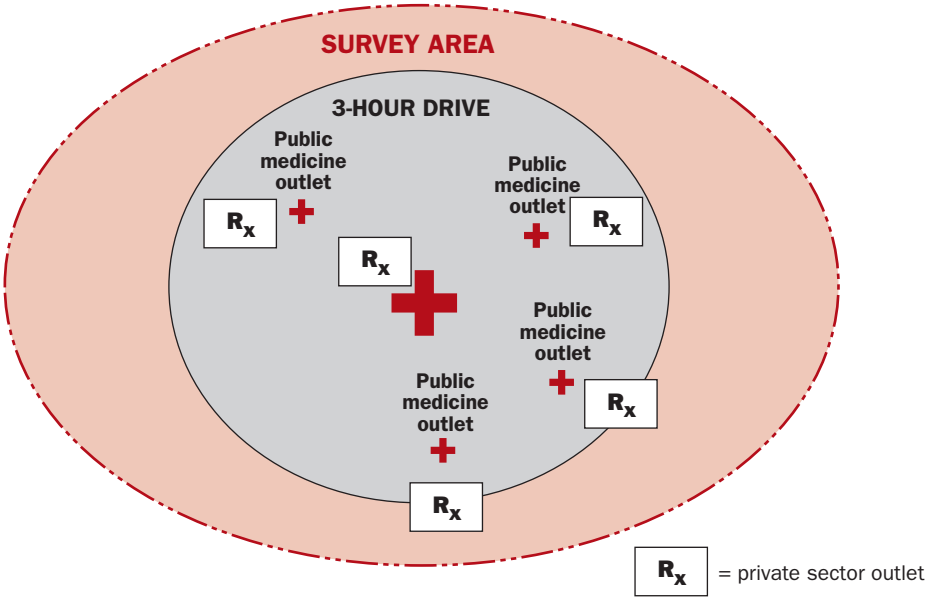
STEP 5: Select five private sector medicine outlets in each survey area.

While the survey manager should select public health facilities at central or regional level, area supervisors may have to identify private retail medicine outlets.

- Obtain lists of licensed pharmacies/drug stores registered in each study area, centrally if they are available (e.g. from the ministry of health, drug controller's office, pharmacy association or business registry). The lists may be incomplete so the area supervisor in the study area should check and update them by consulting with local officials. These lists can help to guide the selection process. If it is not possible to obtain a list of licensed pharmacies/drug stores from a central source, the area supervisors will need to develop it for their region(s).
- Choose the private medicine outlet that is *closest* to each public medicine outlet selected (including the main public hospital). If there are a number of private outlets close to each public facility, one should be selected at random, using the list of facilities obtained at central or regional level.
- If there is no private outlet within 10 km of a remote public facility, another private outlet in the urban centre should be selected.

Only licensed pharmacies and licensed drug stores should be included in the private sector sample. Unlicensed drug stores and drug-sellers in markets or elsewhere should not be included.

You should now have five private medicine outlets selected for each survey area.



STEP 6: Select an additional five private sector medicine outlets in each survey area, as back-up facilities.

From the lists of pharmacies/drug stores registered in each survey area, select the next closest private medicine outlet to each public medicine outlet selected (including the main public hospital), to serve as back-ups should they be needed.

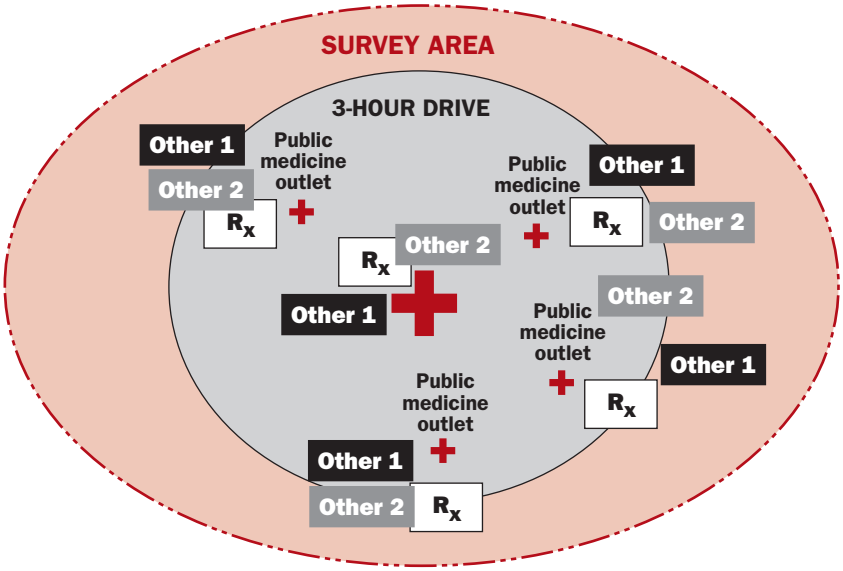
STEP 7: Select five medicine outlets for each 'other' sector in each survey area.

For each 'other' sector in your survey, five outlets in each survey area will also need to be selected.

For each 'other' sector:

- Create a list of all the medicine outlets in this sector in each survey area. In many cases this list can be obtained centrally by consulting the appropriate administrative authority (e.g. a list of NGO outlets). In other cases, the list will have to be developed by area supervisors in the field.
- In each survey area, select the 'other' sector medicine outlet that is *closest* to each public medicine outlet selected. If there are a number of medicine outlets close to the public sector outlet, one should be selected at random.
  - — If there are fewer than five 'other' sector medicine outlets in the survey area, select all of them.
  - — If there is no 'other' sector medicine outlet on the list within 10 km of a given public sector outlet, substitute with an additional outlet in the main urban centre.

For each 'other' sector, you should now have up to five medicine outlets selected for each survey area.



STEP 8: In each survey area, select an additional five medicine outlets for each 'other' sector in your survey, as back-up facilities.

From the list(s) of other sector medicine outlets in each survey area, select the next closest outlet to each public sector outlet selected (including the main public hospital), to serve as a back-up facility. Repeat this process for each 'other' sector in the survey. Note that in some cases, there may not be a sufficient number of outlets in other sectors to identify back-up facilities. Where limited data are available for other sectors, it may be preferable to present results as a case study rather than a quantitative analysis.

STEP 9: Create a contact list of medicine outlets for each survey area.

For each survey area, create a contact list of the medicine outlets that will be surveyed (as identified above), including their up-to-date contact information, if available. Group outlets by sectors (public, private, etc.) and number them (e.g. 1 to 20) for easy identification. For each outlet, indicate the back-up outlet that should be visited if fewer than 50% of medicines are found.

Example:

Survey area: Eastern Region

Name of medicine outlet	Contact details	Sector	Number	Back-up outlet name and contact details
ABC Pharmacy	45 Main Street Eastern City +22 414 000	Private	01	Main Street Chemist 59 Main Street Eastern City

3.3 DEVELOPING THE LIST OF MEDICINES TO BE SURVEYED

In every country, many different medicines are registered and sold on the market, and therefore could be included in the survey. A national essential medicines list, which is frequently only applied in the public sector, generally contains between 200 and 400 medicines. In the private sector, however, several thousand medicines may be available.

To make the survey manageable, up to 50 medicines will be surveyed. These medicines come from three different sources:

1. A **global core list** of 14 medicines that are included in all medicine price surveys to enable international comparisons;
2. A **regional core list** of 16 medicines that accounts for regional differences in medicine usage but still allows for comparisons across countries within the same region;
3. A **supplementary list** of at least 20 medicines, selected at the country level for their local importance.

Each survey medicine has a specific dosage form and strength; **this is the only dosage form and strength for which data are collected**. Different dosages forms and/or strengths of the same medicine may have different prices. Data must be collected on the same dosage form and strength in all medicine outlets so that results are comparable.

Medicines on the global and regional core lists have pre-determined dosage forms and strengths for which data are collected. If it is of interest to collect data on a different dosage form and/or strength (e.g. amoxicillin 250 mg cap/tab in addition to amoxicillin 500 mg cap/tab), this medicine can be added to the supplementary list of medicines and considered as a separate survey medicine with a distinct set of availability/price data. Data collectors must be very careful to avoid errors when collecting data on alternate dosage forms and/or strengths of the same medicine.

In addition, each medicine has a recommended pack size, which generally corresponds to a standard course of treatment. **When a medicine is available in multiple pack sizes, data are collected on the recommended pack size or – if this is not available – on the next largest pack size**. This standardizes results as much as possible, and counteracts price differences arising from economies of scale (i.e. lower unit price offered for larger pack sizes).

For each medicine, prices and availability are collected for two products: the originator brand and the lowest-priced generic equivalent. Originator brand products are standard for the country and do not vary from outlet to outlet. They are identified centrally before data collection. Lowest-priced generic equivalents are defined as the generically equivalent products with the lowest unit price available at each medicine outlet (e.g. health centre, private pharmacy) on the day of the survey. The actual product can therefore vary from outlet to outlet according to which generic products are available.

To enable price comparisons between countries and for repeated surveys, it is important to comply with the recommended lists of global and regional medicines, in their specified strengths, dosage forms and pack sizes.
In conducting repeat surveys, if a medicine is no longer generally available, it can be removed from the list of survey medicines.

While it is important to survey all global and regional core medicines that are registered in the country so that international comparisons can be made, it is equally important from the national perspective that 20 supplementary medicines be surveyed.

3.3.1 Global and regional core lists of medicines to be surveyed

Global and regional core medicines are standardized across WHO/HAI surveys to enable international comparisons of medicine prices, availability and affordability. Core survey medicines are divided into a global list and region-specific lists to account for the wide variations in the general usage of individual medicines across regions.

The medicines on the global and regional core lists have been selected based on the following criteria:

- **Global/regional burden of disease/prevalence patterns:** used to treat common acute and chronic conditions that cause significant morbidity and mortality, including cardiovascular diseases, diabetes, asthma, respiratory tract infections and mental illness.
- **Evidence-based:** recommended, usually as first-line courses of treatment, in global, regional and national treatment guidelines. However, medicines on core lists should not be considered as a recommendation for inclusion in national treatment guidelines.
- **Availability:** available in standard formulations and widely used in many countries/regions, as demonstrated by the medicine prices surveys conducted to date and by IMS Health national databases.
- **Importance:** the majority are included in the WHO Model List of Essential Medicines (WHO EML).[1]

Medicine price surveys have shown the global core medicines (Table 3.1) to be widely available in all regions, thereby allowing international comparisons to be made.

All the medicines on the global core list are in oral solid form (tablet or capsule), with the exception of:

- Ceftriaxone injection;
- Co-trimoxazole paediatric suspension;
- Salbutamol inhaler; and
- Paracetamol suspension.

Regional core medicine lists (available in the workbook Part I, on the CD-ROM and on the HAI web site) have been developed as a complement to the global core list to address regional differences in the usage of medicines. Although medicine usage also varies across countries in a region, standardizing the medicines surveyed within a region will facilitate regional comparisons. Regional core medicine lists have been developed based on burden of disease, availability data derived from medicine pricing surveys and other sources (e.g. IMS Health sales volume data), and in consultation with WHO regional pharmaceutical advisers, various pharmaceutical experts and the members of the WHO/HAI Project on Medicine Prices and

[1] http://www.who.int/medicines/publications/essentialmedicines/en/

Table 3.1 Global core list of medicines to be surveyed

	Disease	Name[a]	Strength	Dosage form
1	Asthma	Salbutamol[b]	0.1 mg/dose	inhaler
2	Diabetes	Glibenclamide	5 mg	cap/tab
3	Cardiovascular disease	Atenolol	50 mg	cap/tab
4	Cardiovascular disease	Captopril	25 mg	cap/tab
5	Cardiovascular disease	Simvastatin	20 mg	cap/tab
6	Depression	Amitriptyline	25 mg	cap/tab
7	Infectious disease	Ciprofloxacin	500 mg	cap/tab
8	Infectious disease	Co-trimoxazole	8+40 mg/ml	suspension
9	Infectious disease	Amoxicillin	500 mg	cap/tab
10	Infectious disease	Ceftriaxone	1 g/vial	injection
11	CNS	Diazepam	5 mg	cap/tab
12	Pain/inflammation	Diclofenac	50 mg	cap/tab
13	Pain/inflammation	Paracetamol[c]	24 mg/ml	suspension
14	Ulcer	Omeprazole	20 mg	cap/tab

[a] Medicine names may be spelt differently in different countries. Consult the HAI web site[1] for alternative spellings of global and regional core medicines.
[b] Also called albuterol.
[c] Called acetaminophen in some countries.

Availability. The regional lists will be updated periodically to reflect new data on medicine availability. **When planning a survey, survey managers should check the HAI web site[2] to be sure that they have the most recent list for their region**.

Regions have been selected based on the WHO classification of countries into six administrative regions.[3] In some cases, WHO regions have been further divided into groups of countries with similar socioeconomic and epidemiologic profiles. Such sub-divisions are largely dependent on the availability of IMS Health medicine sales data upon which to base the development of medicine lists; additional lists will be created for other regions as more data become available. Regional core medicine lists are currently available for:

- Central Asia
- Eastern Mediterranean
- Sub-Saharan Africa
- Central and South America
- South East Asia
- Western Pacific

Medicines on both the global core list and the applicable regional core list should always be included in the survey if they are registered in your country. This will enable you to compare your prices with those in other countries.

In the surveys conducted to date, perceived non-availability of certain medicines has often proved to be wrong. Before removing a medicine from the global or regional list, verify its availability and, when in doubt, include it in the survey to avoid a missed opportunity.

The following are instructions for finalizing the global and regional core lists of medicines to be surveyed:

[1] http://www.haiweb.org/medicineprices/
[2] http://www.haiweb.org/medicineprices/
[3] WHO African Region (AFR), WHO Region of the Americas (AMR), WHO Eastern Mediterranean Region (EMR), WHO European Region (EUR), WHO South-East Asia Region (SEAR), WHO Western Pacific Region (WPR).

1. Review the lists of global and regional core medicines.
2. If any global or regional core medicine is not registered in your country, remove it from the list.
3. If a medicine is registered in your country, but the stated dosage form or strength differs from that on the global/regional core list, remove the core medicine from the list and add the alternate form and/or strength to the supplementary list of medicines. For example, while atenolol 50 mg is a global core medicine, in Country X atenolol 100 mg is the only strength available. In this case, atenolol 50 mg should be removed from the global core list, and atenolol 100 mg should be added as a supplementary medicine.
4. If a therapeutically equivalent medicine is widely used in addition to or instead of a medicine on the global or regional core list, add it to your supplementary list of medicines. For example, simvastatin 20 mg is a global core medicine, however in Country X lovastatin 20 mg is also widely used. In this case, simvastatin should be kept on the global core list, with lovastatin added as a supplementary medicine.

Instructions are provided in Section 3.4 for generating the Medicine Price Data Collection form from the workbook according to the global core, regional core and supplementary medicines to be surveyed in your country.

If any medicine from either the global or regional core list is excluded from the survey, this should be reported and justified in the survey report.

BOX 3.2

Patent status

Some substances remain under patent in countries that observe medicine patents; others are off patent or have never been patented. Since patent status varies by country and over time, this manual cannot identify the patent status of medicines. Once the national list of medicines to be surveyed has been finalized, the patent status of each medicine should be checked with the local patent office. Generic equivalent products might not be available for medicines that are still on patent; this should be considered in the analysis of availability (See Chapter 8, page 125).

3.3.2 Supplementary list of medicines to be surveyed

The survey methodology allows for the addition of supplementary medicines selected at the national level. Where all 30 global or regional core medicines are included in the survey, 20 supplementary medicines should be selected. If some core medicines have been removed due to lack of registration in the country, additional supplementary medicines can be selected to obtain a total list of 50 medicines. As stated above, the supplementary list of medicines should include:

- different strengths and/or dosage forms of medicines on the global and regional lists (where commonly used); and
- commonly used therapeutic alternatives to those on the global or regional core lists, such as another ACE-inhibitor or antidiabetic medicine.

BOX 3.3

Modified release formulations

Most tablets and capsules are designed so that the active ingredient(s) is released immediately after the medicine is taken. Others have modified release characteristics. These are referred to using a number of terms, including:

- sustained release (SR)
- slow release (SR)
- controlled release (CR)
- retard (R)
- modified release (MR)
- long acting (LA)

These work by gradually releasing the active ingredient as the capsule or tablet moves down the gastrointestinal tract. Some medicines are marketed in both immediate release and modified release formulations. In Kenya, for example, nifedipine is available as 10 mg, 20 mg and 30 mg capsules, 10 mg and 20 mg tablets, 10 mg and 20 mg retard tablets, 10 mg and 20 mg SR tablets, and 30 mg LA tablets. It is vital that you collect the price of the medicine, dosage form and strength as stated on the form. While plain, film-coated tablets and plain capsules are equivalent, modified release formulations must be considered separately.

The following selection criteria should also be considered when developing the supplementary list of medicines to be surveyed:

- **International reference price**

  Medicine price data obtained in the survey are analysed in relation to an international reference price (Box 3.5). Supplementary medicines, in their specified dosage form and strength, must have an international reference price from the same set of prices used for global and regional core medicines (usually MSH).[1]

  In previous surveys, countries have identified medicines for inclusion in their survey that did not have international reference prices. Prices were collected for these medicines, only to find that they could not be analysed. This meant that there was unnecessary time and effort spent on data collection and that a smaller group of medicines was available from which to analyse results and draw conclusions.

All supplementary medicines, in their specified dosage form and strength, must have an international reference price.

The same set of reference prices (usually MSH) must be used for all medicines surveyed – global, regional and supplementary.

- **Burden of disease and national or local disease and treatment priorities**

  The supplementary list can be used to study medicines that are commonly used in the treatment of important national health problems. Drug utilization studies, where available, can assist in identifying common treatments.

- **Global and national treatment guidelines**

  Medicines should be in line with current treatment recommendations as indicated in global and/or national treatment guidelines.

[1] http://erc.msh.org/

- **Expected availability in primary health-care outlets**

  Since primary health-care facilities form most of the public sector sample, the medicines selected for the supplementary list should be available at this level of care. However, a small number of medicines that are only available at hospitals can be included on the supplementary list if they are of special interest. To ensure that sufficient price data are collected to allow for robust analysis, it is recommended that no more than four 'hospital-only' medicines be included on the supplementary list.

  Note that the supplementary medicine list can include medicines on the national essential medicines list as well as those that are not, and should include both if price differences are suspected between the two categories.

- **Registration or market authorization**

  The availability and use of medicines not approved by the relevant authorities can be a serious problem in some countries, particularly in those where there is a poor regulatory framework or inadequate enforcement of relevant laws and regulations. To ensure that information is only collected on approved medicines, **all products included in the survey must be registered or have market authorization in your country, and only licensed premises should be included in the survey**.

- **Local production**

  In some countries, it may be of interest to study the availability and price of medicines that reflect local production capacity.

- **'Problem medicines'**

  It may be of interest to investigate medicines that represent or are suspected to represent a high financial burden to patients or governments or those thought to be irrationally used. Such 'problem medicines' can be included as supplementary medicines provided they have an international reference price (see above).

- **Availability of fixed-dose combination products**

  In many countries, combination products exist together with products containing single agents. The WHO Model List of Essential Medicines prefers to use products with one single ingredient (co-trimoxazole being one of the few exceptions), which allows more flexibility in prescribing and dosing, although there is now an increasing move towards fixed-dose combinations for malaria, tuberculosis and HIV. Many regulatory authorities and agencies that develop therapeutic guidelines also have this policy. This is one reason why there are few combination products on the core lists of medicines. You may wish to include some combination products on your supplementary list to better reflect the national situation. Be aware, however, that this may limit the number of generically equivalent alternatives because different manufacturers may use different combinations. It will also limit the selection of reference price sources.

- **Prescription status**

  In most countries, only prescription medicines should be included on the supplementary list of medicines. However, in countries where prescription control is limited to a small number of medicines (e.g. analgesics, narcotics, psychotropics) prescription status may not be an appropriate selection criteria.

BOX 3.4

Surveying therapeutic groups

The supplementary list of medicines can be used for studying medicines from a particular therapeutic category or group of conditions, such as paediatrics, reproductive health or chronic diseases. For example, surveys of chronic disease medicines have been carried out in six countries using the WHO/HAI standard methodology (*1*). Surveying all therapeutic alternatives for a particular condition provides a more accurate representation of availability and price than if one or two medicines are surveyed when alternative products exist. However, the global and regional core medicines should still be surveyed to enable comparisons with other countries.

For conditions with a large number of treatment alternatives, the supplementary list of medicines can become quite long. The time and resources required to conduct a survey with an extensive medicine list should be considered carefully.

Guidance on conducting therapeutic group surveys is provided on the CD-ROM that accompanies this manual. Supplementary medicine lists that have been used to study selected therapeutic categories will be included on the CD-ROM and on the HAI web site.[1]

When surveying a particular therapeutic class of medicines, care should be taken to ensure that the common routes of distribution are covered in the survey sample. For example, the centralized nature of HIV/AIDS treatment has thus far limited the ability to include antiretrovirals (ARVs) in the survey. In future, as treatment becomes more decentralized, the inclusion of ARVs in the survey may become more feasible.

In most countries, a total of 50 medicines should be surveyed. In surveys studying a particular therapeutic group, the list of medicines to be surveyed may be considerably longer.

To ensure that the selection of supplementary medicines reflects availability and usage patterns, it is useful to check with large public and private wholesalers from various regions when developing the supplementary medicine list.

The core and supplementary lists of medicines should be reviewed following the pilot test conducted as part of the training workshop and, where necessary, revised before the survey begins.

3.4 PREPARING THE WORKBOOK AND CREATING THE MEDICINE PRICE DATA COLLECTION FORM

The Medicine Price Data Collection form is the survey tool used in the field to collect data on medicine prices and availability. The form is automatically generated from the survey workbook Part I, where all relevant information on the survey medicines is stored. Chapter 7 contains detailed instructions on using the computerized workbook. **Before beginning your survey, check the HAI web site[2] to make sure that you have the most recent version of the workbook**.

You will need to generate the data collection form for use in the pilot test conducted as part of the survey training workshop (see Chapter 4). However, before you do this, you need to do the following in the workbook:

[1] http://www.haiweb.org/medicineprices
[2] http://www.haiweb.org/medicineprices

BOX 3.5

International reference prices

In this survey, medicine prices are expressed as ratios relative to a standard set of reference prices to facilitate national and international comparisons. Median prices listed in MSH's *International Drug Price Indicator Guide* have been selected as the most useful standard since they are updated frequently, are always available and are relatively stable.[1] These prices are recent procurement prices offered by both not-for-profit and for-profit suppliers to developing countries for multi-source products. When *no* supplier prices are available, buyer prices are used, but a single supplier price is still preferable to multiple buyer prices.

The 2007 MSH reference prices, which were current when this manual was produced, are already entered in the workbook. When planning your survey, check the HAI web site to make sure you have the current set of reference prices. If there is an updated version of the workbook with more recent MSH reference prices, download it and use it for entering your survey data.

How representative reference prices are generally depends on the number of suppliers quoting for each product. For example, if a medicine has a single, high supplier price, a low median price ratio (MPR) will be obtained, which can be misinterpreted as low national prices. This has been observed in previous surveys with losartan 50 mg; in this case, a high 2005 MSH buyer price (no supplier prices available) resulted in very low MPRs. When very high or low MPRs are observed, it is useful to check the international reference price to see if this is the reason. If the international price is indeed found to skew the MPR of a medicine, affordability results will provide a better reflection of national price since these are based on medicines prices measured in local currency.

All survey medicines must have an international reference price, and the same set of reference prices must be used for all survey medicines (global core, regional core and supplementary). If you have a medicine on your supplementary list for which there is no MSH reference price, you should consider replacing it with another medicine for which there is an MSH reference price. Otherwise, you will need to use a different set of reference prices for all medicines.

Since the vast majority of surveys conducted thus far have employed MSH reference prices, using a different set of prices will limit your ability to conduct international comparisons and is therefore discouraged. Should you choose to use an alternative set of reference prices, you might consider using the New Zealand Pharmaceutical Management Agency (PHARMAC) prices[2] or the Australian Pharmaceutical Benefits Scheme (PBS) prices.[3] PHARMAC prices are reimbursement prices paid by the Government of New Zealand; since some products are not fully subsidized, median supplier prices should be used. PBS prices are reimbursement prices that the Government of Australia has agreed to pay for the medicines it makes available in government-supported insurance programmes.

Careful interpretation is required when using an alternative set of reference prices. For example, while MSH prices are procurement prices (mainly not-for-profit and not including insurance and freight charges), PHARMAC and PBS prices are reimbursement (similar to retail) prices. Furthermore, PHARMAC and PBS prices differ in that PBS prices include a dispensing fee while PHARMAC prices do not.

If an alternative set of reference prices is used, you should always add the name of the reference price in the workbook and include the following information in the final report:

- The name of the reference price list you chose
- Your reasons for choosing it
- The date on which you obtained the price data from the list
- The dates for which the price list was reported to be valid.

[1] MSH prices are available at http://erc.msh.org.
[2] http://www.pharmac.govt.nz/
[3] http://www.pbs.gov.au/html/healthpro/home

- upload the relevant regional core list of medicines for your survey;
- delete any medicines from the global and regional core lists which are not registered in your country;
- add the supplementary medicines, including strengths and dosage forms, that you are surveying;
- check that the MSH prices already entered in the workbook are current, and enter the reference price for each supplementary medicine;
- identify which medicines are on the national essential medicines list, where one exists;
- for the public sector, identify the level(s) of care where each medicine is expected to be available; and
- identify and enter the name of the originator brand product and its manufacturer for each supplementary medicine to be surveyed, and check the name of each originator brand on the global and regional core list (the identification of the lowest-priced generic product is done at each individual medicine outlet).

STEP 1: Transfer the workbook to your computer

You can do this by:

- copying the file from the CD-ROM that accompanies this manual
- downloading the latest file from the HAI web site:[1]

Start Microsoft Excel® and open the file WHO/HAI Medicine Price WorkbookI.xls that you copied onto your hard disk. Note: Macros will need to be enabled in order for the workbook to function correctly (see below).

Macros

A macro is a series of commands and functions that enable tasks to be performed automatically. The survey workbook contains macros that must be enabled for it to function correctly.

Microsoft Excel provides safeguards that help protect against viruses, which can be transmitted by macros. Depending on the security settings of your computer, macros may always be enabled when you open files (low security), or you may receive a warning when a macro is encountered (medium security), or macros may be automatically disabled without any warning (high or very high security).

To be sure that the workbook is run with the necessary macros, open Excel and in the Toolbar, click on Tools → Macros → Security, and set the Security Level to "Low" or "Medium". You should now receive a security warning when you open the workbook; select "Enable Macros" to open the workbook with the necessary macros.

[1] http://www.haiweb.org/medicineprices

Do not save data in the original workbook since it is useful to retain a clean version. As soon as you open the file, save it with a filename that indicates the country and date of your survey. For example, you might choose a filename such as SouthAfricaVersion1.May2006.xls.

STEP 2: Enter general survey information and upload the relevant regional core list of medicines

The *Home* page of the workbook is used for recording important general information about your survey. At the top of the page you are asked to enter your country name. By right-clicking on the empty box (Cells C/D5) you will access a drop-down list of countries. Once you have selected your country, the WHO region corresponding to your country will be automatically uploaded into Cells C6/D6.

You should also enter:

- if a state or provincial survey is being conducted, the name of the state or province in Cells C/D7
- the name of the first 'other' sector surveyed, if applicable, in Cells C/D8
- the name of the second 'other' sector surveyed, if applicable, in Cells C/D9
- the names of the six survey areas in Cells C/D12

The date of the first day of data collection (Cells C/D10) should only be entered once data collection has been initiated.

Next, go to the *International Medicine Reference Price Data* page where information on the medicines in the survey is entered and stored. Note that the 14 global core medicines are already listed in Rows 11–24. Click on the "Add regional medicines" button in Cell C9; a pop-up box containing the regional core medicines for your WHO region will appear. You can add one regional medicine at a time by selecting the medicine name and clicking on the "Add medicine" button, or you can add all regional medicines at once by clicking on the "Add all medicines button" (adding all medicines may take several seconds).

STEP 3: Delete any medicines on the global or regional core list that are not registered in your country

The *International Medicine Reference Price Data* page should now contain the global and regional core medicines in the survey. This page is described in more detail in Chapter 7, page 84. Click on the cell containing the medicine you wish to delete and hit <Backspace> or <Delete>. A pop-up box will appear asking "Do you want to delete this medicine?". Click <Yes> to delete. If you confirm the deletion, all information about the medicine contained in the row will be deleted, and the empty row will be removed.

STEP 4: Add your supplementary medicines to the *Reference Price* page

For each supplementary medicine, enter the following information:

1. **Medicine Name (Column C):** The name is usually the International Nonproprietary Name (INN). The workbook requires that each medicine have a unique name to avoid confusion during data entry and analysis. If the survey includes two

different strengths or dosage forms of the same medicine, then each must be given a unique name. For example, if amoxicillin suspension is to be added as a supplementary medicine, it should be called "amoxicillin suspension" and the name of the core medicine changed to "amoxicillin capsules" to prevent confusion. As well as the name, it is also recommended that you include the dosage form in the name for all cases other than immediate release tablets and capsules e.g. co-trimoxazole suspension, salbutamol inhaler, benzylpenicillin injection.

2. **Medicine Strength (Column D):** The strength of the medicine, usually expressed as the number of milligrams or grams of active ingredient per dosage form (see item 3 below). Take special care in expressing the strength of inhalers, injections and liquids (suspensions, syrups) to prevent confusion in determining the unit price.

3. **Dosage Form (Column E):** The dosage form of the medicine for which the unit price is to be determined. The dosage form will most commonly be "cap/tab" for medicines administered as normal release capsules or tablets. Note that dispersible tablets should be considered separately from non-dispersible tablets. Other dosage forms include:

   — "millilitre" for orally administered liquids, suspensions, topical solutions, eye drops, and injections in liquid form

   — "gram" for powder for injection, eye ointments, topical creams and ointments.

   — "dose" for medicines administered through inhalers or nebulizers.

   — "MR tab" for modified release tablets, "MR cap" for modified release capsules

   — "pessary" or "suppository"

Be very careful in expressing the strength and dose form of injections. For example, if gentamicin injection is available as 80 mg/2 ml in your country, you should enter this strength in the workbook so that it is printed on the data collection form. However, you need to enter 'millilitre' as the dosage form since that is the unit (not one ampoule, which is 2 ml). For an injection such as benzathine penicillin 2.4 MIU/ml injection, the unit will also be millilitre. These units should be the same as those used in the MSH reference price list.

4. **Target Pack Size (Column F):** Different pack sizes are used in many countries, and unit prices often vary by pack size. Field data collectors should try to find a pack size identical to or larger than the target pack size. The target pack size is not used in workbook calculations and is included for reference purposes only.

5. **Medicine List:** This identifies whether the medicine is on the global, regional or supplementary list. Select "Supplementary" from the drop-down list by clicking on the arrow next to the empty cell.

To facilitate data collection, the workbook will automatically combine core medicines and supplementary medicines into one list in alphabetical order by medicine name (this may take several seconds). Medicines will therefore appear in alphabetical order on the Medicine Price Data Collection form, and not according to global/regional/supplementary list.

STEP 5: Identify medicines on the national Essential Medicines List (EML) (Column H)

Previous surveys have shown that it is often useful to disaggregate medicine price and availability results by EML and non-EML medicines, particularly in the public sector. Column H: *National Essential Medicine List* allows you to identify those survey medicines that are contained in the national Essential Medicines List. Select "Yes", "No", "Don't Know" or "No List" (if your country does not have a national EML) from the drop-down list by clicking on the arrow next to the empty cell.

STEP 6: Check/enter the reference price information for each medicine

As described in Box 3.5, there are several sources of international reference prices that can be used in the survey. **Whatever source is chosen, it must be used for the entire list of medicines in your survey (global core list, regional core list and supplementary list)**.

MSH reference prices, which are recommended as the most useful standard, have been provided for the global and regional core medicines in Column I of the *Reference Prices* page. *Even if you choose to use another reference price list for national analysis, it is a good idea to include the most up-to-date MSH reference prices in the workbook. This will allow for comparisons of prices for individual medicines with other countries, most of which have used MSH reference prices in their surveys*.

- For the global and regional core medicines, check that Column I of the *Reference Prices* page contains the most up-to-date MSH international reference prices.[1]
- For each supplementary medicine, enter the most recent MSH international reference price (median supplier price, or median buyer price if there is no supplier price) into Column I of the *Reference Prices* Page.
- If another set of reference prices is being used for the analysis, enter the appropriate unit price for each medicine into the "Other Unit Price" column (Column J). Take special care to use the correct dosage form for injections, inhalers and liquids. Note that these prices need to be entered in US$ equivalents, otherwise the conversion to local currency will be incorrect. For example, if you use the PBS prices, you should first convert them from Australian dollars to US dollar equivalents, then enter that price. Enter the source of the unit prices you used in cell I7.

STEP 7: Identify which levels of public health facilities are expected to stock each survey medicine (Column O)

As mentioned in Section 3.3.2, the supplementary list of medicines can include a small number of medicines that are only available at specialized hospitals (if this is of special interest). Further, some global or regional core medicines may also only be available at more specialized centres. To prevent under-reporting of the availability of these medicines, the availability analysis must be restricted to those public sector health facilities where the medicine is expected to be available. For example, primary health care centres should not be included in the availability analysis of a specialized medicine that is only provided at secondary or tertiary hospitals. The workbook is therefore programmed to calculate the availability of individual medicines based on the level of care where they are expected to be available.

[1] MSH prices can be found in the MSH International Drug Price Indicator Guide at http://erc.msh.org

- For each medicine, indicate the level of care where the medicine is expected to be available in Column O on the *Reference Prices* page. Enter "1" for primary, "2" for secondary and "3" for tertiary. For the purposes of the survey, primary care refers to the first point of contact with the health system for access to essential health care (e.g. rural health posts, community health centres); secondary care refers to specialized ambulatory medical services and first line referral to outpatient and inpatient hospital care (e.g. district hospitals); and tertiary care refers to medical and related services of high complexity (e.g. regional or central hospitals). Your national EML may be broken down by level of care; if not, consult treatment guidelines for common conditions or check with your survey advisory committee.
- If levels of care are not relevant to your survey, enter "1" for all medicines so that the availability analysis includes all health facilities in the public sector sample.

If a medicine is selected as "level 1", i.e. available at primary care level, this medicine should also be available at secondary and tertiary levels of care. The availability analysis will therefore include all health facilities in the public sector sample.

If a medicine is selected as "level 2", i.e. available at secondary care level, this medicine should also be available at the tertiary level. The availability analysis will include all secondary and tertiary health facilities in the public sector sample, but will not include level 1 facilities.

If a medicine is selected as "level 3", i.e. available at tertiary care level, this medicine should only be available at tertiary level facilities. The availability analysis will be restricted to tertiary health facilities.

STEP 8: Identify the originator brand product for each medicine to be surveyed

The originator pharmaceutical product or originator brand is generally the product that was first authorized *worldwide* (not nationally) for marketing (normally as a patented product) on the basis of the documentation of its efficacy, safety and quality, according to requirements at the time of authorization. The originator product always has a brand name (e.g. Valium®), however this may vary between countries. That is, the manufacturer may not use the same name worldwide; for example fluoxetine is called both Prozac® and Fontex® in different countries.

While lowest-priced generically equivalent products are identified at individual facilities during data collection, originator brand products are identified centrally before fieldwork begins.

- Go to the *Study Medicines: Originator Brand Products Surveyed* page of the workbook.
- For each global and regional core medicine, the originator brand name that is most commonly used by the manufacturer in English-speaking countries, is listed in Column H. Check that the name in this column is the name used in your country. A list of originator brand names for commonly surveyed medicines, as well as medicines for which there is no originator brand name, is available on the HAI web site.[1] Occasionally the manufacturer listed in Column I may license production to another manufacturer. Where this happens, change the name but make it clear it is a licensing arrangement.

[1] http://www.haiweb.org/medicineprices/

- If the originator brand name used in your country differs from the one in the workbook, change the name of the medicine in Column H, *as long as the medicine, dosage form and strength are the same*. This change should be noted in your survey report.
- For each supplementary medicine, enter the originator brand name used in your country in Column H. Enter the name of the manufacturer in Column I. If the manufacturing entity is complex, or if there are multiple sources for a single originator brand, enter all the relevant information, e.g. "Wockhardt Ltd. under licence from Merck".

The originator brand products and manufacturers identified on the *Study Medicines: Brand Products Surveyed* page of the workbook are automatically entered into the Medicine Prices Data Collection form.

Some substances are so old that no originator brand can be identified and patent was probably never claimed. This is the case with such substances as penicillin V, prednisolone and isoniazid. If your supplementary list includes old medicines that were probably never patented, leave Columns H and I blank for these medicines.

Multinational manufacturers may have a licensing agreement with a local manufacturer for the in-country production of an originator brand product. In such cases, identify both the multinational and the local subsidiary to ensure that data collectors do not overlook any products.

It is important to identify the originator brand name used in your country correctly for each of the survey medicines. If the wrong name is used the product will not be found, which will bias the availability results and reduce the number of medicines included in the price analysis. If in doubt contact HAI[1] or WHO[2] for advice.

STEP 9: Generate the Medicine Price Data Collection Form

To access the Medicine Price Data Collection form, press on the Data Collection tab at the bottom of the workbook. From the *Medicine Price Data Collection Form* page you will be able to view and print the form (Select File → Print from the Excel toolbar). Note that the form is not complete until it contains the complete list of survey medicines, including the originator brand names used in your country.

A draft form should be generated for use in the training workshop, following which changes may need to be made to the list of survey medicines based on the results of the data collection pilot test (see Chapter 4, Page 63). Once the list of medicines has been finalized, the Medicine Price Data Collection form should be used to record data in all sectors, including public sector procurement prices.

Fig. 3.2 shows an extract from the Medicine Price Data Collection form, generated using the computerized workbook. Note that some cells are shaded grey; these cells should not be amended or altered during data collection.

[1] info@haiweb.org
[2] medicineprices@who.int

Figure 3.2 Extract from the Medicine Price Data Collection form

A	B	C	D	E	F	G	H	I	J
Generic name, dosage form, strength	Medicine type	Brand or product name(s)	Manufacturer	Available: "yes" or "no"	Pack size recom-mended	Pack size found	Price of pack found	Unit price (4 digits)	Comments
Amitriptyline cap/tab 25 mg	Originator brand	Tryptizol	MSD		100			/tab	
	Lowest-priced generic				100			/tab	
Amoxicillin cap/tab 500 mg	Originator brand	Amoxil	GSK		21			/tab	
	Lowest-priced generic				21			/tab	
Atenolol cap/tab 50mg	Originator brand	Tenormin	Astra Zeneca		60			/tab	
	Lowest-priced generic				60			/tab	

BOX 3.6

Customizing the Medicine Price Data Collection form

You may wish to further customize the Medicine Price Data Collection form that is generated by the survey workbook. For example:

- You may wish to highlight the dosage forms or strengths of certain medicines that may lead to error (e.g. "Nifedipine **retard** 20 mg tab")
- For those medicines that are not tablets or capsules, a common mistake is to record the pack size as "1 inhaler" instead of "200 doses", or "1 bottle" instead of "100 ml". This makes calculation of the unit price impossible. To guard against this error, you can indicate the unit (e.g. " /ml") in the Pack size found column (Column G).
- If a medicine is under patent, there could be no generics available for which to collect data. Contact the regulatory authority to verify whether there are generics registered for the medicine despite a patent being in force. Similarly, if a medicine is so old that the originator brand cannot be identified, there will be no originator brand for which to collect data. In such cases it may be useful to black out these rows of the data collection form so that it is clear that data is not being collected on these products.

To customize the Medicine Price Data Collection form, go to the *Medicine Price Data Collection form* page and select the cells that correspond to the full form. Copy and paste the selection into a Microsoft Word® document. Once in Word format, you will be able to modify, save and print the form.

3.4.1 Elements of he Medicine Price Data Collection form

For each medicine, the Medicine Price Data Collection form contains two rows (originator brand and lowest-priced generic equivalent) and ten columns (A to J).

Row 1: The first row is for recording information on the *originator brand*. Since originator brands are identified centrally prior to data collection, the Medicine Price Data Collection form already contains the originator brand name for each of the survey medicines.

Row 2: The second row is for collecting information on the *lowest-priced generic equivalent product* to the originator brand in Row 1. The data collectors will identify this product in each medicine outlet surveyed and will enter the following information onto the form (see Chapter 6):

Definitions

For the purpose of this study, the following definitions are used:

- **Originator brand:** the international originator brand product for the medicine.
- **Generic equivalent:** all products other than the originator brand that contain the same active ingredient (substance), whether marketed under a brand name ("branded generic") or the generic name.

Refer to the Glossary for expanded definitions of originator brand and generic equivalent.

- Column C: the name of the lowest-priced generic equivalent product
- Column D: the manufacturer of the lowest-priced generic equivalent product.

The generic equivalent product with the lowest unit price may vary from one medicine outlet to another.

Column A: Name of medicine, dosage form and strength

Column A lists:

- the medicine's International Nonproprietary Name (INN)
- the medicine's dosage form
- the medicine's strength

A medicine may be available in different dosage forms: tablet/capsule, mixture/syrup, suspension, injection, cream/ointment and so on. Tablets and capsules are normally considered equivalent, unless they are retard, sustained release, etc. (see page 76). *Information should only be collected for the dosage form listed in Column A*. The solid oral form is used for most medicines.

Many medicines will be marketed in more than one strength. For example, amoxicillin may be marketed as 250 mg and 500 mg tablets/capsules. The Medicine Price Data Collection form lists the strength selected for inclusion in the survey; *this is the only strength on which information should be collected*.

Column B: Medicine type

This column is used to distinguish between the two product types collected in the survey: the originator brand product and the lowest-priced generic equivalent.

Column C: Brand or product name(s)

While Column A contains the medicine's INN, Column C contains the names of individual products. For generically equivalent medicines, the product name may be the same as the INN and will be entered in Row 2 by the data collectors at each medicine outlet.

Column D: Manufacturer

In Row 1, this column contains the name of the originator (patent holder). The data collectors will complete Row 2 in each individual outlet with the name of the manufacturer of the lowest-priced generic equivalent found (see Chapter 6).

Column E: Available: "yes" or "no"

- *Public Procurement Prices:* Column E will usually be completed at central level in the office of the procurement officer or central medical stores.
- *Public Sector Patient Prices, Private Sector Patient Prices and Other Sector Patient Prices:* the data collectors in the field will complete this column. For each medicine, they should record that the originator brand and lowest-priced generic equivalent are available *only if they actually see a pack of the medicine*.

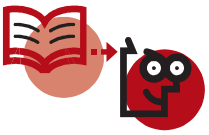
Column F: Pack size recommended

For each medicine several pack sizes may be available, such as a pack of 30, 100, 250 or even 1000 tablets or capsules, and single vials or 10 vials for an injection. Mixtures may also be available in different volumes: e.g. 70 ml or 100 ml. The price per unit may vary between pack sizes, generally with larger pack sizes sold at a lower unit price.

In order to facilitate comparisons between products, sectors and countries, a "recommended pack size" has been selected for each medicine (See Chapter 6, page 77). These are as close to recommended treatment lengths as possible. If the pack size of a medicine is standard and is known centrally, the data collection form should be amended before data collection begins.

Column G: Pack size found

The data collectors in the field should complete this column. If several pack sizes are available for the same product, data collectors should select the recommended pack size or the next larger pack size. Note that the public sector and 'other' sectors are likely to have less variety of products and larger pack sizes.



In some cases medicines may not be sold as a full pack but rather by individual strip (e.g. a pack of 60 tablets may be composed of 6 strips of 10 tablets each). If certain medicines are *only* sold by the strip, record the number of tablets/capsules in the strip as the pack size found (Column G), record the price of the strip as the price of pack found (Column H), and note this in the Comments column (Column J). If medicines are sold both as a complete pack and as individual strips, record the pack size and price of the full pack.

In some cases pharmacies or health centres may only stock a bulk pack of a medicine, from which smaller quantities are dispensed to patients. In such cases data collectors should use the recommended pack size listed in Column F as the pack size found (Column G), and should record the price of purchasing this pack size (Column H).

The pack size and price of that pack is only entered on the form if it is physically in stock (the data collector must actually ask for and see it). If the outlet is temporarily out of stock of the product, then it is recorded as not available and no price and pack size is entered on the data collection form.

Column H: Price of pack found

The data collectors in the field should complete this column. If patients receive the medicine free of charge or pay a fixed fee, the price of pack found should be left blank.

Column I: Unit price

Unit price refers to the price per individual tablet, capsule, millilitre (for injections, liquids, etc.), gram (for creams, etc) or dose (for inhalers). This column is completed by dividing the price of the pack found by the pack size. For example, if a pack of 60 atenolol 50 mg tablets costs 80.00 in local currency, the unit price is 80.00/60 or 1.4167 per tablet. Unit prices are generally calculated by area supervisors following data collection, except in cases where data collectors need to calculate the unit prices of several generic equivalent products to determine the lowest-priced generic (See Chapter 6, pages 75–76).

Column J: Comments

Column J is used for recording any comments on the medicines included in the core or supplementary lists, such as their temporary unavailability in a specific pharmacy. The survey manager, area supervisors or data collectors may add comments.

Fig. 3.3 shows an extract from a completed Medicine Price Data Collection form: Public Sector Procurement Prices in which the tender prices have been entered at central level. In the example below, public sector procurement is limited to generic versions of medicines listed on the national essential medicines list (NEML). As such, procurement data was not found for originator brand products or for non-NEML medicines such as atenolol, as indicated in the Comments column.

Fig. 3.3 Extract from a Medicine Price Data Collection form: Medicine Procurement Prices, with information entered at central level

A	B	C	D	E	F	G	H	I	J
Generic name, dosage form, strength	Medicine type	Brand or product name(s)	Manufacturer	Available: "yes" or "no"	Pack size recommended	Pack size found	Price of pack found	Unit price (4 digits)	Comments
Amitriptyline cap/tab 25 mg	Originator brand	Tryptizol	MSD	*No*	100			/tab	*generics only*
	Lowest-priced generic	*Amitriptyline*	*Pharma*	*Yes*	100	*1000*	*970.00*	*0.9700*/tab	
Amoxicillin cap/tab 500 mg	Originator brand	Amoxil	GSK	*No*	21			/tab	*generics only*
	Lowest-priced generic	*Amoxicillin*	*Ratio-pharma*	*Yes*	21	*500*	*2407.00*	*4.8140*/tab	
Atenolol cap/tab 50mg	Originator brand	Tenormin	Astra Zeneca	*No*	60			/tab	*Not on EML*
	Lowest-priced generic			*No*	60			/tab	*Not on EML*

BOX 3.7

Collecting public sector procurement prices

Procurement price data can be gathered at a government central medical store from a series of procurement orders during the past year. Alternatively, they can be obtained from tender documents held by the ministry of health. These tender prices generally result from negotiations between manufacturers or importers and a government procurement agency, and the prices usually remain valid for an entire year.

In some countries, central and regional tender prices may vary. For national surveys, use the central tender price except where decentralized procurement predominates for the medicines being studied, in which case use collect regional tender prices. For regional surveys, use the regional tender price.

Where individual public health facilities purchase directly from distributors and/or wholesalers, procurement prices should be collected at all medicine outlets in the public sector sample where such purchasing is known to occur. If multiple procurement systems are operating at the central, regional and local level, procurement prices should again be collected at individual medicine outlets. One advantage of this method is that facility prices will include any local ad hoc purchases,[1] which would not be reflected in central/regional procurement data.

The same procedures should be followed for completing the Medicine Price Data Collection form for patient price data. These procedures are described in Chapter 6.

REFERENCES

1. Mendis S et al. The availability and affordability of selected essential medicines for chronic diseases in six low- and middle-income countries. *Bulletin of the World Health Organization*, 2007, 85(4):279–288.

[1] If local purchasing of medicines is known to occur, this should be described in the survey report.

4

Training area supervisors, data collectors and data entry personnel

This chapter provides practical guidance on conducting a training workshop for area supervisors, data collectors and data entry personnel. It does not cover training on price components, since this is generally a separate activity with different personnel. Chapter 9 provides guidance on training for the price components survey. Training is an important element of survey preparation because it helps ensure the accuracy and reliability of the data-gathering and data entry procedures. Consequently, this chapter also covers the issue of ensuring data quality.

When multiple surveys are being carried out in the same region, WHO and HAI sometimes hold regional training sessions for survey managers who, in turn, train their survey personnel during a national workshop. It is useful to check with WHO and HAI to see if any such regional training workshops are being planned or could be organized. **This chapter has been developed to assist survey managers in conducting training workshops for their survey personnel, regardless of whether they have attended any previous training**.

- **Training of survey personnel is an essential part of survey planning**
- **Comprehensive training is required to ensure data quality**
- **Area supervisors and data collectors must be trained prior to initiating fieldwork**
- **Generally, training on price components is conducted as a separate activity from the broader training workshop (see Chapter 9)**
- **A trainer's guide (Annex 3) and sample training materials are provided on the CD-ROM that accompanies this manual**

4.1 THE IMPORTANCE OF DATA QUALITY AND THE CONSEQUENCES OF POOR-QUALITY DATA

Why is data quality important?

- Solid data supports conclusions and recommendations
- Future policy decisions may rely on the evidence generated in the survey
- Critics and opponents will look for weaknesses in the survey methods and results

- Results will be publicly accessible and may be used by others, e.g. in conducting international comparisons
- To respect the values of integrity and transparency in the WHO/HAI Medicine Prices and Availability project

In previously conducted surveys a number of common data problems have been identified:

- Wrong prices collected in the field – wrong medicine, wrong strength (the most common mistake), or wrong dosage form
- Illegible or incomplete data collection forms or both
- Mistakes in entering the price (e.g. decimal in the wrong place, extra or missing zeroes)
- Medicine price entered without indication of whether medicine was available
- Originator brand prices collected and/or entered as lowest-priced generic prices or vice versa
- Ambiguous data, e.g. unclear pack size (e.g. 'one bottle' rather than the number of millilitres, leading to incorrect calculation of unit price); absent/unclear comments (e.g. medicine is available but no price data are recorded, with no comment to confirm medicine is provided for free)
- Prices noted on paper forms and entered in the workbook when medicine is out of stock
- A discount was applied to the recorded price, but was not applicable to all patients
- Recorded price was actually a flat dispensing fee rather than the true price
- Recorded price included additional fees, such as injection fees
- Errors in the calculation of unit prices
- Data entry errors

Data collection errors need to be verified and corrected or deleted from the results. In some surveys, large segments of incorrect or unreliable data have had to be excluded from the analysis or re-collected. This weakens the overall survey results and wastes resources, since time and effort have been spent on collecting data that cannot be used.

There are several reasons for the data problems commonly encountered as part of the survey:

- The survey manager did not read the manual thoroughly or misunderstood it
- Area supervisors, data collectors and data entry personnel received insufficient or poor-quality training
- The pilot survey was not conducted properly
- There was inappropriate selection of supplementary medicines
- Work in the field was of poor quality (insufficient supervision, no quality control for submission of completed forms, misunderstanding of instructions, etc.)
- Data were not checked at every stage of the survey process

- Data were entered only once (double entry not used)
- Data-checking function of workbook was not used or questionable values were not verified
- Human error

Data problems can therefore be avoided by:

- Studying the survey manual and accompanying materials carefully at every step and following instructions
- Selecting capable and reliable personnel and ensuring they are well trained in the survey methodology
- Encouraging personnel to communicate openly about uncertainties in survey procedures and questionable data
- Double-checking data collection forms for accuracy and completeness after each data collection visit, at the end of each day of fieldwork and prior to data entry
- Conducting double entry of the survey data into the workbook – data are entered twice by different people and then cross-checked
- Conducting a manual check of data entered into the workbook and running the automated data-checker programme (identifies unusual or outlying results that require verification)

Experience from previous surveys shows that data problems are a normal and expected part of data collection and data entry.

Data checking and cleaning can be a time-consuming process, but it is critical to ensuring reliable results. Do not move on to analysis and report writing until you are sure that data are accurate.

Thorough training of survey personnel is one of the most important ways of ensuring accurate data collection and good-quality data. Experience from previous surveys has shown that poor survey preparation, including inadequate training of survey personnel, results in onerous and time-consuming data checking that can significantly delay the survey's completion. It is therefore more effective and efficient to apply rigorous data collection methods than to try to clean or correct data once they are already collected.

Thorough training of survey personnel and consequent rigorous application of the survey methodology will save much time and effort during the data checking and data entry stages.

4.2 OVERVIEW OF TRAINING

All personnel involved in data collection, supervision and data entry require training to ensure reliable and accurate data collection, completion of the data collection form and transfer of data to the workbook. Training should also foster an appreciation among survey personnel of the importance of generating high-quality data. The training ensures a common understanding of the terms and definitions used in the survey manual.

A training workshop for survey personnel should be held as part of survey preparation. The training workshop's overall objective is to provide area supervisors, data collectors and data entry personnel with the knowledge and skills required to carry out the medicine prices and availability survey in an accurate and reliable manner. Upon completion of the training, participants should:

- be familiar with the key aspects of the survey and how it is conducted;
- understand their roles and responsibilities in the survey, including specific tasks, timelines and reporting requirements;
- understand the critical content required to do their job effectively and possess the skills required to undertake each of their activities;
- be aware of common issues that may arise during survey activities, and trouble-shooting/problem-solving strategies to address these issues; and
- recognize the intrinsic value of good-quality data and be motivated to ensure data quality as part of their activities.

Training should therefore focus on teaching the participants:

- the survey's overall purpose;
- the consequences of poor-quality data;
- how to conduct medicine outlet visits and collect price and availability data;
- how to complete the Medicine Price Data Collection form;
- problem-solving in the field;
- how to enter data into the electronic workbook and use the double-entry feature; and
- common data collection and data entry mistakes.

It is recommended that a training workshop that covers both data collection and data entry last at least three days (a two-day workshop may be sufficient for data collection only). It should include a data collection pilot test in which survey personnel visit public and private sector medicine outlets and collect data in the same way they would during actual fieldwork. This will not only provide survey personnel with practical experience in collecting data, but will also serve as a check of the appropriateness of the draft list of survey medicines.

The trainer is usually the survey manager or could be a resource person from the WHO/HAI project. The participants should include all area supervisors, data collectors and data entry personnel. Training on data entry can be held as a separate workshop/session for data entry personnel, if this is more convenient (e.g. if the survey is being conducted in a region or state but data entry will be undertaken at the central level). However, there may be some advantage in holding a combined training session on data collection and data entry, since it will sensitize area supervisors and data collectors to the difficulties in entering poor-quality data. Note that a basic understanding of Microsoft Excel is required for data entry using the electronic workbook; if data collectors lack such technical knowledge then data collection and data entry should be conducted as two separate training sessions. It is also recommended that the members of the Advisory Group be invited to the introductory session of the training workshop to meet survey personnel and discuss the survey methodology.

The training workshop should be held as close as possible to the initiation of data collection – immediate departure for data collection can be scheduled if the

BOX 4.1

Training recommendations from previous surveys

- A training workshop is crucial for ensuring successful data collection. All survey personnel must be trained.
- Ideally all area supervisors and data collectors should be trained together at the same workshop to ensure consistency in the instructions received. Data entry personnel can be trained together with other personnel or separately.
- Only survey managers should be required to read the entire manual; simplified handouts and instructions should be available for other personnel (examples are available on the CD-ROM).
- The data collection pilot test is the most important part of training; sufficient time should be allocated to ensure that the test is conducted thoroughly, with adequate time for debriefing.
- A variety of training formats and tools (e.g. presentations and exercises) should be used to keep the training interesting and promote recall of training material.

survey manager has prepared well. Time lags between training and data collection should be avoided so that survey personnel have better recall of the data collection protocol.

4.3 PREPARING FOR THE TRAINING WORKSHOP

Planning the training workshop can require substantial time and preparation. Workshop preparations should begin early in the survey development process and should run in parallel to other survey planning and preparation activities. In preparing the training, it is essential to ensure that there is an adequate budget for the training venue, daily allowance and accommodation for participants, transport and materials.

BOX 4.2

What the trainer should do before the workshop

- *Above all, become thoroughly familiar with all aspects of the survey methodology*. This requires careful study of the survey manual and tools on the accompanying CD-ROM. Contact HAI[1] or WHO[2] to clarify any uncertainties.
- Organize the training workshop's logistics, including the data collection pilot test.
- Follow the guidance on training given in the Trainer's Guide and plan how to conduct each session.

Select a training venue

Select a training venue based on the following criteria:

- availability of a room of appropriate size to hold the workshop;
- availability of essential technical resources, namely an accessible printer and photocopier;
- proximity to medicine outlets that can be surveyed during the data collection pilot test;

[1] info@haiweb.org
[2] medicineprices@who.int

- accessibility by routine modes of transport;
- on-site or nearby refreshments and accommodation for out-of-town participants; and
- reasonable cost.

It is useful to check with Advisory Committee members to see if a meeting room can be made available for the training workshop at low or no cost.

Schedule dates of the training workshop

The training workshop should be scheduled close to the anticipated start of data collection. Do not plan the workshop during a time when weather or other conditions may delay the initiation of data collection. All survey personnel must attend the workshop and should be advised of the dates as early as possible. Invitations to attend the introductory session of the workshop should also be sent to Advisory Committee members.

Training should be held close to the initiation of data collection. Time lapses between training and data collection increase the chances that important details about the survey protocol will be forgotten.

Plan data collection pilot test

During the data collection pilot test, each data collection team (area supervisor and his or her data collectors) will visit one public medicine outlet and one private medicine outlet and collect data by following the survey procedures. Thus, one public medicine outlet and one private medicine outlet is required for each data collection team to serve as pilot sites. The participation of pilot sites should be secured well in advance of the training workshops. The appointments should be made in advance and reconfirmed before the training session, avoiding peak periods when outlets may be busy with patients.

Do not send more than five survey personnel (e.g. one area supervisor and four data collectors) to a pilot site. In small retail drug stores, it may only be possible to send three people. If survey teams consist of larger numbers of personnel, they will need to be split into smaller groups for the pilot test.

Prior to the training workshop a written schedule should be prepared for each data collection team, indicating the time and location of each medicine outlet visit, including the name and contact details of the person in charge at the facility. The schedule should also contain the survey manager's telephone number so that survey personnel can call if there is a query/problem.

Secure equipment needed

- Ideally, one computer per data collection team, plus one for data entry personnel, with Microsoft Excel installed. If training on data entry is being conducted separately, two computers (one per data entry personnel) are required;
- Access to printer and photocopier for reproducing Medicine Price Data Collection forms;

- Calculators for participants to determine the unit prices of medicines;
- Pens, notepad, clipboards;
- Mobile phones for data collection teams to carry during the pilot test.

Prepare documentation materials

- One copy of handouts, exercises and tests for each participant (samples are provided on the CD-ROM);
- Two copies of the Medicine Price Data Collection form for each participant for use during the pilot test (see below).

Prepare sufficient copies of the Medicine Price Data Collection form for use in pilot test

You should generate a draft Medicine Price Data Collection form from the workbook,[1] where all relevant information on the survey medicines is stored, and photocopy it for use during the data collection pilot test. However, before generating the data collection form for use in the pilot test, in the workbook you need to:

- delete any medicines from the global and regional core lists that are not registered in your country;
- add the supplementary medicines that you are surveying;
- check whether the MSH prices already entered in the workbook are current, and enter the reference price for each supplementary medicine;
- identify which medicines are on the national essential medicines list, where one exists;
- for the public sector, identify the level(s) of care where each medicine is expected to be available; and
- identify and enter the name of the originator brand product for each supplementary medicine to be surveyed, and check the name of each originator brand on the global and regional core list (the identification of the lowest-priced generic product is done at each individual medicine outlet).

Chapter 3 provides detailed instructions on preparing the workbook for your specific survey.

To access and print the Medicine Price Data Collection form, press on the Data Collection tab at the bottom of the workbook. From the *Data Collection* page you will be able to view and print the form. Note that the form is not complete until it contains the complete list of survey medicines, with the corresponding international reference prices and the originator brand names used in your country.

Each workshop participant will need two copies of the Medicine Price Data Collection form – one for each medicine outlet to be visited as part of the data collection pilot test.

[1] See Chapter 3, page 47.

Load Excel workbook onto each computer

A copy of the survey workbook Part I, *prepared for your specific survey* (e.g. survey medicines entered and sectors identified), should be loaded onto each computer for use during the training workshop. During the workshop participants will enter the data they collected during the pilot test into the workbooks.

Important: To allow participants to view summary results of data generated from the pilot test, you will need to make the following adjustments *before loading the workbook onto the computers*:

1. Enter an exchange rate in cell J3 of the Reference Prices page. Enter a sample/average exchange rate of your local currency to US$.
2. Set the minimum number of unit prices required for median price ratios to be computed to '1'. During the survey a minimum of 4 unit prices is needed for the median price ratio to be calculated, however since only one set of data per sector is being collected during the pilot test, setting this parameter to 1 will allow participants to view summary results. On the *Field Data Consolidation* pages for both the public and private sectors, select 'Ratios On' to display columns of summary data, and set cell H10 to '1'.
3. Enter the daily wage of the lowest-paid government worker in Cell J6 of the Standard Treatment Affordability page, if you want to show participants sample affordability results.

In addition, the workbook relies on a series of automated commands (called macros) to function. You will need to ensure that macros are enabled on each of the computers to be used. In the Excel toolbar, click on Tools → Macros → Security, and set the Security Level to 'Low' or 'Medium'. If 'Medium' is chosen, then the participants will have to be instructed to choose 'Yes' when asked whether they should allow macros to run upon opening the workbook.[1]

As part of the training tools provided on the CD-ROM, a data-checking exercise using a workbook containing fictitious data has been developed to assist personnel in identifying common data errors ('Data Checker exercise.xls'). If you choose to use this exercise as part of the training workshop you will also need to load the Data Checker workbook onto each computer.

4.4 CONDUCTING THE TRAINING WORKSHOP, INCLUDING THE DATA COLLECTION PILOT TEST

A trainer's guide is provided in Annex 3 and on the CD-ROM that accompanies this manual. Survey managers are strongly encouraged to use this guide as a starting point for planning their training workshop. The guide provides guidance to survey managers in conducting a training workshop for their survey personnel, including:

- how a training programme can be conducted;
- what basic steps should be followed;
- what material should be covered; and
- training activities and aids that can be used.

Sample presentations, handouts and exercises are also available to accompany the guide. The Trainer's Guide and materials have been developed based on previ-

[1] See Chapter 3, page X

ous experience in conducting training workshops for the medicine prices and availability survey.

The Trainer's Guide is divided into modules according to the sample training agenda. Each module outlines the objectives of the training session, instructions for training activities to be conducted, materials required and the key messages that should be emphasized. Refer to the sample presentations for a more detailed outline of the content to be covered in each of the modules.

The Trainer's Guide should serve as an example only; the training plan and materials will need to be adapted to fit the specificities of each survey. For example, if medicines are provided for free in the public sector of a country, all training activities and materials will need to reflect this. Similarly, the specific 'other' sectors that will be included in the survey will need to be incorporated into the training materials.

Considerations in developing country-specific survey materials should include survey personnel's level of experience, the survey's specific objectives; any deviations from the standard methodology; and logistics issues (e.g. the data collection pilot test should preferably be conducted at the most convenient time for pharmacy staff). However, the following basic principles can be applied to all training workshops:

- Standardized training materials, including simple, ready-to-use handouts and tools, should be used. The survey manual should be used as a master resource, but shorter, simpler instructions are required for survey personnel.
- A range of activities (e.g. presentations, group discussions, exercises) should be used to cover different learning styles and preferences and promote recall of training material. Learning will be embedded more effectively if information is presented in multi-faceted ways.
- A data collection pilot test is essential to provide personnel with hands-on experience in conducting the survey.
- Practical exercises with the data collection forms and workbook, demonstrating the consequences of poor-quality data, should be conducted.
- Recall and memory of survey protocols by survey personnel should be verified before starting data collection.

BOX 4.3

Training skills/techniques

- Motivate participants by showing enthusiasm for the training activities being carried out.
- Promote a cooperative, non-threatening environment with a high degree of participant involvement.
- Keep discussions focused on the topics in question.
- Leave time for and encourage questions from participants.
- Assess participants' understanding of each topic and review material as necessary.
- Solve problems encountered on topics that are difficult to master.

Fig. 4.1 shows a sample agenda for a workshop involving area supervisors, data collectors and data entry personnel.

Fig. 4.1 Sample training agenda

DAY 1	
8:30–10:00	Welcome, survey objectives and training overview
10:00–10:15	**BREAK**
10:15–12:00	Overview of survey methodology • Key aspects of survey design • Roles and responsibilities of personnel
12:00–13:00	**LUNCH**
13:00–14:30	Data collection procedures • Preparation for data collection • Procedures before, during and after medicine outlet visits • What to do at the end of data collection
14:30–14:45	**BREAK**
14:45–17:15	Completing the Medicine Prices Data Collection form • Instructions for completing the form • Key rules to remember
DAY 2	
8:30–9:30	Review of Day 1
9:30–10:00	Instructions for data collection pilot test
10:00–15:00	Data collection pilot test (includes lunch break) • Data collection at one private and one public medicine outlet
15:00–15:15	**BREAK**
15:15–16:00	Unit price calculation
16:00–17:30	Debrief of data collection pilot test
DAY 3	
8:30–9:30	Review of Day 2
9:30–10:30	Data entry • How to enter unit price data into the survey workbook • How to conduct double entry and check results
10:30–10:45	**BREAK**
10:45–12:45	Data entry • Entry of data collected during pilot test
12:45–13:45	**LUNCH**
13:45–15:45	Checking workbook data • Using the workbook's data-checker function • Manual checking of workbook data
15:45–16:00	**BREAK**
16:00–17:00	Logistics for data collection • Next steps
17:00–17:30	Final comments, evaluation of workshop

Conducting the data collection pilot test

During the pilot test, data collection teams, consisting of area supervisors and their data collectors, will visit medicine outlets and collect data on the price and availability of medicines in the same way they would during the actual survey. Each area supervisor and data collector should complete their own Medicine Price Data Collection form to gain hands-on experience. Area supervisors should also supervise and watch out for common mistakes, such as information collected on the wrong strength or dosage form. It may be necessary to hold a preliminary pilot test with area supervisors to ensure that they are sufficiently knowledgeable about the survey protocol to supervise data collectors and identify mistakes. During the pilot test, any questions or uncertainties should be noted for clarification during the training workshop. The Trainer's Guide provides more detailed instructions for conducting the pilot test.

For the pilot test, each area supervisor and data collector will need two Medicine Price Data Collection forms, pen and clipboard, notepad, instructions for data collection and a calculator for identifying generic medicines with the lowest unit price when multiple generic products are available. The area supervisor should also have a schedule and contact list for the pilot test sites as well as the survey manager's contact details.

4.5 FINALIZING THE MEDICINE PRICE DATA COLLECTION FORM

The pilot test will demonstrate if the selected medicines with the corresponding dosage forms and strengths are the ones commonly used in both the public and private sectors. Based on the pilot test results, modifications to the medicines list may be indicated. After the pilot test, the survey manager should review the results and determine whether any changes need to be made to the survey medicines list. Any changes to this list should be made on the *Reference Price* page of the survey workbook (see Chapter 3). These changes will be reflected automatically in the Medicine Price Data Collection form, which is accessed from the Data Collection tab at the bottom of the workbook. Any changes to the survey medicines list as a result of the pilot test should be reviewed and discussed during the training workshop. If possible, the final Medicine Price Data Collection form should be printed and copied for distribution to area supervisors on the last day of the training workshop.

4.6 TRAINING TOOLS

A selection of sample/template tools is available on the CD-ROM that accompanies this manual. Before use, the tools should be carefully reviewed, and modified or adapted as appropriate to suit individual survey protocols.

Trainer's Guide

The Trainer's Guide provides guidance to survey managers in conducting a training workshop for their survey personnel.

Sample training agenda

The sample agenda, contained in the Trainer's Guide, corresponds to a three-day training workshop for area supervisors, data collectors and data entry personnel.

Sample presentation slides

Six sample PowerPoint presentations are available for adaptation and used in presenting key material to survey personnel during the training workshop:

1. Introduction to the survey
2. Survey overview
3. Preparing for data collection and visiting medicine outlets
4. Completing the data collection form
5. Data entry
6. Data quality and checking

Handouts

Four handouts have been prepared to provide survey personnel with a summary of essential points specific to their roles and responsibilities:

1. Instructions for area supervisors
2. Instructions for data collectors
3. How to complete the Medicine Price Data Collection form
4. Instructions for data entry personnel

Exercises

Exercises are mandatory for ensuring that the methodology is well understood and followed by the whole team. The following two exercises are provided on the CD-ROM; you may also wish to develop your own.

1. A 'Spot the mistakes' exercise (Spot Mistakes Exercise.doc and Spot Mistakes Answer Key.doc) provides a completed Medicine Price Data Collection form that contains common mistakes for training participants to identify. An answer key is also provided.
2. A data-checking exercise (Data Checker exercise.xls) consists of a workbook containing fictitious data developed to assist personnel in identifying common data errors.

5

Preparing for data collection in the field

The success of the medicine price survey depends on the data collectors in the field gathering and recording accurate, reliable data. This requires careful planning and preparation for fieldwork. Preparation for data collection involves the following activities:

- planning the data collection visits;
- preparing the Medicine Price Data Collection forms needed for field visits;
- preparing information materials and tools for data collectors; and
- arranging for regular communications.

The sample of medicine outlets should be selected, the list of survey medicines finalized and survey personnel chosen and trained, before beginning to prepare for data collection in the field.

The survey manager and area supervisors each have specific responsibilities in preparing for data collection.

5.1 PLANNING THE DATA COLLECTION VISITS

Who? Survey manager/Area supervisor

Before data collection starts, a schedule of visits to sample medicine outlets should be prepared for each survey area. The number of days required to collect the data can be estimated on the basis of the number of facilities to be visited in each geographical area, the distance between them and the mode of transport available. In general, two data collectors will require one to two hours plus travelling time for data collection in each facility.

5.1.1 Prepare a letter of introduction

Who? Survey manager

A letter of introduction from the survey manager will be invaluable in introducing area supervisors – and later data collectors – to staff in the medicine outlets being surveyed. The survey manager should prepare a letter of introduction containing the following information:

- the name of the organization conducting the survey and the survey manager's contact details;
- the purpose of the study;
- the names of the data collectors who will visit the facility; and
- the time required for data collection in each facility.

The letter should also provide reassurance that the anonymity of the facility or pharmacy will be maintained. (As countries have different regulations on ethical clearance it is important to check if clearance is necessary before starting a survey).

An example of a letter of introduction is included in Annex 4 and is provided as a Word file on the CD-ROM for local adaptation, as appropriate. The survey manager should provide area supervisors with sufficient signed copies for use during both the scheduling of field visits and the data collection visits.

5.1.2 Make initial contact with medicine outlets

Who? Area supervisors

It is essential that good relations be established with the pharmacist/dispenser in each facility to be surveyed, since they will have to set aside considerable time to provide information on medicine prices and availability. Ideally, area supervisors should visit them personally, in advance, to seek their permission for data collection in their facility or medicine outlet. They should show them the letters of endorsement and introduction, but should not inform them about the specific medicines included in the survey. An appointment should be made for data collection on a date and at a time that is convenient for the manager of the medicine outlet, avoiding peak periods when he or she may be busy with patients. Area supervisors should note the contact person's name and telephone number at each outlet. If in-person visits are not possible, then pharmacists/dispensers should be contacted by phone.

The day before the scheduled data collection visit, area supervisors should telephone medicine outlets to confirm the appointment.

If medicine outlets are located too far away to visit in person, they should be contacted by phone.

In addition to visiting sample facilities, back-up facilities should also be contacted and alerted of a potential data collection visit.

Contacting medicine outlets may be time-consuming, but it is important because it will greatly facilitate data collection.

5.1.3 Prepare a schedule of data collection visits

Who? Area supervisors

A written schedule should be prepared for each data collection team, indicating the date, time and location of each medicine outlet visit, including the name of the contact person. An example is provided in Fig. 5.1.

Fig. 5.1 Sample schedule of data collection visits

Survey area: Eastern Region

Date and time of appointment	Medicine outlet name	Contact person	Location	Sector	Number	Back-up outlet name and contact details
23 March, 13h00	ABC Pharmacy	Mrs Nguyen	45 Main Street Eastern City Tel:+22 414 000	private	01	Main Street Chemist 59 Main Street Eastern City Mr Shah

5.2 PREPARING THE MEDICINE PRICE DATA COLLECTION FORMS NEEDED FOR FIELD VISITS

5.2.1 Generate the final Medicine Price Data Collection form using the automated workbook[1]

Who? Survey manager

Following the data collection pilot test conducted as part of the training workshop, the survey manager should review and, if necessary, revise the list of survey medicines. For example, the strength of a supplementary medicine may need to be changed for one that is more commonly available.

Once the medicine list has been finalized, the final Medicine Price Data Collection form can be printed directly from the workbook. To access the Medicine Price Data Collection form, press on the Data Collection tab at the bottom of the workbook. From the menu of options at the top of the page, select File → Print.

5.2.2 Make sufficient copies of the Medicine Price Data Collection form for field visits

Who? Survey manager

A separate Medicine Price Data Collection form will be needed for:

- each medicine outlet in the study sample;
- each back-up facility; and
- each validation visit (area supervisors will collect data at 20% of medicine outlets surveyed for comparison with that of their data collectors).

For example, in a survey that includes 30 medicine outlets (5 per survey area x 6 survey areas) in each of the public, private and one 'other' sectors, you would need: 30 outlets/sector x 3 sectors = 90 forms for the study sample; an additional 90 forms for each back-up facility and 90 x 20% = 18 forms for validation visits, for a total of 198 forms.

If possible, the Medicine Price Data Collection form should be colour coded by sector by photocopying forms onto different coloured paper. Alternatively, coloured pens can be used to mark each form according to sector. Each area supervisor should receive the requisite number of forms corresponding to the sample in their survey area, including back-up facilities and validation visits. Where feasible, these should be distributed to area supervisors on the last day of the training workshop.

[1] See Chapter 3

5.2.3 Prepare a facility-specific Medicine Price Data Collection form for each medicine outlet to be visited

Who? Area supervisors

A separate Medicine Price Data Collection form should be prepared for each sample medicine outlet, back-up facility and validation facility. The area supervisor should add details of the medicine outlet to the first page of each form before the data collection visits in his/her survey area. On each day of data collection, data collectors should be supplied with Medicine Price Data Collection forms specific to the outlets they will be visiting that day.

Fig. 5.2 shows the front page of the Medicine Price Data Collection form with information to be completed by area supervisors shaded in pink. Note that the date, the names of people who provided information on medicine prices and availability as well as the data collectors' names should be left blank for the data collectors to complete when conducting the survey.

5.2.4 Arrange for storage of completed Medicine Price Data Collection forms

Who? Area supervisors/Survey manager

Area supervisors should arrange to copy and store completed data collection forms in plastic bags until fieldwork is completed, at which time they will be transferred to the survey manager. The area supervisors should always keep a copy of all data collection forms, in case those sent to the survey manager are lost or damaged. The survey manager should arrange for the safe storage of all completed forms in secure conditions for an indefinite period, in the event that data need to be checked at a later date. Forms should be stored in a location that is protected from moisture, direct sunlight, rodents and insects.

Experience from the field has shown that data sometimes need to be checked several months after the data collection is completed. All data collection forms should therefore be kept in a safe location for an indefinite period.

5.3 PREPARING INFORMATION MATERIALS AND TOOLS FOR DATA COLLECTORS

Who? Area supervisors

Data collectors will need to bring the following tools and information with them on each day of data collection:

1. A list of data collection teams and contact information
2. Their area supervisor's contact details, including a mobile phone number to call in case of difficulty in the field
3. A schedule of visits to survey sites
4. The contact details of the sites to be visited
5. Details of back-up facilities to be visited if scheduled visits are not possible, or less than 50% of the medicines are available

Fig. 5.2 Front page of Medicine Price Data Collection Form showing information to be completed by area supervisors (in pink)

Medicine Price Data Collection form

Use a separate for for each medicine outlet

Date: _____ Survey area number: _____

Name of town/village/district: _____

Name of medicine outlet (optional): _____

Medicine outlet unique survey ID (mandatory): _____

Distance in km from nearest town (population >50 000): _____

Type of medicine outlet:

☐ Public sector facility (specify level of care below):
- ☐ Primary care facility
- ☐ Secondary care facility
- ☐ Tertiaty care facility

☐ Private sector medicine outlet

☐ Other sector medicine outlet (please sepcify):

Type of price:

☐ Procurement price ☐ Price the patient pays

Type of data:

☐ Sample outlet ☐ Back-up outlet ☐ Validation visit

Name of manager of the medicine outlet:

_____

Name of person(s) who provided information on medicine proces and availability (if different from manager):

_____

Name of data collectors:

_____

_____

Verification

To be completed by the area supervisor at the end of the day, once data have been verified

Signed: Date: _____

6. Copies of letter(s) of endorsement and letter of introduction
7. Relevant handouts or instruction sheets
8. A Medicine Price Data Collection form for each sample medicine outlet to be visited that day
9. A Medicine Price Data Collection form for each back-up site that may need to be visited that day
10. A calculator for calculating the unit price of medicines
11. Pens (pencils should not be used to record data), a clipboard and other supplies
12. A notebook to record any significant events or findings
13. Field allowance for local expenses

Where feasible, each data collection team should also be equipped with a mobile phone and credit for use in contacting their area supervisor. Additional supplies that may be useful include an identity document with a photograph, a local map and extra calculator batteries.

Area supervisors should prepare resource kits containing the above items for each data collection team. Before each day of data collection, the area supervisor should ensure that data collectors have all the necessary tools and information with them, including the Medicine Price Data Collection forms specific to the medicine outlets and back-up facilities scheduled for that day.

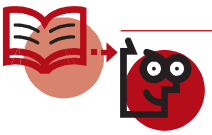
LESSONS FROM THE FIELD

Give clear written guidelines to data collectors and make sure that they have the area supervisor's and survey manager's contact details. Ensure that everyone (all personnel involved in the survey) understands the survey's importance.[1]

5.4 ARRANGE FOR REGULAR COMMUNICATIONS

Who? Survey manager/Area supervisor

Throughout data collection, area supervisors should be available to provide advice to data collectors and answer any questions they may have. Providing data collectors with their area supervisor's mobile phone number, when feasible, is one way of ensuring timely communication.



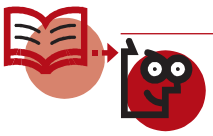
It is preferable to resolve any issues while data collectors are on site, since return trips to medicine outlets can be costly and time-consuming.

Data collectors should also meet with their area supervisor on a regular basis so that completed forms can be checked and any issues can be resolved. Ideally, this should occur at the end of each day of data collection so that errors do not carry

[1] Dr Anita Kotwani, Principal Investigator, Rajasthan Survey and technical adviser for medicine price and availability surveys in India. First regional training workshop on medicine prices. *Essential Drugs Monitor*, No.33, 2003. http://mednet2.who.int/edmonitor/33/EDM33_24_Workshop_e.pdf

over into future data collection visits. In addition, data collectors will be better able to recall the data collection visit, which may be useful in clarifying erroneous or illegible data. During data collection, data collectors should record how problems were solved or how data collection was simplified. These notes should be reviewed with the area supervisor during the debriefing.

The survey manager should also be available throughout data collection to respond to questions from area supervisors, and should provide them with a mobile phone number for this purpose. Ideally, the survey manager should visit each survey area during data collection to supervise activities. If this is not possible, he or she should arrange for regular communications with each area supervisor to receive updates on the data collection process.



Remember, the more you prepare, the smoother the survey will go.

6

Data collection in the field

This chapter describes procedures for data collection in the field, i.e. at medicine outlets. Public procurement price data are generally gathered centrally at a government central medical store from a series of procurement orders or from tender documents held by the ministry of health (see Chapter 3). However, if procurement prices are being collected at individual public health facilities, the data collection procedures described in this chapter should be followed.

Each day of data collection involves the following activities:

When?	What?	Who?
Before going out to collect data each day:	Check that data collection teams have all the materials necessary for field visits and confirm transport arrangements	Area supervisors/Data collectors
	Call each facility to be visited and confirm appointment	Area supervisors
On arrival at the facility:	Introduce survey team and remind staff of visit's purpose	Data collectors
	Verify and complete the outlet information on first page of the Medicine Price Data Collection form	Data collectors
	Collect and record data on medicine prices and availability	Data collectors
	Check all data entered into the Medicine Price Data Collection form before leaving facility	Data collectors
At the end of each day:	Conduct meeting between area supervisors and their data collectors, and discuss any difficulties	Area supervisors/Data collectors
	Review each Medicine Price Data Collection form and clarify missing/unreliable information	Area supervisors/Data collectors
	Calculate the unit prices of the medicines found	Area supervisors
	Sign all checked data collection forms, copy and store in plastic bags	Area supervisors

Each step of data collection is described below according to the personnel responsible, namely area supervisors and data collectors.

6.1 FIELDWORK: AREA SUPERVISORS

Area supervisors are responsible for ensuring the accuracy and reliability of data collection. This involves the activities described below.

BOX 6.1

Lessons from the field: tips for successful data collection

- Data collectors should always be neatly dressed and polite – they are the face of a national medicine price and availability survey
- Data collectors should carry identification and letter of endorsement and/or introduction from the survey manager
- Data collectors should make themselves known to the pharmacy or health facility manager when they arrive, and before they begin collecting prices
- Data collectors should collect prices as quickly as possible, causing minimal disruption (if the facility is extremely busy and the manager requests that they return later in the day, they should comply)

6.1.1 Field supervision

Area supervisors should meet with their data collectors at the end of each day to check completed data collection forms, get feedback on the data collection process and resolve any problems. They should go out into the field regularly with the data collection teams to ensure that the agreed procedures are being followed.

6.1.2 Daily check of completed Medicine Price Data Collection forms

It is important that area supervisors review completed Medicine Price Data Collection forms at the end of each day to check that the data are complete, consistent and legible. Once the team has left the field, it becomes difficult to verify information that may be missing or incomplete.

The supervisors should highlight any missing or unreliable information on the form and identify the source of the problem. If necessary, data collectors should return to the facility to collect any further data required. If any Medicine Price Data Collection form shows that less than 50% of medicines were available at the outlet, the area supervisor should ensure that a back-up facility has been visited.

Once the area supervisor is satisfied with the completeness and reliability of a Medicine Price Data Collection form, he or she should sign the form's first page to record that it has been checked. Forms should then be safely stored until completion of data collection, at which time they will be transferred to the survey manager (see 6.1.5).

6.1.3 Validation of data collection

Area supervisors should validate data collection by conducting the survey again at selected medicine outlets and checking their results against those of their data collectors. This validation should be performed for 20% of the facilities per sector per survey area (or one public outlet and one private outlet in each survey area where the recommended sampling frame has been followed in these sectors). Where possible, medicine outlets visited for validation should be selected at random. Ideally, the validation should be done on the same day as data collection to avoid changes in the availability of the survey medicines (soon after the data collectors have left the facility). Any discrepancies between the results of the area supervisor and those of their data collectors should be discussed with the data collectors and the data collection protocol should be clarified as necessary. Any problems that cannot be resolved in the field should be discussed with the survey manager.

6.1.4 Calculating the unit prices of medicines

After checking the completed Medicine Price Data Collection forms, the area supervisors should calculate the unit prices of the medicines that have been found, using the following procedure:

- For each product, divide the *Price of Pack Found* (Column H) by the *Pack Size Found* (Column G).
- Retain at least four digits after the decimal point.
- Enter the calculated unit prices in Column I of the Medicine Price Data Collection form and double-check the calculations.

Some unit prices may have already been calculated by data collectors to determine the lowest-priced generic product for certain medicines; these should be double-checked by the area supervisor.

6.1.5 Storing completed Medicine Price Data Collection forms

Completed forms should be copied and stored in waterproof plastic bags in the field, in a location that is protected from moisture, direct sunlight, rodents and insects. Originals should be stored in a separate location from copies. All original data collection forms, including those for validation visits, should be transferred to the survey manager upon completion of fieldwork. Area supervisors should retain the copies for use in the event that the originals become lost or damaged.

6.2 FIELDWORK: DATA COLLECTORS

6.2.1 Before going out into the field each day

Before going out into the field each day, data collectors should check that they have all the materials they will need for data collection, namely:

1. A list of data collection teams and contact information
2. The contact details of their area supervisor, including a mobile phone number to call in case of difficulty in the field
3. A schedule of visits to survey sites
4. The contact details of the sites to be visited
5. Details of back-up facilities to be visited if scheduled visits are not possible, or less than 50% of the medicines are available
6. Copies of letter(s) of endorsement and letter of introduction
7. Relevant handouts or instruction sheets
8. A Medicine Price Data Collection form for each sample medicine outlet to be visited that day
9. A Medicine Price Data Collection form for each back-up site that may need to be visited that day
10. A calculator for determining the unit price of medicines so as to identify lowest-priced generic products
11. Pens (pencils should not be used to record data), a clipboard and other supplies
12. A notebook to record any significant events or findings
13. Field allowance for local expenses

Where feasible, each data collection team should also be equipped with a mobile phone and credit for use in contacting their area supervisor. Additional supplies that may be useful include an identity document with a photograph, a local map and extra calculator batteries.

6.2.2 On arrival at the facility

On arrival at the health facility, pharmacy or other medicine outlet, data collectors should do the following:

- Introduce themselves and remind pharmacy staff of the survey's purpose as well as the scheduled data collection visit. Data collectors should also thank medicine outlet staff for their cooperation and, if necessary, remind them that the outlet's identity will be kept confidential.
- Check that the facility information on the first page of the Medicine Price Data Collection form is complete and correct, and inform the area supervisor at the end of the day if there were any inaccuracies.
- Enter the following information on the first page of the Medicine Price Data Collection form:
  - — Date of the data collection visit;
  - — Name of the person(s) who provided information on medicine prices and availability (if different from the facility's manager); and
  - — Name(s) or codes of the data collector(s).

6.2.3 Procedure for completing the Medicine Price Data Collection form

Data collectors should complete a separate Medicine Price Data Collection form for each medicine outlet. Information on prices and availability should be entered with the aid of the person in charge of the facility. The Medicine Price Data Collection form should not be left at a facility or pharmacy to be collected later, with the promise that it will be filled in. Medicines must be physically seen to confirm availability. Prices can be recorded from the product label, or from a price list or computer if this is how price information is stored.

FOR EACH MEDICINE LISTED IN COLUMN A:

1. Identify the lowest-priced generic product available at the medicine outlet

While the Medicine Price Data Collection form already contains the name and manufacturer of the originator brand product, the lowest-priced generic product must be identified during the field visit. *The lowest-priced generic product is the one with the lowest unit price or price per pill, tablet, dose or ml*.

- If you only find one generically equivalent product, it is the lowest-priced generic available at that outlet. In the row marked *Lowest-price generic*, enter the product name in Column C and the manufacturer's name in Column D.
- If you find more than one generically equivalent product, you must identify the one with the lowest unit price (price per pill, tablet, ml, dose). When the generic product with the lowest unit price is not immediately obvious (i.e. several products with varying pack sizes are available), calculate the unit prices of each product to identify the lowest. Divide the price of the pack by the pack size using the calculator provided. Once the lowest-priced generic is identified, enter the

product name in Column C and the manufacturer's name in Column D, in the row marked *Lowest-priced generic*.

2. Complete Column E: available

Complete Column E by answering 'yes' or 'no' as to whether each of the following is available:

- Row 1: Originator brand
- Row 2: Lowest-priced generic equivalent

Always ask to see a pack of the product and only record that it is available if you actually see it.

A medicine may be available in different dosage forms, such as tablets/capsules, mixture/suspension, injection or cream/ointment. In addition, a medicine may be available in different strengths, such as 10 mg or 20 mg. **For each survey medicine, collect data only for the dosage form and strength listed.**

Tablets and capsules are considered equivalent.

Plain, coated and film-coated products are considered equivalent.

Modified release formulations (e.g. slow release, retard) should be considered as separate products.

If the dosage form listed in Column A is not found, the medicine product should be treated as 'unavailable'. Similarly, if the strength listed in Column A is not found, the medicine product should be treated as 'unavailable'.

If a product is temporarily out of stock:

- Record medicine as 'unavailable' (Column E: Available = 'no').
- Do not enter any pack size or price data in the relevant row.
- State that the product was out of stock in Column J: Comments.
- **Do not substitute an alternative product.**

If several medicines listed on the form are unavailable:

- Collect data for as many medicines as possible.
- If less than 50% of the medicines on the form are available, you will need to visit an additional facility, identified in advance as a back-up, and conduct the survey again. Contact the area supervisor, who will advise you on the best time to visit the back-up facility. Depending on your data collection schedule and the time available as well as the distance between outlets, it may be preferable to visit the back-up facility that same day or on another day.

NOTE: If less than 50% of the medicines are available at a back-up facility, no additional medicine outlet is visited.

3. Complete Column G: Pack size found

In Column G for each medicine, enter the pack size actually found in the facility for:

- Row 1: Originator brand
- Row 2: Lowest-priced generic equivalent.

If the recommended pack size is available, record data on this pack size. If it is not available, select the closest, larger pack size found. Whenever possible, select the same pack size for the originator brand and the lowest-priced generic product.

If a medicine is available in a bulk pack (e.g. jar or container) and the pharmacist re-packages smaller quantities for patients (e.g. in a bag, envelope or bottle), record the *patient* pack size and price.

Each medicine has a recommended pack size (Column F). When a medicine is available in multiple pack sizes, data are collected on the recommended pack size or, if this is not available, on the next largest pack size. This standardizes results as much as possible.

The pack size and price of that pack is only entered on the form if it is physically in stock (you must actually be able to see it).

For each product, only collect the price for one pack size.

4. Complete Column H: Price of pack found

In Column H, enter the price of the pack found, in the national currency, for:

- Row 1: Originator brand
- Row 2: Lowest-priced generic equivalent

Ask to see either the price list or price label on the product before entering the price on the Medicine Price Data Collection form.

If part of the price is paid by insurance or other means, record the total price. For instance, if the pharmacy is reimbursed 80% and the patient pays 20%, you should record the full price (100%).

Do not record 'special discounts' (discounts available only to certain group of patients). However, you should record discounted prices if they apply to all patients. Add a note in the Comments section (Column J).

In the public sector, medicines are often distributed free of charge or for a fixed fee for either the medicine or the visit. If this is the case in your country, you will likely be instructed to:

- collect the prices the pharmacy/dispensary pays to its supplier; or
- collect medicine availability only (for the public sector).

In some cases, certain medicines are free or available for a fixed fee, while others are not. For example, this may occur if a certain medicine is paid for through donations or a special treatment programme. In these cases:

- record both the availability and prices of medicines that are not free or only available for a fixed fee; and

- record only the availability of free/fixed fee medicines and record this in the Comments section (Column J).

If medicines are available free of charge or for a fixed fee, their availability should still be recorded.

If some, but not all, medicines are available for free or for a fixed fee, this must be recorded in the Comments column (Column J) for each free/fixed fee medicine. Otherwise, it may appear that you have simply forgotten to enter the price.

Where a fixed fee is paid, record what it covers in the Comments (Column J). For example, in the public sector it may include the consultation cost plus the medicine dispensing cost.

5. Complete Column J: Comments, as required

Column J can be used for explanatory comments or any additional information, such as:

- Product temporarily out of stock (note: no price data should be recorded).
- Percentage discount offered.
- Medicine is free or available only for a fixed fee.

6.2.4 Before leaving the facility

Data collectors should check that the data collection form is legible, accurate and complete before leaving the facility and returning completed forms to the area supervisor. They should report any problems as soon as possible. They should also check to see whether at least half of the survey medicines were available to determine whether a visit to a back-up facility is required.

Data collectors should thank the medicine outlet staff for their participation, and alert them of a potential second visit by the area supervisor to validate the data collected.

Tables 6.1 and 6.2 show an extract from a completed Medicine Price Data Collection form, which data collectors in the field have completed. The area supervisor has entered the unit prices.

6.3 ENSURING DATA QUALITY

The quality of the information that the medicine price and availability survey generates depends on the accuracy of data collection. The survey manager has overall responsibility for the quality of the data, though all survey personnel have a role to play in ensuring the accuracy of the data collected. The area supervisors and data collectors should receive regular supervision. Rigorous enforcement of data collection procedures will pay off with the ease with which data entry and analysis occur. The following steps will also help to ensure greater accuracy.

1. Thorough preparation and training is the first step in minimizing errors.
2. Establish procedures to check for data completeness, consistency, plausibility and legibility in the field when it is still possible to correct errors or to fill in missing information. Area supervisors should review data collection forms every day after completion of the field work and resolve any problems before the next day of data collection. Entries on the data collection form must be complete

Table 6.1 Extract from a completed Medicine Price Data Collection form: Public sector patient prices

A	B	C	D	E	F	G	H	I	J
Generic name, dosage form, strength	Medicine type	Brand or product name(s)	Manufacturer	Available: "yes" or "no"	Pack size recom-mended	Pack size found	Price of pack found	Unit price (4 digits)	Comments
Amitriptyline cap/tab 25 mg	Originator brand	Tryptizol	MSD	*No*	100			/tab	
	Lowest-priced generic	*Amitriptyline*	*Pharma*	*Yes*	100	*1000*	*1261.00*	*1.2610*/tab	
Amoxicillin cap/tab 500 mg	Originator brand	Amoxil	SKB (GSK)	*No*	21			/tab	
	Lowest-priced generic	*Amoxicillin*	*Ratio-pharma*	*Yes*	21			/tab	*Free of charge: donation*
Atenolol cap/tab 50mg	Originator brand	Tenormin	Astra Zeneca	*No*	60			/tab	*Not on EML*
	Lowest-priced generic			*No*	60			/tab	

Table 6.2 Extract from a completed Medicine Price Data Collection form: Private sector patient prices

A	B	C	D	E	F	G	H	I	J
Generic name, dosage form, strength	Medicine type	Brand or product name(s)	Manufacturer	Available: "yes" or "no"	Pack size recom-mended	Pack size found	Price of pack found	Unit price (4 digits)	Comments
Amitriptyline cap/tab 25 mg	Originator brand	Tryptizol	MSD	*No*	100			/tab	*Out of stock*
	Lowest-priced generic	*Amitriptyline*	*Cosmos*	*Yes*	100	*1000*	*80.00*	*0.8000*/tab	
Amoxicillin cap/tab 500 mg	Originator brand	Amoxil	SKB (GSK)	*Yes*	21	*100*	*776.00*	*7.7600*/tab	
	Lowest-priced generic	*Moximed*	*Medivet*	*Yes*	21	*1000*	*3334.00*	*3.3400*/tab	
Atenolol cap/tab 50mg	Originator brand	Tenormin	Astra Zeneca	*No*	60	*60*	*5392.70*	*89.8783*/tab	
	Lowest-priced generic	*Moximed*	*Pacific*	*Yes*	60	*100*	*7396.90*	*73.9690*/tab	

and clearly written, no confusion existing between originator brand and generics prices, and unit prices accurately calculated.

3. Plan random checks to ensure the quality of data collection. The area supervisor should return to randomly selected medicine outlets to collect the same data so as to check the accuracy of the data collected earlier. Ideally, the validation should be done on the same day as data collection to avoid changes in the availability of the survey medicines (soon after the data collectors have left the facility). This validation should be undertaken for 20% of the facilities; namely, one public outlet and one private outlet per survey area, when the sample size is five outlets per sector in each survey area. If other sectors are surveyed (e.g. NGO sector), include 20% of the facilities in each of these sectors, per survey area, in the validation process.
4. Double-check all completed Medicine Price Data Collection forms; verify any suspicious, incomplete or illegible data, prior to the initiation of data entry.

7

Data entry

Data entry will generally take place at the central level under the survey manager's supervision. Part I of the computerized Excel® WHO/HAI Medicine Pricing *Workbook* that accompanies this manual is used to enter price and availability data collected in the field, consolidate and summarize results, and print tables that will serve as the basis for reports. The workbook contains various pages for data entry and analysis:

- Medicine unit price data are entered in the *Field Data Consolidation* pages for procurement, public, private and any 'other' sectors. The workbook will automatically calculate the per cent availability and median price ratio (MPR) of each medicine. The workbook will also generate summary data (mean per cent availability and median MPR) for each sector.
- On the *Sector Availability and Price Summary* page, the workbook provides comparable data between sectors to allow for cross-sector comparisons.
- On the *Standard Treatment Affordability* page, the workbook automatically calculates the number of days' wages required to purchase selected standard treatment courses. The daily wage of the lowest-paid unskilled government worker must be entered in local currency.
- Data collected on the components of medicine prices are entered into Part II of the workbook on the *Price Components: Data Entry* page and analysed on the *Price Components: Data Analysis* page.

You should have the *Workbooks* open as you read this chapter. Start Excel and open the file WHO/HAI Medicine Price WorkbookI.xls and WHO/HAI Medicine Price WorkbookII.xls that you copied onto your hard disk. Depending on the security settings on your computer, you may need to choose the option to 'Enable Macros' as the file is opening.

7.1 OVERVIEW OF THE WORKBOOK AND ITS OPERATIONS

The specially designed, two-part computerized WHO/HAI Medicine Pricing workbook that accompanies this manual allows rapid entry and analysis of medicine price data. After data have been entered, the workbook automatically generates summary tables that form the basis of data analysis. In preparing for data collection, you will have already used the workbook to finalize the list of medicines to be surveyed and to generate the Medicine Price Data Collection form (see Chapter 3, page 47).

The computerized workbook consists of the following pages:

Part I

1. *Home* page
2. *International Medicine Reference Price Data* page
3. *Field Data Consolidation: Medicine Procurement Prices* page
4. *Field Data Consolidation: Public Sector Patient Prices* page
5. *Field Data Consolidation: Private Sector Patient Prices* page
6. *Field Data Consolidation: Other Sector Patient Prices* page – first other sector
7. *Field Data Consolidation: Other Sector 2 Patient Prices page* – second other sector
8. *Sector Availability and Price Summary* page
9. *Medicines Availability and Price Summary* page
10. *Standard Treatment Affordability* page
11. *Study Medicines: Originator Brand Products Surveyed page*
12. *Medicine Price Data Collection Form page*

Part II

1. *Home Page*
2. *Price Components: Data Entry page*
3. *Price Components: Data Analysis page*

These pages are described further in the sections that follow. If you have problems with the workbook or discover any bugs, please send an e-mail message describing the problem with the problem file attached to HAI[1] or WHO,[2] who will try to respond promptly.

7.1.1 Moving between workbook pages

You can use either of two methods to move between pages.

1. Use the movement buttons. From the *Home* page, click a button with the name (abbreviated) of the desired page to go to that page. From any other workbook page, click the **GO TO HOME PAGE** button to return to the *Home* page.
2. Click on the tabs at the bottom of each page to move between pages of the workbook.

7.1.2 Protected and hidden cells

Within the workbook, some cells are 'protected' from entering data and other areas are 'hidden' from view. These areas contain formulas or data that allow the workbook to carry out its calculations automatically. Errors in the workbook's operation may result if you unprotect or reveal these areas. **In order to guarantee the integrity of the calculations, these cells should not be modified**.

7.1.3 Ensuring accuracy

The quality of the information that the medicine price survey generates depends on the accuracy of data entry. The survey manager has overall responsibility for the quality of the data and should supervise data entry personnel on a regular basis.

[1] info@haiweb.org
[2] medicineprices@who.int

To help ensure greater accuracy, identify the resources needed for data entry and checking before data collection begins and plan data processing carefully. Ideally, data entry should take place at one site where the survey manager can supervise the process. Information on the Medicine Price Data Collection forms should be checked again for legibility and consistency during data entry.

Entering detailed data such as long columns of unit prices can lead to substantial errors. Within each *Field Data Consolidation* page, a double-entry function is provided whereby a second person enters all the data a second time, and the two sets of results can be compared to identify errors. The double entry procedure is critical to ensure the accuracy of data entry.

Once all the data has been double entered and any errors corrected, the workbook needs to be checked carefully. This is done in two ways – by checking the data manually and by running the automated data checker. A list of items to check as part of the manual verification is provided in Annex 5, while instructions for using the data checker are provided in Section 7.10.

7.1.4 Saving and backing up your work

Save the workbook periodically as you work to prevent data loss in the event of power failure. Each time that substantial changes are made, you should save the workbook under a different date or version number so you can refer back to previous versions as needed. This will also be useful during the WHO/HAI project staff's external review of data, since it will avoid confusion in identifying the most recent version of the workbook. The ability to save multiple versions of the workbook will depend on the amount of memory you have available on your PC.

7.2 HOME PAGE

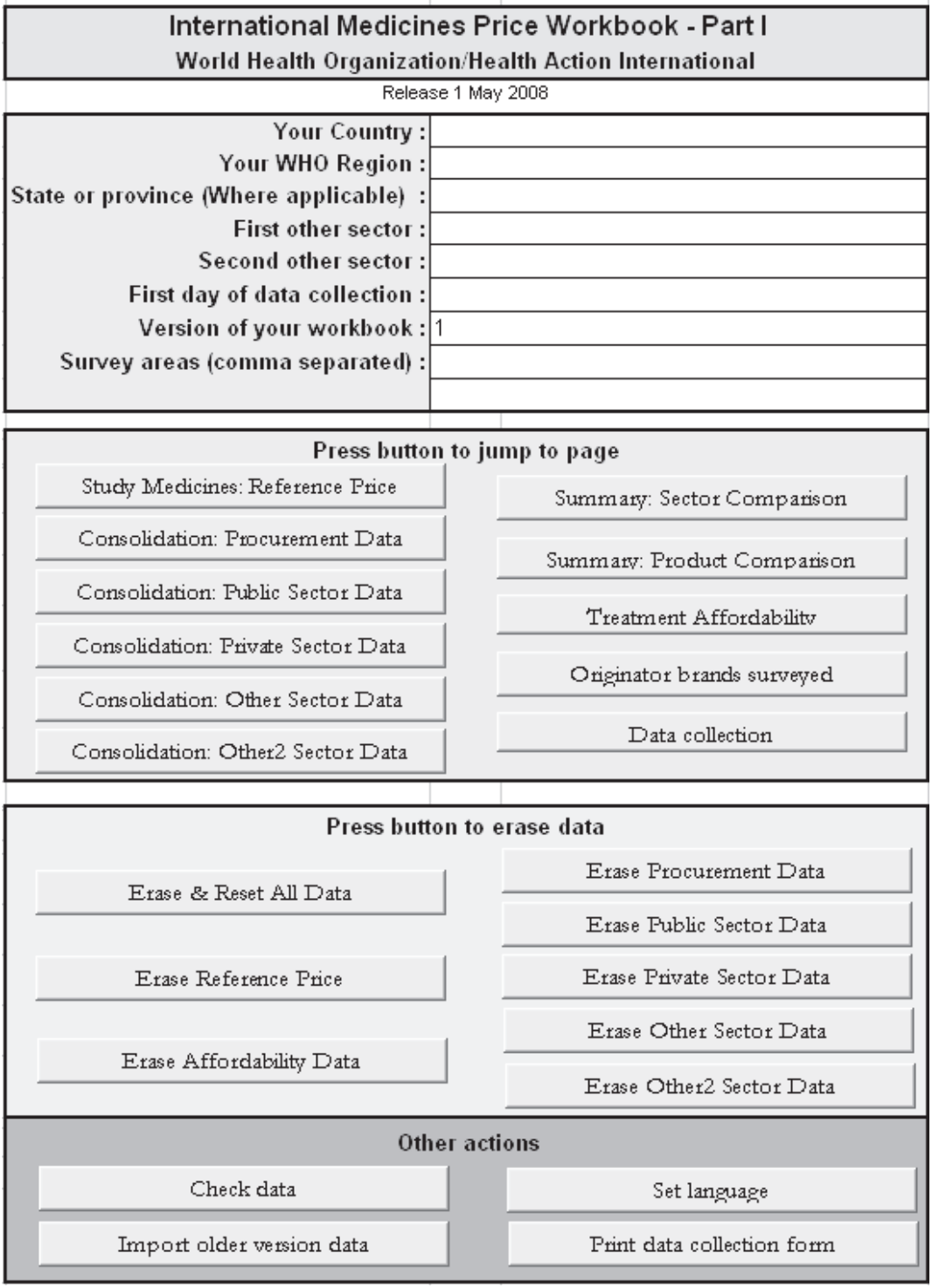
The top section of the *Home* page (Fig. 7.1) is used for recording important general information about your survey, such as country name, WHO region, other sectors surveyed and names of survey areas. This information should have been completed prior to data collection (see Chapter 3, page 43).

The following blue section on the *Home* page contains a box with action buttons that are used to move to different parts of the workbook. Click a button to jump to the page indicated.

The lower yellow section of the *Home* page contains a box with action buttons that allow you to erase previously entered data from the workbook. It is generally easier to start a new survey by opening and renaming the original master workbook. In some circumstances, however, it may be more efficient to erase parts of an existing workbook to start a new survey, for example, if you have collected data on the same list of medicines from several provinces and use the same medicine lists, defined treatments and so on for each province.

Click on a button to erase data on a specific page or click on the **ERASE & RESET ALL DATA** button to erase all data in the workbook. After clicking the button, you will be prompted to confirm that you want to erase the data indicated. Once you confirm, all data you have entered on a page will be erased, so take care using this function.

Fig. 7.1 Home page of survey workbook



CAUTION

Before erasing anything, you may want to save the entire workbook under a separate file name as a back-up in case you need to return to it later.

7.3 INTERNATIONAL MEDICINE REFERENCE PRICE DATA PAGE

The *International Medicine Reference Price Data* page contains important information on the medicines in the survey, which is used in subsequent pages. With the exception of exchange rate information (Rows 3–6), which must be entered for the first day of data collection, all the information on this page should have been entered during survey preparation (See Chapter 3, pages 43–47). Fig. 7.2 contains an example of the page as it appears in the workbook.

Fig. 7.2 International Medicine Reference Price Data page

International Medicine Reference Price Data

Go To Focus Page | Exchange Rate: $US 1.00 in local currency =

Brand Products Surveyed | Name of local currency:

MSH/Other Prices | Date of exchange rate:

Add regional medicines | Source of exchange rate:

Source of Other Unit Price:

Number of: Global: 14; Supplementary: 20; Regional: 16; EML: 32; All: 50

Price Data Used = MSH 2006

Med. No.	Medicine Name (Name must be unique)	Medicine Strength	Dosage Form	Target Pack Size	Medicine list	National Essential Medicine List	2006 MSH* Unit Price ($US)	Other Unit Price ($US)	Price of Target Pack ($US)	Price of Target Pack (local currency)	Reference Unit Price (local currency)	Level of care (for which the meds is available)
1	Albendazole	200 mg	cap/tab	2	Regional	yes	$0.0091		$0.0182			1
2	Amitriptyline	25 mg	cap/tab	100	Global	yes	$0.0066		$0.6600			1
3	Amoxicillin	500 mg	cap/tab	21	Global	yes	$0.0280		$0.5880			1
4	Amoxicillin suspension	50 mg/ml	millilitre	100	Regional	yes	$0.0057		$0.5700			1
5	Atenolol	50 mg	cap/tab	60	Global	yes	$0.0107		$0.6420			1
6	Atorvastatin	20 mg	cap/tab	30	Regional	no	$1.0765		$32.2950			1
7	Beclomatasone inhaler	0.05 mg/dose	dose	200	Regional	yes	$0.0143		$2.8600			2
8	Captopril	25 mg	cap/tab	60	Global	yes	$0.0112		$0.6720			1
9	Carbamezepine	200 mg	cap/tab	150	Regional	yes	$0.0178		$2.6700			1
10	Ceftriaxone injection	1 g/vial	gram	1	Global	yes	$1.1571		$1.1571			1

7.3.1 Entering the exchange rate

1. At the top of the page (cell J3), enter the Exchange Rate of 1 US dollar to your local currency. Note: it must be the exchange rate on the first day of data collection so you cannot add this until that day. Once you have entered the exchange rate, you should not change it.

   Note that there may be a buying rate and a selling rate. In some countries, multiple rates may co-exist. For example, there may be an official rate, a commercial rate and a parallel or black market rate. Use the commercial 'buy' rate on the first day of data collection. The recommended source is Oanda FX-History.[1]

2. To document your decision, enter:
   - The name of your local currency (cell H4)
   - The date for which the exchange rate is valid (cell H5)
   - The source of the exchange rate you used (cell H6).

7.3.2 Medicine identifying information

Following the preparatory work undertaken before data collection, Column C of the *International Medicine Reference Price Data* page should already contain the full list of medicines (global core, regional core and supplementary medicines) surveyed

[1] http://www.oanda.com/convert/fxhistory

during fieldwork. For each medicine, the *Reference Price Data* page contains the following identifying information:

1. *Medicine Name (Column C)*: The name is usually the International Non-proprietary Name (INN).
2. *Medicine Strength (Column D)*: The medicine strength, usually expressed as the number of milligrams or grams of active ingredient per dosage form (see item 3 below).
3. *Dosage Form (Column E)*: The dosage form of the medicine for which the unit price is to be determined.
4. *Target Pack Size (Column F)*: The pack size for which data are collected (when the target pack size is not available in an outlet the next largest pack size is used). The Target Pack Size is not used in workbook calculations and is included for reference purposes only.
5. *Medicine List (Column G)*: Medicines are identified as either Global, Regional or Supplementary. Note that a running total of the number of global, regional and supplementary medicines in the survey, as well as the number of EML medicines and total number of medicines in the survey, is provided in the top right-hand corner of the page.
6. *National Essential Medicine List (Column H)*: By identifying which medicines are contained on the National Essential Medicine List (where one exists), the workbook allows you to restrict your analysis to this group of medicines. For each medicine, select one of the following from the drop-down box: 'yes' (medicine is on the EML), 'no' (medicine is not on the EML), 'don't know' (EML exists but you were unable to access it) or 'no list' (there is no EML). Identifying medicines on the EML is particularly useful when the public sector is only expected to carry EML medicines. Further information on restricting analysis to EML medicines is provided in Chapter 8, pages 108–109 and 114–115.
7. *MSH Unit Price (Column I)*: The median unit price of the medicine in the most recent MSH International Drug Price Indicator Guide. Even if another set of reference prices is being used for your national analyses, entering the most recent MSH prices will allow you to compare your data to those of other countries.
8. *Other Unit Price (Column J)*: This column is used if another set of reference prices is being used for the analysis. You can switch between the two different sets of reference medicine prices (i.e. MSH and Other) by clicking the **MSH/ OTHER PRICES** button at the top of the page.

   All price calculations depend on the set of reference prices chosen. Switching reference prices will change the calculations. If you wish to obtain reports using both sets of prices:

   1. Select the MSH prices.
   2. Print all reports.
   3. Switch sets of reference prices.
   4. Print all reports a second time. All pages that depend on reference price indicate the source used.
9. *Price of Target Pack (US$), Price of Target Pack (local currency), Reference Unit Price (local currency) (Columns K–M)*: Once you have entered an exchange rate, unit prices (MSH or Other) and target pack sizes, the workbook automatically calculates:

- Price of Target Pack (US$) (Column K).
- Price of Target Pack (local currency) (Column L).
- Reference Unit Price (local currency) (Column M). The values in the Reference Unit Price (local currency) column are used in calculating the price ratios.

10. *Level of care for which medicine is available (Column O)*: This column identifies the minimum public-health facility levels that are expected to stock each survey medicine. For each medicine, the workbook will automatically restrict the availability analysis in the public sector to those outlets in which the medicine is expected to be found. For example, a medicine marked '2' should be available at secondary and tertiary health facilities, but not at the primary level. In calculating the per cent availability of this medicine, only secondary and tertiary health facilities in the public sector sample will be included. Further information on analysis by level of care is provided in Chapter 8, page 113.

7.4 FIELD DATA CONSOLIDATION PAGES

The *Field Data Consolidation* pages are used to enter unit price data collected in the field using the Medicine Price Data Collection forms.

There are five *Field Data Consolidation* pages in the workbook, allowing price information from up to five sectors to be entered.

1. Procurement prices.
2. Public sector patient prices.
3. Private sector patient prices.
4. Other sector patient prices: for example, prices from the church mission sector.
5. Other sector patient prices 2: second other sector.

The unit prices entered on the *Procurement Prices* page should be prices from recent government medicine orders, usually from public sector centralized medicine procurements. In some cases, procurement prices from other sectors have been collected; these should also be entered on this page but must be analysed separately. For the *Field Data Consolidation* pages for the other four sectors, the prices entered will be the medicine-specific patient or customer charges that were collected at different facilities and medicine outlets in the survey.

The survey workbook has a separate page for entering 'Public Sector Procurement Price' data and 'Public Sector Patient Price' data. Government procurement prices should only be entered in the *Public Sector Procurement Price* page, while public sector patient prices should only be entered in the *Public Sector Patient Price* page.

If procurement prices from another sector (e.g. mission sector) have been collected, these should also be entered into the *Public Sector Procurement Price* page. **However, procurement data from each sector must be analysed separately (See Chapter 8, page 106).**

7.4.1 Field Data Consolidation page sections

The *Field Data Consolidation* pages contain two different 'views': the 'data entry' view and the 'sector summary' view. You can switch between these two views by pressing the **DATA/SUMMARY** button in the top left-hand corner of each view.

1. Data entry view

The 'data entry' view contains the empty data grid in which you enter the unit prices found for each medicine.

Fig. 7.3 Field Data Consolidation: Medicine Procurement Prices page, in data entry view

	A	B	C	D	K	L	M	N	O	P	Q
1		Field Data Consolidation:									
2		Medicine Procurement Prices									
4		Go To Home Page	Data/Summary								
5		Ratios On/Off	Double Entry		Sort by:	ID	Agency	Date	Number		
6					Data for Procurement Orders (Enter Medicine Unit Prices in Local Currency)						
7	Procurement ID										
8	Procurement Agency										
9	Date (Mon-YY as in Jan-02)										
10	Include order in analysis (1=yes, 0=no)?				0	0	0	0	0	0	0
12	No.	Medicine Name	Medicine Type	Include in analysis?	1	2	3	4	5	6	7
13	1	Albendazole	Brand	1							
14	1	Albendazole	Lowest Price	1							
15	2	Amitriptyline	Brand	1							
16	2	Amitriptyline	Lowest Price	1							
17	3	Amoxicillin cap/tab	Brand	1							
18	3	Amoxicillin cap/tab	Lowest Price	1							

Medicine list

On the left-hand side of the grid (Column B), the list of survey medicines is displayed. This list is generated automatically from the medicines listed on the *International Medicine Price Reference List* page. For each medicine, Column C lists the two different types of products for which data are collected:

- Row 1 'Brand': Originator brand
- Row 2 'Lowest Price': Lowest-price generic equivalent

Column D: 'Include in analysis' allows you to include or exclude specific medicine products from the analysis. Medicines marked '1' in Column D are included in data analysis, while medicines marked '0' are not included. The default setting for Column D is '1', i.e. all medicines are included in the analysis. You can exclude a medicine by clicking on the appropriate cell and entering '0'.

If a medicine is under patent and no generics are registered, the lowest-priced generic row for this particular medicine should be 'turned off' (i.e. this product should be excluded from analysis). Similarly, for an older substance where the originator brand product cannot be identified, the originator row for this particular medicine should be turned off.

Data entry grid

An empty data grid is provided in which you enter information about:

- The source of each column of unit price data (Rows 7–9)
- The unit prices found for each medicine (Rows 13–112)

The *Medicine Procurement Prices* page allows you to enter up to 120 sets of procurement prices for each medicine. To identify each set, you specify:

- An arbitrary Procurement ID (Row 7)
- The Procurement Agency (Row 8)
- The Procurement Date (Row 9)

This information is contained on the front page of the Medicine Price Data Collection form.

The other four *Field Data Consolidation* pages allow you to enter data from up to 120 public sector, private sector and 'other' sector medicine outlets. For each set of prices, you specify:

- An arbitrary Medicine Outlet Study ID (Row 7)
- A code for the Region or Survey Area where the outlet was located (Row 8)
- A measure of Distance From Population Centre (Row 9), which allows you to classify facilities as urban or rural

This information is contained on the front page of the Medicine Price Data Collection form.

Row 10: Include outlet in analysis (1 = yes, 0 = no)

This row allows you to exclude various medicine outlets/procurement orders from the analysis. For example, if you would like to analyse medicine prices in a particular region, you would include medicine outlets in this region and 'turn off' data from other regions by setting the corresponding cells in Row 10 to '0'. Chapter 8 (page 123) contains additional information about conducting sub-analyses by type of medicine outlet.

The default in Row 10 is set to '0'. When unit prices are entered for a facility, the default automatically changes to '1' and the data are included in the analysis. This poses a problem in cases where none of the survey medicines is found in a given medicine outlet; this outlet should still be included so that it will be taken into account in the availability analysis. Since the corresponding cell in Row 10 does not change to '1' automatically, it must be changed manually by clicking on the cell and entering '1'. Note that the outlet study ID, region, and distance from population centre (Rows 7–9) should be entered as usual.

Row 11: Level of care (Public sector patient prices only)

In this row, the level of care provided at each public sector facility is identified. Enter '1' for primary care facilities, '2' for secondary care facilities and '3' for tertiary care facilities as indicated on the first page of the Medicine Prices Data Collection form. The identification of each public sector facility according to its level of care will allow the workbook to calculate the availability of individual medicines based on the level of care where they are expected to be available. For example, primary and secondary facilities will not be included in the availability analysis of a specialized medicine that is only provided at tertiary hospitals.

The analysis of availability of medicines by level of care is only conducted for public sector patient prices. While some other sectors may also have levels of care (e.g. NGO hospitals), this will vary according to the other sector selected. As such, the workbook cannot accommodate levels of care for other sectors. Levels of care will generally not apply to the private sector or to procurement prices.

Summary data for individual medicines

Once data have been entered into the data-entry grid, you can obtain summary data for individual medicines by pressing the **RATIOS ON/OFF** button in the top left-hand corner of the page. This will 'hide' the data entry grid and display the following summary information for each survey medicine:

- Median (MPR): ratio of median medicine unit price to international reference price
- 25th percentile
- 75th percentile
- Minimum
- Maximum
- Per cent with medicine: per cent of the medicine outlets in which medicine was found. For the *Public Sector Procurement* page, this is replaced with # orders: the total number of procurement prices (orders) entered for each medicine.
- Median price: median medicine unit price in local currency.

Fig. 7.4 shows part of the *Field Data Consolidation: Private Sector Patient Prices* page with the summary data cells for individual medicines displayed. These summary data are further described in Chapter 8.

Fig. 7.4 Field Data Consolidation: Private Sector Patient Prices page displaying the summary data cells for individual medicines

	A	B	C	D	E	F	G	H	I	J	El
1		Field Data Consolidation:									
2		Private Sector Patient Prices									
4		Go To Home Page	Data/Summary								
6		Ratio On/Off	Double Entry								
7	Medicines Outlet Study ID				Summary Comparisons to Reference Prices and Percent Availability in Outlets						
8	Region										
9	Distance From Population Centre										
10	Include outlet in analysis (1=yes,0=no)?				(Blank if found in < 4 outlets)						
12	No.	Medicine Name	Medicine Type	Include in analysis?	Median Price Ratio	25%ile	75%ile	Min	Max	% with med.	Median Price
13	1	Albendazole	Brand	1							
14	1	Albendazole	Lowest Price	1							
15	2	Amitriptyline	Brand	1							
16	2	Amitriptyline	Lowest Price	1							
17	3	Amoxicillin cap/tab	Brand	1							
18	3	Amoxicillin cap/tab	Lowest Price	1							

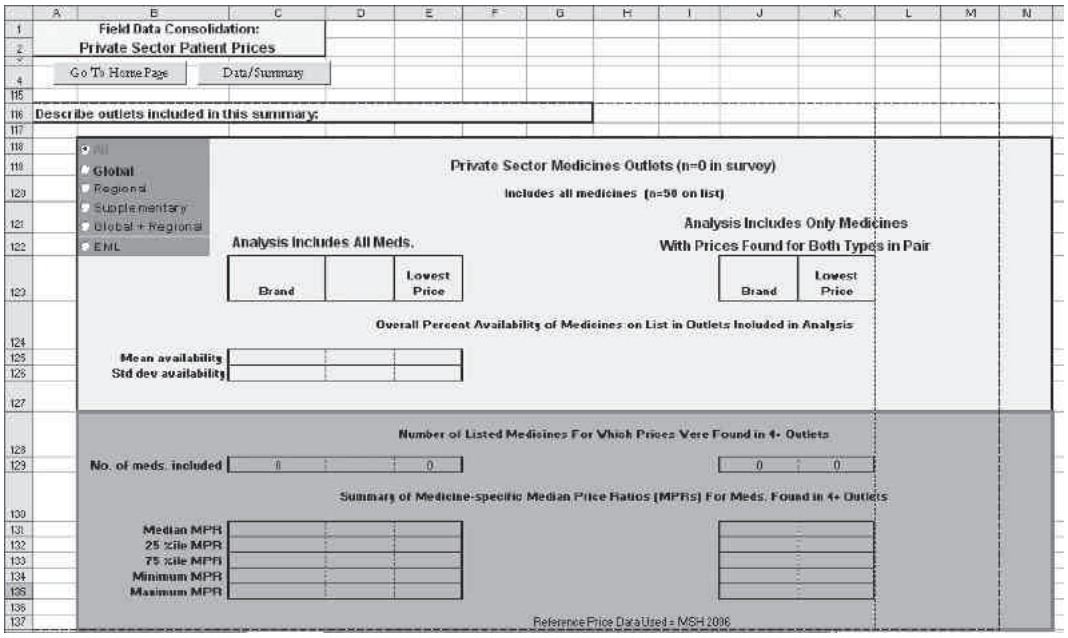
At the top of the summary ratio section is a blue area in which you enter (cell H10) the minimum number of unit prices required for each medicine in order for the median price ratio to be computed:

- A minimum of four unit prices should be obtained from different public health facilities or medicine outlets, private sector outlets, and outlets in the other sectors.
- Where procurement data have been collected centrally, a single procurement price is sufficient (so the blue area should state 'Blank if med. has <1 orders' on the *Procurement Price* page). However, if a number of local procurement agents (e.g. hospitals, regional medical stores) have been surveyed, you should set the figure to < 4 orders.

2. 'Sector summary' view

In the 'sector summary' view, price and availability data for individual medicines are summarized across all medicines in the survey or according to groups of medicines such as 'EML medicines only'. By consolidating data across a range of medicines, a summary of medicine availability and price for the sector is obtained. Fig. 7.5 shows a *Field Data Consolidation: Private Sector Patient Prices* page in the 'sector summary' view. The measures in the summary tables are explained in detail in Chapter 8.

Fig. 7.5 'Sector summary' view from the Field Data Consolidation: Private Sector Patient Prices page



NOTE: In Row 116, you are asked to describe the procurements/outlets in this summary. It is important to describe clearly the data contained in the summary, particularly if subgroup analyses are being conducted or if different sets of procurement data are being analysed.

7.4.2 Action buttons

Each *Field Data Consolidation* page has a set of action buttons at the top that control the way the page is displayed. There are four buttons in the upper left corner (see Fig. 7.3):

GO TO HOME PAGE button.

DATA/SUMMARY This button causes the page to display either the data entry grid (Data) or the sector summary (Summary).

RATIOS ON/OFF This button switches between the data entry grid (Ratios Off) and the summary data for individual medicines (Ratios On).

DOUBLE ENTRY Once data from the field have been entered the first time, clicking this button displays a menu that allows you to carry out double entry (See page 93).

In addition, there are four action buttons at the top of the data entry grid that allow you to sort the columns in the grid from left to right according to the identifying information in Rows 7, 8, 9 and 12. Sorting will allow you to select certain subsets of the data for analysis (see Chapter 8). You can sort the columns on the *Medicine Procurement Prices* page by:

- **ID** (Row 7)
- **AGENCY** (Row 8)
- **DATE** (Row 9)
- **NUMBER** (Row 12, the default sort order).

You can sort the columns on the other four *Field Data Consolidation* pages by:

- **ID** (Row 7)
- **REGION** (Row 8)
- **DISTANCE** (Row 9)
- **NUMBER** (Row 12, the default sort order).

To the right of the data sorting buttons, there is one additional action button, the **INCLUDE ALL OUTLETS** button. During data analysis, you may wish to limit analysis to selected medicine orders (on the *Medicine Procurement Prices* page) or selected outlets (on the other *Field Data Consolidation* pages) by changing the '1's in Row 10 to '0's for all outlets to be excluded from analysis. The **INCLUDE ALL OUTLETS** button restores all the orders or outlets to the analysis by replacing all '0's with '1's.

7.4.3 How to enter data

All the *Field Data Consolidation* pages use the same procedures for entering data, whether it is procurement price data or patient price data. The following steps describe how to enter data on the *Private Sector Patient Prices* page as an example.

1. Use the action buttons on the *Home* page to go to the *Field Data Consolidation: Private Sector Patient Prices* page.
2. If the sector summary is displayed, click on the **DATA/SUMMARY** button to switch to the data entry grid.
3. If the columns containing summary data for individual medicines are visible, click on the **RATIOS ON/OFF** button to hide them.

4. Enter the identifying information for the first medicine outlet:
   - Enter the Medicine Outlet Study ID in Cell K7.
   - Enter the Region code in Cell K8.
   - Enter the Distance from Population Centre in Cell K9. Distance should be entered as the approximate number of kilometres from the medicine outlet to the largest population centre in the region.
   - Note: for the public sector, you would also need to identify the level of care of the medicine outlet (primary = '1', secondary = '2', tertiary = '3') in Cell K11.

   This information should be obtained from the front page of the Medicine Price Data Collection form.

5. Starting at Cell K13 and proceeding down the column, enter the unit prices for each of the medicines in the list. Medicine unit prices are found in Column I of the Medicine Price Data Collection form. The unit medicine prices should always be entered in local currency, with four decimal points. Do not enter '0' if the medicine was not found.

   As you begin to enter data, the column colour should switch from grey (inactive) to white (active). Row 10, Include Outlet in Analysis, should automatically change from '0' (No) to '1' (Yes). **If, at any given outlet, no medicines were found, you will need to manually change Row 10 to '1' so that the outlet is included in the analysis**.

   Note: if your computer is set to use commas rather than full stops to denote decimals, you must enter all unit prices using commas, for example 0,0031 and not 0.0031. An error message will result if you enter 0.0031.

   If a medicine is recorded as 'available' but does not have a price (e.g. for medicines that are free or available for a fixed fee), enter an 'F' into the appropriate cell in the data entry grid. This will allow this medicine to be included in the availability analysis even though there are no price data for it. This situation will usually occur in public sectors that offer some/all medicines to patients for free or for a fixed fee.

Always check the Comments column of the Medicine Price Data Collection form to see if the medicine has been recorded as 'free' or available for a 'fixed fee'. If there is no comment, the data collector may have simply forgotten to record the price. In this case, alert the survey manager who will need to investigate further.

6. Repeat steps 4–5 for each private sector retail outlet included in the survey, using Columns L–DZ. You can enter data for up to 120 outlets.

To protect against data loss, save the workbook periodically throughout the data entry process and again when data from all medicine outlets have been entered.

You can view summary statistics for individual medicines at any time by pressing the **RATIOS ON/OFF** button. Note that median price ratios will not be calculated until at least one procurement price, or at least four public, private or other sector patient prices are entered for the medicine in question.

7.4.4 Double entry procedures

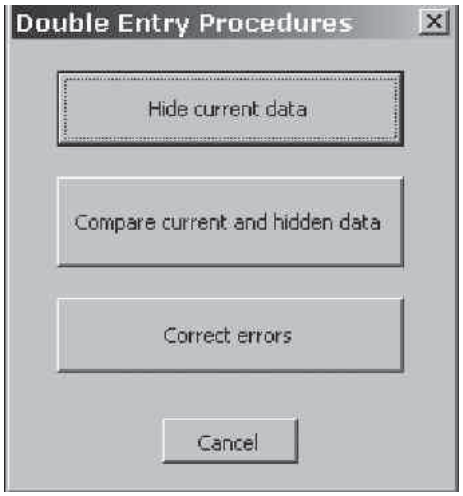
Entering detailed data, such as long columns of the unit prices of medicines, can lead to a substantial number of errors. The quickest and most efficient way to find these data entry errors is to have a second person enter all data a second time and then identify where the numbers entered disagree. The workbook contains a set of procedures to lead you through this process. Pressing the **DOUBLE ENTRY** button at the top of each *Field Data Consolidation* page will display the menu of double entry procedures, as shown in Fig. 7.6. The functions of the four action buttons on the menu are described below.

The double entry process is conducted separately for each Field Data Consolidation page.

All data for a Field Data Consolidation page, i.e. all data for a given sector, should be entered before conducting double entry.

Double entry should be conducted for one Field Data Consolidation page, and any errors corrected, before proceeding to the next page.

Fig. 7.6 Menu of double entry procedures



Note that pressing the **CANCEL** button will exit the double entry menu without making any changes.

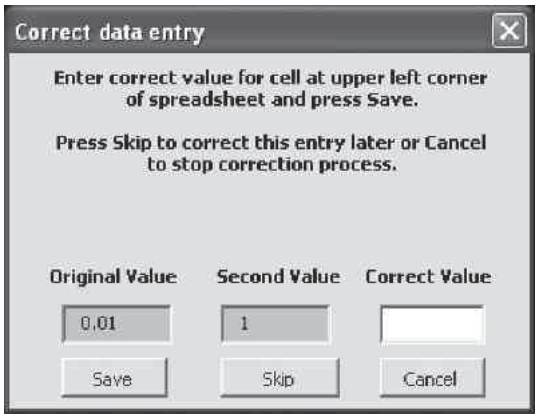
STEP 1: Select HIDE CURRENT DATA. Pressing this button will copy all the data in the data entry grid to a 'hidden' part of the workbook, leaving an empty data grid into which a second set of data can be entered. The identifying information for the facilities or outlets will remain to ensure that the same columns are used for the second round of data entry.

STEP 2: Re-enter data. All data for the sector should be re-entered by a second person. This is highly preferable to the same data entry personnel entering the data twice, since they are likely to make the same mistakes.

STEP 3: Compare the two sets of data. After you complete the second round of data entry, press the **DOUBLE ENTRY** button at the top of the page and select **COMPARE CURRENT AND HIDDEN DATA**. Pressing this button will generate an automatic comparison of the data entered in the second round with the data entered in the first (hidden) round. Any cells that do not agree will be highlighted in red. If there are no errors, all the cells in the data entry grid will remain clear with no red cells.

STEP 4: Correct errors. Once any errors have been identified and highlighted in red, you can return to the original data collection forms to determine the correct values. Press the **DOUBLE ENTRY** button at the top of the page and select **CORRECT ERRORS**. A pop-up window (Fig. 7.7) will appear, which will allow you to proceed through the highlighted errors one by one and enter and save the final value to be used.

Fig. 7.7 'Correct data entry' window



For each error, the pop-up window will show you the original value and the second value entered. Enter the correct value in the space provided and press 'Save'. Or, press 'Skip' to pass over this error and move to the next error to be corrected (e.g. in cases where further investigation is required) or 'Cancel' to close the double entry window.

The survey manager should make all final decisions about ambiguous data values.

CAUTION

It is vital that you manually check all the data on the *Field Data Consolidation* pages since the data-checker will not identify all possible errors. Print these pages since it can be difficult to do the manual checking of so much data on a computer screen.

7.5 STANDARD TREATMENT AFFORDABILITY PAGE

The *Standard Treatment Affordability* page defines standard treatments and expresses the costs of the treatments in terms of:

- Median treatment prices (using the median unit prices of the originator brand and lowest-priced generic equivalent products from each sector).
- The number of days' wages of the lowest-paid government worker (useful for inter-country comparisons).

There have been 14 standard treatments entered on this page, corresponding to the global medicines list (see Table 7.1 for the list of conditions, medicines and treatment schedules).

Table 7.1 Standard treatments used to calculate the affordability of global medicines

	Condition	Medicine name	Strength	Dosage form	Treatment schedule
1.	Asthma	Salbutamol	0.1 mg/dose	inhaler	1 inhaler of 200 doses
2.	Diabetes	Glibenclamide	5 mg	cap/tab	1 cap/tab x 2/day x 30 days = 60
3.	Hypertension	Atenolol	50 mg	cap/tab	1 cap/tab x 30 days = 30
4.	Hypertension	Captopril	25 mg	cap/tab	1 cap/tab x 2/day x 30 days = 60
5.	Hypercholesterolaemia	Simvastatin	20 mg	cap/tab	1 cap/tab x 30 days = 30
6.	Depression	Amitriptyline	25 mg	cap/tab	1 cap/tab x 3/day x 30 days = 90
7.	Adult respiratory infection	Ciprofloxacin	500 mg	cap/tab	1 cap/tab x 2/day for 7 days = 14
8.	Paediatric respiratory infection	Co-trimoxazole	8+40 mg/ml	suspension	5ml x 2/day x 7 days = 70 ml
9.	Adult respiratory infection	Amoxicillin	500mg	cap/tab	1 cap/tab x 3/day x 7 days = 21
10.	Adult respiratory infection	Ceftriaxone	1 g/vial	injection	1 injection
11.	Anxiety	Diazepam	5mg	cap/tab	1 cap/tab x 7 days = 7
12.	Arthritis	Diclofenac	50mg	cap/tab	1 cap/tab x 2/day x 30 days = 60
13.	Pain/inflammation, paediatric	Paracetamol	24mg/ml	suspension	child 1 year: 120mg (=5ml) x 3/day x 3 days = 45ml
14.	Ulcer	Omeprazole	20mg	cap/tab	1 cap/tab x 30 days = 30

If your survey did not include one of the global medicines, Columns C, D, H, J, L and N will contain '#N/A' for that medicine. You can replace the medicine with another from the regional or supplementary list (see below). When you do this '#N/A' will disappear. In addition to the 14 standard treatments, space is provided to enter up to 8 additional standard treatments using survey medicines.

Additional standard treatments should be locally defined for a target condition by the ministry of health, a professional association or an expert panel. If there are no locally defined standard treatments for a condition you wish to include in the affordability analyses, you can use a standard treatment defined by an international organization, such as WHO.

Standard treatments are entered as follows:

- Acute conditions: full courses of therapy
- Chronic conditions, where therapy continues indefinitely: one-month course of therapy.

Click on the **TREATMENT AFFORDABILITY** button on the *Home* page to move to the *Standard Treatment Affordability* page. There is space to analyse the affordability of up to 22 standard medicine treatments.

In Cell J6 enter the *daily* wage of the lowest-paid unskilled government worker in local currency (Note: yearly, monthly, bimonthly and weekly salaries should be reduced to a daily wage by dividing by 365, 30, 14 or 7, respectively). You may be

able to obtain this information from the personnel office in the ministry of health. If it is not available, contact a recently employed low-paid worker to find out the net salary after all compulsory deductions of charges and taxes. If allowances are a standard part of the salary given to all similar government workers (e.g. housing allowance), then include the allowance as part of the wage. If allowances are only applied to certain workers (e.g. allowance for dependent family members) then it should not be included in the wage.

The daily wage of the lowest-paid unskilled government worker must be entered in cell J6 in order to obtain affordability results by number of days' wages.

To define new standard treatments:

1. Enter the name of the first standard treatment to be defined in Cell B78 overwriting the default text 'Enter Condition'. Type the name of a selected condition and press 'Enter'.
2. In Cell B80, select the Medicine Name of the medicine used in the standard treatment. The medicine must be one included in the survey. Move the cursor into the cell and click on the selection arrow that appears to the right of the cell. You will then see an alphabetical drop-down list of all medicine names in the survey. Use your mouse or the arrow keys to select the medicine that you want on the list, and click on it. After a medicine name is entered, the 'Medicine Strength' and 'Dosage Form' will appear automatically in Columns C–D.
3. In Column E, enter the Treatment Duration, which is the number of days for a typical course of therapy. For a chronic disease for which a medication is taken daily, the treatment duration would be 30 (to define a monthly treatment), while for acute illnesses it would be the total duration of therapy.
4. In Column F, enter the Total # of Units per Treatment, which is the number of units of the medicine that would be given for the treatment duration that you specified. For example, for amoxicillin 250 mg taken 3 times per day for 7 days, the treatment duration will be 7 days and the number of units per treatment will be 21 cap/tab.
5. After the Medicine Name and the Total # of Units per Treatment have been entered, the workbook automatically calculates the Median Treatment Price in local currency for each sector based upon the median unit prices of the data that you collected. It also expresses the treatment price in terms of 'Days' Wages' for the wage rate specified in Cell J6.
6. Repeat steps 2–5 for additional treatments you wish to define. Further space is provided, starting in Cell B83. Alternatively, you can replace one (or more) of the pre-selected treatments that were not surveyed. In this case, you will be overwriting the name of the condition, Medicine Name, Treatment Duration and Total # of Units per Treatment.

If a particular treatment requires more than one medicine, you can enter the same treatment name in more than one block of data and enter the information for the different medicines required in separate blocks. In reporting the Median Treatment Price and Days' Wages for this condition, you would need to add together the information from all medicines to get totals for the treatment. For example, if you would like to calculate the affordability of treating asthma with both salbutamol and

beclometasone, you would need to calculate the affordability of purchasing each medicine separately, and then add them together to obtain the total treatment cost.

Be careful when entering the units required for liquids, injections or inhalers. Note that for inhalers the unit is a single dose of inhalant, not the number of inhalers. This would mean that you need to calculate and enter the total number of doses required in a month as the Total # of Units per Treatment (Column F). Expressing the dose of combination products can also be confusing. For co-trimoxazole, the medicine unit is written as 8+40 mg/ml. The treatment regimen might be 2 doses of 5 ml per day for 7 days, which would amount to 70 ml (2 doses x 5 ml x 7 days) for the total treatment course.

7.6 PRICE COMPONENTS: DATA ENTRY PAGE

Information on entering data for price components is provided in the price components section of the Manual (Chapter 9).

7.7 DATA CHECKER

Once all the data have been double entered and any errors corrected, the workbook needs to be checked carefully. This is done in two ways – by running the automated data checker and by checking the data manually. A list of items to check as part of the manual verification is provided in Annex 5.

You will not be able to use the data checker until double entry has been performed.

Automated check of the data

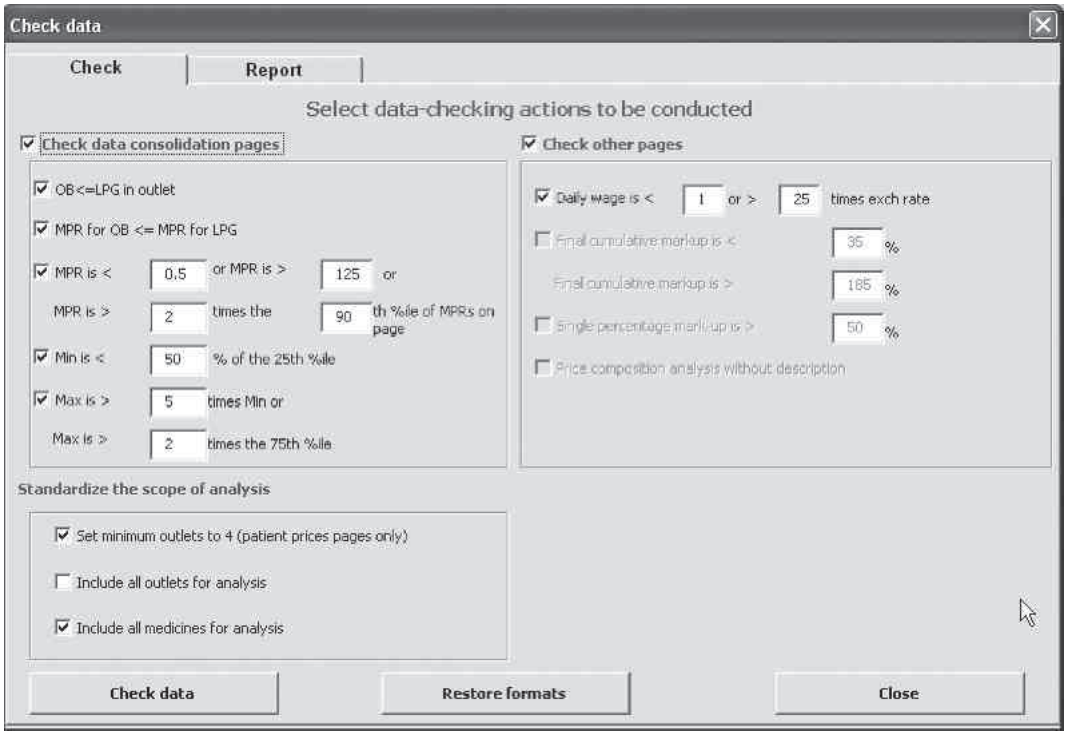
Once you have manually checked the data and corrected any errors, click the button **CHECK DATA** on the *Home* page of the workbook to activate the automated data-checking system. A pop-up window will appear showing data-checking actions and their related settings (Fig. 7.8).

Three data-checking actions are conducted:

1. Checking the consolidation pages
2. Checking other pages in the workbook, i.e. affordability and components
3. The scope of analysis (number of outlets, medicines etc.)

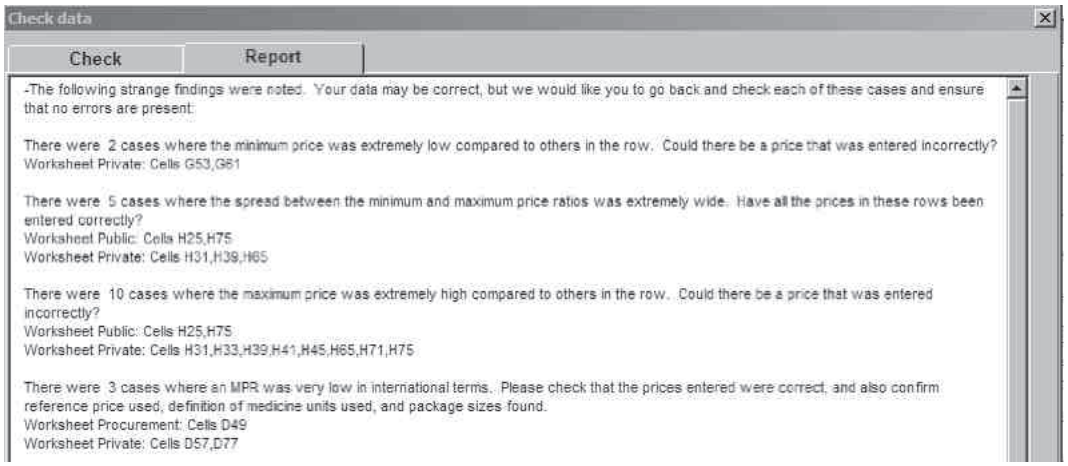
A series of default settings are provided to determine which data should be flagged for checking. For example, as Fig. 7.8 shows, the workbook is set to flag median price ratios of less than 0.5 or greater than 125 as 'outliers' or unexpected data that require further verification. It is suggested that you use the default settings provided; however, you can alter a setting or turn a specific check off (click on the ticked box). The defaults have been set to highlight wide variations or unexpected data but these data may not be incorrect.

Fig. 7.8 'Check data' window



Then click 'Check Data'; the data checker will verify all the data in the workbook according to the parameters specified in the 'Check data' window (this can take a few minutes). Once the data checker has completed verification, a new window will appear listing all the data (identified by their specific pages and cells in the workbook) that need to be checked, and the reason that the data were flagged (see example in Fig. 7.9).

Fig. 7.9 Example of results generated using the data checker



In the workbook all the cells listed in the report will now be coloured purple so you can easily identify them. Data in the purple cells may be correct; they are highlighted merely to indicate that they need checking.

By clicking on the Report tab at the top of the Check Data pop-up window, you will access a list of all data that require checking. Copy and save the report as a Word document, and hit the **CLOSE** button. Then carefully check each purple cell in the workbook. You are likely to find a high concentration of purple cells on the consolidation pages; here you need to check the unit prices entered against the Data Collection form for that medicine outlet.

If you find an error, change the data and save the workbook. Once you have checked all the purple cells you can turn off the colour by clicking on 'Check Data' again on the *Home* page of your workbook to access the 'Check Data' window (Fig. 7.8), then click on 'Restore formats' and 'Close'.

7.8 OTHER PAGES

Six other pages of the workbooks do not relate specifically to data entry and are therefore not discussed in this chapter. These are:

Part I

- *Originator Brands Surveyed* page: This page is used to record information on the originator brand products surveyed. It is discussed further in Chapter 3.
- *Data Collection* page: This page is used to generate the Medicine Price Data Collection form used to record medicine prices and availability in the field. It is discussed further in Chapters 3, 5 and 6.
- *Sector Availability and Price Summary* page: This page provides comparable data between sectors to allow for cross-sector comparisons. It is discussed further in Chapter 8.
- *Medicines Availability and Price Summary* page: This page summarizes the per cent availability and median price ratios obtained for individual medicines in the different sectors included in the survey. It is discussed further in Chapter 8.

Part II

- *Price Components: Data Entry* page: This page is used for entering data collected in the price components part of the survey. It is discussed further in Chapter 9.
- *Price Components: Data Analysis* page: This page generates results for the price components part of the survey. It is discussed further in Chapter 9.

8

Data analysis and interpretation

The survey data can be used for many different types of analyses at both national and international levels. This chapter shows how to examine, summarize and print your survey data, and makes suggestions on how to interpret and report your findings. It focuses on national-level analysis, while Chapter 10 provides guidance on international comparisons. The workbook automatically generates summary tables that provide the evidence base for your report. You should have the workbook open as you read this chapter.

8.1 OVERVIEW OF DATA ANALYSIS

Data collected during the survey can be used for different types of analyses:

- medicine availability: per cent availability of individual medicines; mean (average) per cent (%) availability across a group of medicines; and variations between product types (originator brand vs generic), sectors and geographical areas;
- medicine prices: median prices of individual medicines; ratios of median local price to international reference price (median price ratio or MPR); median MPR across a group of medicines; and variations between product types (originator brand vs lowest-priced generic), sectors and geographical areas;
- treatment affordability in relation to the daily wage of the lowest-paid unskilled government worker; and
- components of the prices of medicines paid by purchasers and consumers (covered in Chapter 9).

The workbook simplifies the process of analysing data by conducting calculations automatically and producing summary results.

To carry out data analysis you will need to complete the steps below.

- Look at the availability, price and price variation for *individual medicines* in each sector.
- Examine and compare *summary results* on medicine availability, MPR and price variation:
  - for each sector, including comparison between originator brands and lowest-priced generics;
  - across sectors; and
  - across regions or survey areas.

- Examine overall treatment cost and affordability of standard treatments for important clinical conditions in the sectors for which patient price data were collected.
- Compare the add-on costs at each stage of the supply chain for medicines tracked in the price components survey, and compare final purchase prices in different sectors with import or manufacturers' prices when these medicines entered the market (see Chapter 9).

Price and availability results are analysed for individual medicines, as well as for overall 'baskets' of medicines surveyed.

8.1.1 Within-sector analysis of medicine prices and availability

For each sector surveyed, availability and prices can be examined for individual medicines, as well as for the sector as a whole – both are important elements of data analysis. Analyses of data from a single sector include comparisons between originator brand and generically equivalent products.

For individual medicines, the workbook calculates the following:

- Per cent availability: percentage (%) of outlets where an individual medicine product was found. Bear in mind that the availability data only refers to the day of data collection at each particular facility and may not reflect average monthly or yearly availability of medicines at individual facilities.
- Median price of each medicine in local currency.
- Median prices in relation to international standard prices (MPR).
- Variations in price across medicine procurements or medicine outlets, including 25th/75th percentiles and maximum/minimum values.

In addition to results for individual medicines, the workbook also generates summary data for each sector. The following summary results are provided for originator brands and lowest-priced generics:

BOX 8.1

Median Price Ratio (MPR)

Medicine prices found during the survey are not expressed as currency units, but rather as ratios relative to a standard set of international reference prices:

$$\textit{Medicine Price Ratio (MPR)} = \frac{\textit{median local unit price}}{\textit{international reference unit price}}$$

The ratio is thus an expression of how much greater or less the local medicine price is than the international reference price, e.g. an MPR of 2 would mean that the local medicine price is twice that of the international reference price. Median price ratios facilitate cross-country comparisons of medicine price data.

Since averages can be skewed by outlying values, median values have been used in the price analysis as a better representation of the midpoint value. The magnitude of price variations is presented as the interquartile range. A quartile is a percentile rank that divides a distribution into four equal parts. The range of values containing the central half of the observations, that is, the range between the 25th and 75th percentiles, is the interquartile range.

- Mean (average) % availability across a basket of medicines (this can be all survey medicines, or a subset such as EML medicines only, 'Global core medicines only' (see Section 8.2.1)).
- Median of the MPRs for a basket of medicines (again, this can be all survey medicines, or a subset such as EML medicines only).
- Comparison of MPRs for originator brands and lowest-priced generics, whereby analysis is limited to those medicines for which both product types were found (matched pair analysis).

8.1.2 Cross-sector comparisons

Medicine availability and prices can be compared between the different sectors for which price data were collected in the survey (e.g. public sector procurement prices vs public sector patient prices; public sector availability vs private sector availability). Cross-sector comparisons can be made for individual medicines, as well as for summary results (baskets of medicines) in each sector – both are important elements of data analysis. The workbook enables comparisons of summary results between two sectors by limiting the analysis to medicines found in both sectors.

8.1.3 Treatment affordability

The affordability of treating key health problems using standardized treatment regimens is calculated using the median prices collected during the survey. The treatment cost for an episode of illness is compared to the daily wage of the lowest-paid unskilled government worker to determine the number of days' wages needed to pay for the cost of treatment.

8.1.4 Price components

Price composition analysis includes both qualitative analysis of policy data collected at the central level (e.g. official mark-up rates), and quantitative analysis of the prices of selected medicines as they move through the distribution chain. Central level data are not entered into the workbook but rather are summarized as a case study. Data for individual medicines are entered into the workbook and analysed by:

- examining the cumulative per cent (%) mark-up that occurs at each stage of the supply chain; and
- examining the per cent (%) contribution of mark-ups at each stage of the supply chain to the final patient price.

Chapter 9 provides instructions on data analysis and interpretation of price components.

8.2 CONDUCTING DATA ANALYSIS

Data analysis should only be conducted after data have been entered twice, and checked both manually and using the workbook's data checker function (See Chapter 7). Survey managers should be confident that the data in the workbook are accurate prior to initiating analysis.

Errors in data collection, processing or entry may cause substantial errors in summary results.

If the prices for one or several medicines appear to be suspicious, you should first check to be sure that the difference is not due to error. One common error is incorrect calculation of the unit price. For example, the price of an entire 200-dose inhaler may have been entered in the workbook instead of the price of a dose. Ideally, most errors will be caught during data processing, but surprising findings should be checked once again for errors during data analysis.

Once data have been verified, data analysis can be started. As described above, many different types of results can be obtained from the survey. Some results are standard and are included in most survey reports (see Chapter 12). However, if all of the possible results were reported, the most relevant findings would be lost. Therefore, survey managers need to generate the full range of survey results and, together with the advisory committee, select the most significant findings for inclusion in their report. It is only in conducting a complete analysis of the survey data that it can be assured that important findings have not been overlooked. Following data analysis, a meeting with the advisory committee should be held to assist in interpreting results and developing recommendations.

The rest of this chapter explains how to use the workbook to perform several different analyses of medicine prices, availability and affordability, and how to interpret and report the results. Data analysis should be conducted using a systematic approach to avoid oversights. A framework for conducting data analysis is provided in Table 8.1. Detailed information on generating and interpreting results is provided in the sections that follow. Before starting analysis, you should prepare a time schedule for outputs to prevent delays in writing up and releasing results. In countries with inflation, fluctuating currency exchange rates or unstable prices, data need to be analysed and presented quickly to ensure their relevance.

Printing summary tables

All summary pages in the workbook are set up so that the relevant sections will print in a convenient format when you use the Excel print functions. To see how a printed page will appear, first go to the page using the buttons on the *Home* page. For a *Field Data Consolidation* page, be sure that the summary table and not the data grid is displayed.

To preview how the page will look, you can:

- Press the Print Preview icon ( ) if it appears in the toolbar on the top of your Excel screen or
- Select File → Print from the Excel main menu, and press the **PREVIEW** button when the print pop-up window appears.

Depending on your paper size and printer setup, you may need to adjust page margins so that all columns in a summary table appear together on the same page. Once you are satisfied with the layout, you can print the table by:

- Using the Excel print icon ( ) or
- Pressing **OK** from the Print pop-up window.

Table 8.1 Systematic approach to data analysis for medicine prices, availability and affordability

PUBLIC SECTOR PROCUREMENT PRICES		
Question	**Source of information**	**Location of information**
How do purchase prices compare with international reference prices (purchasing efficiency)?	1) Median price ratios (MPRs) for individual medicines; 2) and median MPRs for baskets of medicines.	1) *Field Data Consolidation* page, 'data' view, 'Ratios On'. 2) *Field Data Consolidation* page, 'summary' view.
Where multiple procurement orders have been surveyed, does purchasing efficiency vary significantly across orders?	25th and 75th percentiles, and minimums and maximums, for MPRs of individual medicines.	*Field Data Consolidation* page, 'data view, 'Ratios On'.
Does purchasing efficiency vary significantly between medicines? Are some types of products much more expensive compared to reference prices?	25th and 75th percentiles, and minimums and maximums, for median MPR.	*Field Data Consolidation* page, 'summary' view.
If the public sector is purchasing originator brands (OB), what is the difference in price between these and lowest-priced generic equivalents (LPG) (originator brand premium)?	1) MPRs for the OB and LPG of individual medicines; 2) Median MPRs for all medicines found as both product types (matched pair analysis).	1) *Field Data Consolidation* page, 'data' view, 'Ratios On'. 2) *Field Data Consolidation* page, 'summary' view.
Optional, where central and regional orders have been reported. How do prices vary between central procurement and regional procurement agencies?	Restrict analysis to central and regional orders by including/excluding the appropriate orders (Data page); look at difference in median MPRs.	*Field Data Consolidation* page, 'summary' view.
Optional, where both EML and non-EML medicines are procured: Are procurement prices closer to international reference prices for EML medicines?	Use switch on data summary page to switch between all medicines/EML medicines only; look at difference in median MPRs.	*Field Data Consolidation* page, 'summary' view.
PUBLIC, PRIVATE AND OTHER SECTOR PATIENT PRICES		
Question	**Source of information**	**Location of information**
How do patient prices compare with international reference prices?	1) MPRs for individual medicines; 2) and median MPR for basket of medicines.	1) *Field Data Consolidation* page, 'data' view, 'Ratios On'. 2) *Field Data Consolidation* page, 'summary' view.
Do prices vary significantly across medicine outlets?	25th and 75th percentiles, and minimums and maximums, for MPRs of individual medicines.	*Field Data Consolidation* page, 'data' view, 'Ratios On'.
Do prices vary significantly between medicines?	25th and 75th percentiles, and minimums and maximums, for median MPR.	*Field Data Consolidation* page, 'summary' view.
What is the difference in price between originator brand medicines (OB) and their lowest-priced generic equivalent (LPG) (originator brand premium)?	1) MPRs for the OB and LPG of individual medicines; 2) Median MPRs for all medicines found as both product types (matched pair analysis).	1) *Field Data Consolidation* page, 'data' view, 'Ratios On'. 2) *Field Data Consolidation* page, 'summary' view.
What is the availability of medicines in the sector?	1) Per cent (%) availability of individual medicines; 2) Average % availability across all medicines.	1) *Field Data Consolidation* page, 'data' view, 'Ratios On'. 2) *Field Data Consolidation* page, 'summary' view.
Does availability vary significantly between medicines?	1) Differences in % availability for individual medicines; 2) 25th and 75th percentiles for average % availability.	1) *Field Data Consolidation* page, 'data' view, 'Ratios On'. 2) *Field Data Consolidation* page, 'summary' view.
Does availability vary significantly between OB and LPG medicines?	1) Difference in % availability for OBs and LPGs of individual medicines; 2) Difference in average % availability for all OBs and LPGs.	1) *Field Data Consolidation* page, 'data' view, 'Ratios On'. 2) *Field Data Consolidation* page, 'summary' view.

Table 8.1 ***Continued***

PUBLIC, PRIVATE AND OTHER SECTOR PATIENT PRICES		
Question	**Source of information**	**Location of information**
How do medicine availability and price vary between regions (survey areas)?	For each survey area, restrict analysis by including only medicine outlets in the area (data page). Print summary data for each survey area and look at differences in average % availability and median MPR across areas.	*Field Data Consolidation* page, 'summary' view.
Optional, in public sectors where medicine availability is limited to medicines on the national EML: What is the availability and price for EML medicines only?	On the Data summary page, select EML medicines only; look at average % availability and median MPRs.	*Field Data Consolidation* page, 'summary' view.
CROSS-SECTOR COMPARISONS		
Question	**Source of information**	**Location of information**
What is the difference in the availability and price of individual medicines between different sectors?	1) Difference in per cent (%) availability of individual medicines across sectors; 2) Difference in MPR for individual medicines across sectors.	*Medicine Availability And Price Summary* page.
How does average % availability vary across sectors? How does the relative availability of OBs and LPGs vary across sectors?	Average % availability of OBs and LPGs across sectors.	*Sector Availability And Price Summary* page.
What is the difference in median price for the same basket of medicines across two sectors (e.g. public procurement vs public patient; public patient price vs private patient price)?	Median MPRs and % difference for all medicines found in two sectors (matched pair analysis) – OBs and LPGs.	*Sector Availability And Price Summary* page.
Where patients pay for medicines in the public sector, what is the total public sector mark-up from procurement to final price?	Median MPRs for all medicines found in public procurement and public patient price sectors (matched pair analysis); % difference between final price and procurement price.	*Sector Availability And Price Summary* page.
TREATMENT AFFORDABILITY		
Question	**Source of information**	**Location of information**
How many days' wages does the lowest-paid unskilled government worker need to spend to purchase a standard course of treatment for common conditions?	Days' wages = (Median medicine price found in facilities * # of units in a standard course of treatment)/Daily wage of lowest-paid government worker.	*Standard Treatment Affordability* page.
In each sector, how does treatment affordability vary between OBs and LPGs?	Difference in days' wages between OBs and LPGs for the same treatment course, coupled with % availability of each product.	*Standard Treatment Affordability* page
How does treatment affordability vary between sectors?	Difference in days' wages for the same treatment course across different sectors, coupled with any available data on the contribution of different sectors to the pharmaceutical market.	*Standard Treatment Affordability* page

In Row 116 of the sector summary for each *Field Data Consolidation* page, you are asked to describe the procurements/outlets in the summary. It is important to describe the data contained in the summary clearly, particularly if subgroup analyses are being conducted or if different sets of procurement data are being analysed. Once several data summary pages are printed it is easy to confuse them if they are not clearly labelled!

8.3 WITHIN-SECTOR ANALYSES

Each survey can accommodate price data from up to five sectors: procurement prices, public sector patient prices (where medicines are free or provided for a fixed fee, availability can still be analysed), private sector retail prices, and patient prices in up to two other sectors. The workbook automatically produces analyses, both within and between whichever sectors have been surveyed. Although entry of price data from all five sectors is quite similar (see Chapter 7), the analysis of medicine procurement price data differs somewhat from the analysis of patient price data. The following subsections describe both types of analysis.

8.3.1 Within-sector analyses: medicine procurement price data

Procurement price data represent the amounts paid by large purchasing agencies to obtain medicines from suppliers. *The Field Data Consolidation: Medicine Procurement Prices* page is generally used to enter medicine procurement price data from the public sector. Usually, the purchasing agency will be the central ministry of health purchasing unit although, in some countries, there are regional public purchasing units. In public sectors where medicines are distributed to patients at no charge or for a fixed fee per medicine or per visit, procurement data will be the only public sector price data available. If the fee that patients pay varies by medicine or type of medicine, those variable fees should be entered in the *Field Data Consolidation: Public Sector Patient Prices* page and analysed separately.

Public procurement price data can be based on a single medicine order or on multiple sets of procurement data from different points in time or from different purchasing agencies. For this reason, procurement data analysis is restricted to medicine prices and does not include availability. In your report, remember to identify clearly the purchasing agency or agencies and the period of time over which the procurements took place.

In addition to public sector procurement data, procurement data may also be collected from the private sector or an NGO sector such as mission hospital clinics. This may represent, for example, pooled purchasing systems that supply medicines to mission hospitals. Procurement data from other sectors are also entered into the *Field Data Consolidation: Medicine Procurement Prices* page; however, **data from each sector must be analysed separately**.

Row 10 of the data entry grid is used to include/exclude different procurement orders from the analysis. Begin by analysing public sector procurement data. Keep row 10 as '1' (include in analysis) for each column representing public sector procurement data, and enter '0' in all other columns (so they are not included in analysis). After conducting your analysis for public procurement (see below), include procurement orders from a different sector, exclude all other procurement orders and conduct the analysis for this sector again. In this way, you will obtain separate procurement results for each sector for which procurement data were collected.

Procurement data from different sectors, although entered into the same data entry table, must be analysed separately.

Examining summary statistics on procurement prices for individual medicines

Begin the analysis of procurement prices by examining the summary data for individual medicines. These appear on the *Field Data Consolidation* page in Columns E–EI. If they are not visible, press **RATIOS ON/OFF** to reveal them. The MPR for individual medicine (originator brand and lowest-priced generic), contained in Column E, is the median procurement price observed for each medicine divided by its international reference price. The MPR for procurement data is a measure of purchasing efficiency.

Also provided are the 25th and 75th percentile MPRs (Columns F and G) and the minimum and maximum MPRs (Columns H and I), which show the variation in medicine prices across orders. The number of orders where a price was found is provided in Column J, and the median unit price in local currency, used to calculate the MPR, is contained in Column EI.

In general, procurement prices for the lowest-priced generically equivalent products should be fairly close to the MSH international supplier/buyer prices (that is, ratios up to 1.00). MPRs of 1.00 or less indicate that the procurement system is working very efficiently, while MPRs above 1.00 raise questions about purchasing efficiency. The MPRs for originator brand products may be much higher, since the MSH international reference prices are prices for multi-source products. The difference between the MPR for an originator brand product and the MPR for its lowest-priced generic equivalent is a measure of the 'brand premium' paid for purchasing originator brand products.

Begin the analysis by examining the MPRs:

- across different medicines; and
- across product types (originator, lowest-priced generic) for the same medicine.

Fig. 8.1 shows an example of the MPRs for a few medicines after all procurement data have been entered. The MPR for originator brand and lowest-priced generic amitriptyline cap/tab are 4.76 and 2.40 times the international reference price, respectively, which is a sign that this procurement system is not obtaining very competitive prices for this medicine. Other generics are being procured more competitively at less than international reference prices. For albendazole, the MPR for the originator brand version is more than five times that of the lowest-priced generic (that is, there is a high brand premium); for other medicines the originator brand and lowest-priced generic prices are somewhat closer.

When there are multiple procurement prices for each medicine (the number of orders for each medicine is shown in Column J), you should also examine the range between the 25th and 75th percentiles and between the minimum and maximum to see if there are wide variations in procurement prices across orders. In the example, the ratios across orders are reasonably stable. However, for some products (e.g. generic albendazole and generic amoxicillin cap/tab), the price on at least one order was substantially lower than the typical price. You should examine such outliers carefully to see if they are errors. If not, finding out how a low price was obtained in one order may point to ways to make the procurement process more efficient.

Fig. 8.1 Example of medicine-specific procurement price data

	A	B	C	D	E	F	G	H	I	J	El
1	Field Data Consolidation: Medicine Procurement Prices										
2											
3											
4	Go To Home Page		Data/Summary								
5	Ratios On/Off		Double Entry								
6											
7	Procurement ID				Summary Comparisons to Reference Prices and Number of Orders per Medicine						
8	Procurement Agency										
9	Date (Mon-YY as in Jan-02)										
10	Include order in analysis (1=yes, 0=no)?				(Blank if med. has < 1 orders)						
11											
12	No.	Medicine Name	Medicine Type	Include in analysis?	Median Price Ratio	25%ile	75%ile	Min	Max	# orders	Median Price
13	1	Albendazole	Brand	1	3.20	2.95	3.33	2.70	3.45	3	0.0291
14	1	Albendazole	Lowest Price	1	0.58	0.46	0.73	0.37	0.90	4	0.0053
15	2	Amitriptyline	Brand	1	4.76	3.78	6.09	3.45	7.49	4	0.0266
16	2	Amitriptyline	Lowest Price	1	2.40	1.99	2.75	1.65	2.94	4	0.0134
17	3	Amoxicillin cap/tab	Brand	1	1.60	1.55	1.70	1.50	1.80	3	0.0418
18	3	Amoxicillin cap/tab	Lowest Price	1	0.80	0.55	0.88	0.30	0.95	3	0.0224
19	4	Amoxicillin suspension	Brand	1	2.30	1.35	4.02	1.50	8.59	4	0.0131
20	4	Amoxicillin suspension	Lowest Price	1	0.99	0.90	1.10	0.80	1.20	3	0.0056
21	5	Atenolol	Brand	1	1.95	1.73	2.33	1.50	3.00	4	0.0209
22	5	Atenolol	Lowest Price	1	0.75	0.68	0.88	0.60	1.10	4	0.0080

In your report, you may want to comment about overall procurement price efficiency and highlight examples where there are large differences observed between the MPRs for different types of products or where the range of procurement prices varies widely across orders.

Producing a summary table of procurement price data

While data on the prices of individual medicines can be revealing, the survey's main purpose is to analyse the 'typical' prices paid for an entire set of medicines, both within and across sectors. Each *Field Data Consolidation* page in the workbook automatically creates summary tables that contain statistics calculated across medicines from the MPRs in Column E. The five summary measures calculated for procurement are:

- median (mid-point) of the MPRs for individual medicines
- 25th percentile MPR
- 75th percentile MPR
- minimum MPR
- maximum MPR.

To produce and print the summary table on the *Medicine Procurement Prices* page, carry out the following steps:

1. If the data entry grid is displayed on the page, click on the **DATA/SUMMARY** button to make the summary table visible (as shown in Fig. 8.2).
2. In Cell D116, enter a description of the procurements that are included in this analysis, including the procurement agency and range of dates.
3. Decide on the group or basket of medicines for which you would like to display summaries. In the top left-hand corner, you can select between:
   - — All: all the medicines that you have studied in the survey (global, regional and supplementary)
   - — Global: the global survey medicines only (i.e. the set of 14 global medicines recommended for international comparisons)

— Regional: the regional survey medicines only (i.e. the set of 16 regional medicines recommended for regional comparisons)

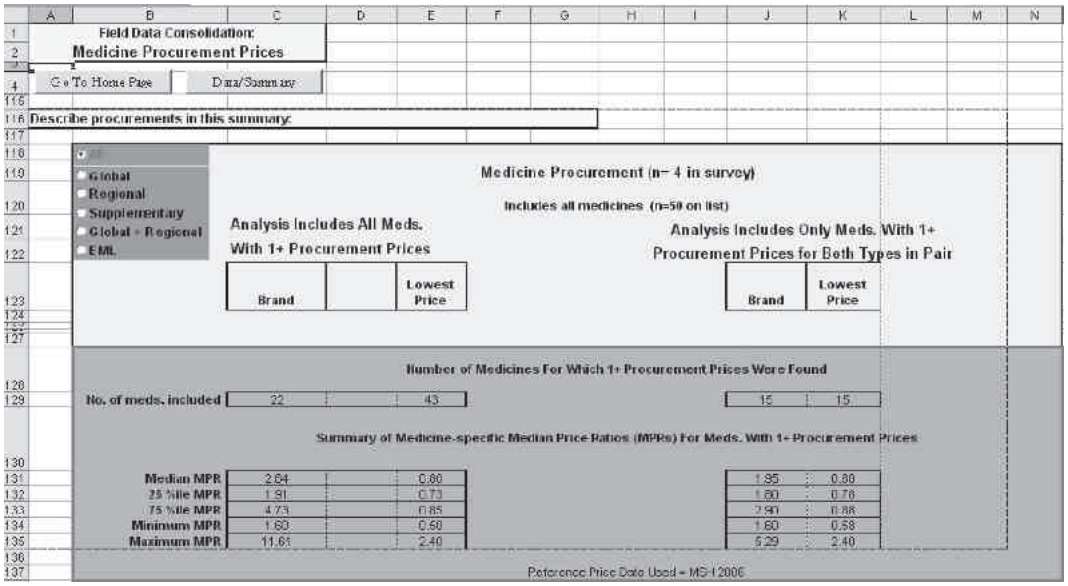
— Supplementary: the supplementary medicines selected at national level

— Global + Regional: the 30 global and regional medicines

— EML: Medicines on the national Essential Medicines List only (as entered in Column H of the *International Medicine Reference Price Data* page).

For national analyses, it is most useful and accurate to analyse the full list of survey medicines. For international comparisons, the global and/or regional lists should be selected. You may also wish to limit your analysis to those medicines on the National Essential Medicines List, particularly in the public sector (procurement and patient prices).

Fig. 8.2 Example of summary table containing procurement price data



Field Data Consolidation:
Medicine Procurement Prices

Go To Home Page | Data/Summary

Describe procurements in this summary:

All
Global
Regional
Supplementary
Global + Regional
EML

Medicine Procurement (n= 4 in survey)

Includes all medicines (n=50 on list)

	Analysis Includes All Meds. With 1+ Procurement Prices			Analysis Includes Only Meds. With 1+ Procurement Prices for Both Types in Pair	
	Brand		Lowest Price	Brand	Lowest Price
Number of Medicines For Which 1+ Procurement Prices Were Found					
No. of meds. included	22		43	15	15
Summary of Medicine-specific Median Price Ratios (MPRs) For Meds. With 1+ Procurement Prices					
Median MPR	2.64		0.80	1.35	0.80
25 %ile MPR	1.91		0.73	1.60	0.76
75 %ile MPR	4.73		0.85	2.90	0.88
Minimum MPR	1.60		0.58	1.60	0.58
Maximum MPR	11.61		2.40	5.29	2.40

Reference Price Data Used = MS-I 2006

4. Examine the summary table to be sure that the data look sensible. Investigate any values that look unusual to check they are not based on errors. After previewing the printed version of the summary table, print the table and use it as the basis for your report.

Interpreting the procurement price data summary table

First, note the table headings. The first heading contains data on the number of different sets of procurement orders included in the survey. If prices from only one set of orders have been entered, this heading would read 'Medicine Procurements (n=1 in survey)'. If you have entered procurement data from multiple sectors into the *Procurement Prices* page, double-check to make sure that the appropriate number of procurement orders has been included in the analysis (e.g. if n = 7 and you have 8 procurement orders from the mission sector, you may have forgotten to include one order in the analysis).

The next heading describes the medicines that are included in the table, either All, Global, Regional, Supplementary, Global + Regional or EML medicines only. The heading calculates the number of medicines listed on the *International Medicine Reference Price* page that fall into whichever of these six categories has been selected. Note that the set of reference prices used for comparisons (MSH or an alternative set of prices) is indicated at the bottom of the table.

The third row of headings describes the two different types of summary data contained in the table. On the left of the table are two columns of data summarizing the MPRs for medicines that had the minimum number of procurement prices (usually 1). These two columns are for the two product types (originator brand and lowest-priced generic) surveyed. The first row of data in this section shows how many medicines of each product type had the minimum number of procurement prices reported. In the example table, of the 50 medicines in the survey, 22 originator brand products had at least one procurement price, while 43 lowest-priced generic equivalents had at least one price.

The bottom section on the left calculates the five different summary measures from the MPRs for individual medicines. In the example table, the median of the MPR across the 22 originator brand products for which prices were found was 2.64, while the 25th and 75th percentiles of the MPRs for these medicines were 1.91 and 4.73 (meaning that 50% of the 22 originator brand medicines found had MPRs in this range). For lowest-priced generics, the median of the MPR across the 43 medicines found was 0.80. The 75th percentile was 0.85, meaning that the MPR of 75% of the medicines found was 0.85 or less. Thus, for the majority of medicines the government is obtaining procurement prices less than international reference prices.

For individual medicines, the 25th/75th percentiles and maximum and minimum values show the range of prices across *medicine outlets*. For summary data the 25th/75th percentiles and maximum and minimum values show the range of prices across *medicines*.

If prices were found for nearly all of the medicines within each product type, the summary data on the left side of the table will be fairly representative and comparable across the two product types. However, if prices for all medicines were not found, and especially if different medicines were found for each product type, data will not be comparable. That is, summary data for originator brand products and lowest-priced generics will be based on two different baskets of medicines.

To compare summary data for originator brands and lowest-priced generics accurately, only those medicines for which both product types were found should be included in the analysis (i.e. based on the same basket of medicines). The results of this 'matched pairs' analysis are presented on the right side of the table. In this analysis, only medicines that match are included; that is, each pair of columns limits analysis to medicines where prices were found for both of the product types in the pair. In the sample (Fig. 8.2), 15 matching medicines were found for the comparison between originator brand and lowest-priced generic equivalent. The matched pairs analysis shows that where the government is procuring medicines as both originator brands and lowest-priced generics, it is paying about 2.4 times (1.95/0.80) more for the brand product.

If few pairs of prices are found in a particular survey, the comparisons are less likely to be representative of the broader procurement prices in this sector. For government procurement data, it may well be that a high percentage of prices are found only for generic products, since the government may purchase few or no originator brands.

Reporting summary results on procurement prices

The data in this table can be used to explore how efficiently a procurement system is working. Results from surveys conducted to date have shown that many countries are able to obtain procurement prices less than MSH international reference prices. If the median of the MPR is lower than 1.00, then (after checking your data for errors), congratulate your procurement officer. If the median of the MPR for generic products is high, you should investigate the reasons. Reasons for high price ratios in comparison to international reference prices may include:

— Patent protection on originator brand items

— Lack of generic competition

— Generic medicines priced by suppliers only slightly below the originator brand

— Small quantities being procured

— Lack of transparency in procurement

— Procurement process excludes low-price suppliers

— Inefficiency in procurement

— Lack of price regulation.

Your survey will give you data to start such an assessment. Remember that occasionally an MPR may be low because the international reference price is high. Relatively new medicines can have high reference prices. You need to check these as part of your data analysis.

In your report, you should try to describe the overall situation regarding the number of medicines procured and the levels and variability of the MPRs that you found for each product type. To the extent that product types have enough common medicines to be compared, you should also compare MPRs across product types. The standard report template (Chapter 12) provides guidance on reporting procurement prices, which can be adapted and/or expanded as appropriate.

To compare the prices of originator brand and lowest-priced generic products, you should use the data on the right 'matched pairs' side of the table since these provide fairer comparisons. You interpret these paired summaries in a similar way as the unpaired ones on the left side, but you should explain that the statistics are for matched pairs.

8.3.2 Within-sector analyses: patient price and medicine availability data

Four *Field Data Consolidation* pages are used to summarize patient price data gathered from the different types of facilities or medicine outlets that you included in your survey. You can use the same approaches to summarize and analyse data from each of these pages. The analysis process will be described in detail below using example data from a set of 30 private sector medicine outlets. Simply adapt and repeat this approach to analyse data from the *Public Sector Patient Prices* or the *Other Sector Patient Prices* pages.

Examining summary statistics for individual medicines

As with the procurement price data, begin the analysis of patient prices by examining the summary data for individual medicines. These appear on the *Field Data Consolidation* page in Columns E–EI. If they are not visible, press **RATIOS ON/OFF** to reveal them. The MPR for individual medicines, contained in Column E, is the median price to patients across four or more outlets surveyed divided by the medicine's international reference price. Also provided are the 25th and 75th percentile MPRs (Columns F and G), the minimum and maximum MPRs (Columns H and I). Availability is reported as the percentage of medicine outlets in which the medicine was found (Column J). The median unit price in local currency, used to calculate the MPR, is contained in Column EI. Fig. 8.3 shows an example of these summary data after price data for a sample of 30 private sector medicine outlets have been entered.

Fig. 8.3 Example of summary data for individual medicines

	A	B	C	D	E	F	G	H	I	J	EI
1		Field Data Consolidation:									
2		Private Sector Patient Prices									
3											
4		Go To Home Page	Data/Summary								
5		Ratio On/Off	Double Entry								
6											
7	Medicines Outlet Study ID				Summary Comparisons to Reference Prices and Percent Availability in Outlets						
8	Region										
9	Distance From Population Centre										
10	Include outlet in analysis (1=yes,0=no)?							(Blank if found in < 4 outlets)			
11											
12	No.	Medicine Name	Medicine Type	Include in analysis?	Median Price Ratio	25%ile	75%ile	Min	Max	% with med.	Median Price
13	1	Albendazole	Brand	1	6.00	5.00	10.00	3.00	12.00	83.3%	0.0546
14	1	Albendazole	Lowest Price	1	3.85	3.00	5.00	1.30	10.00	60.0%	0.0350
15	2	Amitriptyline	Brand	1	16.00	12.00	24.00	10.00	29.00	83.3%	0.0840
16	2	Amitriptyline	Lowest Price	1	9.00	8.80	11.10	5.00	12.00	76.7%	0.0504
17	3	Amoxicillin cap/tab	Brand	1	2.70	2.00	3.20	1.00	5.00	73.3%	0.0756
18	3	Amoxicillin cap/tab	Lowest Price	1	1.90	1.30	2.45	1.00	3.50	66.7%	0.0532
19	4	Amoxicillin suspension	Brand	1	10.00	9.00	14.00	5.00	15.00	90.0%	0.0570
20	4	Amoxicillin suspension	Lowest Price	1	2.55	2.10	3.00	1.50	4.50	33.3%	0.0145
21	5	Atenolol	Brand	1	24.00	14.00	26.00	10.00	30.00	80.0%	0.2568
22	5	Atenolol	Lowest Price	1	22.84	17.31	23.48	5.00	30.00	70.0%	0.2444

Begin the analysis by examining the MPRs and per cent availability:

- across different medicines; and
- across product types (originator, lowest-priced generic) for the same medicine.

Note that the summary price for a medicine will be blank if fewer prices than the minimum number specified in Cell H10 were found (prices in less then four private sector outlets in the example). However, the per cent availability of each medicine will still be reported (no minimum required), and in fact, the low availability of such medicines is an important finding to be highlighted. Remember, medicines have been included in the calculation of per cent availability even if they were available free of charge or for a fixed fee.

By default, medicines need to be found in at least 4 outlets for their MPR to be calculated, except for procurement prices where a single data point is usually sufficient (unless procurement prices were collected from many public facilities in which case the default should be reset to 4).

BOX 8.2

Availability in the public sector is analysed according to the levels of care where the medicine is expected to be available

The survey medicines list may include some medicines that are only provided at secondary or tertiary care public sector facilities. In such cases, the medicine's availability should be restricted to those outlets where it is expected to be available. For example, primary health-care centres should not be included in the availability analysis of a specialized medicine that is only provided at secondary or tertiary hospitals. The minimum level of care where each medicine is expected to be available should have been entered in Column O of the *International Medicine Reference Price Data* page, and the level of care of each public sector outlet should have been entered in Row 11 of the *Field Data Consolidation: Public Sector Patient Prices* page. Using this information, the workbook calculates availability as follows:

- If a medicine is selected as 'level 1', i.e. available at primary care level, this medicine should also be available at secondary and tertiary levels of care. The availability analysis will therefore include all health facilities in the public sector sample.
- If a medicine is selected as 'level 2', i.e. available at secondary care level, this medicine should also be available at the tertiary level. The availability analysis will include all secondary and tertiary health facilities in the public sector sample, but will exclude primary facilities.
- If a medicine is selected as 'level 3', i.e. available at tertiary care level, this medicine should only be available at tertiary level facilities. The availability analysis will be restricted to tertiary health facilities.

Example:
Let us assume that in the public sector, ceftriaxone injection 1g/vial is only available in level 2 and 3 health facilities. On the *International Medicine Reference Price Data* page, the minimum level of care for which this medicine is available is therefore entered as '2'. The public sector sample is composed of 20 primary health-care centres, 7 secondary hospitals and 3 tertiary hospitals. Ceftriaxone injection 1g/vial is found at 0 primary health-care centres, 3 secondary hospitals and 3 tertiary hospitals. The availability of this medicine is the number of outlets where the medicine is found (3 + 3), divided by the number of outlets where it is expected to be found (7+3), i.e. 6/10 or 60%. Since ceftriaxone injection is not expected to be stocked at primary care facilities, these are not included in the availability analysis.

Unlike procurement prices, there are no easy rules of thumb for determining if the MPRs for patient prices are high, low or about right. An MPR of 2.00 would mean that the final price of the product to a patient (after all intermediate charges and distribution costs) was two times the international reference price. Generally, the MPRs for originator brand products will be higher since the international reference prices are for multi-source products.

It is important to emphasize that MSH reference prices are international not-for-profit (and sometimes for-profit) supplier/buyer prices, not retail prices. While centralized procurement prices or patient charges in public sector facilities may be fairly close to the MSH prices, private retail prices and patient charges in other sectors (e.g. NGO or private hospitals) are likely to be considerably higher. This is due to the charges and profits added on to the procurement price of a medicine as it proceeds through the distribution system. The extent to which these retail prices are higher depends on the country and situation. If a medicine is rarely used, the price differential is likely to be greater. Under some circumstances, medicines sold in private sector outlets may cost as much as 100 times the MSH price or more. For medicines with very large price differentials, your price component analyses may reveal why the prices are so high (high manufacturer's selling price or high add-ons or both).

In the example table, the MPRs are variable; some are high (e.g. 3.85 for lowest-priced generic albendazole) to very high (e.g. 22.84 for lowest-priced generic atenolol). This also indicates that the relative prices charged to patients for different medicines are not uniform when compared to international prices. Examining either high or low prices may uncover interesting medicine-specific factors influencing prices. Very large originator brand premiums like that for amoxicillin suspension (10.00 MPR for originator brand vs 2.55 for the lowest-priced generic equivalent) are worth noting. In this case, the availability of generic amoxicillin suspension is only 33.3%, therefore patients may be spending nearly four times more to purchase the originator brand when the lowest-priced generic is not available.

You should also examine the range between the 25th and 75th percentiles and between the minimum and maximum to see if there are wide variations in patient prices in different outlets. In the example in Fig. 8.3, the price ratios showed considerable variability across the 30 pharmacies included in the survey, with substantial differences between the maximums and minimums. You should examine outliers carefully to see if they are errors. If not, finding out why some outlets charge lower or higher prices may point to strategies to lower prices in this sector.

In your report, you may want to highlight specific examples where there are large differences observed between the MPRs for different types of products or where the range of prices that patients pay varies widely across outlets.

Producing a summary table of patient price data

Focusing too much on the observed availability, price levels and differentials for individual medicines can be misleading. The survey's main purpose is to analyse the 'typical' availability and prices that patients pay, for an entire set of medicines. The summary table of patient prices and availability, which you can access by clicking the **DATA/SUMMARY** button, contains data calculated across medicines from the medicine-specific MPRs in Column E, and per cent availability in Column J of the medicine-specific summaries. The summary measures calculated are:

- mean (average) per cent availability;
- standard deviation for mean per cent availability;
- median (mid-point) of the MPRs calculated for each medicine;
- 25th percentile MPR;
- 75th percentile MPR;
- minimum MPR; and
- maximum MPR.

You can produce and print the summary tables for patient prices by following the same steps outlined for the summary procurement price table in the previous section. Remember to enter a description of the outlets included in the analysis for each sector in Cell D116 before printing.

As with procurement data, in the top left-hand corner you can select between different groups or baskets of medicines to be analysed:

— All: all the medicines surveyed (global, regional and supplementary);

— Global: core global medicines only (i.e. the set of 14 core global medicines recommended for international comparisons);

— Regional: core regional medicines only (i.e. the set of 16 core regional medicines recommended for regional comparisons);

— Supplementary: the supplementary medicines selected at national level;

— Global + Regional: the 30 global and regional medicines; and

— EML: Medicines on the national Essential Medicines List only (as entered in Column H of the *International Medicine Reference Price Data* page).

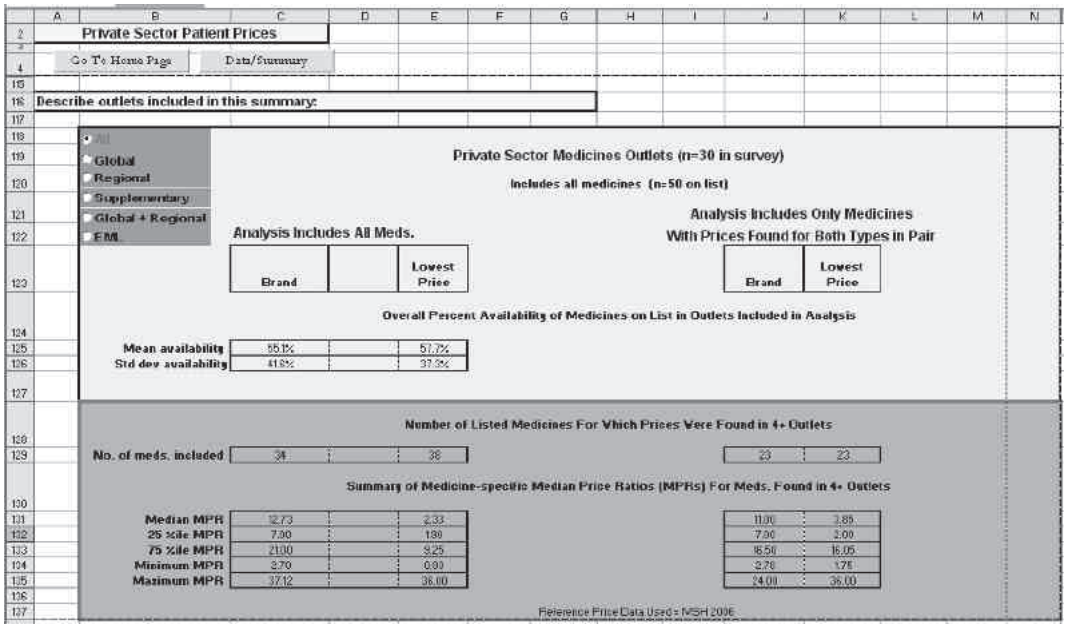
For national analyses, it is most useful and accurate to analyse the full list of survey medicines. For international comparisons, the global and/or regional core list should be selected to increase the validity of the comparisons. You may also wish to limit your analysis to those medicines on the national Essential Medicines List, particularly in the public sector (procurement and patient prices).

Interpreting a patient price data summary table

Fig. 8.4 shows an example of a summary table for patient price data for 30 pharmacies in the private sector. The structure of the table summarizing patient price data is similar to the summary table for procurement price data described previously. The first table heading indicates the sector and the number of medicine outlets included in the summary, while the second heading indicates the group of medicines analysed (e.g. all, global) and the number of such medicines in the reference list. The set of reference prices used in the analysis is indicated at the bottom of the table.

As with the procurement price summary, the main body of the table has two sides. On the left of the table are two columns of data summarizing the findings for medicines that had the minimum number of prices (usually four) found in the outlets included in the analysis. The two columns are for the two product types surveyed (originator brand and lowest-priced generic equivalent). In comparing product types,

Fig. 8.4 Example of summary table containing patient price data



if the minimum number of prices was found for a low percentage of medicines, and especially if different medicines were found for each product type, it is more valid to use the data in the two columns on the right side of the table. On the right side, only medicines that match are included in comparisons between product types: that is, the analysis is limited to only those medicines for which both product types were found.

The first section of data in the table summarizes overall medicine availability in the medicine outlets included in the analysis. Two summary measures are reported:

- mean (average) per cent (%) availability; and
- standard deviation of mean per cent availability.

Standard deviation is used to measure the spread or dispersion around the mean. It is a measure of variation in a distribution.

These summary availability measures are calculated from the medicine-specific values labelled '% with med' in Column J in Fig. 8.3 (note that all medicines are included in the availability analysis regardless of how many times they were found). In the table in Fig. 8.4, of the 50 medicines for which prices were sought, the mean availability was 55.1% for originator brand products and 57.7% for lowest-priced generics. The standard deviation was similar for originator brands (41.6%) and for lowest-priced generics (37.3%), indicating a similarly high amount of variability in the aavailability of individual medicines for both product types.

The next section of data in the table shows how many medicines of each product type obtained the minimum number of prices needed for price analysis. Of the 50 medicines in the survey, 34 originator brand products were found in at least four private sector outlets (of the 30 in the analysis), while 38 lowest-priced generically equivalent products were found this frequently. Because the basket of medicines for originator brands and lowest-priced generics differs, a matched pairs analysis is preferable when making direct comparisons between product types. As shown on the right side of the table, 23 medicines were found as both originator brands and lowest-priced generics in the minimum number of outlets required for price analysis.

The final section of the table summarizes the MPRs found in Column E of Fig. 8.3. In Fig. 8.4, the median of the MPR across the 34 originator brand products for which prices were found was 12.73. Lowest-priced generic equivalents were less expensive (median MPR = 2.33), but were still more than double international reference prices. The 25th and 75th MPR percentiles for both originator brands (7.00 and 21.00 respectively) and lowest-priced generics (1.90 and 9.25 respectively) show a high degree of variability in the MPRs of individual medicines; that is, medicines are not priced uniformly with respect to their international reference prices. Limiting analysis to medicines for which matching prices were found (on the right side of the table), originator brand products were about 2.9 times more expensive than lowest-priced generic equivalents (MPR_{OB}/MPR_{LPG} = 11.00/3.85 = 2.86).

Reporting summary results on patient prices

The data in this table can be used to explore whether patients are paying reasonable prices for medicines in this sector and how much they would save by purchasing generically-equivalent products as compared to originator brands. Because there

BOX 8.3

Medicines available for free or for a fixed fee

In the public sector, medicines are sometimes distributed free of charge, or for a fixed fee for either the medicine or the visit. In other cases, certain medicines are free or available for a fixed fee, while others are not. For example, this may occur if a certain medicine is paid for through donations or a special treatment programme. In these cases, data are collected on the availability of the medicine on the day of data collection, but not the price (See Chapter 6, pages 77–78).

If a medicine is available for free or for a fixed fee, an 'F' is entered into the appropriate cell in the data entry grid on the appropriate *Field Data Consolidation* page (See Chapter 7, page 92). This will allow this medicine to be included in the availability analysis even though there are no price data for it. An example is provided below:

	A	B	C	D	K	L	M	N	O	P	Q	R
1		Field Data Consolidation:										
2		Public Sector Patient Prices										
4		Go To Home Page	Data Summary									
5		Ratio On/Off	Double Entry		Sort by:	ID	Region	Distance	Number			
6					Data for Individual Medicines Outlets (Enter Medicine Unit Prices in Local Currency)							
7		Medicines Outlet Study ID			1	2	3	4	5	6	7	8
8		Region			East	East	East	East	East	North	North	North
9		Distance From Population Centre			5	0	3	7	12	4	8	20
10		Include outlet in analysis (1=yes,0=no)?			1	1	1	1	1	1	1	1
11		Level of care			1	2	1	3	1	1	2	1
12	No.	Medicine Name	Medicine Type	Include in analysis?	1	2	3	4	5	6	7	8
13	1	Albendazole	Brand	1								
14	1	Albendazole	Lowest Price	1	0.01001		0.012012	0.009828		0.01274	0.009	
15	2	Amitriptyline	Brand	1	0.01848		0.015712		0.02184	0.02352		0.01848
16	2	Amitriptyline	Lowest Price	1	0.011088	0.014112		0.016128		0.014112	0.01008	0.01176
17	3	Amoxicillin cap/tab	Brand	1								
18	3	Amoxicillin cap/tab	Lowest Price	1	F		F	F	F	F	F	
19	4	Amoxicillin suspension	Brand	1	0.009405	0.014364	0.053866	0.0171	0.011115	0.01197	0.00855	0.01197
20	4	Amoxicillin suspension	Lowest Price	1	0.007524		0.006207			0.009576		0.00456
21	5	Atenolol	Brand	1		0.023112					0.01605	
22	5	Atenolol	Lowest Price	1	0.02354	0.0178904	0.026248		0.030288	0.032542	0.034906	

Because generic amoxicillin is provided free of charge, the workbook will calculate per cent availability (56.7%), but not median price or MPR:

	A	B	C	D	E	F	G	H	I	J	El
1		Field Data Consolidation:									
2		Public Sector Patient Prices									
4		Go To Home Page	Data Summary								
5		Ratio On/Off	Double Entry								
6											
7		Medicines Outlet Study ID			Summary Comparisons to Reference Prices and Percent Availability in Outlets						
8		Region									
9		Distance From Population Centre									
10		Include outlet in analysis (1=yes,0=no)?			(Blank if found in < 4 outlets)						
11		Level of care									
12	No.	Medicine Name	Medicine Type	Include in analysis?	Median Price Ratio	25%ile	75%ile	Min	Max	% with med.	Median Price
13	1	Albendazole	Brand	1						0.0%	
14	1	Albendazole	Lowest Price	1	1.15	1.06	1.32	0.90	2.10	66.7%	0.01
15	2	Amitriptyline	Brand	1	3.52	3.30	3.90	3.30	10.50	56.7%	0.02
16	2	Amitriptyline	Lowest Price	1	2.34	1.98	2.52	1.65	3.78	70.0%	0.01
17	3	Amoxicillin cap/tab	Brand	1						0.0%	
18	3	Amoxicillin cap/tab	Lowest Price	1						56.7%	
19	4	Amoxicillin suspension	Brand	1	2.62	1.95	4.60	1.50	9.46	70.0%	0.01
20	4	Amoxicillin suspension	Lowest Price	1	1.32	0.99	1.66	0.80	2.62	43.3%	0.01
21	5	Atenolol	Brand	1	2.13	1.65	2.31	1.50	5.25	40.0%	0.02
22	5	Atenolol	Lowest Price	1	2.64	2.41	3.16	1.67	4.37	63.3%	0.03

are no easy "rules of thumb" for determining a 'reasonable' price, you should be cautious in your conclusions about price levels. However, medians of the MPRs much greater than 2.00 for lowest-priced generically equivalent products would generally be cause for concern, since this is twice the price of these medicines if procured from international suppliers. The standard report template (Chapter 12) provides guidance on reporting patient prices; this template can be adapted and/or expanded as appropriate.

If the median of the MPRs seems high, you should investigate the reasons. Some possible reasons for high patient prices are similar to those for high procurement prices:

- originator brand patent protection;
- lack of generic competition; and
- suppliers of generic medicines pricing popular products only slightly below the originator brand version.

Additional reasons might include:

- high manufacturer profit margins;
- high government taxes and duties on medicines;
- inefficient supply system; and
- high wholesale or retail mark-ups.

Your survey will give you data to start such an assessment.

In your report, you should try to describe the overall product availability situation, and the levels and variability of the MPRs that you found for each product type. To the extent that originator brand and lowest-price generic products have enough common medicines to be compared, you should also compare MPRs across product types. If some or all medicines are provided for free or for a fixed fee in certain sectors, this should be described in your report.

8.4 CROSS-SECTOR ANALYSIS: PRICE AND AVAILABILITY COMPARISONS

After looking at each individual sector, the next stage in the analysis is to compare results across sectors, drawing contrasts between procurement data and whichever sectors of patient data were included in the survey. It will be informative to analyse both relative price levels (both procurement and patient prices) and product availability (in medicine outlets).

As for within-sector analyses, there are two different types of cross-sector analysis:

- comparisons of the results for individual medicines; and
- comparison of the sector summary results.

There are two separate pages in the workbook that automatically prepare summary tables for these two types of analysis.

If you have collected procurement data from multiple sectors, be aware of which data set is included in the analysis (data columns set to '1') at the time that you are conducting cross-sector comparisons.

8.4.1 Cross-sector comparison of data for individual medicines

Begin the cross-sectoral analysis by using the **SUMMARY: PRODUCT COMPARISON** button on the *Home* page to go to the *Medicine Availability and Price Summary* page. This page is divided into two sections. The left side contains results on medicine availability for each surveyed medicine (Fig. 8.5), while the right side contains medicine-specific MPRs (Fig. 8.6). The data in this table are identical to the information in Columns J and E, respectively, of the individual *Field Data Consolidation* pages when the data view is displayed and ratios are turned 'on'. They are collected here for easy comparison. Both sections will automatically print in order when you use the Excel print functions described at the beginning of the chapter.

Interpreting medicine availability and price summaries

In Fig. 8.5, medicine availability results are displayed for the three sectors for which patient prices were collected (public, private, NGOs); the price results in Fig. 8.6 also contain MPRs for the procurement sector.

Fig. 8.5 Example of the summary page comparing medicine-specific availability across sectors

Medicines Availability And Price Summary

Go To Home Page

Medicine Name	Medicine list	Medicines Availability in Outlets: Brand – Public (n=30)	Brand – Private (n=30)	Brand – NGOs (n=22)	Brand – Other2 (n=)	Lowest Price – Public (n=30)	Lowest Price – Private (n=30)	Lowest Price – NGOs (n=22)	Lowest Price – Other2 (n=)
Albendazole	Regional	0.0%	83.3%	45.5%		36.7%	60.0%	54.5%	
Amitriptyline	Global	66.7%	83.3%	72.7%		70.0%	76.7%	63.6%	
Amoxicillin capitab	Global	0.0%	73.3%	36.4%		66.7%	66.7%	72.7%	
Amoxicillin suspension	Regional	70.0%	90.0%	100.0%		43.3%	33.3%	45.5%	
Atenolol	Global	40.0%	80.0%	54.5%		53.0%	70.0%	90.9%	
Atorvastatin	Regional	73.3%	20.0%	100.0%		0.0%	0.0%	0.0%	
Beclometasone inhaler	Regional	23.3%	0.0%	36.4%		23.3%	46.7%	45.5%	
Captopril	Global	0.0%	0.0%	0.0%		0.0%	0.0%	0.0%	
Carbamazepine	Regional	43.3%	0.0%	0.0%		30.0%	100.0%	100.0%	
Ceftriaxone injection	Global	70.0%	100.0%	81.8%		0.0%	0.0%	0.0%	
Chloramphenicol eye drops	Regional	46.7%	100.0%	54.5%		70.0%	0.0%	45.5%	

For the availability summaries, first look for availability issues for individual medicines to highlight in your report. For example, in Fig. 8.5, no captopril was found in any outlets, and the overall availability of beclometasone inhaler was quite low. These examples may point to policy or supply system issues that can be addressed to improve availability.

Next, examine the MPR data for issues to highlight (Fig. 8.6). In your report, you may want to give examples of medicines that have particularly high (e.g. originator brand atorvastatin) or low (e.g. lowest-priced generic co-trimoxazole suspension) MPRs in all sectors. Alternatively, you can highlight examples of medicines that have a particularly high originator brand premium (e.g. amoxicillin suspension in the private sector). Again, these examples may lead to insights into how the medicine supply system is working.

Fig. 8.6 Example of the summary page comparing medicine-specific median price ratios (MPRs) across sectors

	A	B	C	L	M	N	O	P	Q	R	S	T	U
1		Medicines Availability											
2		And Price Summary											
3													
4		Go To Home Page											
5													
6				Medicines Median Price Ratios (MPRs) in Procurements and Outlets									
7				(Reference Price Data Used - MSH 2006)									
8				Brand					Lowest Price				
9		Medicine Name	Medicine list	Procurement (n=4)	Public (n=30)	Private (n=30)	NGOs (n=22)	Other2 (n=)	Procurement (n=4)	Public (n=30)	Private (n=30)	NGOs (n=22)	Other2 (n=)
10		Albendazole	Regional	3.20		6.00	6.00		0.58	1.15	3.85	2.16	
11		Amitriptyline	Global	4.76	3.52	15.00	11.00		2.40	2.34	9.00	5.00	
12		Amoxicillin capfab	Global	1.60		2.70	2.80		0.80		1.80	1.70	
13		Amoxicillin suspension	Regional	2.30	2.62	10.00	9.00		0.99	1.32	2.55	2.10	
14		Atenolol	Global	1.95	2.13	24.00	16.00		0.75	2.64	22.84	5.50	
15		Atorvastatin	Regional	11.61	15.15	7.00	12.00						
16		Beclometasone inhaler	Regional		2.16		2.24		0.70	1.07	9.25	9.50	
17		Captopril	Global	4.10					0.96				
18		Carbamazepine	Regional		1.95				0.70	0.79	2.00	1.50	
19		Ceftriaxone injection	Global	5.62	1.70	21.00	14.00						
20		Chloramphenicol eye drops	Regional										
21		Ciprofloxacin	Global	1.80	2.11		1.80		0.80	0.81	9.25	6.90	
22		Co-trimoxazole suspension	Global	1.60	10.19	2.80	2.80		0.70	0.84	1.75	1.15	

8.4.2 Comparison of summary data for each sector

To compare summary data for medicine availability and price across sectors, click the **SUMMARY: SECTOR COMPARISON** button on the *Home* page. This will bring you to the *Sector Availability and Price Summary* page. Note that you can use the buttons in the left-hand corner to switch between analyses that report on all medicines, global medicines only and EML medicines only, etc.

There are two sections on the *Sector Availability and Price Summary* page. The top section (Fig. 8.7) contains the following information for each sector:

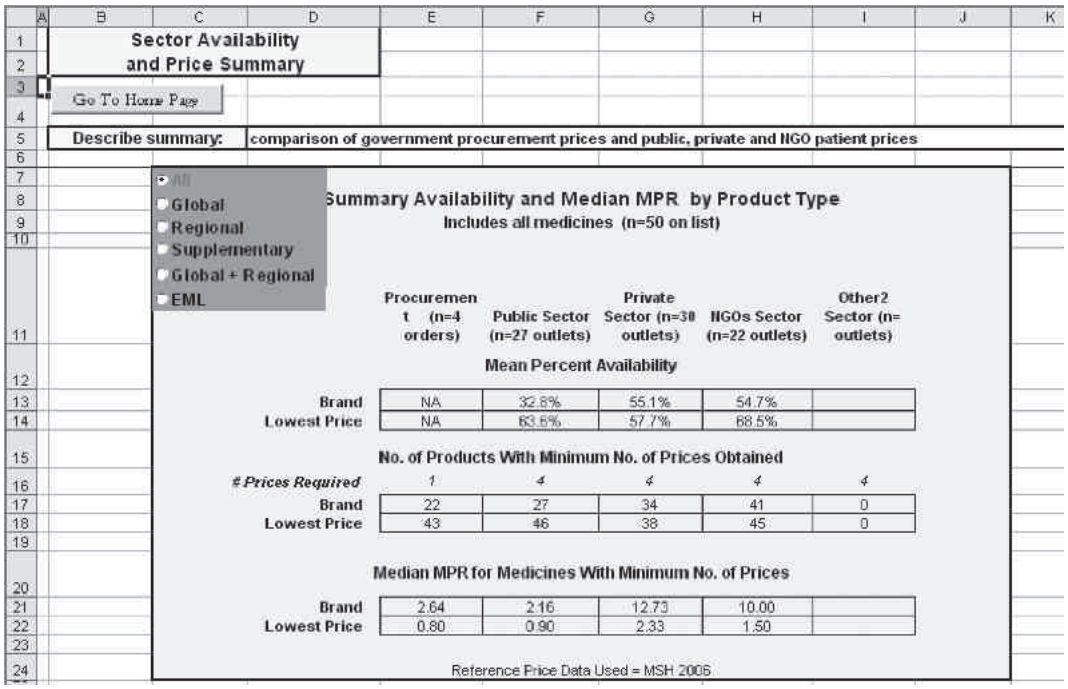
- mean (average) % availability of medicines;
- numbers of products with the minimum number of prices found; and
- median of the MPRs for medicines with the minimum number of prices found.

These data are identical to the data in the summary tables on the individual *Field Data Consolidation* pages. They are collected here for easy comparison. However, since data from different sectors will almost always be based on different baskets of available medicines, they may not be truly comparable.

The bottom section of the *Sector Availability and Price Summary* page (Fig. 8.8) contains matched pairs analysis between different pairs of sectors. In each comparison, only medicines found in both sectors are included in the analysis (i.e. based on the same basket of medicines). This enables valid price comparisons between sectors by controlling for differences in the availability of individual medicines.

Each table shown in Fig. 8.8 reports the median of the MPRs for the group of matching medicines found in two sectors. To the right of each table is the number of matching medicines found in both sectors, and the percentage difference between the median MPR in the right column of the table to the median MPR in the left column. Note that there are sufficient tables to allow comparisons between procurement, public sector, private sector and two 'other' sectors. However, if one or more of these sectors was not surveyed then some of the tables will be blank.

Fig. 8.7 Example of the summary page comparing overall medicine availability and price ratios (median MPR) across sectors



Sector Availability and Price Summary

Go To Home Page

Describe summary: comparison of government procurement prices and public, private and NGO patient prices

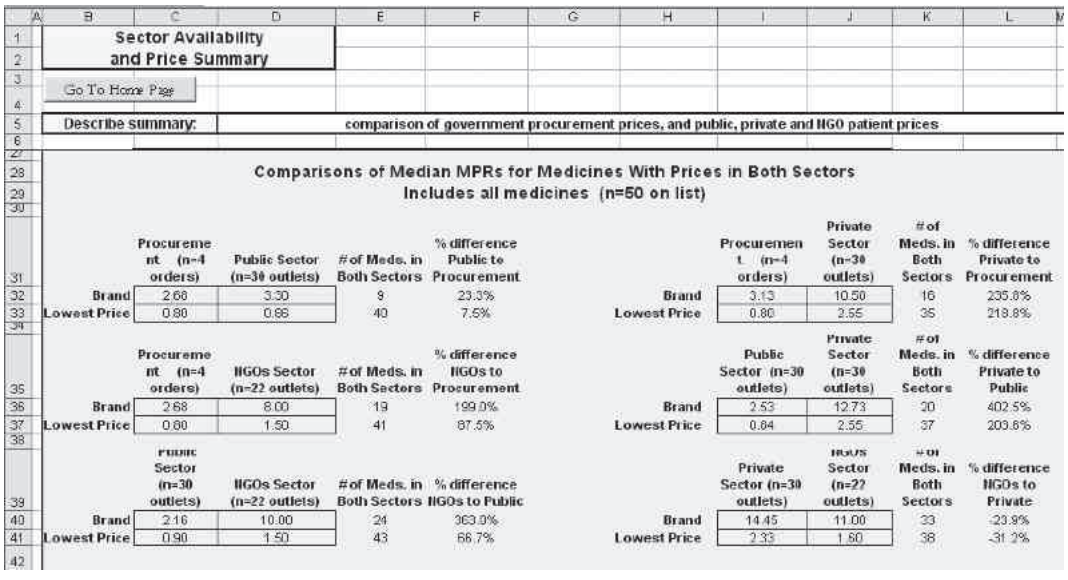
All
Global
Regional
Supplementary
Global + Regional
EML

Summary Availability and Median MPR by Product Type
Includes all medicines (n=50 on list)

	Procurement (n=4 orders)	Public Sector (n=27 outlets)	Private Sector (n=30 outlets)	NGOs Sector (n=22 outlets)	Other2 Sector (n= outlets)
Mean Percent Availability					
Brand	NA	32.8%	55.1%	54.7%	
Lowest Price	NA	63.6%	57.7%	68.5%	
No. of Products With Minimum No. of Prices Obtained					
# Prices Required	*1*	*4*	*4*	*4*	*4*
Brand	22	27	34	41	0
Lowest Price	43	46	38	45	0
Median MPR for Medicines With Minimum No. of Prices					
Brand	2.64	2.16	12.73	10.00	
Lowest Price	0.80	0.90	2.33	1.50	

Reference Price Data Used = MSH 2006

Fig. 8.8 Example of summary page comparing medians of median price ratios (MPRs) across sectors using matched pairs analysis



Sector Availability and Price Summary

Go To Home Page

Describe summary: comparison of government procurement prices, and public, private and NGO patient prices

Comparisons of Median MPRs for Medicines With Prices in Both Sectors
Includes all medicines (n=50 on list)

	Procurement (n=4 orders)	Public Sector (n=30 outlets)	# of Meds. in Both Sectors	% difference Public to Procurement
Brand	2.68	3.30	9	23.3%
Lowest Price	0.80	0.86	40	7.5%

	Procurement (n=4 orders)	NGOs Sector (n=22 outlets)	# of Meds. in Both Sectors	% difference NGOs to Procurement
Brand	2.68	8.00	19	199.0%
Lowest Price	0.80	1.50	41	87.5%

	Public Sector (n=30 outlets)	NGOs Sector (n=22 outlets)	# of Meds. in Both Sectors	% difference NGOs to Public
Brand	2.16	10.00	24	363.0%
Lowest Price	0.90	1.50	43	66.7%

	Procurement (n=4 orders)	Private Sector (n=30 outlets)	# of Meds. in Both Sectors	% difference Private to Procurement
Brand	3.13	10.50	16	235.8%
Lowest Price	0.80	2.55	35	218.8%

	Public Sector (n=30 outlets)	Private Sector (n=30 outlets)	# of Meds. in Both Sectors	% difference Private to Public
Brand	2.53	12.73	20	402.5%
Lowest Price	0.84	2.55	37	203.6%

	Private Sector (n=30 outlets)	NGOs Sector (n=22 outlets)	# of Meds. in Both Sectors	% difference NGOs to Private
Brand	14.45	11.00	33	-23.9%
Lowest Price	2.33	1.60	38	-31.2%

Interpreting cross-sector comparisons of medicine availability and price summary data

Begin your analysis by focusing on the top section of the *Sector Availability and Price Summary* page, which summarizes medicine availability and price by originator brand and lowest-priced generic equivalent. In the example in Fig. 8.7, lowest-priced generic equivalents are more widely available than originator brands in all sectors. The lower availability of originator brands is not necessarily a cause for concern provided that generic equivalents are available.

Price comparisons across sectors must be based on comparable baskets of medicines in each sector. If prices were found for nearly all of the medicines within each sector, the summary data at the top of the page would be fairly comparable across sectors. However, if prices for all medicines were not found, and especially if different medicines were found in each sector, data will not be comparable.

Fig. 8.7 shows that the number of medicines found varied by sector. For example, only 27 originator brands were found in at least four outlets in the public sector, while 34 and 41 originator brands had the minimum number of prices in the private and NGO sector outlets, respectively. Because of variability in medicines between sectors, inter-sector price comparisons should be based on the matched pairs analyses in Fig. 8.8 and not on the MPRs shown in Fig. 8.7.

The results of the matched pairs analysis are presented in the bottom section of the page (Fig. 8.8), in which summaries are based on the same basket of medicines.

While the workbook provides sector comparisons for each of the sectors included in the survey, some comparisons may not be particularly useful or relevant. Where patients pay for medicines in the public sector, the difference between procurement prices and patient prices represents the total medicine mark-up in the public sector distribution chain, provided no local purchasing is taking place. In the upper left table of Fig. 8.8, it can be seen that government facilities charge a 23.3% mark-up on originator brand medicines and a 7.5% mark-up for generic medicines.

It is also useful to compare patient prices in the public, private and other sectors to see which sectors have large price differentials. In the example in Fig. 8.8, the prices in private sector outlets are 203.6% higher than public sector prices for lowest-priced generics and 402.5% higher than public sector prices for originator brands. The charges to patients in NGO facilities are lower than the prices charged in the private sector (23.9% lower for originator brands and 31.2% lower for lowest-priced generics). However, originator brands and lowest-priced generics in the NGO sector cost 363.0% and 66.7% more, respectively, than in the public sector.

Several factors may explain the variability in prices paid by patients in different sectors:

- The three sectors have different purchasing and distribution efficiency.
- The public and NGO sectors may use medicine sales as a cost-recovery mechanism to finance operating expenses.
- Prices and mark-ups are unregulated and highly variable.

These issues are examined further in the price composition analyses (Chapter 9). Future studies can focus on hypotheses generated about the reasons for similarities and differences in prices.

Reporting cross-sector comparisons of medicine availability and price summary data

The way in which you report intersector comparisons will vary considerably from survey to survey, depending on the nature of the differences between sectors in your setting and the actual results of the comparisons. The standard report template (Chapter 12) provides guidance on reporting medicine availability and price summaries that can be adapted or expanded as appropriate.

Begin by comparing medicine availability. You might expect that availability for originator brand items would be better in the private sector while generics might be more widely available in the public sector. However, your situation may be different. If it is, check your data and investigate the reasons for these differences.

For pricing analyses, you have the opportunity to compare median patient prices in each sector to:

- international reference prices, either from MSH or another set;
- public procurement prices; and
- patient prices in other sectors.

Results may differ across sectors for originator brands and generics. Depending on the findings, your report could go into great detail on these comparisons, including references to individual products that reveal interesting facts about the way in which pricing operates in your setting.

In your report's text you do not need to quote all the comparison price ratios or percentages, but you may wish to highlight important or particularly interesting ones, while referring readers to tables with individual medicine or sector summary results for more detailed examination of differences.

8.5 SUBGROUP ANALYSIS

The national analyses using the complete sample of field data are the pricing survey's primary focus. However, you may also wish to assess or compare prices in different subgroups within a sector, such as:

- prices in outlets from different regions;
- prices in urban vs rural areas;
- prices in public facilities for a specific level of care (e.g. primary, secondary or tertiary);
- public procurements by the central ministry of health versus regional procurement agencies; and
- prices for specific groups of medicines, such as medicines from the same therapeutic class.

If you have collected procurement data from multiple sectors, data from each sector must be analysed separately. This can be done by following the procedures for subgroup analysis described below.

To allow for analysis by subgroups of medicines and facilities, the *Field Data Consolidation* pages permit you to select individual columns (i.e. facilities) and rows (i.e. medicines) of data for the analysis. That is, you can include or exclude data from specific medicine outlets by turning on/off the column where the data are contained, and include or exclude data for specific medicines by turning on/off the corresponding row.

By default, analyses in the workbook include all the columns and rows of data you enter. To make it easier to exclude certain columns, the *Field Data Consolidation* pages allow you to sort procurements or outlets (left to right) by variables you entered as identifying information. For the *Medicine Procurement Prices* page, these identifying variables are:

- Procurement ID number (Row 7)
- Procurement agency (Row 8)
- Procurement date (Row 9)
- Number (Row 12)

For the other *Field Data Consolidation* pages, the variables are:

- Medicine outlet study ID number (Row 7)
- Region (Row 8)
- Distance from the nearest population centre (Row 9)
- Level of care (Row 11)
- Number (Row 12).

Pressing the Number button returns to the original sort order.

8.5.1 Selecting subgroups

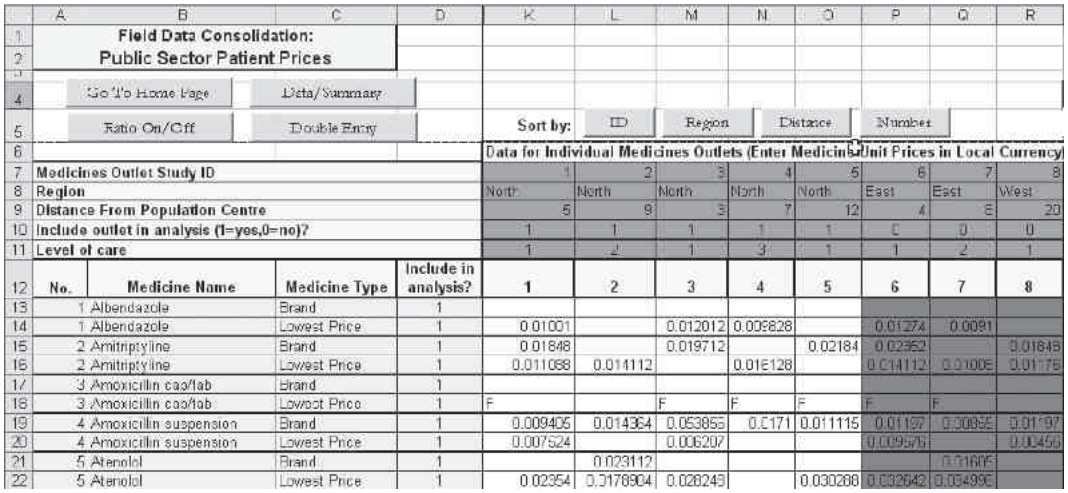
Row 10: Include outlet in analysis (1 = yes, 0 = no) allows you to include/exclude data from individual medicine outlets in the analysis. Changing the '1's in Row 10 to '0's will exclude the columns from calculations (excluded columns are shaded grey). To include columns again, either change the '0's back to '1's, or press the **INCLUDE ALL OUTLETS** button.

For example, Fig. 8.9 shows prices from public sector outlets that have been sorted by region; in this example, all outlets except those in the North region have been excluded. Alternatively, if you were interested in the effect of distance, you could sort by distance and exclude all columns above or below a target distance (e.g. include all outlets further than 10 km from a population centre). Fig. 8.10 shows procurement data from two different sectors that have been entered into the same *Field Data Consolidation: Medicine Procurement Prices* page. Because each sector must be analysed separately, procurement data from the NGO sector has been excluded while data from the public sector are analysed.

Column D: Include in analysis also allows you to include/exclude data from individual medicine products. For example, you may wish to conduct a subanalysis of a specific therapeutic category. Changing the '1's in Row 10 to '0's will exclude medicine products from calculations (excluded rows are shaded grey).

If a medicine is under patent and no generics are registered, the lowest-priced generic row for this particular medicine should always be 'turned off' (i.e. excluded from all analyses since it was not surveyed). Similarly, for an older medicine where the originator brand cannot be identified, the originator row should always be 'turned off'. Otherwise, your analysis will include medicine products that were not surveyed, which will skew the results.

Fig. 8.9 Selecting subgroups of outlets for analysis: analysis by region



		Field Data Consolidation: Public Sector Patient Prices											
		Go To Home Page	Data/Summary										
		Ratio On/Off	Double Entry	Sort by:	ID	Region	Distance	Number					
				Data for Individual Medicines Outlets (Enter Medicine Unit Prices in Local Currency)									
		Medicines Outlet Study ID		1	2	3	4	5	6	7	8		
		Region		North	North	North	North	North	East	East	West		
		Distance From Population Centre		5	9	3	7	12	4	6	20		
		Include outlet in analysis (1=yes,0=no)?		1	1	1	1	1	0	0	0		
		Level of care		1	2	1	3	1	1	2	1		
No.	Medicine Name	Medicine Type	Include in analysis?	1	2	3	4	5	6	7	8		
1	Albendazole	Brand	1										
1	Albendazole	Lowest Price	1	0.01001		0.012012	0.009828		0.01274	0.0091			
2	Amitriptyline	Brand	1	0.01848		0.019712		0.02184	0.02352		0.01848		
2	Amitriptyline	Lowest Price	1	0.011088	0.014112		0.016128		0.014112	0.01008	0.01176		
3	Amoxicillin cap/tab	Brand	1										
3	Amoxicillin cap/tab	Lowest Price	1	F		F	F	F	F	F			
4	Amoxicillin suspension	Brand	1	0.009405	0.014364	0.053855	0.0171	0.011115	0.01197	0.00855	0.01197		
4	Amoxicillin suspension	Lowest Price	1	0.007524		0.006207			0.009576		0.00456		
5	Atenolol	Brand	1		0.023112					0.01605			
5	Atenolol	Lowest Price	1	0.02354	0.0178904	0.028243		0.030268	0.032642	0.024996			

Fig. 8.10 Analysis of procurement data by sector

		Field Data Consolidation: Medicine Procurement Prices											
		Go To Home Page	Data/Summary										
		Ratios On/Off	Double Entry	Sort by:	ID	Agency	Date	Number					
				Data for Procurement Orders (Enter Medicine Unit Prices in Local Currency)									
		Procurement ID		A	B								
		Procurement Agency		MOH	NGO								
		Date (Mon-YY as in Jan-02)		Feb-07	Mar-07								
		Include order in analysis (1=yes, 0=no)?		1	0	0	0	0	0	0	0		
No.	Medicine Name	Medicine Type	Include in analysis?	1	2	3	4	5	6	7	8		
1	Albendazole	Brand	1	0.029	0.0514								
1	Albendazole	Lowest Price	1	0.006	0.0034								
2	Amitriptyline	Brand	1	0.0218	0.0315								
2	Amitriptyline	Lowest Price	1	0.015	0.0118								
3	Amoxicillin cap/tab	Brand	1	0.0420									
3	Amoxicillin cap/tab	Lowest Price	1	0.0084									
4	Amoxicillin suspension	Brand	1	0.0086	0.0120								
4	Amoxicillin suspension	Lowest Price	1	0.0068	0.0046								
5	Atenolol	Brand	1	0.016	0.0103								
5	Atenolol	Lowest Price	1	0.0086	0.0118								

8.5.2 Comparing subgroups

Go to the *Field Data Consolidation* page for the sector for which you would like to conduct subgroup analysis. The data entry grid should be visible ('data' view with ratios turned 'off').

To compare subgroups of medicine outlets, use Row 10 to include ('1') the medicine outlets corresponding to the subgroup you wish to analyse and to exclude ('0') all other data. To compare subgroups of medicines, use Column D to include ('1') the medicines corresponding to the subgroup you wish to analyse and to exclude ('0') all other data. Go to the summary view by clicking on the **DATA/SUMMARY** button. You are provided with a space to describe the sample of data included in the analysis; **be sure to complete this description before printing**. After printing out the summary table you can go back to the data entry grid and change the subgroup of medicine outlets/medicines included in the analysis. By printing a (clearly labelled!) summary table for each subgroup, you can then compare different subgroups as you write your report.

When analysing subgroups, you should take account of the sample size of each group. In some cases the sample size will be so small that the results are no longer representative. For example, in analysing medicine availability in the public sector according to level of care, you may only have a small number of tertiary hospitals. In this case you should report results as absolute numbers (e.g. medicine X was found in two out of three outlets) rather than as a percentage value (e.g. availability of medicine X was 66.7%).

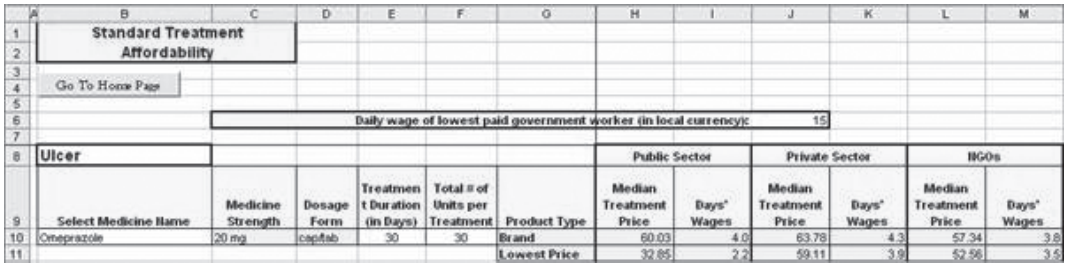
Always make sure you re-include medicine outlets and medicine products before proceeding with the general survey analysis. The number of medicine outlets and medicines included in the analysis can be checked on the *Field Data Consolidation: Summary* pages.

8.6 ANALYSIS OF TREATMENT AFFORDABILITY

The affordability analysis expresses the survey results in a different way. Instead of comparing medicine prices with an index price, the cost of a course of therapy for important conditions can be compared with the daily wage of the lowest-paid unskilled government worker. This analysis is very valuable as an advocacy tool since it expresses prices in relation to an individual's ability to pay rather than to international prices. It is much easier to explain to policy-makers that the cost of a month's treatment for a specific condition with Medicine X would require 10.5 days' wages with originator brand products and 6.3 days' wages with a low-cost generic alternative. To the extent that standard treatments are similar across countries, expressing results in this way also allows international comparisons of price levels that are not affected as much by differences in economic structures and exchange rates.

Click on the **TREATMENT AFFORDABILITY** button on the *Home* page to go to the *Standard Treatment Affordability* page. The process for defining and entering data on days' wages and on the standard treatments for individual conditions is described in Chapter 7 (pages 95–97). After you have completed this process, the workbook will automatically calculate the affordability measures in each sector and for each product type for which you have sufficient price data in the *Field Data Consolidation* pages. An example of affordability analysis for treatment of an ulcer is provided in Fig. 8.11.

Fig. 8.11 Example of standard treatment and affordability for treating an ulcer with one month's supply of omeprazole 20mg daily



Standard Treatment Affordability

Go To Home Page

Daily wage of lowest paid government worker (in local currency): 15

Ulcer

Select Medicine Name	Medicine Strength	Dosage Form	Treatment Duration (in Days)	Total # of Units per Treatment	Product Type	Public Sector: Median Treatment Price	Public Sector: Days' Wages	Private Sector: Median Treatment Price	Private Sector: Days' Wages	NGOs: Median Treatment Price	NGOs: Days' Wages
Omeprazole	20 mg	capltab	30	30	Brand	60.03	4.0	63.78	4.3	57.34	3.8
					Lowest Price	32.85	2.2	59.11	3.9	52.56	3.5

To analyse the data, compare the median treatment price and number of days' wages required across sectors and for different product types. Although it is difficult to assess true affordability, treatments costing one day's wage or less (for a full course of treatment for an acute condition or a 30-day supply of medicine for chronic diseases) are generally considered affordable. In the example, median treatment costs for omeprazole treatment in public sector health facilities, private pharmacies and NGO facilities are very similar, with the exception of lowest-priced generics in the public sector. In all other cases, purchasing a month of therapy with originator brand or lowest-priced generic omeprazole would require 3.5 to 4.3 days' wages. In contrast, purchasing the lowest-priced generic omeprazole from the public sector is about half as expensive, costing 2.2 days' wages. Several conclusions can be drawn:

- Treating an ulcer with omeprazole may be unaffordable for many patients in all sectors.
- Even the lowest-priced generic omeprazole in the public sector is still unaffordable for many low-income patients, at just over 2 days' wages.
- In the public sector, patients would need to spend nearly twice as much to purchase originator brand omeprazole than the lowest-priced generic.

When analysing standard treatment data, be sure to examine the range of variation in medicine prices within each of the sectors in the summary ratio section of the *Field Data Consolidation* pages (see Fig. 8.3). Treatments for which the median prices are similar in two sectors may actually vary widely across outlets within the sectors.

Remember that for standard treatments that require more than one medicine, it will be necessary to enter each medicine separately and then add together the data on Median Treatment Price and Days' Wages for both medicines to get correct summary information for the treatment as a whole.

Treatment affordability should always be examined in conjunction with availability data. A treatment may appear affordable in a given sector, but if the availability of the medicine in that sector is low, patients will not benefit from this low cost. Instead, they will be forced to obtain medicines from a different sector where treatments may be much less affordable. When analysing affordability, always check the availability of medicines used in different courses of treatment. Where a treatment appears affordable in a given sector but availability in that sector is low, this should be noted in the survey report.

The section on affordability in your report should highlight the findings for key conditions of public health importance in your setting. Some conditions may be affordable

for low-paid workers to treat, while others may be completely out of their range. Try to describe the situation for both acute and chronic illnesses. For chronic illnesses, you should express the treatment in monthly amounts, which you would calculate by multiplying the daily dose by 30. Be sure to use the amount for a month's treatment for chronic conditions in the Total # of Units per Treatment field.

In some countries, many people may earn much less than the lowest government wage. Therefore, treatments that appear relatively affordable may still be out of reach for much of the population. This can be illustrated in the survey report by noting the proportion of the population living on less than 1 US dollar per day (international poverty line) and 2 US dollars per day.[1]

[1] World Bank Development Indicators, (http://devdata.worldbank.org/wdi2006/contents/Section2.htm, accessed 25 February 2008).

9

Measuring price components

9.1 BACKGROUND

The price paid for a medicine comprises a number of *price components*, the manufacturer's selling price (MSP) being just one of them. As medicines move along the supply chain, from the manufacturer to the patient, additional costs are added to the MSP. These price components come from a variety of sources, such as freight costs, government-collected tariffs, taxes and mark-ups collected by middlemen to meet their overheads, and procurement procedures. Such fees are often high, regularly constituting between 30% and 45% of the price of the dispensed medicine but they can even exceed 100% (*1*–*3*). Price components are a concern for all actors involved in public health and access to medicines, from governments, nongovernmental organizations (NGOs) and social insurance plans to prescribers and patients.

Price components have both a direct and cumulative impact on the price of the medicine. Since price components are cumulative (i.e. each is applied to the running total), each price component rises from the base (MSP) price on which all subsequent charges are levied. Even a relatively small price component early in the supply chain can contribute significantly when its effects are compounded as other price components are applied.

Governments may not always have a complete picture of medicine price components because different ministries may be involved in purchasing and distributing essential medicines. However, accurate information on the various price components, including the MSP, is needed to develop measures that reduce the prices paid for medicines, make distribution systems as efficient as possible and enable reliable international price comparisons.

Before the WHO/HAI Project on Medicine Prices and Availability, there was no methodology to systematically collect, analyse and compare information on medicine price components. Accurately budgeting total costs for service delivery and making careful predictions about how many patients can be treated are difficult without a clear understanding of the costs incurred in procuring, storing and distributing medicines. Unreliable information on medicine prices and the inability to analyse their price components hamper governments from constructing sound medicine pricing policies and evaluating their impact. It also makes it hard for governments to determine whether their medicine expenditure is comparable to that of other countries at a similar stage of development. Finally, those responsible for purchasing

medicines cannot negotiate better deals because they have no sound basis from which to start their negotiation.

As part of the WHO/HAI medicine prices survey, individual price components and their impact on medicine prices at the point of delivery are being investigated. The data collected on price components can be used to develop national pharmaceutical policies, such as creating tax and tariff exemptions, controlling mark-ups and establishing government-recommended selling prices, which aim to increase access to life-saving medicines.

The Price Components study has two goals. The first three-pronged goal is to help the participant categorize price component costs in the national health system; identify those components with the most significant contribution to the final price; and develop pharmaceutical policies that can reduce the price paid for dispensed medicines. The second goal is to gather data on the manufacturer's selling price for reliable international price comparisons. As with the data gathered on medicine prices, availability and affordability, price component data will also be posted on the WHO/HAI Medicine Prices web site, which will provide global market intelligence of the manufacturers' selling prices. The web site will also allow international comparisons of medicine prices at different stages of the supply chain.

The price components survey is an integral part of the medicine prices survey.

9.2 OVERVIEW OF THE PRICE COMPONENTS SURVEY METHODOLOGY

The price components data collection methodology has two parts: a pharmaceutical policy investigation at the central level and research into actual price components along the medicine distribution chain. WHO and HAI conducted an in-depth validation study in three countries (Morocco, Pakistan and Uganda) in 2005 and an additional study in New Delhi, India, in 2007 (*4*, *5*), which confirm the appropriateness of the methodology.

Data collection begins at the central level where investigators gather information on national policies that affect pharmaceutical prices. This includes:

- information on import tariffs on finished products, including exemptions for particular products and for certain buyers;
- financial charges incurred in importing pharmaceuticals, such as charges for letters of credit at the central bank or charges for foreign currency transactions;
- policies on taxes levied on medicines, both along the supply chain and to the final customer;
- policies that control mark-ups in the supply chain;
- policies on quality assurance, as set by the ministry of health, and associated charges for any required quality control tests;
- the entry points of imported medicines into the country as well as the port fees and the costs for customs clearing that are incurred.

Collecting these data will require interviewing staff in various ministries and healthcare delivery systems to identify what mark-ups are allowed by law and any restrictions that are imposed on them (for example, a maximum mark-up).

The survey's second part comprises collecting the actual price components of selected medicines as they move along the supply chain. Since there are many possible distribution routes and intermediaries, the survey begins at the end of the supply chain and tracks each medicine backwards to the beginning. That is, researchers must begin at the end of the supply chain – at the dispensaries in the public sector or retail pharmacies in the private sector – and track the targeted medicine to the beginning of the supply chain – the manufacturers or importers.

Data are collected in at least the public and private sectors, as well as any 'other' sector used in the medicine prices survey, in two regions. Five to seven medicines are tracked from the time they are procured from the manufacturer until they reach the patient. Medicines are selected to reflect a range of categories (e.g. single- and multi-source products, imported and locally produced products) in which different price structures could be found. Where possible, data are collected for both the originator brand product and a generic equivalent for each medicine.

At the dispensaries or private retail pharmacies, investigators collect information on the procurement price and the dispensing price, and identify the wholesaler or public sector supplier for each medicine. They also note any mark-ups, taxes and dispensing fees. Once investigators have visited all dispensing points they aggregate the wholesaler information to identify which wholesalers should be interviewed. Next the investigators visit these wholesalers and public sector suppliers, and collect information on wholesale mark-ups, local distribution costs and any taxes collected. At the wholesalers/public sector suppliers, investigators will identify the international supplier or local manufacturer. Investigators will visit as many of the supply chain stages as possible, and gather as much information on the price components as can be found. Data collection continues at each stage of the supply chain within the target country, ending with the importer (for imported medicines) and the manufacturer (for those medicines that are locally produced).

The data collected on the components of medicine prices are analysed according to five common stages of the supply chain that all medicines traverse as they move from manufacturer to patient:

- manufacturer's selling price + insurance and freight (Stage 1);
- landed price (Stage 2);
- wholesale selling price (private) or central medical stores price (public) (Stage 3);
- retail price (private) or dispensary price (public) (Stage 4); and
- dispensed price (Stage 5).

This categorization allows comparisons both among health systems and between countries. The collected data are entered into the *Price Components Data Entry* page of the computerized workbook (Part II). The *Price Components Data Analysis* page will help investigators study the different components and identify those with the most significant impact. The price components survey findings should be included as a case study in the general medicine prices and availability survey report. As with other survey data, price components data are published on the HAI web site for cross-country analyses of the manufacturers' selling prices and price component structures.

Results from the price components survey are presented as a case study, rather than as quantitative research results.

9.3 OVERVIEW OF PRICE COMPONENTS

Price components vary among countries, among sectors of the health-care system and among medicines. For example, certain classes of medicines (e.g. life-saving medicines) might be exempted from a mark-up or the public sector might be exempted from certain taxes and tariffs. Some countries administer originator brand and generically equivalent medicines differently. The following price components are commonly found in the medicine price chain:

- MSP
- Insurance and freight
- Port and inspection charges
- Pharmaceutical import duties
- Mark-ups by importers, wholesalers and retail distributors
- Value Added Tax (VAT)/Goods and Services Tax (GST)
- Dispensing fees.

To understand the impact of these component costs, the supply chain has been divided into five stages that medicines traverse as they move from manufacturer to patient (see Fig. 9.1). The components in each stage vary by country, and components are incurred in different orders. However, using the five-stage approach allows for comparisons at the end of each stage among sectors and among countries.

STAGE 1: MSP plus insurance and freight. For locally produced medicines, the Stage 1 cost is the MSP for the recommended or surveyed pack size, plus (possibly) domestic transport to the purchasing entity. For imported medicines, the Stage 1 cost is the MSP plus insurance and international freight (CIF).

STAGE 2: Landed price. The landed price includes all other price components that arise during medicine procurement and delivery to the procurement office. This includes banking fees for foreign currency purchases, inspection charges (either pre- or post-shipment), port fees (docking, storage, handling, insurance in port), customs clearing, import tariff and importer's mark-up. Any fees collected centrally are listed here, e.g. the Pharmacy Board fee. The landed price also includes local transport charges to the central warehouse, the importer or the wholesaler but does not include domestic storage and distribution costs after the medicines leave the purchasing warehouse.

STAGE 3: Wholesale selling price (private) or Central Medical Stores price (public). The wholesale selling price or Central Medical Stores price is based on the landed price, and includes either the wholesaler's additional expenses or the central warehouse's overhead costs, e.g. quality control, storage, handling, overhead expenses (such as salaries, security and rent) and profit margin as well as local transport to the retailer/health facility. Many of these might be included in the wholesale mark-up; it is important not to count them twice.

STAGE 4: Retail price (private) or dispensary price (public). The retail (pharmacy) selling price is based on the wholesale selling price, and includes the retailer's/dispensary's additional expenses, e.g. storage, handling, overhead expenses and profit margin. Many of these expenses might be included in the retailer's mark-up; it is important not to count them twice.

STAGE 5: Dispensed price. The dispensed medicine price includes the Stage 4 price plus any dispensing fees and any sales taxes (VAT or GST), if applicable. Where there is no dispensing fee or sales tax applied, there are no Stage 5 costs and the price at the end of Stage 4 is the dispensed price. Furthermore, in many public sector programmes the patient does not pay; the cost at the end of Stage 5 is intended to reflect the cost at the point of delivery, whether to the health system, insurance group or patient.

BOX 9.1

A note on mark-ups

A mark-up is a charge added to the purchasing price to cover the costs and margins of the wholesaler or retailer. The mark-up may be a fixed amount or a percentage charge. In some countries, the government sets a maximum wholesale or retail mark-up. In other cases, pricing is unregulated: the government does not restrict the margins and manufacturers, wholesalers and pharmacies may charge what they wish. Some countries apply a combination at the retail level of a smaller fixed mark-up plus a set dispensing fee. Where a government sets limits on mark-ups but is not able to enforce these limits, the result can be that wholesalers and retailers charge higher mark-ups than allowed by law. But in very competitive markets wholesalers and retailers might collect less than the maximum mark-ups to gain more customers.

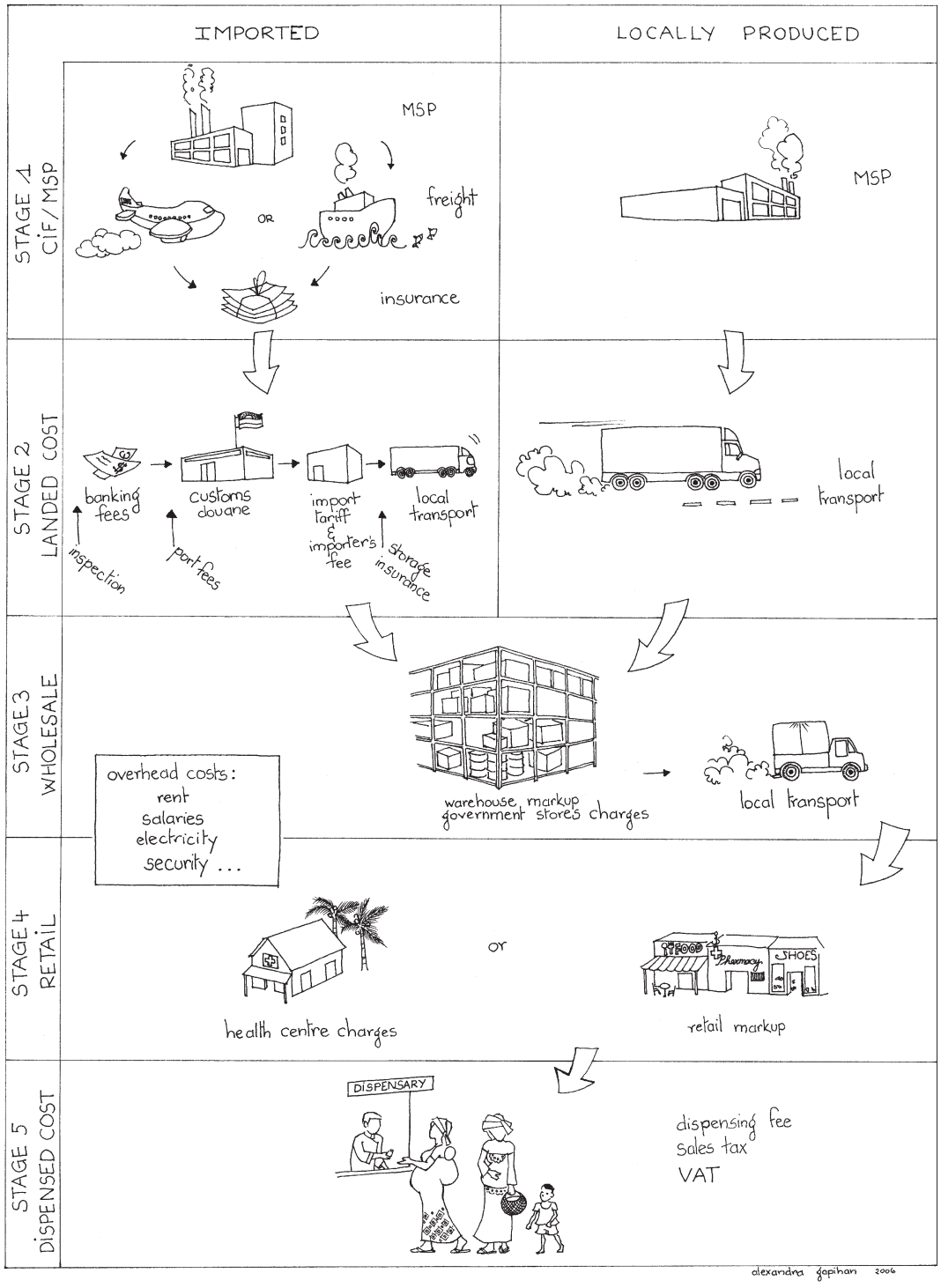
Fig. 9.1 illustrates the staged approach to price components. Dividing the supply chain into stages in this way has several advantages. The division into Stage 1 and Stage 2 allows countries to examine the MSP cost separately from the costs of procuring and landing the product. The division between Stage 2 and Stage 3 allows for comparison of the landed cost of the medicine at the port or at the importer's warehouse before it enters the domestic distribution system. Distinguishing between the wholesaler and the retailer selling prices (Stage 3 from Stage 4) allows the investigator to examine the mark-ups that cover the overhead costs and profit margins of these actors in the supply chain. The information collected in Stage 5 is important for understanding fees the patient pays that are separate from the retailer's mark-up, plus any taxes applied at the retail level.

Price component names vary widely between countries. The next section provides a list of price components, with a definition and an example for each. Use these descriptions both as a guide to what costs to look for and to match the price components you find in your research. These are the most common price components discovered to date; other countries might have different ones.

9.3.1 Stage 1: Manufacturer's selling price + insurance and freight

The Stage 1 price comprises two prices: a medicine's base price (MSP) and insurance and freight charges. For an imported product, this is the MSP plus costs for insurance and freight to the importing country. For a locally produced medicine, the Stage 1 price is the MSP. Defining Stage 1 in this way allows for comparisons of

Fig 9.1 The staged approach to price components



prices between imported and locally produced equivalent medicines, and identifies the MSP.

Manufacturer's selling price (MSP)

The MSP is the price the manufacturer charges for the medicine.

Insurance and freight

Insurance and freight are the costs of insuring and shipping the products to the destination country. For locally manufactured products, these components do not apply.

Shipping costs are accounted for in different ways. The principal shipping terms are:

EXW: EX-Works: The selling price reflects the price at the purchase site. The buyer is responsible for all insurance and freight costs.

FOB: Free on Board: The seller is responsible for transport to the port of shipment (in the exporting country); the buyer is responsible for international shipping and insurance.

CIF: Cost, Insurance, Freight: The seller is responsible for freight to the destination port and includes this cost in the selling price; the buyer is responsible for insurance once goods are loaded on the carrier and all costs after arrival in port.

DDU: Delivered Duty Unpaid: The seller is responsible for insurance and freight to a named place of destination; the buyer assumes responsibility for insurance and transport, including import duties, once delivered.

It is important that investigators try to separate the MSP from insurance and freight, although it might not always be possible. Manufacturers sell the same product to different organizations for different prices: when the MSP is coupled with the shipping costs this is difficult to see. These price differences occur for many reasons, among them: some procurement offices have better negotiating skills; some have better access to market intelligence; and some are being penalized for a poor payment history. Separating the MSP and the insurance and freight will allow for more accurate international price comparisons.

MSP information can be a challenge to find (although countries have managed to do so), particularly in the private sector. However, this survey's aim is to identify it as accurately as possible. In the public and 'other' sectors, the investigator should check the awarded tender price. For imported products it is necessary to check if the tender price is EXW, FOB, CIF or DDU. In the private sector, the wholesaler(s), the customs office or the ministry of health will often be able to provide information on the import price (Stage 1 price), which they know for tariff purposes. For locally procured products, the MSP is the price that the wholesaler or the public or private procurement agency pays a local manufacturer. Remember that there are two sides to every transaction: one side might be easier to approach than the other.

9.3.2 Stage 2: Landed price

The landed price is the cost of the medicine after it has arrived in a country, has cleared all customs and import requirements, and is then transported to the wholesaler, the importer or Central Medical Stores. This stage also includes the price components that arise from the procurement process. The landed price therefore

includes, among others, the MSP, insurance and freight costs, inspection, import tariffs, inspection and port charges and local transport costs to the wholesaler, importer or Central Medical Stores. These are described below.

Finance/banking fees

Procuring pharmaceuticals usually involves large tenders worth millions of dollars. Investigators should ask about the cost for letters of credit, the purchase of foreign exchange, special foreign currency bank accounts, commissions and special licences for importation. Moreover, banks often require a currency deposit or a contingency fee to guarantee the availability of funds. Contingency fees only become price components when the contingency fee is collected, but bank handling or administrative fees are often collected. Investigators should consult with an international bank to identify these and other financial costs.

International inspection

Products crossing borders are inspected to verify quantity, quality, export market price, import customs value and import eligibility. Inspection can be carried out either prior to shipment or upon arrival in the receiving country. Fees for inspection are either based on a percentage of the order value or are a minimum flat fee (usually for small orders). The inspection fee is paid either by the importer/buyer or, in the case of pre-shipment inspections, can be included in the selling price. Pre-shipment inspection fees are often labelled 'SGS fees'. Investigators should check with the customs office and the ministry of trade to find these costs.

Inspection fees are a special case when filling in the Collection sheet and the workbook. In order to allow comparisons of all inspection fees, you are asked to record both pre-shipment and in-country inspection fees as Stage 2 price components.

Import tariff or duty

If there is an import tariff, it may apply to all imported medicines or there might be a system to exempt certain products and purchasers. Investigators should check whether an import tariff is levied on the target medicines. In addition, check whether the same level of tax or duty applies to all products. Exemptions for different products, different sectors, and different delivery programmes should be reported. (Note that import tax or duty may also apply to imports of raw material for local production, but this is outside the scope of this study. You can mention this in the final report.) Investigators can check with any tax official about tariffs that apply to medicines.

Importer's mark-up

The importer purchases pharmaceuticals internationally and sells them domestically to various health systems. The importers will add a mark-up to cover their costs and profit. Importers' costs include local storage (rent, utilities, staff), local transport, packaging and marketing. When listing the importer's mark-up, take care not to 'double count' costs recorded elsewhere (e.g. the import tariff). If the

importer's mark-up is government-regulated in your country, please note that fact in your final report.

Port and clearing charges

Other charges may be collected to cover such costs as clearance, temporary storage, stamp duty, handling and insurance in port. Governments may charge for documentation, such as data collection for statistical purposes. Investigators should interview importers to identify these costs.

Pharmacy board fee or national drug authority fee

A pharmacy board fee is a charge on medicines (percentage or fixed fee) collected in some countries that goes to the pharmacy board (council) or similar body, or the national drug regulatory authority. In some countries, this fee is applied to all medicines, while others apply it only to imported medicines or locally manufactured medicines. The pharmacy board fee should not be confused with the registration fee collected by the national drug regulatory authority to register a product for use in country. The pharmacy board fee is based on volume or number of purchases, while the registration fee is a one-time (or once a year) per item fee. Check with the pharmacy board, as well as the ministries of health or trade and the medical stores to find the pharmacy board fee. If the pharmacy board fee varies by category of medicine (i.e. essential or non-essential), these variations should be recorded in the final report.

Quality control testing

Medicines are often tested as each new batch arrives in the country (or at the procurement office) to ensure that they meet quality standards. The costs for running these tests, for collecting samples of each batch of medicine and of storing it for later comparison can be add-on costs.

Quality control fees differ from other price components because their cost has a direct benefit to the patient; they are intended to guarantee the product's quality. These price components show that all price components do not have to be eliminated, but simply accounted for. It is important to identify these costs, to increase overall transparency in pricing and to reduce the chance of hiding other price components behind the claim that they are necessary for safeguarding the medicine supply. Medicine quality control costs should not be eliminated, but they should be closely examined. Check with the national drug regulatory authority.

Transport costs

Stage 2 transport costs represent the cost of moving goods from the port or airport (for imported medicines), from the importer (if applicable) or from the factory (for locally produced medicines) to the wholesaler's warehouse or central medical stores. Check with importers, wholesalers and central medical stores on these costs.

Other fees and tariffs

Many countries have additional fees and tariffs that do not fall into the above categories. Examples include the Defence Levy that used to be collected in Sri Lanka on all imported medicines, the Consular Invoice which is used in Central America, or

fees for health, safety and technical standards documentation accompanying each order. Please describe all other fees and tariffs incurred after purchase and during Stage 2 of the supply chain in detail in your final report, being sure to describe variations by product or sector.

The ministries of health, trade and finance, as well as customs, the medical stores and private sector importers should be able to identify additional fees and tariffs.

National taxes

Some countries collect national, state and/or local taxes on the procurement of medicines. These taxes are collected in addition to the Goods and Services Tax (GST) or Value Added Tax (VAT) paid by the final purchaser.

If there is a national tax levied on goods bought by the importer or supplier, list it in Stage 2. Check with the ministry of finance, importers, and medical stores. GST and VAT are handled specially, and are discussed in Stage 5 below.

9.3.3 Stage 3: Wholesale selling price or central medical stores price

The 'wholesale selling price' is the total cost at the end of Stage 2, plus the wholesaler's costs and profit margin, as well as any costs for moving the medicines from the wholesaler to the retailer and any regional taxes that are applicable. In the public sector (and often the 'other' sector), this is the price of the goods when they leave the Central Medical Stores. In the private sector, this is the price when the medicine leaves a wholesaler.

Wholesale mark-up

The wholesale mark-up is the percentage added by the wholesaler or Central Medical Stores to cover overhead costs. These costs encompass overhead expenses such as rent, security, electricity, staff salaries and loss. In some situations, it includes costs to transport medicines to retailers. In the private sector, the mark-up also includes a profit margin; in the public and mission sector, the margin can provide capital for future investment or cover unforeseen increases in costs (e.g. inflation or devaluation).

If the medicines move through more than one wholesaler on their way to the patient, multiple wholesale mark-ups might be levied. This tends to happen as medicines move from central, urban areas to more rural ones. (6)

In some countries, the government applies a ceiling or maximum percentage limiting the mark-up that a wholesaler can add. In some cases, this mark-up is not enforced and much higher percentages can be observed. Where applicable, both the maximum allowable mark-up and the actual observed mark-up should be described in the final report.

Regional or state taxes

Some countries collect state or regional taxes on medicine procurement. These taxes are collected in addition to the national taxes discussed above, and the GST or VAT the final purchaser paid.

If there is a regional tax levied on goods bought by the wholesaler or medical stores, list it here. Check with the ministry of taxation, wholesalers and medical stores. GST and VAT are handled specially, and are discussed in Stage 5 below.

Transport costs

Stage 3 transport costs include the cost of moving goods from the warehouse (wholesaler) to the point of delivery (retailer) or, in the public sector, from the central or regional medical stores to the hospital pharmacies/dispensaries or health post.

In the public sector and in some 'other' sectors (e.g. church mission sector), medicines are distributed from a central warehouse directly to health facilities or via regional and/or district storage facilities. Mark-ups can be charged by a regional store as well as the central store, so check this information.

9.3.4 Stage 4: Retail price (private sector) or dispensary price (public sector)

The Stage 4 price components include the retailer's/dispensary's additional expenses, e.g. storage, handling, overhead and profit margin. The 'retail selling price' at the end of Stage 4 reflects the total cost to the public sector dispensary or private sector pharmacy, including overhead costs and profit margin.

Retail mark-up

The retail mark-up is the percentage that retailers (pharmacies) add to cover their costs, including their profit. These costs include those overhead costs that retailers incur in their practice, such as rent, staff salaries, repackaging and loss, as well as profit. Retail mark-ups are not limited to the private sector: the public and other sectors can also use mark-ups to cover their costs.

Mark-ups can vary between products: imported and locally produced medicines often have different mark-ups. Pharmacies may also charge different mark-ups on originator brands and generically equivalent products. In some countries, for example, the mark-ups are higher on generic equivalents because, even with the mark-up, they are considered to be affordable. If this applies in your survey area, it should be reported in the final report.

In some cases, the government applies a ceiling or maximum percentage limiting the mark-up that a retailer can add. However, it is also common to find that this mark-up is not enforced and much higher percentages can be found in practice. Where applicable, both the maximum allowable mark-up and the actual observed mark-up should be described in the final report.

In some countries, there may be different maximum mark-ups for different price bands: this is called a 'regressive mark-up' and means that the mark-up decreases as the price of the medicine increases. If this is the case, enter the appropriate mark-up for your target drug in the workbook, and describe the range of the mark-up system in the final report.

In countries where prices are not regulated or where regulations are not enforced, there might be great variation in retail mark-ups. If medicines are sold in the informal sector (medicine outlets), price variations can be even greater. (In this study, investigators are only required to collect information in one retail establishment per sector: however, if investigators are aware of these variations, they are encouraged to describe the variations and the surveyed establishments in their final report).

Local or town taxes

Some municipalities collect local or town taxes on medicines. These taxes are collected in addition to the national and state taxes discussed above, and the GST or VAT the final purchaser paid.

If there is a local tax levied on goods the retailer or health post bought, list it here. Check with the ministry of taxation, retailers and public sector health posts to identify these taxes. Remember that GST and VAT are handled specially, and are discussed in Stage 5 below.

9.3.5 Stage 5: Dispensed price

At Stage 5 of the supply chain, the price components are the VAT, GST and any dispensing fees that are collected when the medicine is dispensed. These price components are included in the survey, regardless of whether the patient, the public sector, an insurance organization or another institution pays for the medicine because they are still a component that raises the final cost of medicine delivery.

Value Added Tax (VAT) and Goods and Services Tax (GST)

VAT and GST can be levied on sales. These taxes vary from country to country, and also from state to state within a country. In many countries, medicines or certain sectors are exempted from VAT or GST; in other countries, VAT is collected at each stage of the supply chain. Each participant in the supply chain pays cost plus VAT, and then adds VAT to its selling price. The VAT is thus refunded to the participant so that the final purchaser is the only one who pays VAT. In these cases, VAT should only be recorded as a Stage 5 cost and should not be listed on each intermediate sale along the supply chain. Similarly, if the government reimburses VAT applied in the distribution chain's intermediate stages, it should not be counted. However, if VAT is applied in more than one stage of the distribution chain and this amount is not recovered in the selling price or reimbursed by government, then it should be counted in each appropriate stage. In some countries, GST is charged on medicines. As with VAT, only the tax added to the final price should be recorded.

Dispensing fees

Pharmacies may be allowed to charge a dispensing fee per item dispensed or per prescription filled. The fee is intended to reflect the work involved in handling a prescription; it is not a doctor's fee for service. The dispensing fee can take various forms: a percentage mark-up, a fee per item or a fee per prescription. Dispensing fees can also vary for originator brand and generic formulations.

Dispensed medicine price

Investigators should record the final dispensed medicine price paid by the final purchaser. This could be the patient, the government or an insurance provider. For countries that use a maximum retail price (MRP), investigators should check if the patient pays the MRP or if a different price is charged, and note this in the report.

In other cases, the government sets a maximum retail price, and it is left to the wholesaler and retailer to agree on their respective mark-ups. If there is a maximum sales price for your target medicines, report whether the dispensed medicine price is different from the maximum sales price in your final report.

9.4 COSTS THAT ARE *NOT* INCLUDED IN PRICE COMPOSITION ANALYSIS

The following medicine price components should not be included in the price components analysis.

Registration fees

The national medicines (or drugs) regulatory authority may charge a fee when a product is registered in the country, plus a renewal fee for as long as the product is on the market. Since these fees are charged only when a market authorization is issued or as an annual fee, and are independent of the quantity of medicine sold, they should not be included here as a price component.

Patient fees for service

Information on the following charges should not be included in the price components survey:

- fees for services other than the cost of the medicine (and the dispensing fee) such as the doctor's consultation; and
- travel expenses for a patient to reach a dispensing site.

However, if these fees are a significant burden for the patient they should be discussed in the final report.

Where a standard charge (e.g. a fee for the consultation/fee for service, including medicines) is set for all patients in public health facilities, this information should be included in the survey report.

Co-payments

A co-payment is a payment an individual makes, usually at the time a medicine is obtained, to offset part of the medicine and/or dispensing cost. Since co-payments may not be universally applied (e.g. different fees may be charged for different classes of patients), and are usually not related to the value of the product being supplied, these charges are not included in the price components analysis.

Informal charges

There may also be informal charges about which no information is publicly available. The only way of measuring them is by household surveys (interviewing patients at home) or exit interviews (interviewing patients when they leave the pharmacy or doctor). Surveys of this kind are not covered here, but can be developed as separate projects. However, participants are encouraged to describe additional informal charges in their final report.

Discounts and rebates

Manufacturers and suppliers sometimes reward buyers with discounted prices[1] or rebates.[2] Discounts are also sometimes offered to patients, with pharmacies

[1] A discount can take several forms, including: 1) a price reduction given to customers at the date of sale; 2) bonus deals: additional units supplied to customers below list price; 3) sale of equipment at a reduced rate; 4) contributions to salaries or other incentives or services.

[2] A rebate is a payment made by the seller to the purchaser after the date of sale.

reducing the price of a medicine (e.g. for customer loyalty); offering the patient a non-medical product at a discount when a medicine is purchased; or offering other rewards and enticements.

Discounts and rebates are not uncommon, and can be prolific in some countries. Often they vary depending on the medicine or the patient. In many countries, it is extremely difficult to collect information on the discounts and rebates being offered, and in such cases these should be excluded from the price components survey. However, in some countries discounts and rebates are standardized and information is more readily available. For example, a price components study in New Delhi, India, found evidence of bonus deals (e.g. buy nine get one free) on pharmacy invoices (*3*).

If it is possible to collect information on discounts and/or rebates, then these should be included in the price components survey. That is, they should be noted in the Comments columns of the Price Components Data Collection form and the *Price Components: Data Entry* page of the workbook. They should also be discussed in the final report, ideally including a separate analysis that shows their impact on various profit margins in the supply chain.

Manufacturing price components

Price components exist in all supply chains, including those for the materials needed to manufacture essential medicines locally. For example, there are import tariffs and sales taxes on raw active pharmaceutical ingredients; the excipients and the machinery used in manufacturing; local distribution charges to transport supplies to the factory; and operating costs to cover rent, electricity and business taxes.

Countries with a significant local production capacity might be interested in production line price components. However, the goal of the price components survey is to understand the MSP as it relates to the costs to distribute medicines to the point of delivery – the price components of distribution. Understanding the MSP and manufacturing price components requires a different type of analysis, including assigning indirect factory costs to individual tablets and amortizing costs across a subset of locally produced medicines. It is also likely that it would not be possible to analyse manufacturing price components before a complete analysis of distribution price components had been completed. Thus, price components are restricted in this survey to the procurement and distribution of finished products.

9.5 PLANNING THE PRICE COMPONENTS SURVEY

9.5.1 Meeting with the advisory committee

An advisory committee meeting is essential in planning the price components survey. The meeting's objectives include:

- identifying the goals of the price component survey and the information to collect;
- receiving advice on which medicines to track and which price components to survey;
- gaining insight into medicine procurement and supply chains in various sectors; and
- discussing and planning data collection, namely: identifying key informants, determining how they should be approached and by whom (this could include advisory committee members).

The advisory committee for the price components survey could be the same as that for the general medicine prices and availability survey, or could be a subcommittee with particular knowledge of the medicines supply chain in various sectors.

9.5.2 Personnel

Finding price component information can be difficult and requires specific expertise. Since gathering data on price components will require interviewing government, procurement and financial officials, researchers should have experience in qualitative research, specifically in conducting open-ended interviews. Some price components might be considered 'trade secrets' that participants are not willing to reveal: for example, a wholesaler might not be willing to publish his mark-up for fear of losing customers. Researchers will therefore need good investigative and interpersonal skills, including an inquisitive, non-threatening approach. They also require an understanding of the relationships and the political situations in their country, and should ideally be recognized in the pharmaceutical sector. Investigators or the advisory committee should have connections that can facilitate obtaining meetings with key informants.

Survey personnel from the general medicine prices survey can be used for the price components survey provided that they have the necessary skills and are available during/following the general medicine prices survey. The survey manager is the most likely to possess the skills necessary to conduct price components data collection. In cases where the survey manager lacks the necessary skills or is subject to time constraints, separate survey personnel will need to be recruited to conduct the price components survey; possibly someone from the Advisory Committee.

Two people should undertake data collection visits for various reasons, among which is to ensure that comprehensive notes are taken during interviews. The data collection team can be composed of the survey manager and an area supervisor, particularly when local knowledge of a region is required. Alternatively, the survey manager could conduct the interviews with a member of the advisory committee, or with a researcher recruited specifically for the price components survey.

9.5.3 Seeking endorsements

As with the general medicine prices survey, a signed, official letter of endorsement can be of great help in carrying out the price components survey. A sample letter of endorsement, shown in Annex 2, is included as a Word file on the CD-ROM for local modification as appropriate. WHO will also provide a letter of endorsement on request.

9.5.4 Planning timeline

The price components survey can either be conducted at the same time, or after the general medicine prices survey. Conducting both surveys simultaneously will require less time and resources, since survey teams will only need to travel to the field once. For example, area supervisors can collect data on price components during the validation visits conducted as part of the general medicine prices survey. However, conducting the price components survey after the general medicine prices survey has the distinct advantage that the sample medicines and facilities can be selected based on the results of the medicine prices and availability survey. For this reason, it is strongly recommended that the price components survey be conducted directly after the general survey.

Table 9.1 below presents a sample timeline of activities for the price components survey. It is understood that officials are busy and appointments might not occur in this order, and that more time might be needed for certain activities. In addition, countries might have other organizations to be added to the interview list. Multiple meetings with certain stakeholders might also be needed, i.e. two or three manufacturers, or follow-up meetings with the same informant. Experience from previous price components surveys shows that meetings at the central level require at least one full hour and sometimes two hours; three meetings a day is therefore realistic. Any remaining time should be used for the team to review data collected on the day, corroborate that team members heard the same thing and transcribe notes.

9.5.5 Planning where to conduct the study

The price components survey includes two types of data collection: central data collection on official policies related to price components, and tracking specific medicines through the supply chain to identify add-on costs. Central data collection generally takes place in the main urban centre, though visits to key informants located in other areas may be required. Medicine tracking is conducted in two of the six survey areas where the general medicine prices and availability survey was conducted, namely

- the main urban centre; and
- one additional survey area.

The additional survey area should be rural and should be located as far from the urban centre as possible. This will ensure that data are collected on the mark-ups by intermediary distributors and on local distribution and storage costs as medicines move out to the district and health centre levels. Ideally, the additional survey area should also contain multiple retailers, so that alternatives are available if one retailer does not agree to participate.

Table 9.1 Sample timeline for price components survey

DAY	TASK	DETAILS
1–2	Planning	Survey planning meeting with advisory committee. Select regions, sectors, dispensing sites and medicines to be surveyed. Identify key informants and schedule appointments for data collection visits. Seek endorsements, prepare data collection forms and plan travel.
3	Training/briefing	Training of national team. Meeting with private sector professional (e.g. wholesaler), who can give private system overview.
4–8	Central data collection	Meet with ministries of health, finance and trade, WHO, pricing authority, drug regulatory authority, manufacturer's association, pharmacists' council, tax consultant, importers, Central Bank, transport company, pharmacy sellers' association, quality control laboratory.
9–11	Medicine tracking (capital)	Data collection at dispensing sites: public and mission health centres and retail pharmacy. Collect central data from procurement agents, Central Medical Stores, local manufacturers.
12–14	Medicine tracking (rural area)	Data collection at dispensing sites: public and mission health centres, and retail pharmacy. Identify and visit other resellers, procurement agents, local manufacturers and local wholesalers.
15–16	Medicine tracking (capital)	Visit wholesalers and collect data.
17–20	Analysis	Data analysis.
21	Clarification	Day for additional meetings to clarify data, as necessary.
22	Synthesis	Meeting of advisory committee to review results, develop recommendations and consider further research.
23–24	Write-up	Report writing.

When collecting pricing data, price components should be surveyed in both the urban centre and a rural region to capture the full extent of possible mark-ups by middlemen.

9.6 SELECTING THE MEDICINES TO BE SURVEYED

Researchers should select five to seven medicines that illuminate pricing policies in their country. Some countries may need to survey additional medicines if it is known that mark-ups and other add-on costs vary according to different categories of medicines. Targeting more than seven medicines complicates data collection in busy retail pharmacies.

Where a medicine prices and availability survey has been conducted, the results should be used to select medicines with high prices, and/or variable pricing patterns. Target medicines should be selected from the global and regional core lists of medicines included in the medicine prices survey (three to four from the global list and two to three from the regional list). Target medicines should also have high use/sales volumes and should be commonly found in all sectors surveyed. Depending on the local situation, the medicines selected should also cover categories of medicines that will provide the full range of pricing structures. These should include both imported and locally produced medicines, where these exist. Other categories can include:

- single-source, multi-source and limited-source (e.g. ACTs) products;
- National Essential Medicines List (NEML) and non-NEML medicines;
- price-controlled and non-price controlled medicines;
- taxed and tax-exempt medicines;
- treatment of acute and chronic conditions;
- various formulations (tablet, liquid, injection); and
- adult and paediatric treatment/ailment.

In some countries, it may be useful to select a medicine used in public health emergencies or provided by international donors such as the Global Fund to Fight AIDS, Tuberculosis and Malaria, since these may be exempted from certain mark-ups. These data can also help to plan budget requirements to store and distribute these 'donated' medicines.

It is useful to draft a table showing the characteristics of the medicines selected for the components survey, and to include it in the final report.

Data will be collected on both the originator brand and a generic equivalent, where these exist. The generic product should be the lowest-priced generic most commonly found during the medicine prices and availability survey. If this medicine is not available at a dispensing site, the lowest-priced generic product available at the dispensing site should be used.

Up to 7 medicines, with 2 product types per medicine, in up to 4 sectors, results in a total of 56 possible items to track per region, as illustrated in Table 9.2. But it is unlikely that all forms are available. The public sector in many countries stocks only generics, and many 'single' source medicines will not have a generic equivalent.

Table 9.2 Data to be collected

MAIN URBAN CENTRE							
	Med 1	Med 2	Med 3	Med 4	Med 5	Med 6	Med 7
Public	Generic Originator	Generic Originator	Generic Originator	Generic Originator	Generic Originator	Generic Originator	Generic Originator
Private	Generic Originator	Generic Originator	Generic Originator	Generic Originator	Generic Originator	Generic Originator	Generic Originator
Other 1	Generic Originator	Generic Originator	Generic Originator	Generic Originator	Generic Originator	Generic Originator	Generic Originator
Other 2	Generic Originator	Generic Originator	Generic Originator	Generic Originator	Generic Originator	Generic Originator	Generic Originator
ADDITIONAL REGION (RURAL SURVEY AREA)							
	Med 1	Med 2	Med 3	Med 4	Med 5	Med 6	Med 7
Public	Generic Originator	Generic Originator	Generic Originator	Generic Originator	Generic Originator	Generic Originator	Generic Originator
Private	Generic Originator	Generic Originator	Generic Originator	Generic Originator	Generic Originator	Generic Originator	Generic Originator
Other 1	Generic Originator	Generic Originator	Generic Originator	Generic Originator	Generic Originator	Generic Originator	Generic Originator
Other 2	Generic Originator	Generic Originator	Generic Originator	Generic Originator	Generic Originator	Generic Originator	Generic Originator

9.7 SELECTING DISPENSING SITES (MEDICINE OUTLETS) TO SURVEY

In tracking medicines through the supply chain, data are collected for all sectors in the price survey (public, private sectors and other sectors).

In each region, at least one dispensing site is surveyed per sector. Survey sites are selected before data collection begins, from the facilities used in the Medicine Prices survey. Selection of facilities should be based on the following criteria:

- All/most of the target medicines were available at the time of the medicine prices survey
- Medicine prices were found to be outside the normal range (e.g. outside inter-quartile range)
- Pharmacist (or facility staff) at the dispensing site were cooperative and would be likely to participate in additional data collection
- Convenience/feasibility – public and other sector facilities can be selected based on their proximity to a private sector outlet satisfying the above criteria.
- For rural facility: medium to long supply chain.

9.8 SELECTING WHICH PRICE COMPONENTS TO SURVEY

Section 9.3 provided definitions of different price components, however, it is not necessary to collect information on each component. Investigators should make the best use of their time by selecting components to survey based on the following criteria:

- **Financial impact**. Small, one-time charges have a minimal impact on the final medicine price, especially when compared with, for example, the retail mark-up. Researchers should focus on those price components that have a more significant financial impact. These should include price components that appear early in the supply chain (e.g. bank charges), since their contribution is compounded by increasing the base price of components that occur later in the supply chain.
- **Changeability**. Some price components are easier to regulate and enforce than others. Price components that are already part of a country's pharmaceutical pricing policy might be easier to research and discuss.
- **Distributed responsibility**. Select price components that are the responsibility of different participants in the supply chain. There are three principal actors involved in procurement whose actions influence price components: the government, the private sector and the procurement office. The target price components should include some that are under the influence of each participant, e.g. for the government, import tariffs and taxes; for the private sector, wholesale and retail mark-ups; and for the procurement office, overhead expenses and the cost of procurement.
- **Advocacy**. Select price components that lend themselves to an advocacy campaign. A retail mark-up of 10% or less is difficult to argue against, without seeming insensitive to retailers and their families. In contrast, a government tax on medicines of 7% might be easier to bring to national attention, with the argument that a tax on medicines is a regressive tax on the sick.
- **Transparency**. Pick price components to investigate that are not already well understood or transparent. Focus on components that have not been researched.

9.9 TRAINING

Since collecting data on price components is sometimes challenging, appropriate training of survey personnel is essential to ensure that comprehensive and reliable information is obtained. The price components research team is quite small (two to three people), therefore, the training session can consist of an informal meeting of a half to a full day's duration. Training should focus on ensuring that researchers have a clear understanding of the various price components applied at each stage of the supply chain, and how to identify these components through both central level data collection and medicine tracking. Topics to be covered include:

- Survey objectives
- Background information on the medicines supply chain in the country's various sectors
- The staged approach to price components
- Description of price components in each stage of the supply chain
- Overview of the price components survey methodology

- Central data collection
  - — identifying informants and setting up appointments
  - — conducting interviews – process and techniques
  - — consolidating and synthesizing data
  - — frequently encountered problems and how to address them (role play exercises, e.g. uncooperative minister)
- Medicine tracking
  - — the price components data collection form
  - — medicine tracking – process and techniques
  - — frequently encountered problems and how to address them
- Data entry
- Data analysis
- Report writing.

During the training session, substantial guidance should be provided on conducting price components interviews, since specific skills are required when obtaining what can sometimes be perceived as sensitive information. Trainers should emphasize the following:

- Upon arrival for the interview, the interviewers should introduce themselves, explain the visit's purpose, and provide informants with a copy of the letter of endorsement and business cards (where appropriate). Interviewers may also want to reassure commercial informants that their confidentiality will be maintained.
- Interviewers should explain the survey's objectives, namely to improve access to affordable medicines for all by researching medicine prices and charges along the supply chain.
- It is useful to stress that the supply chain's viability is a key consideration in this work.
- To establish a dialogue, researchers should begin the interview by asking general, factual questions about the function of the interviewee's office.
- Interviewers will need to gauge the informant's interest and manage discussions accordingly. If time is short, researchers should focus on the key objectives and critical information to be obtained.
- Above all, it is important to understand and be sensitive to each informant's role in the medicines supply chain.
- The wording of delicate questions must be carefully selected. During training, it may be useful to provide examples of the right and wrong ways of asking the same question.
- Throughout the interview, allow the interviewee time and space to question the survey team or express thoughts/opinions.
- Being able to listen to and incorporate the interviewee's opinions into the questioning will build a common ground for further discussion.
- It may be useful to ask the interviewee to provide examples of specific medicines to illustrate complex policies or pricing formulas.

- At the interview's conclusion, researchers should leave room for ongoing communication. It is often necessary to contact informants a second or third time to clarify the information obtained and/or verify information from other sources.

9.10 PLANNING DATA COLLECTION VISITS

As much as possible, data collection appointments should be planned in advance. Researchers should allocate time to plan and schedule meetings with busy professionals before the survey begins. This applies to central level visits to collect information on national pharmaceutical policies, as well as to visits to dispensing points in the public, private and 'other' sectors to track target medicines through the supply chain. Note that in tracking medicines, the public purchasers, wholesalers, importers and manufacturers to be visited will be identified as data collection progresses; as such it will not be possible to make these appointments in advance.

Experience shows that you can obtain more information if you request an appointment rather than visiting without prior notice at what may be the busiest time of day.

Previous surveys have shown that connections with key contacts are important for securing data collection visits. Members of the advisory committee should support the researchers in setting up appointments with key informants. An official letter of endorsement may also assist in securing appointments. It is important to build support for the research by explaining the project and its goals. Emphasis should be placed on understanding price structures in order to increase countrywide access to medicines, for all people, while maintaining the viability of the supply chain.

Within each organization/association/company to visit, consideration should be given to the most appropriate informant to interview. A mid-level staff member may have a better understanding of day-to-day operations than a minister or chief executive officer (CEO), may be more accessible and may have more time available. It can sometimes take two or three phone calls or visits before finding the right person to talk to. When setting up appointments, interviewees should be asked when the best time is to visit in order to avoid peak hours of activity.

It will probably be easier to speak to importers or manufacturers after data have been collected from wholesalers and retailers so that the researcher already has an understanding of the issues that wholesalers and retailers face.

9.11 DATA COLLECTION

The following section provides guidance on the two types of data collection in the price components survey: central data collection on official policies related to price components, and tracking specific medicines through the supply chain to identify all price components. Table 9.3 provides a list of common price components and possible sources of information.

Table 9.3 Price components and possible sources of information

TARIFF/TAX	POSSIBLE SOURCES OF INFORMATION
STAGE 1	
Manufacturer's selling price (MSP)	Manufacturer's list prices (from wholesalers), Public sector tenders, customs declaration forms, local manufacturers
Freight and insurance charges	Importers, customs declaration forms Ministry of health tenders
STAGE 2	
Finance/banking fees	Ministry of finance, Central bank
International inspection	Drugs/Medicines regulatory authority, Ministry of trade
Port charges, clearance	Customs, Importers, Medical stores
Quality control testing	Ministry of health, Procurement office, Quality assurance/Drug testing lab
Import tariff or duty	Customs, Ministries of health, trade, finance, Medical stores, Importers
Importer's mark-up	Importers, Wholesalers, Ministry of trade
Pharmacy council/Board fee	Pharmacy board/association/council, Ministries of health, trade, finance, Medical stores
'Other' fees	Ministries of health, trade, finance; Medical stores, Importers, Wholesalers
National taxes	Ministry of finance
STAGE 3	
Transportation costs	Importers, Wholesalers Ministry of health, Medical stores
Wholesale mark-up, official (hypothetical)	Wholesaler, Ministry of health, retailers, Pharmacy board/association/council, Medical stores, Ministry of health
Wholesale mark-up, observed in the field	Wholesaler, retailer Medical stores
Quality control costs	Wholesaler, Medical stores, Quality assurance/Drug testing laboratory
Regional taxes	Ministry of finance
STAGE 4	
Retail mark-up, official (hypothetical)	Retailers, Drugs/Medicines regulatory authority, Pharmacy board/association/council, Ministry of health
Retail mark-up, observed in the field	Retailers /Health facilities
Local or town taxes	Retailers, Ministry of finance
STAGE 5	
VAT/GST	Retailers, Ministry of finance
Dispensing fees	Pharmacies, Ministries of health or trade, Pharmacy board/association/council
Cost to patient	Retailers

Other sources of information that have proven useful in countries that have conducted price components surveys include:

- local representatives of multinational pharmaceutical companies;
- the WHO local representative;
- independent tax attorneys (for tax code) (meetings with tax and import experts whose business is not exclusively in pharmaceuticals can be very productive); and
- the pharmaceutical manufacturers' association.

9.11.1 Central data collection on national pharmaceutical policies

At the central level, information will be collected on government policies and regulations that affect price components. Researchers will visit ministries, the customs office, the central bank, the pharmacy board and others for this information. Annex 6 contains a list of key informants to interview as part of central data collection, the

key objectives of the interview, and sample questions to ask. Uncovering several of these price components will require good investigative skills, determination and numerous questions. The information gathered at the central level will be compared to the prices reported in the field to see which policies are implemented and whether they are enforced.

It may be useful to start with a visit to a wholesaler or retailer who will be excluded from the price component survey to ask for an overview of the pharmaceutical market in that country.

9.11.2 Collecting data along the supply chain

In the second phase, investigators will collect data along the public, private and 'other' supply chain in the main urban area as well as in one additional survey area used in the medicine prices survey. Participants will begin at the end of the supply chain, at the dispensing point for each sector, and track the targeted medicines backwards along the supply chain to their point of origin, recording the price components incurred. Participants will visit dispensing facilities, retailers, wholesalers, public sector purchasers, local manufacturers and importers in their investigations of the price components. Note that some of the data collected might contradict data collected at the central level. Inconsistencies can illuminate the system structure and system operation and should be recorded.

For each target medicine, track both the originator brand product and the lowest-priced generic product most commonly found during the medicine prices and availability survey. Note that in some countries with a large generic manufacturing capacity, it may be appropriate to collect data on 'branded generics' in addition to/in place of originator brands. If the lowest-priced generic product is not available at a given dispensing site, collect data on the generic product with the lowest price at that site.

In the private sector and some other sectors (e.g. dispensing doctors) it is necessary to start at the end of the distribution chain (the retail pharmacy) and work backwards to identify wholesalers and manufacturers. In the public and mission sectors, however, the distribution chain is known and data can therefore be collected in either direction. For example, it may be more efficient to visit the Central Medical Stores during central level data collection, even though public sector dispensing sites have not yet been visited.

Manufacturers or importers are likely to be supplying medicines to multiple wholesalers, and similarly wholesalers will be supplying multiple retailers. After you visit all the dispensing units in a survey area, compile a list of wholesalers and the products they handle. If there are regional wholesalers, visit them at this time. If there are central wholesalers, wait until data collection in both survey areas is complete, then compile a list of central wholesalers and the products they handle prior to conducting visits.

As you work backwards through the distribution chain, it is useful to consolidate the data collected, e.g. by keeping a running list of the wholesalers you need to visit and the medicine data you need to collect from them.

Wherever possible, try to obtain documentation of the prices you are quoted, e.g. through paper invoices or computer systems. Valuable information on the manufacturer and distributor is often given on the packaging and on package inserts. Secondary data, such as manufacturers' web pages or other Internet sites, can also be a useful source of information. Note that multiple names on packaging can be confusing e.g. when a product is imported but the labelling is done locally. Such cases will require clarification in order to differentiate between imported and locally manufactured products

BOX 9.2

Hints for data collection

- Price components affect both sides of a transaction. Buyers will negotiate a lower purchase price so that they can add a higher mark-up; sellers will ask for a higher mark-up or a greater guaranteed volume of sales to safeguard their profit. It is helpful to ask the same question of both sides of the purchase and sale: wholesalers frequently know what retail mark-ups are, and retailers understand wholesale mark-ups.
- It is also useful to ask the same questions several times. This can include asking one question of several wholesalers, as well as making repeat phone calls to one wholesaler and asking different staff the same question. Even if you believe you have the answer, it is worthwhile checking other participants' perceptions. This should include both those involved with pharmaceuticals and those who are not: port storage charges or banking fees are the same regardless of the import item.
- Ask a question even if you think you know the answer. Each participant might have a different view of the same issue.

Note regarding exemptions

Many countries exempt certain medicines or certain sectors from various tariffs and fees. For example, a country might exempt life-saving medicines from a mark-up. Donated goods are also often exempt from several tariffs, but incur price components such as transport, storage and insurance.

Possible exemptions include:

- **some or all of the medicines on the essential medicines list;**
- **medicines for public health programmes;**
- **some or all of the medicines on the public tender;**
- **medicines imported by NGOs or the mission sector; and**
- **donations.**

Investigators should check whether their target medicines and sectors are exempt from any fees or tariffs. In addition, investigators should check whether the same level of tax or duty applies to all products. Exemptions for different products, different sectors, and different delivery programmes should be reported. Note that import tax or duty may also apply to imports of raw material for local production; these data are not currently being collected, but can be presented in the final report.

9.12 THE PRICE COMPONENTS DATA COLLECTION FORM

The Price Components Data Collection form, found in Annex 7 and on the CD-ROM that accompanies this manual, is used to collect data in the field. A separate form should be completed for each medicine, for each specific product type, sector and

region being surveyed. Participants should photocopy or print the required number of copies of the price components data collection form. Because the medicines are tracked backwards along the supply chain, the Price Components Collection form is filled in from the bottom (Stage 5) to the top (Stage 1).

9.12.1 Elements of the Price Components Data Collection form

Type of charge

The Type of Charge column is for recording the various possible price components in each stage of the supply chain.

Charge status

The status of each charge is described according to two categories:

- Not found: NF: Price component is known to exist, but no data were found
- Value: V: Price component exists and data were found

Charge basis

Charge basis refers to whether the fee is a:

- **Percentage fee**. The price component is a fixed percentage on the previous cumulative total. For example, an import tariff of 8% calculated on the total value of the order.
- **Fixed fee**. A fixed fee is charged regardless of the cumulative total price. Examples include a dispensing fee of US$ 1 on each prescription or US$ 200 for international inspection of an entire shipment.

Price to which charge is applied

This column is used for recording the price to which the charge is being applied. Usually, this will be the cumulative price at the time at which the charge is applied (i.e. the previous line). However, sometimes multiple charges are applied to the same price. For example, in Sri Lanka both the import tariff and the defence levy were applied to the Stage 1 procurement cost. While the order in which fixed fee charges are added does not affect the final price, the price to which a percentage charge is applied will affect the amount of the charge. Suppose there is a procurement with a value of US$ 10 000, with an 8% import tariff and a 4% defence levy, then both the import tariff and the defence levy should be levied on the base of US$ 10 000. The cumulative total should be US$ 11 200. If these two charges are added sequentially, the defence levy will be applied to a higher price, resulting in an incorrect total (US$ 11 432).

Amount of charge

The amount of charge is entered as a percentage (e.g. 8%) or as a fixed fee (e.g. US$ 200).

Comments

The Comments column can be used for explanatory comments or any additional information, such as ‘inconsistent with official rates’.

Source

This refers to where the medicine was obtained. For example, at a private retailer the source usually refers to the wholesaler from which the medicine was purchased. This information is used to track medicines backwards through the supply chain.

Table 9.4 Example of the price components data collection form for Stage 3

Source: *GenLabs Ltd*

Stage 3: Wholesaler or medical store	Type of charge	Charge status	Charge basis	Price to which charge is applied	Amount of charge	Comments
	Procure price	value	N/A	N/A	*100.00*	
	Regional tax	*V*	*%*	*Stage 3 procure price*	*3.0*	
	Wholesale mark-up	*V*	*%*	*Stage 3 procure price*	*10.0*	
	Transport costs	*V*	*Fixed*	*Cumulative Sub-total*	*5.50*	*Not included in mark-up*

It is likely that some price component may have been missed or omitted: please list any costs in the 'Other fees' line of the appropriate stage and provide a description so that we can correct the omission. If you have questions, send an e-mail to HAI or WHO.

Table 9.4 below shows an example of the Price Components Data Collection form completed for Stage 3 of the supply chain.

9.12.2 Instructions for completing the Price Components Data Collection form

STEP 1: Prepare the data collection forms: fill in background information

1. Identify the data collector completing the form.
2. Fill in the region and sector (capital, rural; public, private, other).
3. Fill in the name and/or identifying code of the dispensing outlet.
4. Fill in the name of the target medicine, strength, dosage form, manufacturer and pack size. Describe the target medicine by checking the appropriate boxes and adding any additional information in the space provided (e.g. acute vs chronic condition, medicine for public health emergency).
5. Identify the type of data being collected. This is usually field data (i.e. medicines tracked through the distribution chain), but could also be hypothetical data (official rates obtained centrally).

STEP 2: Visit dispensing points in the public, private and 'other' sectors

Visit each of the selected dispensing points in the public, private and 'other' sectors. The order of the visits does not matter. Dispensing points are visited to obtain

the price at which they purchase and sell the target medicines; to identify Stage 4 and Stage 5 add-on costs; and to identify where the medicines were obtained (e.g. wholesaler, medical store), to allow for tracking backwards through the supply chain.

In the medicine prices and availability survey, medicines are recorded as available only if they are available on the day of data collection. In the price components survey, data should be collected on medicines even if they are not available on the day of data collection, for example by reviewing recent invoices.

Stage 5 costs:

1. On page 2 of the Price Components Data Collection form, in the first row of the table marked Stage 5: dispensed price, record the selling price as the total price of the medicine, whether it is being charged to the government, insurance companies or the patient.
2. In the Type of Charge column list Stage 5 charges (e.g. VAT/GST, dispensing fees) *in the order in which they are applied*. For each charge, indicate the charge status (value or not found), charge basis (flat fee or per cent) and the amount of the charge. For percentage charges, indicate to which price the charge is applied (e.g. MSP, Stage 5 procure price).
3. If the patient pays a different price from the selling price, record this as the cost to patient. In the public and 'other' sectors this might be a fraction of the actual cost or might be zero. Include a description of this in your report.

Stage 4 costs:

1. Record the procurement price paid by the retailer or public dispensary. The Stage 4 procure price should be the same as the price subtotal at the end of Stage 3, however, data from different sources do not always match up.
2. Note the source (e.g. wholesaler, Central Medical Stores) of the target medicine, which is needed to track the medicine along the supply chain.
3. In the Type of Charge column list Stage 4 charges (e.g. retailer's mark-up, local or city taxes) *in the order in which they are applied*. For each charge, indicate the charge status (value or not found), charge basis (flat fee or per cent) and the amount of the charge. For percentage charges, indicate to which price the charge is applied.

Specific questions to ask at the dispensing point include:

- How do you obtain medicines (e.g. distribution lines). Public sector: Do you make any local purchases?
- Who pays for local transport? What is the cost of local transport?
- What is your margin? What is included (overhead, local transport)?
- Do you know what the wholesaler/central store margin is?
- Do you receive any discounts/rebates/schemes?
- Do you give any discounts?

As part of medicine tracking in the public sector, researchers should identify whether any medicines are being obtained through local purchase. If public sector hospitals are procuring medicines directly from the manufacturer, a wholesaler or a retailer, rather than obtaining them through government stores procurement system, they could be paying higher prices or the current drug budget does not accurately reflect real need.

Delays in payment, such as late payments from governments to suppliers or from pharmacies to wholesalers, invariably increase the price of future orders. Researchers should try to ascertain whether delays in payment are common and if so, include this information in their report.

STEP 3: Visit public sector procurement office and wholesalers

Public purchasers and wholesalers are visited to obtain the price at which they purchase and sell the target medicines; to identify Stage 3 add-on costs; and to identify where the medicines were obtained (e.g. manufacturer) to allow for tracking backwards through the supply chain.

Make a list of the resellers (i.e. wholesalers or public purchasers) identified in Step 2. For each wholesaler, list the medicines that they sold or dispensed. Go to a maximum of five wholesalers (those that sell to most of the target facilities) and investigate the price components of the medicines that they sell. Complete the Stage 3 section of the price components data collection form for the drug sold by each reseller.

Stage 3 costs:

1. Record the procurement price paid by the wholesaler or public purchaser. The Stage 3 procure price should be the same as the price subtotal at the end of Stage 2, however, data from different sources do not always match up.
2. Note the source (e.g. manufacturer or importer) of the target medicine.
3. In the Type of Charge column, list Stage 3 charges (e.g. wholesaler's mark-up, regional taxes) *in the order in which they are applied*. For each charge, indicate the charge status (value or not found), charge basis (flat fee or per cent) and the amount of the charge. For percentage charges, indicate to which price the charge is applied.
4. Record the selling price of the medicine to the retailer or dispensing point. Note that this selling price may not match the retailer's reported purchase price.

Specific questions to ask the public sector procurement office or wholesalers include:

- How do you obtain medicines (e.g. distribution lines)?
- Who pays for local transport? What is the cost of local transport?
- What is your margin? What is included (overheads, local transport)? Do you know what the retailer's margin is?
- Do you know what the manufacturer's margin is?
- Do you receive any discounts/rebates/schemes?
- Do you give discounts?

Occasionally, there is an extra step in the supply chain. This occurs when wholesalers or public purchasers procure medicines from other domestic wholesalers. If this is the case in your country, insert an additional Stage 3 table into the data collection form, and repeat Step 3 for this additional level of distribution.

Locally produced medicines:

STEP 4: Visit local manufacturers

Where possible, schedule visits to the local manufacturers of the target medicines identified in Step 3 above. Local manufacturers are visited to obtain the manufacturer's selling price and information about wholesale and retail mark-ups, local transport charges and taxes and about the structure of the distribution system.

It may not be possible to secure visits with all local manufacturers, in which case it will be necessary to extrapolate data from selected manufacturers across target medicines. It might be useful to first visit a manufacturer that is not producing any of the target medicines to obtain general information on transport costs, mark-ups, etc. The sources of information used to estimate the MSP and Stage 1 and Stage 2 add-on costs should be clearly described in your report.

Stage 2 costs:

1. In the Type of Charge column list Stage 2 charges (e.g. transport, pharmacy association/board/council fee, national taxes) *in the order in which they are applied*. For each charge, indicate the charge status (value or not found), charge basis (flat fee or per cent) and the amount of the charge. For percentage charges, indicate to which price the charge is applied.

Stage 1 costs:

1. Enter the MSP for the pack size of the target medicine in the first row of the table. Leave the second row (INF) and third row (CIF) blank.

Specific questions to ask manufacturers include:

- Who pays for local transport to the wholesaler? What is the cost of local transport?
- What is your mark-up? What is included (local transport, taxes, marketing, profit margin)? Do you know what the wholesale mark-up is?
- Do you offer any discounts/rebates/schemes?
- Do you ever sell medicines directly to hospitals or other public sector health centres?

Imported medicines:

STEP 5: Visit importers

For imported medicines, collect the price components associated with importing the target medicine as Stage 2 costs.

Stage 2 costs:

1. In the Type of Charge column, list Stage 2 charges (e.g. finance/banking fees, international inspection, port charges/clearance, import tariff, quality control testing, importer's mark-up, pharmacy board fee, national taxes) *in the order*

in which they are applied. For each charge, indicate the charge status (value or not found), charge basis (flat fee or per cent) and the amount of the charge. For percentage charges, indicate to which price the charge is applied.

Note: Enter any costs of local transportation from the port of entry to the wholesaler that are paid for by the manufacturer.

2. Use the 'Other fee' category to record price components not listed here. Provide an explanation of these 'Other' charges in your report.
3. If you only have access to the price of medicines after they leave the importer or the manufacturer, you can enter this value directly in the final row.

STEP 6: Collect data on international procurement and shipping

For imported medicines, collect the price components associated with procuring the target medicine and international shipping as Stage 1 costs.

Table 9.5 Price components data collection form for Stage 1

Stage 1	Type of charge	Charge basis	Price to which charge is applied	Amount of charge	Comments
	Manufacturers' selling price	price			
	Insurance and freight				
	CIF				

Stage 1 costs:

Case 1: Separate Manufacturer's selling price and shipping costs:

Enter the MSP for the pack size of the target medicine in the first row of the table. For 'Insurance and Freight': note whether this is a fixed fee or a percentage, and enter the amount paid. Enter the shipping terms (e.g. CIF, FOB, EXW) in the Comments column. Leave the third row (CIF) blank.

Case 2: Combined Manufacturer's selling price and shipping costs:

Enter the price found for the medicine, including shipping in the bottom row (CIF). Leave the first two rows blank.

BOX 9.3

A note on maximum retail prices (MRPs)

Labelling packages with the maximum retail price (MRP) does not always guarantee uniform prices across a country. Patients do not always buy an entire package; instead tablets may be sold individually, and the price for each tablet is set to what patients will pay. This leads to price variations across a country even if there is an MRP.

BOX 9.4

Dealing with inconsistent data

Inconsistencies in the collected data are common: two ministries will report different values for a mark-up, or the government-set fee will not match the fee used at the pharmacy. There is already evidence of this for wholesale and retail mark-ups: due to a lack of enforcement, the mark-up used in practice might not match the official rate. Furthermore, prices may differ between shipments or orders, particularly in countries with a volatile currency.

When inconsistent data are found, you should first verify the data, and if an inconsistency is confirmed, attempt to identify the reason(s) for the inconsistency. Any inconsistent data should be identified and discussed in the final report.

Reporting difficulties

Little is known about price components due to the difficulty in discovering the required data. To create a uniform system that will allow cross-country comparisons, we have made certain assumptions. You may discover cases that do not fit into the forms provided. Please send us reports and comments on those price components that do not fit into forms, additional significant price components that are not discussed in this handbook, and other information about your health sector that is relevant to the medicine prices project.

9.13 DATA ENTRY

The data collected on individual medicines is entered into Part II of the workbook, on the *Price Components Data Entry* page of the workbook. The workbook can then be used to generate pie charts and summary tables that can be used in reporting results, as described in the section on data analysis that follows. While information on policies and regulations is not entered in the workbook, other central level data are (e.g. bank fees). Since the price components survey is a case study, results are described in text form.

To enter data on individual medicines, open the workbook and go to the price components data entry page by clicking on the **PRICE COMPONENTS** entry button on the *Home* page, or by clicking on the Price Components entry tab at the bottom of the spreadsheet (if this tab is hidden, use the ▶ arrow to scroll through the tabs until it is visible).

At the top of the page there are three buttons:

HOME PAGE: Clicking on this button will bring you to the *Home* page of the workbook.

SHOW/HIDE DETAILS: This button allows you to switch back and forth between the full data entry grid, and a summarized version that can be copied into your report. When details are hidden, the 'Cumulative price that charge is applied to' column is hidden; be sure that this column is visible during data entry.

PRICE COMPONENTS: ANALYSIS: Clicking on this button will bring you to the page of the workbook where price components data are analysed.

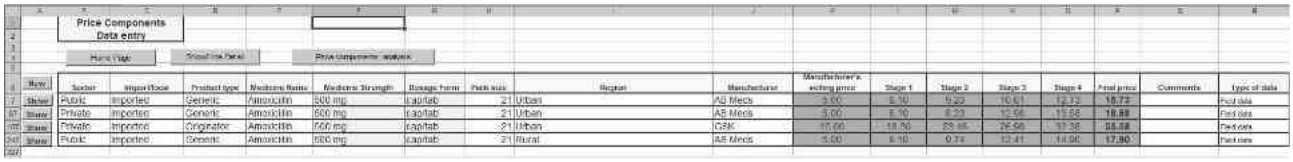
The *Price Components Data Entry* page displays a blank table where you can enter data from a single Price Components Data Collection form. To begin entering data

from a new data collection form, press the **NEW** button (cell A6); the workbook will display a new (blank) data entry table.

For each Price Components Data Collection form, one data entry table is completed.

You can show or hide each data entry table using the **SHOW/HIDE** buttons in Column A. When data are hidden the medicine identifying information is still visible (Fig. 9.2). Once multiple medicines have been entered, it is useful to hide the data that you are not working on to avoid scrolling through large amounts of data.

Fig. 9.2 Price composition page with hypothetical data from individual medicines hidden



9.13.1 Completing the data entry table

The first section of the data entry table is used for entering the medicine identifying information (Fig. 9.2). Complete this section in full, including:

Sector (Column B): Select the applicable sector (public, private, other and other 2) using the drop-down box provided (click on the cell and then on the arrow to the right of the cell).

Import/local (Column C): Select whether the medicine is imported or locally produced using the drop-down box provided.

Product type (Column D): Select whether the medicine is an originator brand or a generic equivalent using the drop-down box provided.

Medicine name, strength, dosage form and pack size (Columns E-H): Enter the target medicine name in Column E, its strength in Column F, and its dosage form in Column G. Enter the pack size for which data was collected in Column H.

Region (Column I): Select whether the data were collected in the urban or rural region surveyed.

Manufacturer (Column J): Enter the name of the manufacturer of this medicine. To the right of the medicine identifying information (Columns L-P), the cumulative price at the end of each stage of the supply chain is provided as a summary (note that Final Price is the price at the end of Stage 5).

Comments (Column Q): You will have chosen to survey different categories of medicines based on anticipated differences in add-on costs between categories. Use this cell to fully describe the medicine being studied according to the identified categories, e.g. on/not on essential medicines list, price controlled/unregulated; imported/locally produced; single source/multi-source.

Type of data (Column R): Select whether the data being reported are field data or hypothetical data.

The following data entry table sections are used to enter price components for each stage of the supply chain. Data entry is essentially a process of copying data from the Price Components Data Collection forms into the data entry grid in the workbook. As such, the data entry grid contains a similar interface to the Price Components Data Collection form, with three additional columns:

- **Value of charge (Column K):** The workbook will automatically calculate the value of each known charge in local currency. For fixed fees, the value will be the same as the amount of charge. For percentages, this column will show the actual amount of the charge.
- **Total (Column L):** This column provides a running total of the target medicine price, in local currency. The workbook calculates the cumulative price automatically as data are entered.
- **Cumulative mark-up (Column M):** The workbook will calculate the cumulative per cent mark-up automatically as each charge is applied. Cumulative per cent mark-up is a measure of how much higher a certain price is above the MSP or CIF.

The data entry table is organized according to supply chain stages, shown in Column E. Depending on the data you have collected for Stage 1, select 'MSP plus insurance/freight', 'CIF' or 'MSP only' using the drop-down menu that appears when you click on the cell containing the label 'MSP + ins/freight' (default). The data entry table will automatically be updated to allow you to enter the Stage 1 data you have collected. Similarly for Stages 3 and 4, use the drop-down menu to select Wholesale/Medical Store (Stage 3) and Retail/Dispensary (Stage 4) according to whether the data being entered are from the private sector or the public sector.

Type of charge (Column F): In Stage 1, charges (Manufacturer's selling price, insurance and freight, or CIF) will be listed automatically once you identify the type of data you collected in Column E (see above). In other stages, the type of charge is selected using the drop-down list. If the drop-down list does not contain the charge in question, select 'Other fees' and identify the charge in the Comments Column (Column N/O).

Charge status (Column G): Select 'Not found' or 'Value' using the drop-down list.

Charge basis (Column H): Select 'per cent' or 'fixed fee' using the drop-down list. Note that for MSP/CIF in Stage 1, procurement price in Stages 3 and 4, and selling price in Stage 5, charge basis is not applicable since these are not charges but the price of the product as it enters into the respective stages of the supply chain.

Price that charge is applied to (Column I): This is the column used to identify the price to which a *percentage charge* is applied, which is essential for calculating the value of the charge correctly. Note that when the charge is a fixed fee, the value of the charge is the same, regardless of the point in the supply chain at which the charge is applied. Column I is therefore not applicable and is 'turned off' (shaded in grey).

Using the drop-down list, you can select the correct point in the supply chain where the percentage charge is applied. Options available are:

1. The cumulative price of a medicine at the end of a stage (e.g. selecting 'Stage 3 cumulative total' from the drop-down list applies the percentage charge to the price of the medicine at the end of Stage 3).
2. The cumulative price of the medicine at the time the percentage charge is incurred, i.e. the total price in the preceding row (most common scenario). In this case, select 'Stage [X] cumulative total after [last charge that was applied]', i.e. the charge in the preceding row. For example, an importer's mark-up is applied as 5% of (CIF + international inspection + port charges + import tariff), with these three add-on costs applied in the order indicated. In Column I, 'Stage 2 cumulative total after import tariff' would be selected since the import tariff was the most recent charge. The workbook would then calculate the mark-up as a percentage of (CIF + international inspection + port charges + import tariff).
3. The value of an individual price component (e.g. selecting 'Stage 4 mark-up' from the drop-down list applies the percentage charge to the value of the retail/dispensary mark-up).
4. In Stages 3 and 4, the price at which the medicine was procured (e.g. selecting 'Stage 3 – procure price' from the drop-down list applies the percentage charge to the Stage 3 procurement price).

In some cases, a percentage charge is applied to a price that occurs later in the supply chain, usually the final retail price. The workbook cannot calculate the value of the charge if the price to which it is applied has not yet been determined. In these cases, it is necessary to calculate the value of the charge manually and enter it as a fixed fee in the data entry grid. In the Comments column, this can be clarified, e.g. 'Defence tax applied to final retail price'.

Amount of charge (Column J): Enter the amount of the charge. For percentages, use per cent values and not decimals (e.g. 13%, not 0.13). Only enter the number – the % sign will appear automatically.

Value of charge (Column K): The workbook will automatically calculate the value of each charge. For fixed fees, the amount of charge and value of the charge will be the same.

Total (Column L): The workbook will automatically calculate the cumulative total price as each charge is applied.

Cumulative mark-up (Column M): The workbook will automatically calculate the cumulative per cent mark-up as each charge is applied.

Comments (Column N): Use this column to record any relevant notes, such as pricing formulas, exemptions, etc. If any charges were recorded as 'other fees' in Column F, be sure to indicate the nature of the charge under Comments.

The workbook automatically calculates the total value of add-on costs applied during each stage (e.g. total Stage 2 add-on costs). It also calculates the cumulative total price (Column L), and the cumulative % mark-up (Column M), of the medicine as it leaves each stage. The total price at the end of a stage is automatically imported into the next stage as the 'starting price'. However, since price components data can be difficult to obtain and involve cross-checking data from multiple sources, data from different stages do not always match. For example, based on a wholesaler's purchase price of 150.00 and a CIF price of 100.00, you know that the total Stage 2 add-on costs must be 50.00. However, the Stage 2 costs you have

entered only total 35.00, probably because it was not possible to identify all the add-on costs incurred in Stage 2.

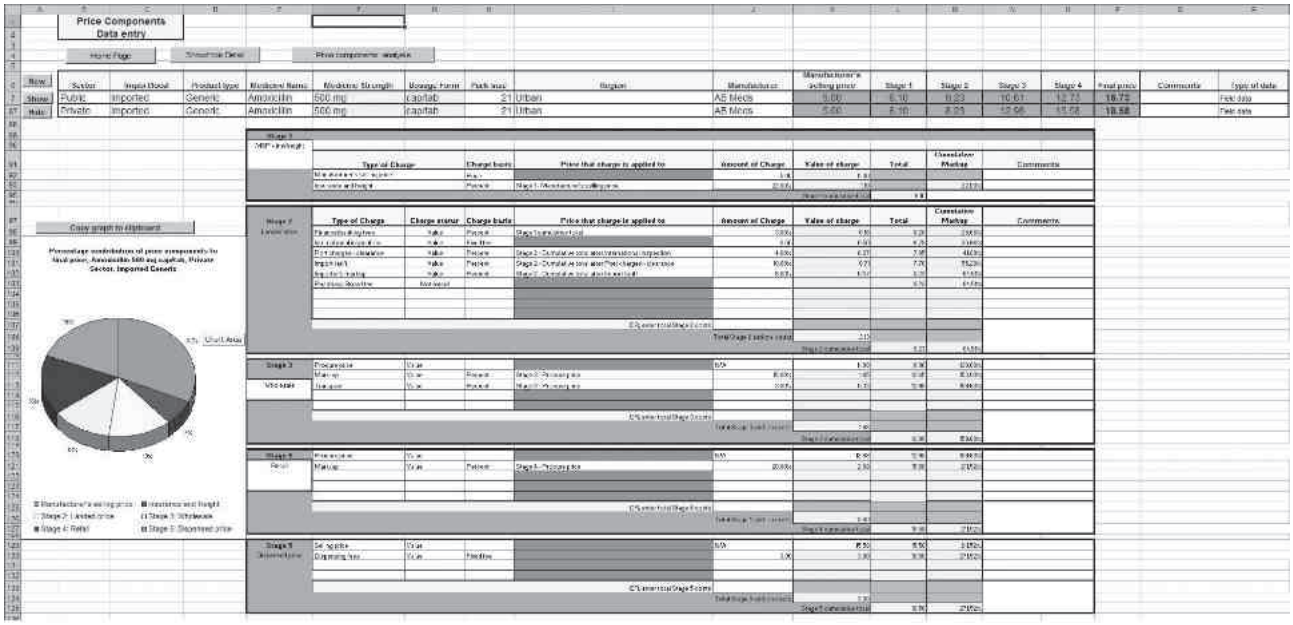
To address issues of mismatching data, you can overwrite the total costs for each stage as determined by the entered data. In the yellow rows marked 'OR, Enter total stage [X] costs', enter the alternative total cost for the stage in question (50.00 in the example above). The workbook will use this new amount to determine the cumulative total price of the medicine as it leaves the stage, as well as the 'starting price' for the next stage. Alternatively, you can also overwrite the starting price in Stages 3, 4 and 5 if you know it to be different from that calculated by the workbook. In the example above, the workbook will calculate the wholesale purchase price to be 135.00 (CIF + Stage 2 costs). By clicking on the cell in Column K containing the wholesale purchase price, you can type in the known procure price of 150.00. All subsequent calculations will then be based on this new value. *Be sure to explain any mismatching data clearly in your report*.

Note that to the left of the data entry table, a pie chart showing the contribution of each stage of the supply chain to the final price is generated as data are entered. These pie charts can be copied by clicking on the COPY GRAPH TO CLIPBOARD button, and then pasted into your report to illustrate results.

Fig. 9.3 shows an example of a completed price components data entry table. In this example:

- In Stage 2, the finance/banking fees charge is applied to the Stage 1 cumulative total, or the MSP plus insurance and freight.
- In Stage 2, the Pharmacy Board Fee is known to be a charge, but its value was not found.

Fig. 9.3 Price components data entry table (hypothetical data)



- The Stage 3 procure price (11.00) was identified as part of data collection, and it does not match the medicine price at the end of Stage 2, i.e. the Stage 2 cumulative total (8.23). This may be due to the fact that data were not found for some individual charges in Stage 2. The Stage 3 procure price has therefore been entered into cell K111, and is automatically used in calculating the cumulative per cent mark-up from this point forward.
- In Stage 3, both the wholesale mark-up and transport charges are applied to the same base price – the Stage 3 procure price.

9.14 DATA ANALYSIS

Once you have completed entering the data from each of the Price Components Data Collection forms into the workbook, check for discrepancies before beginning data analysis.

Analysing data on price components involves three steps:

- analysing data collected at the central level;
- analysing data collected for individual medicines; and
- comparing central information with the add-on costs observed through medicine tracking and identifying any discrepancies.

9.14.1 Analysing central data

Since the results of the price components study are presented as a case study, data analysis of central level data generally involves summarizing and consolidating information obtained through key informants. This should include:

- information on any policies related to price components (including any pricing formulas);
- the official and unofficial add-on costs applied to each stage of the supply chain;
- details of groups of medicines, sectors, etc. that are exempt from certain charges; and
- any prices or charges that you were not able to obtain; these indicate a lack of transparency in pricing information, which is a finding in itself.

The process of analysing centrally collected data is likely to begin during data collection and will evolve as new information is gathered.

Where you have conflicting information on the amount of a charge from different sources, it is useful to report the amount of this charge as a range (e.g. local transport costs range from 3–6%).

9.14.2 Analysing data for individual medicines

Once the price component data have been collected and entered into the workbook, they can be used for different types of analyses. You can use the summaries automatically calculated by the workbook to analyse:

- the cumulative per cent mark-up in the supply chain;
- the contribution of each stage of the supply chain to the dispensed medicine price;
- the price components with the most significant contributions to the final price; and
- comparison of price components across the sectors surveyed, the two regions studied, the product types surveyed, and any other categories of medicines included in the study.

Graphing individual medicines

For each set of data entered into the *Price Components: Data Entry* page, the workbook automatically generates a pie chart showing the per cent contribution of each stage of the distribution chain to the final price of the medicine, as shown in Fig. 9.3. Pie charts can be used in combination to show differences between regions, product types and sectors, etc. Pie charts can be copied by clicking on the **COPY GRAPH TO CLIPBOARD** button, and then pasted into your report (open your report in Microsoft Word and select Edit → Paste).

Producing summary tables

The workbook's *Price Components: Data Analysis* page allows you to generate summary tables across all of the medicines for which price components data were collected. These tables will allow you to compare data for different medicines and identify variations in add-on costs between product types, sectors, regions, and any other categories you have decided to study (e.g. locally produced vs imported medicines).

As shown in Fig. 9.4, summary data tables can be generated for three different measures:

- actual values;
- cumulative per cent mark-up; and
- per cent contribution to the final price.

You can switch between these measures by clicking on the respective buttons in Row 6.

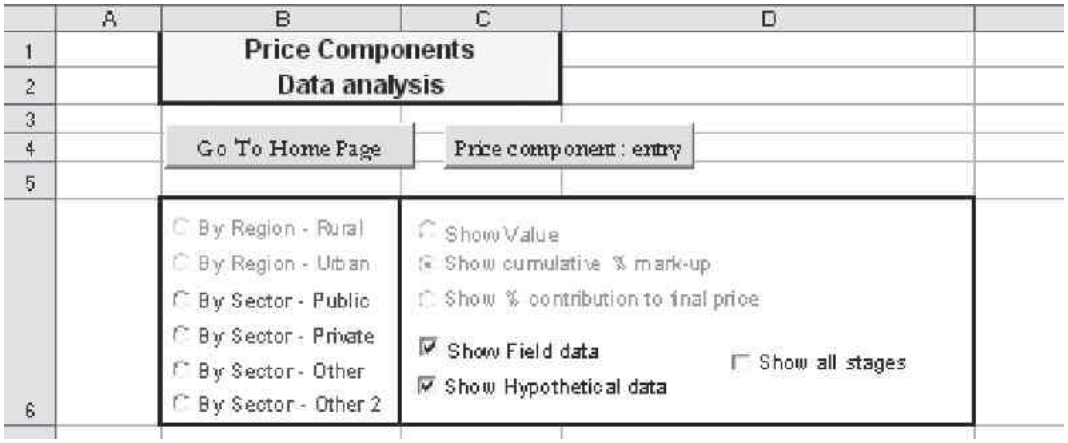
BOX 9.5

Difference between cumulative per cent mark-ups and per cent contribution to the final price.

Cumulative per cent mark-up is a measure of how much higher a certain price is above the MSP price. For example, if the MSP price is 100 and the price at the end of Stage 2 is 118, the cumulative % mark-up is 18%.

Per cent contribution to the final price is a measure of a certain price as a percentage of the final medicine price. For example, if the total Stage 2 costs are 23.00 and the final medicine price is 46.00, the per cent contribution of Stage 2 to the final price is 50%.

Fig. 9.4 Price Components: Data Analysis page showing parameters for producing summary tables



For each set of results, two types of views are possible: tables showing results by region and tables showing results by sector. The Region view will display data from either urban or rural survey areas, depending on your selection, for all sectors included in this survey area. For example, selecting 'By Region – Rural' will display all public, private, other and other 2 sector data collected in the rural survey area. Similarly, selecting the Sector view will display data from both urban and rural survey areas for the sector (public, private, other or other 2) that you select. For each view, select the data or sector you would like to display by clicking on the appropriate button in cell B6.

You can also choose to display hypothetical data, field data or both types of data, by selecting or deselecting the appropriate buttons in Row 6 (the default is that both hypothetical and field data are displayed). For each medicine in the summary table, results are simplified to show only the MSP/CIF, or MSP/CIF contribution to the final price, the final price, and in the cumulative per cent mark-up analysis, the total cumulative mark-up. Selecting the 'Show all stages' button in Row 6 will show the value (price), cumulative per cent mark-up or per cent contribution to the final price, depending on the analysis chosen, for each stage of the supply chain.

Begin by examining the values (prices) for either the urban or rural survey area. First select 'Show Value' and then select either 'By Region – Rural' or 'By Region – Urban'. The workbook automatically generates a table of values (MSP/CIF price and final patient price) for all medicines studied in the survey area, across all sectors studied. If 'Show all stages' is selected, the value for each stage in the supply chain will be displayed in addition to the MSP/CIF price and final price. Note: in your report you should identify if the price in Row 17 was the MSP or CIF price (as entered on the *Price Components Data Entry* page).

Then examine the cumulative per cent mark-ups for either the urban or rural survey area. You can obtain these tables by selecting 'Show cumulative % mark-up', and then selecting either 'By Region – Rural' or 'By Region – Urban'. The workbook will again generate a table displaying data for all medicines studied in this survey area, for all sectors studied. Note any differences you observe between the sectors in the study. You should also look for variations between imported and locally produced medicines, originator brand products and generic equivalents, and between the other categories of medicines you have decided to survey. For example, is the total mark-up for Medicine A, an imported product, higher than for Medicine B, a locally produced product?

Next examine the per cent contributions to the final price for the same survey area by selecting this button in Row 6. The workbook will automatically generate new summary tables. Again, identify any differences between sectors, imported and locally produced medicines, originator brand products and generic equivalents, and between the other categories of medicines you have decided to survey.

Although price components summary tables only stratify data by region or sector, you should also look for variations across the other categories of medicines you have studied (e.g. imported vs locally produced, NEML vs non-NEML)

Once you have completed analysing data for the first survey area, re-do the analysis for the second survey area by re-generating data tables as described above.

Next you should examine the values, cumulative per cent mark-ups and the per cent contributions to the final price for each sector in the study. Generate tables for a given sector by firstly selecting 'Show value' and then selecting the appropriate 'By Sector' button, in Row 6. The workbook will generate a table displaying data for all medicines studied in this sector, for both urban and rural survey areas. Then select 'Show cumulative % mark-up' and generate this summary table for the same sector. Finally select '% contributions to the final price' to generate the third table for this sector. Repeat the analysis for each sector in the study. In each table, note any differences you observe between survey areas, and look for variations between imported and locally produced medicines, originator brand products and generic equivalents, and between the other categories of medicines you have decided to survey.

Fig. 9.5 shows a hypothetical price components summary table comparing values in the private sector (note that the 'Show all stages' button has been selected and as a consequence data are provided for each stage of the supply chain). In this

Fig. 9.5 Example of summary table comparing values (prices) in the private sector

	A	B	C	D	E	F
1		Price Components Data analysis				
2						
3						
4		Go To Home Page	Price component : entry			
5						
6		○ By Region - Rural ○ By Region - Urban ○ By Sector - Public ◉ By Sector - Private ○ By Sector - Other ○ By Sector - Other 2	◉ Show Value ○ Show cumulative % mark-up ○ Show % contribution to final price ☑ Show Field data ☑ Show Hypothetical data ☑ Show all stages			
7						
8						
9		Value analysis by sector				
10		Sector	Private			
14					Amoxicillin	Amoxicillin
15					Generic	Originator
16		Type of region	Import/local	Data	Field data	Field data
17		Urban	Imported	MSP/CIF	5.00	15.00
18				Stage 1 add on costs	1.10	3.30
19				Stage 2 add on costs	2.13	5.16
20				Stage 3 add on costs	1.98	3.52
21				Stage 4 add on costs	2.60	5.40
22				Stage 5 add on costs	3.00	3.00
23				Final price	18.58	35.38

example, both product types of amoxicillin are imported, with the manufacturer's selling price of the originator brand being three times the price of the generic. The final patient price for the originator brand is twice the generic price. Examination of the mark-ups (Fig 9.6) will reveal that the cumulative mark-up is greater for the generic than the originator brand. However, the patient pays less when buying the generic.

Fig. 9.6 shows a hypothetical price components summary table comparing cumulative per cent mark-ups in the urban survey area (again the 'Show all stages' button has been selected so data are provided for each stage of the supply chain). In this example, the cumulative per cent mark-up for generic amoxicillin is higher in the private sector than in the public sector. There are many possible reasons, for example the public sector may be exempt from certain charges (such as taxes), or may apply lower mark-ups at central/regional medical stores and health facilities. Central level data, and data for individual medicines, would need to be checked to explain these findings. Fig. 9.6 also shows that in the private sector, the cumulative per cent mark-up for amoxicillin is higher for the generic than it is for the originator brand. However, bear in mind that higher percentage charges may still result in lower actual add-on costs if the base medicine price is low. Note that in this example, data were not collected for originator brand amoxicillin in the public sector.

Fig. 9.6 Example of summary table comparing cumulative % mark-ups in the urban survey area

Price Components
Data analysis

Go To Home Page | Price component : entry

By Region - Rural
By Region - Urban
By Sector - Public
By Sector - Private
By Sector - Other
By Sector - Other 2

Show Value
Show cumulative % mark-up
Show % contribution to final price

Show Field data
Show Hypothetical data
Show all stages

Cumulative percentage markup by region

Type of region: Urban

Sector	Import/local	Data	Amoxicillin Generic Field data	Amoxicillin Generic Field data	Amoxicillin Originator Field data
Public	Imported	MSP/CIF	5.00		
		Stage 1 mark-up	22.00%		
		Stage 2 mark-up	51.24%		
		Stage 3 mark-up	15.00%		
		Stage 4 mark-up	20.00%		
		Stage 5 mark-up	23.56%		
		Total cumulative mark-up	214.82%		
		Final price	15.73		
Private	Imported	MSP/CIF		5.00	15.00
		Stage 1 mark-up		22.00%	22.00%
		Stage 2 mark-up		34.84%	28.22%
		Stage 3 mark-up		18.00%	15.00%
		Stage 4 mark-up		20.00%	20.00%
		Stage 5 mark-up		19.26%	9.27%
		Total cumulative mark-up		271.52%	135.86%
		Final price		18.58	35.38

Fig. 9.7 shows a hypothetical price components summary table comparing per cent contributions to final price in the public sector. Note that in this example add-on costs in the supply chain contribute a greater proportion to the final medicine price in the rural area than in the urban area. Again, there are many possible reasons, including higher transport charges to the rural area.

Fig. 9.7 Example of summary table comparing % contribution to final price in the public sector

Price Components
Data analysis

Go To Home Page | Price component : entry

By Region - Rural
By Region - Urban
By Sector - Public
By Sector - Private
By Sector - Other
By Sector - Other 2

Show Value
Show cumulative % mark-up
Show % contribution to final price

Show Field data
Show Hypothetical data
Show all stages

Percentage contribution to final price by sector

Sector: Public

Type of region	Import/local	Data	Amoxicillin Generic Field data	Amoxicillin Generic Field data
Rural	Imported	MSP/CIF Contribution		27.94%
		Stage 1 Contribution		6.15%
		Stage 2 Contribution		20.34%
		Stage 3 Contribution		14.94%
		Stage 4 Contribution		13.87%
		Stage 5 Contribution		16.76%
		Final price		17.90
Urban	Imported	MSP/CIF Contribution	31.78%	
		Stage 1 Contribution	6.99%	
		Stage 2 Contribution	19.87%	
		Stage 3 Contribution	8.80%	
		Stage 4 Contribution	13.49%	
		Stage 5 Contribution	19.07%	
		Final price	15.73	

9.14.3 Comparing central data with data from individual medicines

The third step in data analysis is to compare the data obtained at the central level with the actual mark-ups observed through medicine tracking. Any discrepancies should be highlighted in your case study.

9.15 REPORTING RESULTS

The price components case study should be included as a section of the medicine prices survey report. The case study should include:

1. Introduction

2. Methods

This should include the regions, sectors, medicines and components selected for medicine tracking, with rationale.

3. Results

This should include:

- A written summary of central level data on price components;
- Results of medicine tracking, including pie charts for selected medicines and summary tables;

- Comparison of central level data with results of medicine tracking.

4. Discussion and recommendations

In this section of the case study the researcher can identify those price components that could be changed so as to reduce the final price of the target medicines. To do this, the participant should have an understanding of the current pharmaceutical policies, as well as have identified the price components with the most significant contributions to the final price of medicines. Not all price components can be reduced: they might be required (e.g. to finance quality control testing), or the small financial gain from changing them will not out-weigh the administrative and implementation costs. However, most health programmes will find that there are always some price components that can be reduced. Researchers should compare the largest contributing costs with existing policies and identify and discuss those price components that are not currently addressed by policies.

However, changing policies at the central level does not mean that they will be enforced at the periphery or that patients will see the expected price reductions. It is likely that a monitoring system will need to be set up at the same time to guarantee that the policy changes have the expected effect and the cost savings reach the patient and do not end up as a larger margin for some middleman.

5. Conclusion

The researcher can use this section to highlight key points and suggest further areas of study, if needed.

Further information on reporting is provided in Chapter 12.

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10

International comparisons

While median medicine price ratios within a country can provide insight into the local medicine pricing policies, comparison with medicine prices in other countries can give further information and is particularly powerful in advocacy messages. Reliable evidence that the governments and/or populations of two similar countries are paying very different prices for the same medicine gives advocates and policy-makers in the higher-price country a chance to examine the underlying reasons and to identify ways of obtaining lower prices. Chapter 10 offers suggestions on how international price differences can give clues to possible lines of action to reduce medicine prices.

International comparisons must be undertaken carefully so that valid similarities and differences between like products in like sectors can be identified. The data that you and others using this manual have collected enable international comparisons to be made of:

- the availability and prices of individual originator brand or generic medicines from each defined sector on the global and regional core lists;
- the brand premium – the difference in price between purchasing an originator brand compared to the lowest-priced generic equivalent of the same active ingredient and strength;
- the affordability of selected courses of treatment, measured against each country's public-sector minimum wage; and
- the way in which the retail price of a medicine is composed in different countries.

10.1 PITFALLS IN INTERNATIONAL COMPARISONS

While it is possible to simply take the prices or median price ratio (MPR) for a medicine in two (or more) countries and compare them, the interpretation can be difficult. The medicine market volumes may differ; the surveys may have been conducted in different years with the countries subject to diverse inflation rates (and having used MSH reference prices from different years); and the retail buying power of a currency may vary, depending on the wealth of the respective countries. Adjustment of the data for inflation and purchasing power parity (PPP) may be necessary (Section 10.4).

The comparison of a composite sample or basket of medicines between countries, rather than individual items, can be used to determine whether medicines are more

expensive, in general, in one country than in another. However, such a comparison is relatively more complex than the other comparisons and requires special statistical methods and skills, as well as additional data. This chapter provides some guidance on this, but the assistance of a health economist can be useful.

It should be noted that international comparisons of availability, affordability and price composition of individual medicines are not affected by the factors described above for MPRs and can be performed without adjustment.

10.2 WHERE TO OBTAIN COUNTRY DATA FOR COMPARISON

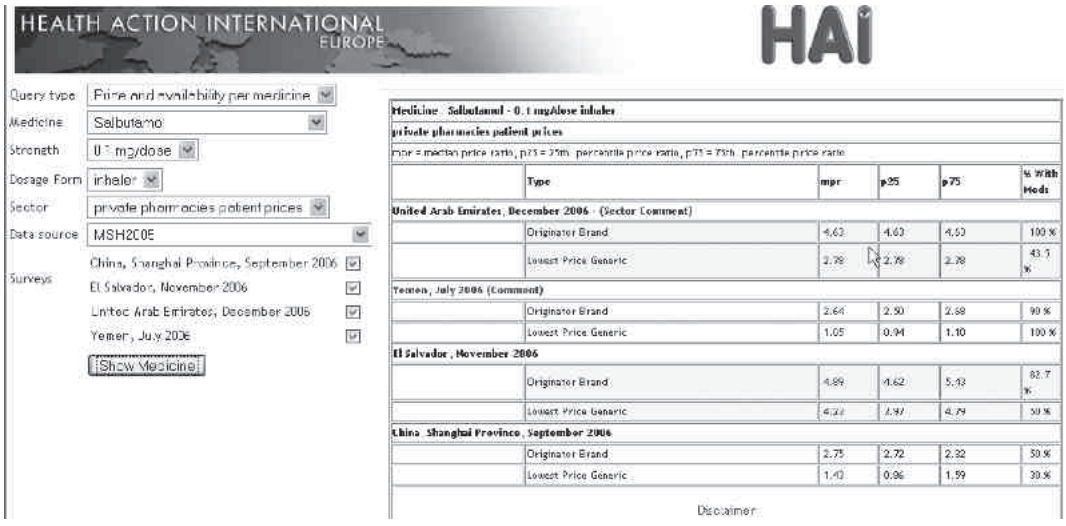
The HAI web site[1] has a publicly accessible global database dedicated to the storage of country price data collected in accordance with the procedures suggested in this manual. It will allow you and others to compare your data with those from other countries in which similar price surveys have been carried out.

The database can be queried according to:

- price and availability per medicine;
- price and availability per survey;
- summary data from a single survey;
- affordability per survey; and
- affordability per condition.

Fig. 10.1 shows a typical database query and results, in this case, examining the price and availability of salbutamol inhaler in surveys that used 2005 MSH international reference prices for their analysis.

Fig. 10.1 Database query for retail pharmacy salbutamol inhaler price and availability



You are strongly encouraged to send your completed workbook to HAI so that it can be checked and entered in this publicly accessible database.

In addition to the global database, a data extraction tool has been designed to facilitate generation of results across multiple surveys. The data extractor allows

[1] http://www.haiweb.org/medicineprices

for more specificity in the extraction of survey data and will be developed to adjust data for inflation, MSH year used and country wealth. The data extractor is available upon request by contacting HAI.[1]

10.3 CHOOSING WHAT TO COMPARE

10.3.1 Choosing countries

Normally, when making comparisons, the countries with which you compare your data should be similar in terms of economic wealth and development; be of similar population size; and have a health system similar in structure and use to that in your country. Neighbouring countries are not always the most appropriate choice, though comparing neighbouring countries may be relevant when investigating sub-regional approaches to improving access to medicines, e.g. pooled procurement or subregional medicine pricing policies. The choice of countries for comparison will vary, depending on the purpose of the comparison; sometimes comparisons to very poor or very rich countries can carry powerful advocacy messages, e.g. to show that the prices in a relatively poor country are the same as in a relatively rich country. If the survey data chosen are from a different year to that of your survey then adjustments of MPRs may be necessary (see Section 10.4).

As the vast majority of surveys conducted thus far have used MSH reference prices, using a different source of reference prices in your survey will limit your ability to conduct international comparisons and is therefore discouraged.

10.3.2 Choosing medicines

When selecting a medicine whose price is to be compared across countries, ideally it should be one that has one major indication and is used in a similar manner across countries. Often, suitable drugs are those for chronic diseases, such as diabetes medicines like metformin and asthma medication like salbutamol inhaler. Medicines for acute conditions often have multiple indications and their prescribing patterns as well as corresponding market volumes can be very country-specific.

10.4 ADJUSTING DATA IN INTERNATIONAL COMPARISONS

If you are comparing data between two or more surveys conducted in different years, you should adjust the data so that they use the same MSH reference prices; are corrected for inflation/deflation in local currencies; and, if necessary, PPP in the respective countries. The adjustments specified below are recommended.

Public procurement prices: standardize to the same MSH reference price year and adjust for inflation/deflation. PPP adjustment should not be necessary if most medicines are procured as generics since these are available from multiple suppliers within a global marketplace just as for many other non-health commodities, i.e. rich and poor countries should be able to purchase multisource products at around the same price; in practice, national regulations, bargaining power and other factors may limit the degree to which this is true in a particular instance. The prices of single-source (originator brand) products will be more subject to the pricing strate-

[1] info@haiweb.org

gies of the manufacturing companies and the procurement authority's negotiating power and skills.

Public sector and retail pharmacy patient prices: standardize to the same MSH reference price year, adjust for inflation/deflation and adjust for the local currency's buying power (PPP). The latter step is needed since the cost of living varies between rich and poor countries; the costs of running the retail pharmacy (including pharmacist's salary, local taxes, rental and overheads) and the currency's buying power will affect medicine prices. Therefore, the prices of the latter will vary considerably between countries according to the strength of their local currency.

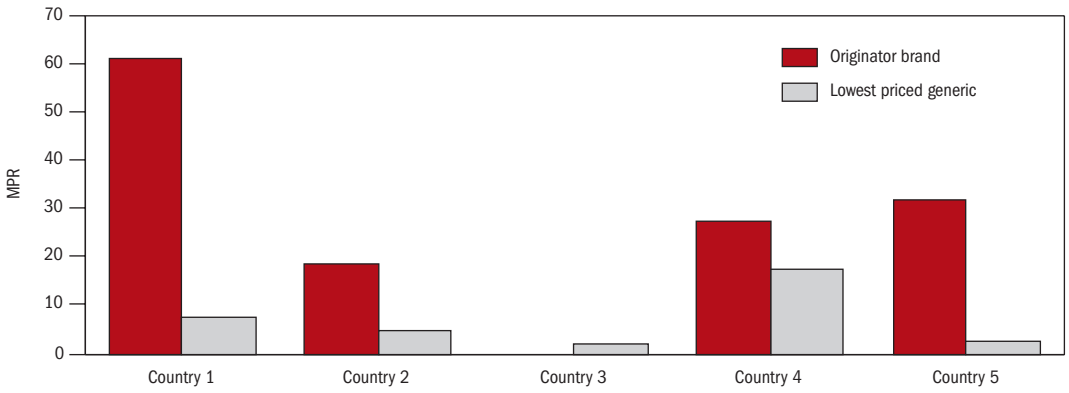
Annex 8 provides basic instructions on how to perform these adjustments along with a sample calculation. In the examples given elsewhere in this chapter, it should be assumed that the appropriate adjustments have been made to allow reliable comparisons of medicine prices.

The large majority of surveys conducted to date have used MSH prices as the standard set of international reference prices to which median local prices are compared. As such, the adjustment instructions provided in Annex 8 assume the use of MSH prices; similar adjustments would also be needed if other reference prices are used.

10.5 COMPARISONS OF THE PRICES OF INDIVIDUAL MEDICINES

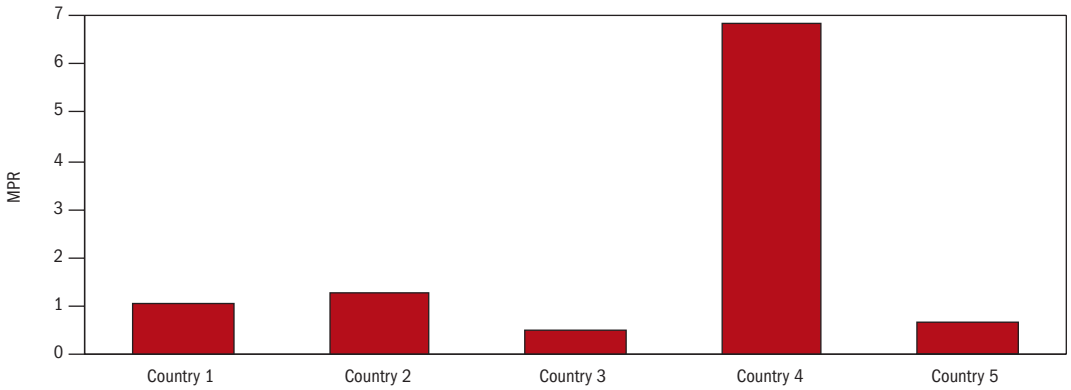
When making international comparisons with the survey data, the most robust method to use is the one whereby you compare the prices of individual medicines, i.e. take a medicine and look at its price in various countries. Fig. 10.2 shows a fictitious example of how you can use your data and data from other countries to compare the MPR for the same medicine in several countries. Private sector price ratios for ranitidine in five countries show that while the originator brand MPR in all countries except Country 1 is less than 35 times the international reference price, countries' prices differ markedly from the international benchmarks. Country 1's private sector price for the originator brand is about 60 times the international reference price but only 8 times higher for the generic equivalent. Comparable ratios in Country 4 are 27 (originator brand) and 17 (lowest-priced generic). Notice the difference between originator brand and generic price in each country – the brand premium. The originator product costs almost 8 times that of the lowest-priced generic in Country 1, while in Country 4 the originator is only 1.5 times the price of the generic.

Fig. 10.2 Ratio of local price to international reference price MPR[a] for ranitidine 150 mg tablets, private sector, in five countries (2004)



[a] Median Price Ratio

Fig. 10.3 Ratio of local price to international reference price MPR[a] for lowest-priced generic omeprazole 20 mg capsules, private sector, in five countries (2004)



[a] Median Price Ratio

You can, of course, further simplify this by, for example, comparing only the originator brand price ratios or only the lowest-priced generic price ratios between countries, as in Figure 10.3. In this example, the price of lowest-priced generic omeprazole in Country 4 is 7 times higher than in the other selected countries. It would be worth investigating why this is so.

Each of the surveys using this approach employs the same set of reference prices for all studies conducted in a given year, so the MPR for originator brand ranitidine or omeprazole in Country 3 can be compared directly to its equivalent in Country 1 or any other country. These can be adjusted for PPP, where necessary, as explained in Annex 8. Remember, an MPR of 1 means that the medicine's price is exactly equal to the international reference price; a median price of 10 means that it is 10 times more expensive than the international reference price, and so on.

You should not add up or average these median prices across different medicines since, for the reasons mentioned above, developing reliable composite price indices requires different methods and additional data. However, it might be useful to identify the four or five highest-and lowest-priced medicines in each country. Where these 'Top Five' and 'Bottom Five' lists differ widely between countries, local charges such as mark-ups, duties and taxes may be contributing more to these differences than manufacturers' selling prices. Where the same items recur in the Top and Bottom Five, the manufacturers' selling prices may be the major component in the retail price. Further investigation of price composition will probably be necessary to ascertain this, before the focus of policy is turned to manufacturers' selling prices.

10.6 COMPARISONS OF THE AVAILABILITY OF MEDICINES

The availability of medicines can be compared in a similar manner to their prices. As with prices, it is possible to compare the availability of baskets of medicines or individual medicines. In the public sector, it is likely that not all survey medicines are supposed to be available in all facilities or levels of care, and it is possible that medicines not on the essential medicines list should not be available at all. In such cases, comparisons of individual medicines rather than baskets of medicines are preferred to avoid making inappropriate comparisons. For private sector medicine outlets, comparing baskets of medicines presents less of a problem although, ideally, they should be matched so that they contain the same medicines in each

basket, for example, only compare core medicines, not supplementary medicines. Comparing individual medicines is also possible. Table 10.1 shows the availability of carbamazepine tablets in private retail pharmacies in five African countries as an example.

The limitations of the methodology should always be borne in mind when making these comparisons; even if a particular medicine is not available on the day of data collection, alternative dosage forms or strengths or therapeutic alternatives may have been available. In addition, be aware that earlier surveys measured *median* availability, whereas later surveys measure *mean* availability.

Table 10.1 Availability of carbamazepine 200 mg tablets in private sector medicine outlets in five African countries

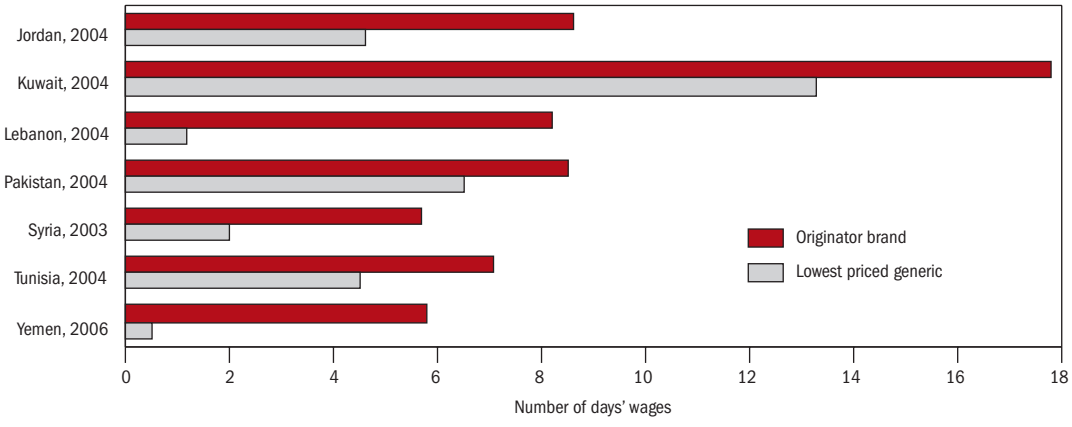
Survey	Median availability	
	Originator brand	Lowest-priced generic
Ethiopia, Sept. 2004	20%	72%
Ghana, Oct. 2004	9%	29%
Kenya, Nov. 2004	59%	81%
Uganda, April 2004	20%	80%
United Republic of Tanzania, Sept. 2004	15%	38%

10.7 COMPARISONS OF THE AFFORDABILITY OF TREATMENT

International comparisons of affordability can be made by transferring the data on the number of days' wages required to pay for a course of treatment (8.6 Analysis of treatment affordability) to a cross-country comparison chart, as in the example in Fig. 10.4.

Fig. 10.4 shows that ulcer treatment with ranitidine bought from a retail pharmacy in Kuwait would cost over 12 days of income for a person on the lowest government wage, while the same treatment course in the other countries would be 6–8 days' wages for the originator brand and 1–6 days' wages for the lowest-priced generic. However, it is important to interpret the results in the context of the country, which can be obtained from the survey reports posted on the HAI web site. In Kuwait, everyone is covered by health insurance, whereas there are millions of people in Pakistan who do not even earn as much money as the lowest-paid unskilled govern-

Fig. 10.4 Intercountry comparison of affordability: number of days' wages needed to purchase 30 days' treatment with ranitidine 150 mg tablets from a private sector medicine outlet



ment worker. Even though ranitidine is more affordable in Pakistan than in Kuwait, it is likely to be unaffordable for much of the population.

Once again, sectors should be compared separately. In these comparisons, there is no need to adjust the data for inflation or PPP since the price of a course of therapy is compared directly to the lowest government wage of that year, with both in local currency units. However, bear in mind that country situations can change over time and old data may be outdated.

As discussed in earlier chapters, the use of the daily wage of the lowest-paid government worker to estimate treatment affordability is limited in that:

- many people may earn less than the lowest-paid government worker or be unemployed;
- other non-discretionary expenditures such as food and housing are not taken into account; and
- many poor people experience seasonal fluctuations in income;
- a number of dependents may live on this wage, who themselves may require medicines, or one person may need more than one medicine, even for the same disease.

Despite these limitations, the daily wage of the lowest-paid government worker has been shown to be a reliable measure that can provide some indication of the affordability of medicines. In conducting international comparisons, it may also be useful to report the proportion of the population living on less than US$ 1.00 or US$ 2.00 per day (accessible from *World Development Indicators* published by the World Bank[1] since medicines that appear affordable for the lowest-paid government worker are still likely to be out of reach for these groups.

10.8 INTERNATIONAL COMPARISONS OF PRICE COMPONENTS

An awareness of how local retail prices are built up is essential information for understanding the significance of differences between the reference prices, which are not retail prices, and the local price. In comparing the price components in your country to those in other countries identify differences in the manufacturer's selling price and add-on costs, of which you might not otherwise have been aware. Such comparisons can help in deciding the level at which advocacy and policy interventions need to be directed, if appropriate.

The staged approach in analysing price components, as described in Chapter 9, facilitates the comparison of price components between countries. Public sector patient prices and private sector patient prices should be compared separately. To ensure comparability, the same categories of medicines should be compared across countries, for example, originator brands vs generics or imported vs locally produced medicines. An example is given in Fig. 10.5 using fictitious private sector data.

It can be seen from the example that much of the patient price of the medicine in Country 1 comes from Stage 1 (predominantly the manufacturer's selling price). Country 2 has a much lower contribution from Stage 1 but has a significant Stage 5 component (tax and dispensing fees). If the prices of medicines in Country 1 are high, Stage 1 components should be targeted. In Country 2, however, it may

[1] http://www.worldbank.org/data

Fig. 10.5 International comparison of price components using staged analysis

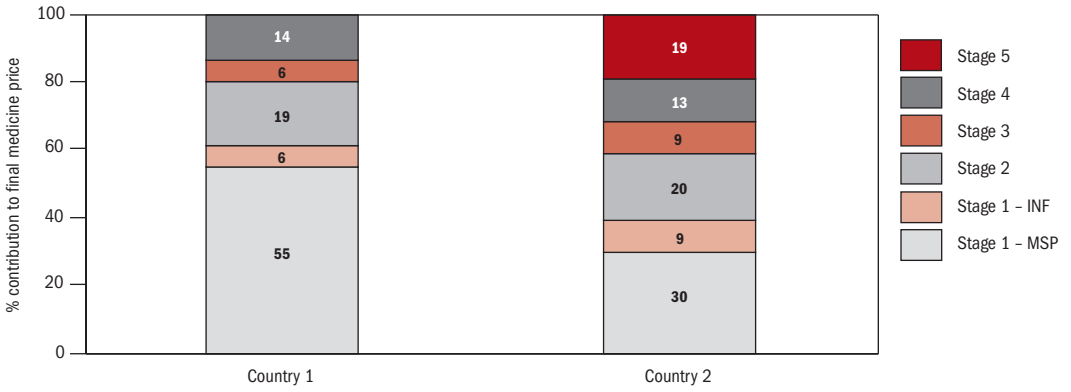
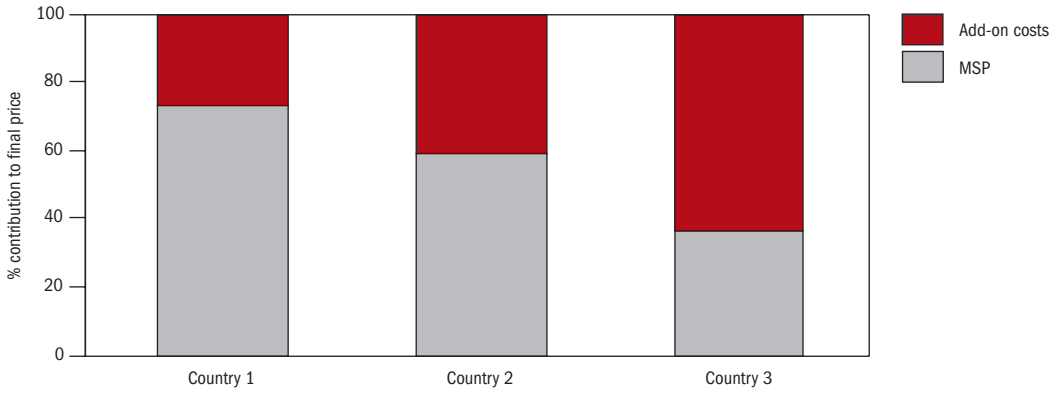


Fig. 10.6 Comparison of the contribution of add-on costs to final selling price for the same medicine across three countries



be more appropriate to investigate whether final taxes and dispensing fees should be reduced. Comparing the individual components within a stage can provide additional information.

Information on price composition from other countries can be found under 'survey results' in the medicine price section of HAI's web site.[1] However, as the staged approach to price components is a new addition to the medicine prices methodology, earlier surveys may not have collected data using this format.

You can compare the per cent contribution of each stage of the supply chain to the final medicine price as in Fig.10.5 or you may choose to examine the contribution of the manufacturer's selling price (MSP) or cost, insurance and freight (CIF) price compared to total add-on costs, as shown in Fig. 10.6. In this fictitious example, MSP makes up a larger proportion of the final price than do add-on costs in Countries 1 and 2. However, in Country 3, add-on costs are more than doubling the MSP price of the medicine and opportunities for reducing add-on costs in the supply chain should be investigated.

Other useful comparisons of price components include:

[1] http://www.haiweb.org/medicineprices

1. Comparisons of total cumulative per cent mark-ups by sector across countries

In some cases, it may be useful to show how cumulative per cent mark-ups vary by sector in different countries. A fictitious example is shown in Table 10.2 below. In Country 1, the cumulative per cent mark-ups in the public and NGO sectors are similar while the mark-up in the private sector is substantially higher. In Country 2, there is less variation in cumulative mark-up across sectors.

When conducting such comparisons, data should be analysed for at least two medicines to be sure of a consistent trend.

Table 10.2 Comparisons of total cumulative per cent mark-ups by sector across countries

	Country 1		Country 2	
	Amoxicillin 500 mg cap/tab	Glibenclamide 5 mg cap/tab	Amoxicillin 500 mg cap/tab	Glibenclamide 5 mg cap/tab
Public	43%	38%	67%	67%
Private	87%	113%	78%	92%
NGOs	49%	40%	80%	83%

2. Comparison of a single price component across countries

The fictitious example shown in Table 10.3 below compares the import tariff for generic amoxicillin in four countries.

Table 10.3 Import tariff on generic amoxicillin in 4 countries

	Country 1	Country 2	Country 3	Country 4
Import tariff	2.75%	10%	4%	5%

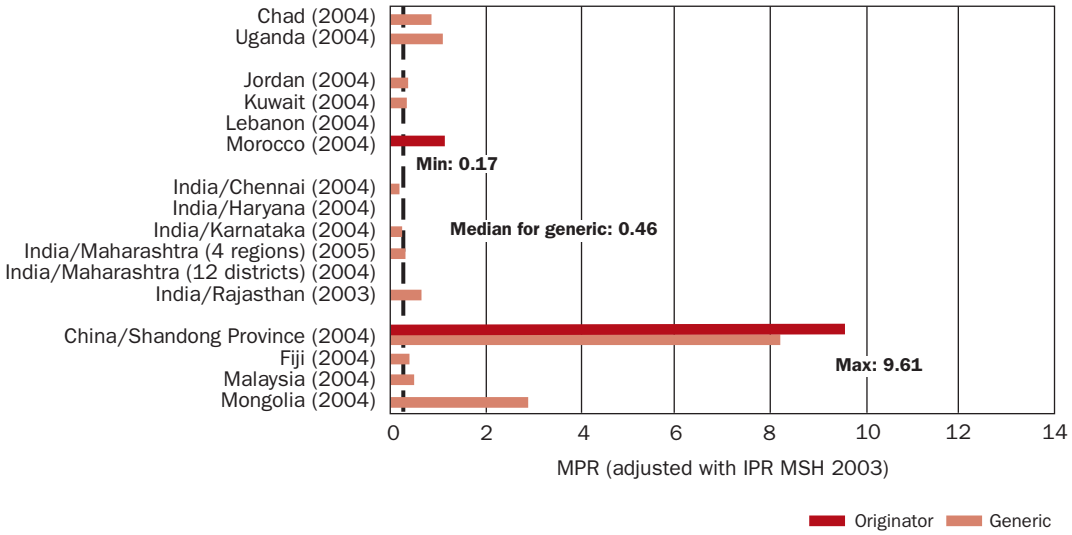
In Table 10.3, the import tariff applied to generic amoxicillin in Country 2 is more than double that applied in the other countries. In presenting such data in a survey report, it would be important to note whether the same import tariff is applied to all imported generic and originator medicines, and to which sectors in the survey it applies. Other useful information to report is the potential savings that would result from removing the tariff. This information can be obtained by opening the *Price Components: Data Entry* page of the workbook Part II, deleting the data on the import tariff (or other price component being studied), and comparing the new (hypothetical) final price with the actual final price obtained in the survey. (Warning: be careful not to save the workbook if you have deleted data).

10.9 INTERNATIONAL COMPARISONS BY DISEASE GROUP

It is possible to undertake international comparisons of medicines that are used in a particular disease or group of diseases. This has been illustrated recently in a publication that used WHO/HAI survey data to look at price and availability of medicines for chronic diseases (*1*). An example is shown in Fig. 10.7.

The figure dramatically illustrates that metformin tablets are being procured at too high a price in China (Shandong Province) and also in the surveys in Mongolia, Morocco and Uganda compared to other countries (*2*). By also examining other diabetes medicines from the surveys, e.g. glibenclamide, a picture of the affordability and treatment of diabetes medicines can be created. Of course, the basic

Fig. 10.7 Comparison of metformin 500 mg tablets MPRs[a] in public procurement across 16 surveys[b]



[a] Median Price Ratio
[b] WHO/HAI, 2006

methodology does not include all medicines used for a particular disease, only certain sample or indicator medicines, and this must be taken into account when interpreting the results.

10.10 INTERNATIONAL COMPARISONS OF PRICES FOR A SAMPLE OF MEDICINES

To find out whether medicine prices systematically differ between countries, some analysts have undertaken comparisons of a representative sample of medicines in different countries. The Governments of Australia, Canada and the USA have commissioned such comparative work in recent years (*3*,*4*,*5*).

A simple average of the medicine prices in the sample means that every medicine in the basket is given equal weight. If some medicines are more important than others (for example, if some account for a very large share of the market and others a very small share), a simple average will understate the share of the more important medicines in the total. In some cases, statisticians assign a weight to the price of each item in the sample to reflect its relative importance. The weighting may also need to take account of differences in market share of the various strengths and dosage forms in which a medicine is available. An average is then calculated of the weighted prices; this is called an index price. This procedure is common with price indices that measure retail prices, for instance. A price index recognizes that some medicines are more important than others, perhaps because of consumption patterns or local disease epidemiology, and it entails assigning relative weights to each item in the sample. Discounting strategies, distribution of market power and other aspects may also need to be accounted for.

The methodology for such studies requires both statistical skills and data which go beyond the scope of the approach to price sampling and comparison described in this manual. For readers who are interested in the details of more ambitious international comparisons, publications in the Reference section at the end of this chapter provide an introduction to the methodology of such comparisons (*6*) and more detailed methodological discussion (*7*,*8*,*9*).

Despite this, it can be tempting to compare your summary MPR values to those in other surveys. If you decide to make such comparisons of baskets of medicines for your report, such as comparing sector summary MPRs across countries, you must acknowledge the limitations of the WHO/HAI survey methodology, i.e. that each basket does not contain exactly the same medicines and their importance in the market (as given by sales or market share) is not known. You must also be careful about the conclusions that you draw; such comparisons can indicate that there is a difference in price between the countries but they are not definite proof. Be aware that comparing overall combined ratios like this may leave you open to criticism that you are not comparing like with like, especially if you draw inappropriate conclusions. This could discredit your report. People who may be exposed and criticized by the study's findings may prefer to attack the methods used in the study rather than address the results. By limiting yourself to individual medicines, as distinct from composite comparisons, you can be confident that your results are totally defensible.

For the reasons given above, it is recommended that cross-country comparisons be limited to comparing the price ratios, affordability and price components of individual medicines. Comparing the top five and bottom five medicines in terms of cost in relation to reference prices or affordability may be more than enough to support your conclusions and recommendations.

Another option is to identify a basket of medicines that was found in all of the countries you wish to compare, and calculate and compare the summary data (e.g. average per cent availability, median MPR) for this limited set of medicines. This allows international comparisons to be made on the same group of medicines. However, this approach is very resource-intensive in that it involves identifying a basket of common medicines found in all countries, recalculating summary measures on this limited basket and comparing results across countries. Moreover, if only a small number of medicines are available for this comparison, the results will not be representative or as robust as countrywide measures.

10.11 INTERNATIONAL COMPARISONS USING OTHER DATA SOURCES

This chapter focuses on making comparisons of medicine prices across countries using the data derived from WHO/HAI medicine price surveys. Other data sources of medicine prices and health-care spending are available such as public National Health Accounts, IMS statistics[1] and household survey data. By investigating relationships between medicine price survey data and these other data sources and comparing them between countries, it is possible to gain a deeper understanding of medicine pricing issues within a region or group of countries. However, this is beyond the scope of this chapter.

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[1] http://www.imshealth.com

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11

Exploring possible policy options and lines of action

A number of factors can cause high medicine prices or low availability. This chapter illustrates a menu of possible policy options that may be relevant in different circumstances of high prices or low availability.

A meeting of the advisory committee should be held following the survey to present the survey results, discuss their interpretation and develop policy recommendations. It is crucial to determine the factors that are the principal causes of low availability or high prices and/or of price variations in your setting.

Whenever a new policy is introduced, it is important to monitor the impact of the policy change to detect unintended consequences.

The underlying purpose of the price and availability survey is to bring about changes that will result in lower prices and improved availability to patients and, hence, increased access to needed medication. Chapters 7, 8 and 9 have shown how to generate and present summary results from the survey for each individual medicine and each sector, as well as how to analyse treatment affordability and price components. This chapter shows some of the linkages between the price and availability information you can now present, and a range of possible policy actions that will improve regular access to essential medicines at prices affordable to all.

More detailed guidance on the various policy options to address high medicine prices, low availability and poor affordability is currently being developed. Check the HAI web site[1] or contact HAI[2] or WHO[3] for updates.

The potential for change varies dramatically between countries and can also vary over time. The ability to build a case and a constituency of support on a particular issue also depends very much on local circumstances. In many instances it may be necessary to collect additional information before identifying and promoting a particular change.

Because the local context is of overriding importance in determining the most appropriate lines of action to follow in a price survey, this manual can only give general guidance. The previous chapters give clear directions on how to proceed with the design, execution and analysis of the price survey, but this chapter simply identifies possibilities, leaving it to the survey manager/commissioning organization and the advisory committee to research and judge which, in the context of local institutions and politics, are the most appropriate actions to follow.

[1] http://www.haiweb.org/medicineprices
[2] info@haiweb.org
[3] medicineprices@who.int

BOX 11.1

Other information sources about the pharmaceutical situation in your country

There are a number of different sources of information that can be reviewed for information about the pharmaceutical and medicine prices situation in your country. These include:

- *National Health Accounts*.[1] The key indicators available from these are the percentage of GDP spent on health, percentage of Total Health Expenditure (THE) spent on pharmaceuticals and percentage of GDP spent on pharmaceuticals.
- *World Health Survey*.[2] This provides data from an extensive household survey. Table 8.2 of the standard report provides information on household health expenditure, including medicines spending as a percentage of total household health spending by different groups.
- *Commercial Surveys Organizations*. Examples of these are IMS Health and Research International, which undertake pharmaceutical market surveys and may, if approached, make available summary reports or relevant information without charging. Enquiring from private sector colleagues may be worthwhile.

Survey findings, for example, may suggest that the prices of individual medicines are 5, 10 or even 40 times higher than the MSH reference prices. Even with the analysis of price composition, however, it may be unclear how much of this price difference is due to high manufacturers' prices and how much to inefficient procurement practices or other price elements in the national system, such as mark-ups and taxes. Each of these possible causes will need to be addressed by a different line of action and will incur support and opposition from different stakeholder groups. A more systematic examination of the different possible contributory factors will always be necessary to ensure that the principal cause is correctly identified.

In some cases, more in-depth research will be required to identify the determinants of high medicine prices, low availability and poor affordability and/or develop appropriate policy responses. For example, in developing a policy to promote increased use of generic medicines, it may be necessary to conduct qualitative research on attitudes and beliefs surrounding generic medicines to determine whether resistance to their use is caused by perceived poor quality, brand loyalty or other factors. Similarly, a country may want to evaluate the effectiveness of its generic substitution policy by conducting a simulated client or a so-called 'mystery shopper' study (more information on conducting these studies is available on the CD-ROM). Survey findings that include poor availability of a particular medicine of national importance may indicate the need to conduct a medicine prices and availability survey for the therapeutic group (see Chapter 3, page 40) to which this medicine belongs so as to better assess availability.

This chapter should be read in conjunction with Chapter 13, which discusses the process of bringing about policy change.

11.1 DATA FROM THE SURVEY AND ITS INTERPRETATION

As described in Chapter 8, your survey results allow four different types of price and availability comparisons.

[1] http://www.who.int/nha/en/
[2] http://www.who.int/healthinfo/survey/en/

Type 1: Individual medicine price comparisons

- For every medicine and in each sector, comparison with international reference price benchmarks and, as they become available, against the relevant prices in other country surveys and regional synthesis reports
- For any originator brand medicine, comparison with the lowest-priced generic equivalents, and comparison of the availability of both
- For every medicine, public and private sector prices and, where appropriate, prices at NGO, church mission or 'other' health facilities
- Comparison of the public sector procurement price with the international reference price and with the retail price for any medicine in each sector.

Type 2: Availability comparisons

- Availability of originator brand medicines and lowest-priced generic equivalents in up to four sectors, separately and compared.

Type 3: Affordability comparisons

Treatment costs in relation to local wages compared by:

- Condition (14 recommended)
- Treatment affordability by sector: public, private and, where appropriate, 'other' sectors
- Treatment affordability by medicine type: originator brand and lowest-priced generic equivalent
- When available, treatment cost for a given condition compared with the cost of the same treatment in other countries or regions.

Type 4: Price component comparisons

- Price components of locally manufactured medicines compared with imported medicines
- Manufacturer's price or tender price compared with retail price
- Comparison of relative size of mark-ups (wholesale and retail), taxes, duties, tariffs, etc. in the final price for originator and generic products
- Comparison of price composition of essential (EML) medicines with non-essential medicines, if applicable
- Comparison of price composition by sector or by region.

In looking for lines of action and policy, it is important to focus on comparisons that show major differences between the following: local and international prices; sectors; originator brand medicines and generics; or between wage levels and treatment costs and in the major components of mark-ups. Differences suggest the possibility that prices can be brought down: the bigger the difference, the greater the scope for change.

Some of the various manifestations of price differences or problems detected will, of course, originate in the same cause. The affordability of treatment may be a problem and prices for an originator brand product may be high in relation to international reference prices, for example, simply because the local manufacturer or agent sets a high price. If procurement is also inefficient, distribution arrangements are expensive due to high mark-ups by wholesalers and retailers, and no generics are available, the price problem could be attacked using several approaches.

Among such approaches would be: better procurement, price negotiation, prescription and dispensing incentive reform – and thus practice reform – promotion of generics or consideration of a compulsory licence or use of any other legal safeguards in national legislation that may make cheaper generic versions of medicines under patent in the country more available.

Where the analysis of price composition suggests that local factors, such as tariffs, taxes and distribution mark-ups contribute significantly to final price, a general review of distribution costs may be necessary. Among other things, this review might consider whether essential medicines are exempt from import duties and other taxes; how distribution costs – particularly mark-ups – compare in the different domestic systems (public, NGO and private); and how medicines distribution costs compare with those of other commodities, such as perishable foods and beverages. In addition, investigation into the economic viability of the supply chain may be necessary to evaluate the feasibility of possible interventions.

Where local add-ons and distribution costs appear to be less important contributors to final price, but prices are high relative to international benchmarks, there may be a need to examine the efficiency of national and subnational procurement processes in getting the best possible manufacturer or seller prices. A supportive national policy on generic medicines – particularly in the selection, procurement, promotion, prescribing and dispensing processes outlined in Table 11.1 – is needed to underpin price regulation. Pooling procurement between hospitals or health authorities, ensuring competitive tendering and use of information about prices in other markets may all help. Where originator brand prices appear to be high relative to prices in other countries, you may wish to consider negotiating for differential prices with the manufacturer or exploring the possibility of parallel importation from a lower-price country, and/or increasing competition, if possible. Compulsory licensing, for local production or importation, may therefore be considered for key limited-source medicines. Fairer financing schemes for medicines can improve access through employment or community-based insurance and social security schemes and other forms of prepayment, and through exemptions in fee systems to minimize the price barrier for poor people.

It is important to provide empirical data to policy-makers on the need for policy change and to develop a close understanding of why the differences exist before selecting the line of action and making suggestions on the direction of government policy. Broadly speaking, it may be helpful to think in terms of policies concerned with getting better prices from manufacturers or intermediaries, on the one hand, and those designed to keep prices as close to the manufacturers' prices, through cost containment measures, on the other.

11.2 POLICY OPTIONS TO ADDRESS LOW AVAILABILITY

There are likely to be different causes of low availability in the public and private sectors. In the public sector, for example, governments may be under-budgeting and not providing enough funds to meet the national needs. Another possibility is that it might be spending the available money on high-cost originator products when quality-assured generics are available or using the funds for hospital and not primary care medicines. In the private sector, a common cause of low availability of a specific product may be price regulations that discourage a manufacturer/supplier from producing, registering or supplying that product. Alternatively, there may be limited demand and for that reason retailers do not stock the product. Just as for high prices, understanding the reasons for low availability must be clear.

A range of policy options is open to governments to improve availability. Options include having government institutions prioritize the drugs budget, with particular emphasis on essential medicines and keeping this list current. Governments need to purchase low-priced quality generics, not more expensive originator brand products, so they can treat more people with the same resource allocation. If the private sector predominates and availability is poor then there may be a case for providing essential chronic disease medicines through the private sector at public sector procurement prices as the Eastern Caribbean countries and Jamaica have done for a limited medicines list for the elderly.

11.3 POLICY OPTIONS VARY FOR ORIGINATOR BRAND AND GENERIC MEDICINES

When considering policy options it is vital to distinguish between originator products that are patent protected – or protected by any other exclusive rights and only produced by the originator company (*single-source*) – and *multisource* products, for which generic equivalent products are also marketed. In the case of *single-source* products, for which no generic versions are available in a country, a monopoly situation exists. Therefore, the government may have to take action to increase access to essential medicines. This may include using therapeutic substitution, direct price negotiations, or use of the flexibilities compatible with the TRIPS Agreement of the World Trade Organization, as reaffirmed in the 2001 Doha Declaration on the TRIPS Agreement and Public Health for the purpose of "promoting access to medicines for all". One of these flexibilities is Member States' ability to issue compulsory licences for public health reasons in relation to any pharmaceutical product under patent in the country. For example, the government can permit the local production or importation of generic versions of patented medicines for purposes of public health (*1*).

Such approaches are inappropriate for *multisource generic products*. Regulating such medicine prices may lead to shortages when the price is set too low, or excessive prices when the price is not adjusted to consider changes in the market. Generic medicines are produced globally and the international market is very competitive such that generic medicine prices in New Zealand and the United Kingdom are very close to the MSH prices.[1,2] Setting a maximum retail price (MRP) for these products will often mean that the MRP comes to mean minimum retail price and all products cluster around this price. If reference pricing is used to set prices for generics, e.g. by stating that generic prices should be no more than 80% of the originator brand price, this creates incentives for agents to import a small quantity of high-priced originator products to set a high price and then sell large volumes of generic products at 80% of this high price. If generic medicines are to be subject to price controls (which we do not recommend) then the price should be set as a fixed margin above procurement prices rather than pricing down from originator prices. Generic medicine prices will be most efficiently reduced while ensuring availability by promoting a transparent market in which prices of quality assured generic medicines are freely published and generic substitution is required or encouraged so that consumers can make choices to purchase the best value generic product (*2*). Note that where countries limit the number of generic equivalent products available on the market, this may have the effect of limiting competition and lead to higher prices.

[1] New Zealand: http://www.pasa.nhs.uk/PASAWeb/Productsandservices/Pharmaceuticals/Electronicmarket informationtooleMIT.htm
[2] United Kingdom: http://www.pharmac.govt.nz/interactive/

11.4 POLICY OPTIONS VARY IF MEDICINES ARE PURCHASED BY THE STATE OR HEALTH INSURANCE SCHEMES COMPARED WITH OUT-OF-POCKET PURCHASES

There are major differences in policy options related to who is paying for the medicines. If the government is purchasing the medicines to be given or sold to its citizens through cost recovery schemes, policies to improve access and reduce prices could include establishing a national Essential Medicines List, pooled procurement of government institutions, tendering and for patent-protected medicines employ the TRIPS flexibilities under the government use provision. (For example, the United States Federal Government has defined these powers in national law).[1] Governments are also in strong positions to use their powers to encourage differential pricing policies and to exempt themselves from tariffs and taxes that are often paid on government purchases.

Health insurance organizations are also in a strong position to negotiate prices of products that they reimburse. For originator products for which there are therapeutic substitutes, the organization may require dramatic price reductions before an originator product could be allowed on the organization's formulary. Where no therapeutic equivalent exists, aggressive use of pharmacoeconomic techniques may be used to drive down prices. If the company is unwilling to reduce its prices, the insurance organization has the option of refusing to reimburse or setting the patient copayment at a high level. Conversely, when the insurer wants to encourage use of a specific product, it can reduce copayments. By monitoring consumption closely insurers can intervene to promote cost-effective therapeutics. For multisource generic products, the insurer can choose to reimburse at the lowest or median market price.

For consumers who pay out of pocket (OOP), the power relationship is very different. Governments have a duty to inform and protect these consumers but the government's power is very different when it is not paying for the medicines. The government can inform these patients by providing objective comparative medicines information, by patient education campaigns and by providing comparative price information in a transparent fashion. To protect the patients who purchase their own medicines, governments can regulate to ensure that generic medicines on the market are of good quality; require or at least promote generic substitution; control mark-ups; and remove taxes and duties charged on prescription medicines. In addition, governments can work with professional associations of doctors and pharmacists to ensure that professional standards are followed and that conflicts of interest, such as occurs with dispensing doctors, are banned. Hopefully, in time, more of those consumers who presently pay for medicines themselves will be covered by health insurance or social security schemes.

11.5 CONTROLLING MARK-UPS IS ALWAYS DIFFICULT

As has been seen in some medicine price and price component surveys, additional charges that occur between the manufacturer and the patient may more than double the price paid by the patient. For some of these, e.g. taxes and tariffs, it is easy to argue that such charges are contrary to the public good in that it is obviously regressive and inequitable to target the sick to pay these taxes. However, for other components, such as storage and transport costs, wholesaler and pharmacy charges, individuals and organizations deserve to be paid for the value of

[1] See also US Code: Title 28, part IV, CHAPTER 91, 1498. Patent and copyright cases

BOX 11.2

Medicine price and availability surveys lead to positive policy changes

Medicine price and availability surveys have already led to positive policy changes in selected countries in the Eastern Mediterranean Region. For example, following a medicine prices and availability survey in Lebanon in February 2004, the Ministry of Health implemented a new pricing structure for all imported medicines:

FOB $	Shipping insurance	Customs clearance	Importer mark-up	Pharmacy mark-up	Cumulative mark-up
0–US$ 10	6.0%	10%	10%	30%	**66%**
US$ 10– US$ 50	4.5%	8.5%	10%	30%	**62%**
US$ 50–US$ 100	3.5%	7.5%	9%	27%	**54%**
> US$ 100	2.5%	6.5%	8%	24%	**46%**

This new pricing structure has reduced medicine prices by an estimated 3–15%.

macy charges, individuals and organizations deserve to be paid for the value of the services that they provide. Moreover, the economic viability of the supply chain must be ensured to maintain or improve medicine availability.

However, unlike groceries, medicines are not common goods and are subject to professional and regulatory controls. Wherever possible, fixed fees are preferable to proportional fees. For example, if a pharmacist is paid a 25% mark-up for dispensing a product, he/she has a strong financial incentive to recommend the highest-priced originator product. However, if a fixed fee is charged, the incentive is reversed and the cheapest generic product will be the most profitable to sell.

The problem with such an approach is that under some circumstances poor patients purchasing low-cost generic products may be charged a great deal, more than the medicine cost. To address this difficulty, many countries have combined a low fixed dispensing fee with a regressive margin in which the percentage mark-up decreases as the price of the medicine increases. The problem is compounded by the fact that the cost of doing business may vary, depending on where a pharmacy is located. A high-volume pharmacy located in a major city with easy access to wholesalers and low transport costs can afford to charge lower mark-ups and remain viable but a rural pharmacy with low volume demand will struggle to survive with equal mark-ups. It may be necessary to cross-subsidize distribution costs and allow a rural premium to ensure the viability of such pharmacies as is done in Sweden.

11.6 DEALING WITH REBATES AND DISCOUNTS IS EVEN MORE DIFFICULT

Developing policy options to take account of rebates and discounts that manufacturers and wholesalers offer is a challenge in all environments. For example, a manufacturer or wholesaler may offer a US$ 10 000 rebate to customers (e.g. pharmacists) who buy US$ 100 000 of its products. Discounts or bundling may be offered with deals such as buy three get one free. Under both of these scenarios the benefits accrue to the wholesalers or the pharmacies and are usually not passed on to the insurers who reimburse at the fixed price or to the patients. These practices contribute to increased margins, which may or may not affect the viability

on rebates and discounts is difficult; however, in a price components study in New Delhi, India, such information was available (*3*).

11.7 MONITORING AND EVALUATION

Any change in policy should have monitoring of implementation and evaluation of outcomes as integral components. When changes are made to regulations or incentives with the intention of lowering prices or increasing availability, sometimes the desired results are not achieved due to unexpected effects or influences. Reliable data are needed to be able to know whether to modify the interventions or introduce additional measures.

11.8 SUMMARY OF POLICY OPTIONS

A wide range of policy measures exists to deal with price and availability problems. Table 11.1 summarizes some of the possible policy actions to influence price, based on the WHO publication *How to develop and implement a national drug policy* (*4*). A mix of options is likely to be required. Different choices will need to be made for the public and for the private or NGO sectors.

11.9 LIMITATIONS OF PRICE CONTROLS

Price floors or ceilings set a minimum or maximum price for a product. Price controls alter free-market outcomes by encouraging over-production by a price floor or over-consumption by a price ceiling or a lack of availability if the ceiling price is set too low. Manufacturers are often prepared to stop producing low-price controlled products and replace them with slightly different products – 325 mg instead of 300 mg – to ensure that they can sell at a profit. When a MRP is defined for a product this often becomes the minimum retail price with all of the prices clustering around this price. When attempts have been made to control mark-ups the market has responded with concealed practices (such as co-marketing fees, where pharmacies are paid to contribute to marketing efforts, as a way of hiding a discount). Under some circumstances, manufacturers may combine into a producer cartel, where they set prices and then compete on rebates and discounts.

11.10 CONCLUSION

In conclusion, bear the following messages in mind about linking the survey findings to lines of policy action:

- Ensuring the availability of essential medicines is the government's responsibility. It can be achieved by government purchase and provision through the public sector, and it requires adequate budgetary provision as well as appropriate procurement and distribution strategies. Many of the initial medicine prices surveys have drawn attention to poor availability in the public sector, suggesting a widespread need to focus advocacy on restoring or strengthening this role of the government in ensuring public sector availability. Availability can also be improved by the government working through nongovernment and private sectors, although this requires that the government work in a different way, facilitating and enabling these organizations to achieve their objectives.

Table 11.1 Regulating price as part of an integrated medicines policy

Component of medicines policy	Examples of actions to influence price, availability and/or affordability
1. Selection of essential medicines	▪ Formulation/updating of essential medicines lists and institutional formularies ▪ Development and use of Standard Treatment Guideline ▪ Development of quality-assured therapeutic substitution policy ▪ Requiring the inclusion of medicines on the national EML in health insurance reimbursement lists with minimal co-pay
2. Procurement/purchasing	▪ Competitive procurement with price transparency ▪ Use of pharmacoeconomics or international price comparisons as guidelines for fixing prices of originator products ▪ Pooled procurement with other national buyers, such as hospitals or health authorities ▪ Examination of purchasing practices in other sectors to ensure best practice ▪ For single-source products, pressure for differential prices and exploration of possible parallel importation and the use of TRIPS flexibilities to stimulate generic competition (seek the advice of an intellectual property expert, review the experiences of countries that have implemented TRIPS flexibilities, and/or consult the *Guidelines for price discounts of single-source pharmaceuticals* (5). ▪ Assurance of transparent and quality price monitoring and public information
3. Distribution system	▪ Analysis of efficiency, transparency, competitiveness and intervention to correct, e.g. by contracting to private and not-for-profit logistics and security organizations with target-setting and performance-monitoring ▪ Monitoring and regulation/control of mark-ups with fixed fees and regressive margins
4. Generic competition	▪ Assurance of effective quality assurance capability and promotion of generic substitution at all levels ▪ Promotion of generic acceptance by professionals, patients and the general community ▪ Prequalification of generic manufacturers and publication of the quality assurance of such manufacturers ▪ Fast-tracking of regulatory approval of generic medicines
5. Prescribing and dispensing	▪ Assurance that consumers, the private sector and NGOs are informed about and involved with generic and therapeutic substitution, where allowed ▪ Building of incentives to prescribe and dispense generic medicines ▪ Encouragement of separation of prescribing and dispensing, including banning dispensing doctors ▪ Assurance of unbiased consumer medicine information ▪ Assurance that promotion of products by pharmaceutical companies is strictly regulated according to WHO Ethical Criteria and prevention of direct-to-consumer advertising of prescription medicines ▪ Monitoring of prescribing and dispensing practices, using WHO Drug Use Indicators
6. Financing	▪ Encouragement of pooled and prepaid financing of medicines, e.g. through employment-based or social insurance schemes ▪ Support of community-based insurance initiatives focused on improved access to essential medicines ▪ Assurance of exemptions or differential fee systems to protect access by indigent and disadvantaged groups ▪ Monitoring of prices and access; for example, routine monitoring of medicine prices and availability is under way in Kenya and Uganda[a] ▪ Assurance that health insurance schemes use limited formularies, based on cost-effective therapeutic guidelines

[a] http://www.haiafrica.org/

- Any individual price problem may have several contributing causes and may require action on several fronts.
- It is critical to be sure about the most important contributing causes before deciding on a strategy to change policy. It is counterproductive to employ cost-containment strategies when the problem lies with manufacturers' prices and vice-versa. Ascertaining this may require more research and technical support. Look for help from international experience with similar problems, such as mark-up levels and regulation.
- Analyse the relevant stakeholder positions, strengths and weaknesses carefully before deciding on how to formulate a plan for change. Build your coalition of support carefully and selectively. Read Chapter 13 on advocacy carefully.

- Use your judgment about whether, when and how to involve the mass media.
- Consider facilitating cohesive policy-making, e.g. a roundtable with ministry of health officials from your region.
- Monitor and evaluate any policy or other interventions intended to lower prices or increase availability.
- Lower medicine prices require much greater transparency in transactions at all levels; more openness and better public information will help to create a constituency for change. Change is possible!

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12

Reporting

The purpose of this survey is to stimulate action to make medicines more available and affordable to the entire population. This effort requires rapid and accurate reporting, as well as effective dissemination and advocacy. The survey findings should be presented in the most meaningful way for the survey's target audiences and should be disseminated both generally and to specific audiences. A standard report template is included in the CD-ROM to help survey managers develop a national survey report in a short timeframe. The workbook, survey report and related documents should be e-mailed to HAI[1] as soon as possible after the survey is completed.

The ultimate objective of conducting the medicine price survey is to contribute to making medicines available and affordable so that the entire population can have access to them when it needs them. Conducting the survey, along with analysing and interpreting the data, is important, but the final use of the results will depend on the effectiveness of an additional three crucial steps:

- reporting;
- dissemination; and
- advocacy.

Without these steps, the survey would be an interesting but futile exercise. This chapter provides guidance on developing a survey report and disseminating the survey findings. Chapter 13 offers guidance on advocacy strategies and activities.

12.1 SURVEY REPORT

Different stakeholders can use the findings from the medicine prices and availability survey for different purposes. The way in which the survey results are reported depends on who is reporting to whom, as well as the survey's objectives. For example, a report prepared by a consumer organization that is advocating for affordable medicine prices will differ from that prepared by a medicine policy section of a ministry of health, which is reporting on the impact of pricing tariffs. Different analyses and tables are likely to be included in the survey report and, correspondingly, different recommended actions. However, information on many aspects of the survey needs to be included in all reports, irrespective of the reporter or objective. All reports should include the following information:

[1] info@haiweb.org

- An executive summary
- The name of the organization that undertook the survey
- The survey's objective(s)
- When the survey was conducted
- Information on the national medicines situation relevant to prices and availability (Chapter 2)
- An outline of the methodology used (Chapter 3), such as:
  - — survey areas and sectors surveyed
  - — sampling method
  - — medicines surveyed
  - — data collection, data entry and quality assurance procedures
- Ethical issues, including:
  - — confidentiality
  - — endorsements
  - — potential conflicts of interest
- Results, with national and international comparisons (Chapters 8, 9 and 10)
- Discussion
- Recommendations (Chapter 11)
- Conclusion.

It is strongly recommended that the survey report be drafted, reviewed, finalized and disseminated as quickly as possible, preferably within one month of completing the survey. The survey findings could otherwise become outdated by policy or market changes, such as inflation, fluctuating currency exchange rates or price changes.

Tips for developing a survey report:

- Policy-makers and key stakeholders may not devote enough time to reading the full report and may only read the executive summary. More will read beyond the executive summary if you create interest at that stage.
- The report should be presented in a straightforward and precise fashion that is understandable to a moderately informed reader.
- Avoid presenting too many numbers, crowding tables or charts or presenting data too scientifically. This would make the report unintelligible to the casual reader; the detail can be provided in an annex, where necessary.
- Avoid overusing abbreviations in the report text.
- Tables and graphs should be employed to avoid long, complicated narrative descriptions of results.
- Results should be presented for the overall basket of survey medicines, as well as for some significant individual medicines (e.g. particularly low availability, high price or poor affordability; medicines of particular local significance).

- To enhance your survey report's local relevance, you may wish to present actual prices in the local currency, in addition to medicine price ratios when comparing originator brand with lowest-priced generic equivalents, for example.
- The findings must be presented to look interesting, with the conclusions and recommendations clearly presented and logically derived from these findings.
- Make logical inferences based on the results of the survey and take into account the limitations of the survey methodology. Where other data are available from other sources, refer to that information as well.
- Recommendations should reflect consultation with the survey advisory committee. They should be realistic, limited and focused on those areas where greatest impact can be achieved. They should identify the problem to be addressed and the proposed activity to deal with the problem.
- Conclusions and recommendations that do not emanate from the findings should not be included.
- Provide references, including to newspaper articles, if your report refers to such sources.

National reports from previously conducted surveys are available on the HAI web site.[1] These should be viewed as examples only. The actual data that will be presented in your report, and the conclusions and recommendations that will be drawn are all country-specific. They can only be determined after proper analysis of your data.

12.1.1 Standard Report template

A Standard Report template is included on the CD-ROM to assist survey managers in developing a national survey report in a short timeframe. It includes basic survey information and standard results that can be reported across as wide a range of surveys as possible. **The template should be considered as a starting point from which to add more information and data relevant to the survey objectives, country context and key findings**.

The Standard Report template is an inherent compromise, since report content and style should vary according to the purpose of the report and its target audiences. The report template was, therefore, created to be as multifunctional as possible, recognizing that one size does not fit all and that the report will not serve all purposes. To be useful to as many audiences as possible, the Standard Report is simple and concise, yet contains sufficient detail to be credible to experts. In cases where a report with a substantially different format or content is required (e.g. a ministerial briefing), the template can still serve as a useful reference document from which key elements can be taken.

The Standard Report template provides a summary of the range of medicine price, availability, affordability and price components data that can be generated from the survey. It is the survey manager's responsibility to identify the survey's key findings and provide more in-depth information, as well as expanded analysis, where warranted. The survey manager is also responsible for the interpretation of findings, since this will depend largely on the country context. Some standard text and examples have been included in the report template, but the survey manager's input in determining what to include is paramount. Similarly, the survey manager, together with the advisory committee, will need to identify the most appropriate policy and programme recommendations emanating from the survey findings.

[1] http://www.haiweb.org/medicineprices.

The Standard Report template is only a starting point from which to add more information relevant to each individual survey.

There are many more ways to analyse and present the data than are offered in the report template. The actual data that will be presented in your report should only be determined after their full analysis and identification of the key results.

The survey's conclusions and recommendations are country-specific and should be developed in consultation with the survey advisory committee.

A national survey report's content will vary considerably, based on whether medicines are free or sold to patients in the public sector and on the number and nature of any 'other' sectors included in the survey. **The Standard Report template contained on the CD-ROM was designed for a national survey in which patients pay for medicines in the public sector, and in which no 'other' sectors have been surveyed**. Where these conditions do not apply, survey managers will need to adapt the report to suit their survey's characteristics. In future, additional templates will be developed to address other common survey formats.

12.2 DISSEMINATING THE FINDINGS

To achieve wide coverage, the survey's findings should be disseminated both generally and to targeted audiences.

Targeted dissemination of the survey report should include, where relevant:

- The ministry of health's medicine policy section
- The ministry of finance
- National bureau of statistics
- National public health and medical associations
- National medical research council
- National pharmacy association
- Consumer organizations (national and international)
- Health, human rights and consumer-related NGOs (national and international)
- Bilateral donors and multilateral organizations (e.g. World Bank)
- WHO (country offices, regional offices and headquarters)
- Associations of pharmaceutical companies (multinational and national)
- Individual pharmaceutical companies (multinational and national).

General dissemination of the survey findings should include:

- Ministry of health officials other than those directly related to medicine policy and procurement
- Ministries of trade and commerce
- Academic and research institutions, public health institutions
- Members of parliament (with a briefing paper)
- Media (along with a press release and article for publication in the press)
- Medical journals (along with a journal article).

The survey report and any other communications materials (e.g. press release, policy briefing paper) should be posted on the web site of the organization that undertook the survey. The press release and key findings should be e-mailed to listservs (electronic mailing lists) such as e-drug and ip-health. Note that these listservs do not accept attachments. Instead, you may include a hyperlink to the full survey report on your web site.

12.3 REPORTING TO HAI AND WHO

To enable international comparisons to be made, data from individual medicine prices and availability surveys are entered into a publicly accessible, searchable database of survey data housed on HAI's web site.[1] Data from over 40 surveys are currently available through the database, and data from additional surveys are being added on an ongoing basis. The database provides a powerful tool for conducting international comparisons of medicine prices, availability, affordability and price components. However, its usefulness is dependent on the ongoing inclusion of new data as medicine prices and availability surveys are conducted. For this reason, it is important that all survey results be sent to HAI.

HAI and/or WHO review(s) all survey results before they are posted in the database of medicine prices on HAI's web site (this provides you with an additional quality control check of your survey data). Information on individual facilities is not shown on the web site so that confidentiality is assured, with any requests for this information forwarded to the survey manager. In addition to the data contained in the database on medicine price ratios, availability, affordability and price components, the web site also contains the survey manager's name and contact details, as well as the survey report and any associated documents.

Please e-mail the following to HAI[2] for posting on the web site:

- The survey manager's name and contact details
- The computerized workbook of survey results (both Part I and Part II)
- Survey report
- Other related documents, such as policy briefing papers, advocacy material, journal articles and media articles.

HAI requires survey managers to complete a Conflict of Interest and Permission to Publish form prior to posting survey material on the web site. These forms are available on the CD-ROM or from HAI.[3] Surveys funded by the pharmaceutical industry or industry associations will not be posted on HAI's web site. While the form does include permission to publish raw data (facility data), this is only made available to researchers in very specific circumstances. HAI and WHO have developed a strict protocol for use of this data and will only permit this after very careful consideration of the research's purpose and will monitor adherence to the protocol (including confidentiality of the facilities in each survey).

WHO and HAI welcome feedback on improving the manual, associated tools (e.g. workbook, standard report template) and database. E-mail your comments to HAI[4] in the first instance. The project's Advisory Group will discuss your comments during the further development of the manual.

[1] http://www.haiweb.org/medicineprices/
[2] info@haiweb.org
[3] Contact info@haiweb.org
[4] info@haiweb.org

13

Using the evidence and getting the messages out

The ultimate objective of conducting a medicine price survey is to contribute to making medicines more affordable so that the entire population has access to the medicines it needs. Conducting the survey and analysing and interpreting the data are important. However, they become really useful when the evidence and the analysis are used to help shape policy and improve practice.

A major point to bear in mind is that change in policy and practice rarely, if ever, happens because of a single intervention. The changes are likely to occur as a result of a longer-term process of communication, influence and persuasion. Planning for this requires as much time, attention and resources as the planning for the survey itself. It needs to happen alongside the planning for the survey activities, rather than being seen as an activity that can be added on after the survey is completed.

In planning to ensure that the evidence and analysis from your survey are used, you need to consider three inter-related areas:

- advocacy and influencing processes;
- communication processes to share findings; and
- materials to produce.

Since these are inter-related areas, they need to be linked together with a clear communication or advocacy strategy that helps to guide your thinking and planning. Without that, you might produce a wonderful report but not be clear about who needs to have it and how you can use it to influence the policy debate in a country. Equally, you might be very successful in setting up a meeting with the minister or the director of pharmaceutical procurement and not have a clear summary of your findings and a set of policy options to pursue.

13.1 ADVOCACY AND INFLUENCING PROCESSES

Advocacy is crucial in shaping policy. Advocacy – carried out in an ethical fashion – is fundamental to democratic decision-making. Effective advocates work to inform decision-makers, to persuade them, sometimes to support them and create support for their policies and, occasionally, to shame them into action.

Advocacy is about building a convincing case and getting it across to people who are in a position to influence, formulate or implement policy and affect the decision-making process. However, there is no single universally accepted definition, as Box 13.1 demonstrates.

One way to define advocacy is in terms of whether it is undertaken for, with or by those most affected by a particular situation. Advocacy may be seen as speaking on behalf of the voiceless (representation), encouraging others to speak with you (mobilization) or supporting the voiceless in speaking for themselves (empowerment). In dealing with access to medicines, it is worth asking whether the advocacy is being done by consumers or patients who lack access; by those consumers and patients along with a network of concerned NGOs, researchers or health workers; or by a group of organizations acting on behalf of those most affected.

BOX 13.1

What is advocacy?

Advocacy is the **process of using information strategically to change policies** that affect the lives of disadvantaged people. – *British Organisation of NGOs in Development (BOND)*

Advocacy is any effort to **influence policy and decision-makers**, to **fight for social change**, to **transform public perceptions** and attitudes, to **modify behaviours** or to **mobilize human and financial resources**. – *GAVI*

Advocacy is speaking up, **drawing attention to an issue** and winning the support of key constituencies in order to influence policies and spending and bring about change. – *WHO TB advocacy*

"Advocacy is an **ongoing process** aiming at change of attitudes, actions, policies and laws by **influencing people and organizations with power**, systems and structures at different levels for the betterment of people affected by the issue." – *Adapted from an advocacy skills-building workshop, India HIV/AIDS Alliance, India, November 2002*

Advocacy is about influencing or **changing relationships of power**. – *World Bank*

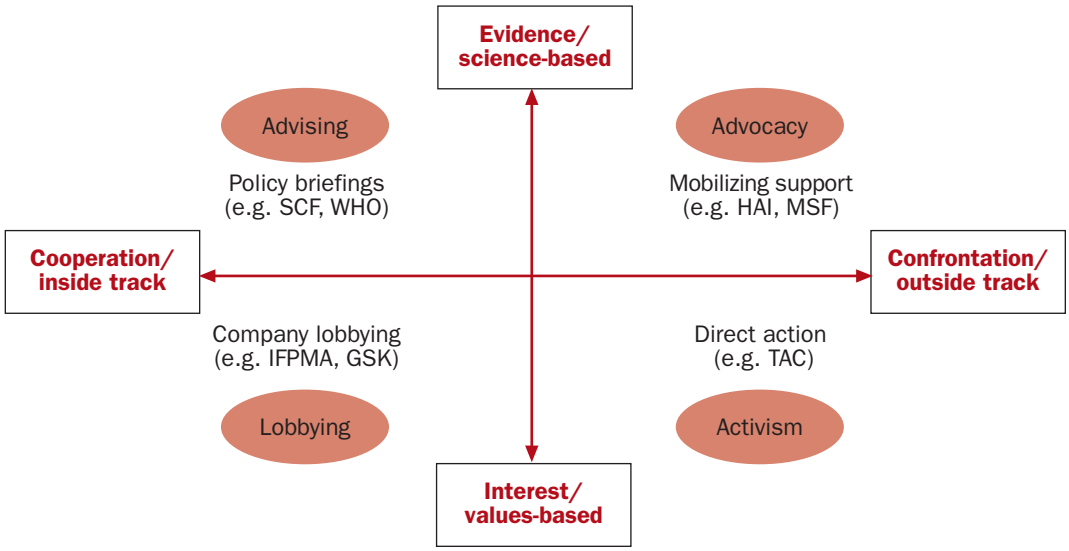
The United Kingdom Overseas Development Institute's Research about Development in Practice (RAPID) programme has developed a useful way to think about the various aspects of advocacy and influencing policy processes. RAPID explores how advocacy, advising or influencing, lobbying and activism relate to one another. It examines them in the light of both the extent to which they are based on evidence or driven by values and whether they are externally or internally located regarding the relationship with those who are the target of influence. Fig. 13.1 shows how this might play out in the area of access to medicines.

13.2 DEVELOPING AN ADVOCACY STRATEGY

Advocacy is a long-term process. It involves a series of connected activities or actions, often happening at different levels and according to different time frames. One or two isolated activities do not represent an advocacy campaign. You should not expect to bring about real sustainable change unless you engage in a number of strategically planned actions that build on each other over a long period of time. For this reason, advocacy should be thought of in terms of *strategies* and *campaigns* rather than individual activities.

It is important that you have a clear strategy which helps to guide you.

Fig. 13.1 Tools and organizations on the medicines cooperation/evidence axes



Source: Adapted from: Start D, Hovland I. *Tools for policy impact: a handbook for researchers* [monograph on the Internet]. London, Overseas Development Institute, October 2004 [cited 2007 Dec 05] (http://www.odi.org.uk/rapid/Publications/Documents/Tools_handbook_final_web.pdf)

The first – and most important – challenge that you have to resolve is to decide on what change you are trying to achieve with your advocacy. This is sometimes described as the objective or goal of any advocacy campaign. Is it a new law to regulate prices? Is it an awareness campaign about the high quality of generics in a country to encourage greater use of lower-priced generics? Is it a call for greater transparency about procurement prices? Is it an attempt to get the government to rescind a tax on medicines? Advocacy can be aimed at:

- creating policies where they are needed but none exist (which may require creating awareness about an issue);
- reforming harmful or ineffective policies; and
- ensuring good policies are implemented and enforced.

However the advocacy is done and whoever is involved, there are some key actions that are almost always essential to its successful outcome, whether you are involved in a local campaign or in international policy advocacy. These actions will help you develop your advocacy strategy. They include the following:

- analyse the problem and define your objectives;
- identify and understand those actors you want to influence;
- get to know the people you want to influence;
- build a strong case;
- identify allies who share your views;
- identify and understand potential opponents;
- develop a long-term plan; and
- take advantage of strategic opportunities.

13.2.1 Analyse the problem and define your objectives

You need to be able to explain the problem and what you think needs to be done to tackle it. You should also set goals that will help you to monitor progress and measure the success of your activities. This may well require an initial period of background research, data gathering, consultation and preparation. It is time well spent.

For example, the international relief NGO Médecins Sans Frontières (MSF) launched its Access to Essential Medicines Campaign around three clear pillars:

- using public health needs to override trade agreements;
- overcoming access barriers; and
- stimulating research and development for neglected diseases.

Similarly, the WHO/HAI Project on Medicine Prices and Availability has an overarching goal and three specific objectives:

Goal:

- improve the availability and affordability of essential medicines.

Specific objectives:

- develop a reliable methodology for collecting and analysing price and availability data across health-care sectors in a country;
- price transparency: put survey data on a freely accessible web site, allowing international comparisons;
- advocate for appropriate pricing policies and monitor their impact.

Developing a clear statement of your objectives will help you to plan your strategy and prioritize key activities. It will also make it much easier for people to understand your campaign and its focus.

13.2.2 Identify and understand those actors you want to influence

When planning your advocacy work, ask yourself the following questions:

- what is the policy environment?
- who are the key actors?
- who makes the decisions?
- whom do they rely on for advice?
- what process is used to make decisions?
- are there key moments or times in the decision-making process?

For example, if you wanted to influence a bill going through parliament in your country, you should try to find out who is responsible for drafting the law and who is advising him or her. You should try to get a clear idea of which committees, departments and outside bodies will be consulted. You need to know how many stages there are to the legislation; for example, first and second reading. You also need to know the timetable for these stages. Often a well-reasoned case presented at an early stage can achieve as much or more than an intensive advocacy campaign, which is started after the basic decisions have been made.

Remember that not everyone needs to be convinced. You do not have to persuade everyone to take up your position or work for the change you are proposing. It helps to do a very simple stakeholder analysis to categorize those you want to reach. Each group then needs a different approach. Some groups may need to be persuaded to take a position, some may need to be encouraged to change a position, some may simply need to be encouraged to stay supportive, while some are best left alone, since it would be a waste of effort.

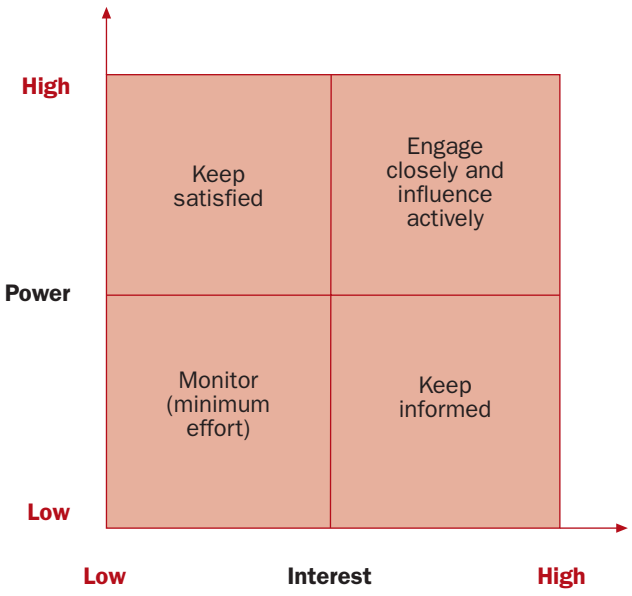
Neutralize or convert	Activate (move from neutral)	Reinforce	No effort required
Opponents	Uncommitted and involved	Allies	• Unmovable opponent • Uncommitted and uninvolved • Hard-core allies

Making use of a stakeholder analysis process is a way to identify whom to target (Fig. 13.2) (*2*). A stakeholder is a person who has something to gain or lose through the outcomes of any intervention or policy change.

Stakeholders can be organizations, groups, departments, structures, networks or individuals, but the list needs to be fairly exhaustive to ensure that no one is left out. Organize the stakeholders according to their interests and power. 'Interest' measures to what degree they are likely to be affected by the research project or policy change and what degree of interest or concern they have in or about it. 'Power' measures the influence they have over the project or policy and to what degree they can help achieve or block the desired change.

Powerful stakeholders with interests aligned with your goals are those people or organizations it is important to fully engage and bring on board. If you are trying to create policy change, these people are the targets of your campaign. At the top of the power list will be the decision-makers, usually members of the government. Below them are those people whose opinion matters – the opinion leaders.

Fig. 13.2 Stakeholder analysis grid



Source: Hovland. I. (2005) *Successful communication: a toolkit for researchers and civil society organisations*. RAPID Toolkit. London, Overseas Development Institute, 2005 (http://www.odi.org.uk/RAPID/Publications/Documents/Comms_tools_web.pdf)

Stakeholders with a high level of interest but little power need to be kept informed. However, if they are organized, they may form the basis of an interest group or coalition that can lobby for change. Those stakeholders with a lot of power but little interest should be kept satisfied and, ideally, brought around as patrons or supporters for the proposed policy change.

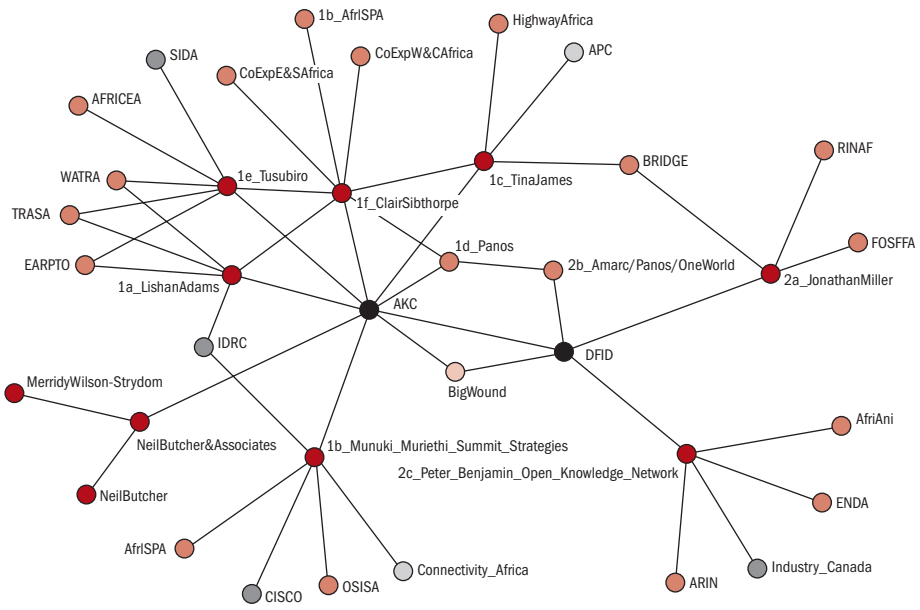
A further refinement to the analysis is to consider what a particular stakeholder's attitude to the change is likely to be. This is assessed as either being positive, neutral or negative to the change. For example, if the policy change is calling for a limitation on the mark-up levels of medicines at the retail level, the group of stakeholders involved in retail pharmacy is likely to be negative, and it will work against the change.

Do you have contact with the people you want to influence? If not, it is important to do some homework and to invest time in developing a list of key people and how to reach them. Analyse whether you need to concentrate on convincing technical experts (e.g. those involved in evaluating applications for registration) or policy-oriented people (e.g. those who design drug registration legislation). Using processes such as social network analysis can help to identify the links between different stakeholders in the process and those who might be particularly influential. The defining feature of social network analysis is the focus on the structure of relationships (*3*).

Fig. 13.3 presents a picture of some of the key connections of stakeholders in an ICT programme in Africa. Analysis such as this helps to identify the key players. In the diagram, it is clear that several individuals (Fig. 13.3, shown in red) played a major role as connectors, with each of them linking between three and five organizations. If this was a picture of the medicine procurement or supply system in a country, the people who are the connectors, or the major facilitating organizations (Fig. 13.3, shown in black) would be important people for you to reach.

Do stakeholders know who you are and what your purpose is? You may need to spend time making appointments as well as developing and presenting simple

Fig. 13.3 Stakeholder linkages in an African ICT programme (existing and potential)



Source: Biggs and Matsaert (1998) in Rick Davies (2003), (see reference 3).

materials such as a position paper or a short briefing note that explains your objectives. Invite stakeholders to address you and let them know that you think they are important.

Do stakeholders hear from you regularly? Once you have established contact, keep it up. You should not pester people but you should let them know that you are serious about the issue and want to work with them over a long period of time.

What can you do for them? You can often establish your own credibility by advising or by being a good, balanced informant on issues. You may also be able to help arrange good press coverage for positive action. The relationships that effective advocates build up are often based on their expertise and their reliability.

13.2.3 Build a strong case

Get your facts straight and organize your information. Exaggerated analyses or inaccurate figures will be bad for your credibility and for your case. You will not be trusted if you give people inaccurate information. In addition, be sure to:

- Anticipate counter-arguments and help to answer them.
- Present useful facts and examples that are relevant and easy to remember.
- Formulate goals that are reasonable and realistic.
- Respond to criticism with positive suggestions for improvements.

MSF often refers to a few key facts to illustrate why it launched its access campaign (Box 13.2). Note that each of the facts is related to a situation that *people* face and that there is an emotional component that comes through in the way the information is set out. This helps to motivate people to see the urgency of the situation and the need to act.

In terms of the medicine prices surveys, the issue of affordability and its relation to people's earnings is likely to be the most graphic and emotive aspect of your research. If poor people in your country have to use the equivalent of one week's income to pay for a one-month course of treatment for a chronic illness, it becomes clear that something needs to be changed.

BOX 13.2

MSF Access campaign – key facts

- Nearly a quarter of patients under treatment for tuberculosis (TB) in Siberian prisons are dying because they do not have access to expensive, second-line TB treatments.
- People with AIDS-related meningitis in an MSF-supported Nairobi hospital are being told to go home and die because the price of the only effective treatment is beyond their means. Patent protection keeps the price high (one day's treatment costs US$ 20 per day in Kenya compared to US$ 0.70 per day in Thailand, where it is not patent-protected).
- In Sudan and Uganda, MSF volunteers are outraged at the lack of access to the life-saving medication DFMO. The drug is prescribed for sleeping sickness, a fatal, neurological disease endemic in Africa. However, DFMO's manufacturer has stopped producing the medication because it has not been profitable.

Source: MSF 1999

13.2.4 Identify allies and experts who share your views

You need to show that others share your views. Try to identify allies from different fields and areas of influence. For example, institutions and organizations working on broad trade agreements may find the medicine prices issue makes a useful case study or an example for the changes they are trying to achieve. Women's organizations may be concerned about access to health care and could see this issue as one that illustrates particular problems for women. Disabled people's organizations working on mental health issues may be strong allies around the price of medicines essential for their members. You may be able to collect signatures, to get other organizations to pass resolutions supporting you or to quote from positions adopted by recognized authorities, such as by quoting WHO publications or resolutions.

You should try to identify experts and opinion leaders who will make a statement in support of your views. Doctors and medical experts are very influential when decisions about health policies are considered. Try to make the point that consumer and patient views are very important but also make use of supportive, medical experts where possible.

13.2.5 Identify and understand potential opponents

No matter what your position is on an issue, there is certain to be someone who does not agree with it. To help make your arguments as strong as possible, you need to consider the arguments that will be advanced by those with opposing views. You should brainstorm with the members of your own organization and with campaign partners about possible opponents. Who will they be? What are their interests? How will they operate on this issue? What is their goal? What or how much do they stand to lose if a change occurs? What do you know about their views and positions? It is important to consider what their strategy might be. You might want to include the use of role-play in helping advocates to understand the opposition's arguments. This will help you to anticipate their actions and be ready with a quick and effective response. Campaigns can lose a great deal of momentum or be completely destroyed by opposing arguments and actions that catch them unprepared. Take time before you launch your advocacy work to consider how those with different views might approach the issue. This will pay off once the campaign is under way. Make sure you collect any information available from the opposition. This can be found in many forms, including leaflets, newspaper advertisements or articles, press releases, speeches and web site information. Become familiar with their line of reasoning. You should understand their arguments and look for flaws in them. Also, check to see if they are saying anything about your campaign's key messages. It is only by understanding their viewpoint and being able to counter it with a better argument that you will succeed against them.

Depending on each advocacy issue, different organizations may support, be neutral or be negative. Thus, do not alienate or demonize organizations that oppose you on one issue, since they may support you on another. For example, local and international manufacturers will support a campaign against taxes on medicines. International manufacturers will support and local manufacturers will oppose a campaign against import tariffs on medicines. Manufacturers will support and retail pharmacies will oppose a campaign to regulate mark-ups. Retailers may support price controls at the end-user level. Ministries of finance may support transparency in pricing but oppose removal of taxes and duties. Ministries of health may support removal of local preference requirements while ministries of industry or commerce may support such requirements. For any advocacy issue, different supporters and opponents are likely to exist, but they will vary from issue to issue.

Be prepared for personal attacks. Remember, if someone does not like the message they will often attack the messenger!

Experience shows that the findings of medicine price surveys are invariably questioned and sometimes criticized. Be prepared for such situations. The Frequently Asked Questions included on the CD-ROM that accompanies this manual will assist in responding to questions on the survey methodology and findings. You may want to develop your own local version of responses, which includes the frequently asked questions that occur in your country.

13.2.6 Develop a long-term plan

You can launch a campaign with a great splash of publicity, for example, around the publication of your prices survey findings. However, if you do not develop follow-up activities and strategies to keep your issue on the agenda, you may find that the launch is soon forgotten and interest in your issue fades. Develop a timeline that takes into account the need for continuity and follow-up but which also plans some events or high points. And make sure that you have access to the resources – both human and financial – to sustain the advocacy work over a period of time.

13.2.7 Take advantage of strategic opportunities

Sometimes unexpected events can work in your favour. These may take the form of political developments in your country (an election or change of government); they may be related to macroeconomic factors or they may be related to local events.

13.3 COMMUNICATION

Your advocacy strategy should form the basis of your communication strategy. It will have helped to identify with whom you need to communicate and about what. This is more than simply identifying messages to be disseminated. You need to be clear about the change you are trying to achieve. For example, do you want an official in a health ministry to set up a review of existing policies? Do you want the parliament to pass a new law? Do you want greater enforcement of existing policies? Do you want improved education about the impact of prices for a group of health workers?

When you are clear about the change you want and the audience you are trying to reach, then you need to determine the best way to reach that audience. The most powerful communication methods are those that involve interaction and engagement of the audience with the content of the message. Putting your report on a web site and hoping that people will find it is the least interactive method. You should be trying to stimulate debate and dialogue around the findings of your prices survey.

A meeting of key national managers and policy-makers should be held after the report has been prepared to brief them on the findings of the survey and initiate a process of improving current medicine policies and programmes. You should outline:

- the survey's purpose and the data collection process;
- a summary of the results and comparison with data from previous national or international price surveys;

- medicine prices, with comparisons by sector, product type and region;
- medicine availability, with comparisons by sector, product type and region;
- affordability of standard treatments for both acute and chronic conditions;
- components of medicine prices for different products, regions;
- the overall findings and possible causal factors (e.g. links to current policies); and
- issues that need to be addressed and recommended policy and programme interventions.

13.3.1 Media

The national media are always interested in good stories and may be willing to report on the survey findings, particularly if they receive a press release or article presenting the information in a reader-friendly form. The media can also help by putting a human face on the issue through telling the story of how high medicine prices affect a particular family, as happened recently in the Philippines (Box 13.3). Encouraging debate in the media starts to generate an enabling environment for change (*4*). Public opinion around an issue helps to put and keep an issue on the political agenda, which encourages action.

BOX 13.3

Giving a human face to the issue in the Philippines

A 2005 survey in the Philippines showed the availability of medicines in the public sector was only about 15% and the prices were excessive – anywhere from 6 to 15 times the cost of international reference prices. In response to the findings, the groups that took part in the survey worked with the media and local community members to produce a short video that described the situation for an elderly couple, dependent on medication to prevent high blood pressure. The news coverage and the video, together with social mobilization and careful briefing of policy-makers, were influential in bringing about the passage of a bill to lower prices in the Philippine Congress.[1]

13.3.2 Networking with civil society organizations

Other key stakeholders with which to engage are the civil society organizations, which may have an interest in the issue. Arrange a workshop or a series of meetings with key organizations to discuss your findings and encourage other groups to take up the issue and become involved in the overall advocacy campaign.

13.3.3 Communicating internationally

Many surveys have been conducted around the globe using the WHO/HAI price measurement methodology, indicating a high level of interest in this issue. Just as you will be interested to learn about the evidence and advocacy work conducted in other countries, so will others be interested in your work. It is easy to communicate your survey findings and advocacy messages internationally through health listservs, such as E-drug and IP-Health. Subscribing to these listservs not only keeps you up-to-date with issues on access to medicines and their rational use; the

[1] (To view the video: http://www.youtube.com/watch?v=hTVjZjGmyoQ, accessed 7 February 2007)

support you can receive may help your campaign. When The Network for Consumer Protection in Pakistan advocated for essential medicines not to be taxed, they regularly posted campaign updates on E-drug. The network reported that they received support for their campaign from unexpected international sources that learnt of their efforts through the listserv.[1]

Contact HAI to get on the mailing list for the project's bulletin *Medicine Pricing Matters*.[2]

This bulletin, published quarterly, highlights pricing news (survey data, advocacy, policy changes, etc.) from around the world. Remember to send an e-mail to HAI about your advocacy work so it can be publicized in the bulletin.

13.4 MATERIALS – WHAT NEEDS TO BE PRODUCED

The findings of the survey can be presented and reported in a number of formats. Indeed, in order to achieve the maximum coverage and impact, it is advisable to present them in the most appropriate form for the different target audiences.

13.4.1 Survey report

The report generated using the standard report template will include results in both descriptive and tabular form. This form of technical report would be particularly useful for ministries of health, researchers and academics. An executive summary at the beginning of the report, highlighting key findings and recommendations, is essential for decision-makers who may not have time to read the full report. Reports from a number of surveys conducted to date can be found on the HAI web site.[3]

13.4.2 Summary report

A short (4–5 page) summary report highlighting the survey's key findings and recommendations in an easy-to-read format, has been developed by a number of countries following the publication of the full survey report. This has proven useful for those people who do not have time to read the full report and may be more appealing to audiences such as the media and NGOs. Examples of summary reports can be found on the HAI web site.[3]

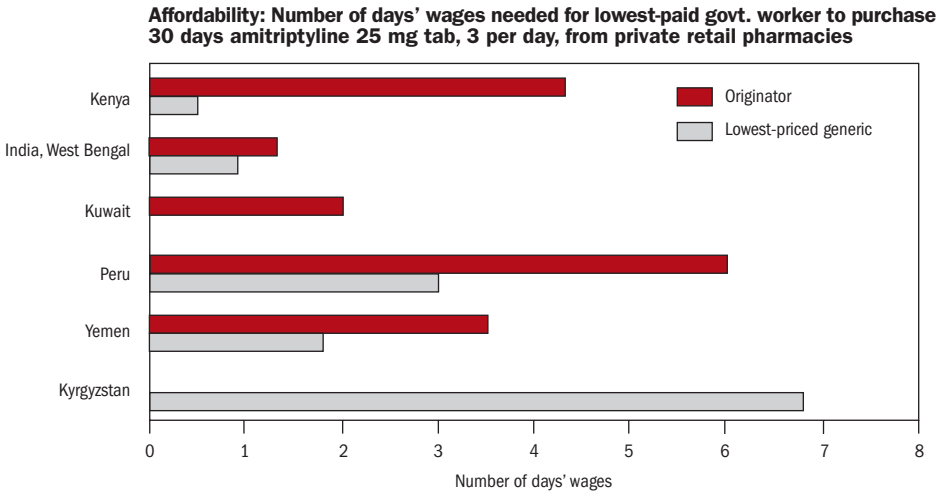
13.4.3 Policy briefing paper

The survey findings and recommendations can be reported as bullet points on a one-page policy brief for busy government ministers, cabinet members and members of parliament. Accompany the briefing paper with the full report for those who want detailed information and as evidence of the strength of your findings.

Adding simple graphics will help to convey the impact of your findings. See the graph in Fig. 13.4, for example, which shows the number of days' wages it would take for a low-paid government worker in a number of countries to be able to pay for a 30-day treatment.

[1] To subscribe to E-drug e-mail e-drug-join@healthnet.org; for IP-Health email Ip-health@lists.essential.org
[2] You can also download a copy from HAI's web site: http://www.haiweb.org/medicineprices.
[3] (http://www.haiweb.org/medicineprices)

Fig. 13.4 Using graphs to illustrate the impact of high medicine prices on the poor



13.4.4 Journal articles

The survey report will provide the basis for an article for publication in the specialist press, such as a medical journal. If the survey has been conducted by a consumer organization or a health-related NGO, consumer magazines or newspapers may be willing to publish an article.

13.5 MONITOR AND EVALUATE YOUR ACTIVITIES

It is important to monitor and evaluate your advocacy activities. You need to know what works and what does not. Feedback and monitoring is especially important in advocacy campaigns. Be prepared to look critically at your activities. Are they working? Is change happening? Is it the change you expected? What else could be done? Are there new questions emerging? Do new people or organizations need to be influenced to achieve change? What have you achieved so far? Sometimes you may find that your activities are having unforeseen effects. For example, it was reported that a campaign in Pakistan to reduce the use of irrational antidiarrhoeals led to an increase in the inappropriate prescription of antibiotics in treating diarrhoea.

Sometimes you will achieve your initial objective. For example, you might be advocating for a national drug policy, which the government agrees to and draws up. You then may have to change your strategy or your objectives to focus more on issues of implementing the policy.

Evaluation helps to demonstrate accountability to members or funders and will not only help you to decide on whether your approach was appropriate but will also help to increase your credibility and enable you to publicize your results.

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BACKGROUND READING

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14

Monitoring medicine prices and availability

14.1 INTRODUCTION

All countries use certain schemes for monitoring and evaluating their health-care system to assess the performance and appropriateness of their government's health-care policies. Pharmaceutical policy-monitoring in developed countries often includes monitoring prescription medicine price trends by monitoring medicine utilization and cost/treatment episode for various diseases or clinical outcomes.

Even though it is well known that medicine prices are a significant barrier to access to effective and safe medicines in developing countries, a paucity of data exists on what people/governments pay for medicines and how prices change with time in these countries. Data that industry and market research agencies (e.g. IMS Health) collect on the private sector in different countries are not publicly available, may not include patient price data and may be too costly to access for policy-makers and researchers in developing countries. Therefore national health-care and procurement agencies may need to set up their own medicine price monitoring systems.

A methodology for the routine monitoring of medicine prices, availability and affordability has been recommended to complement and serve as a continuation of the comprehensive WHO/HAI medicine prices and availability survey methodology. In 2004, a medicine price monitoring methodology was developed based on a framework recommended by WHO/HAI medicine prices project members. Pilot testing of the proposed methodology was attempted in three countries, namely, Kenya, Malaysia and Pakistan. However, each country required that the methodology be significantly customized to the country context. Currently, there is no universally agreed methodology for routine monitoring of medicine prices and availability, and debate continues on how biases and errors can be avoided by different methods. Furthermore, the specific objectives and available resources will greatly influence the methodology to be used in a country.

The issue of routine monitoring of medicine prices and availability remains a priority for the WHO/HAI Project on Medicine Prices and Availability; work is underway to develop guidelines and minimum standards for monitoring that consider the need to develop country-specific protocols that are feasible and sustainable. The guidelines and related material are available on the CD-ROM that accompanies this manual as well as on the HAI web site.[1]

[1] http://www.haiweb.org/medicineprices

Given that efforts in the area of medicine price and availability monitoring are ongoing, this chapter describes general considerations in developing a monitoring system. It also summarizes the methodology developed in 2004 (the full monitoring methodology is available on the CD-ROM that accompanies this manual) and reports briefly on the experiences of the three pilot countries. Reports of medicine price and availability monitoring activities under way in Kenya, Uganda and the United Republic of Tanzania can also be found on the HAI Africa[1] and HAI Global[2] web sites.

14.2 BACKGROUND

14.2.1 Why monitor medicine prices?

Effective public policy-making to improve access to affordable medicines requires the use of evidence from accurate analysis of sound and transparent data on medicine prices and availability. Such evidence-based pharmaceutical policy-making is desirable both to select the correct policy options for making medicines more affordable and available and to ensure transparency and accountability of the policy-making process. Systematic and careful use of medicine price data can help to:

- understand to what extent medicine prices affect the challenges of access to medicines in a country;
- inform policy-makers when selecting alternative policy options to improve accessibility (affordability and availability) of medicines; and
- monitor the impact of policy or regulatory interventions.

The alternatives to this type of evidence-based policy-making include lobbying by special interests (e.g. pharmaceutical industry, retail pharmacists), arbitrary decision-making and the use of anecdotal evidence to support policy. These alternatives, even when well meaning, may result in unwanted effects if they are not based on a clear understanding of how the national/local markets operate. In addition, none of these alternative decision-making processes provides the necessary transparency and accountability that would be required to support sound policies for making medicines more accessible to all.

Specific objectives of any national or international medicine price monitoring system usually fall into two categories:

a. medicine-price reporting systems that provide a measure of current prices of individual medicines of interest; and

b. medicine-price trend monitoring systems that can generate a medicine price index, which accurately measures inflation or price fluctuations.

Some examples are presented below to illustrate outputs from these two types of medicine-price monitoring activities.

14.2.2 Medicine-price reporting systems

Usually, medicine prices are reported as an average or median price to inform purchasers, health professionals or the public of current prices to support decision-making on selection, procurement and/or price-setting policies. Some of the international price reporting systems listed below may report ex-manufacturer or

[1] http://www.haiafrica.org/
[2] http://www.haiweb.org

list prices as declared by the manufacturer or suppliers/wholesalers, without insurance, transport or duty costs, and without any volume discounts. When using such reference price information to decide on selecting and procuring medicines, it is necessary to consider such differences.

Examples include:

- International Drug Price Indicator Guide published by MSH.[1] Since 1986, MSH has been reporting prices of essential medicines provided by not-for-profit and for-profit suppliers to developing countries or buyer prices from these countries.
- Global Price Reporting Mechanism (GPRM), WHO.[2] GPRM is a web-based price-monitoring tool that reports prices for ARV medicines supplied by international not-for-profit suppliers or various procurement agencies purchasing medicines, with financial support from the Global Fund to fight AIDS, Tuberculosis and Malaria.
- *Untangling the web of price reductions: a pricing guide for the purchase of ARVs for developing countries*, published by Médicines Sans Frontières.[3]
- Prescription cost analysis data in the United Kingdom, which provide volumes and prices of prescribed medicines on an individual and aggregate basis.[4]
- EUROMEDSTAT database,[5] which lists retail pharmacy prices (patient prices) of medicines in European countries for individual medicines.
- WHO/HAI Medicine Price Survey database.[6]
- Pharmaceutical market surveys undertaken by commercial survey organizations, such as IMS Health and Research International.

14.2.3 Medicine price trend monitoring systems

These systems monitor prices as part of pharmaceutical-related expenditures (utilization + costs) analysis or as part of a broader economic analysis, often in the form of price indexes. Generally, the cost of a basket of medicines is monitored over time and price changes are weighted by volume of individual medicines sold or dispensed compared to a base time period. The data might be used in international comparisons for reference pricing systems, for adjusting reimbursement price levels or to report the rate of inflation for pharmaceuticals for a given time period. International comparisons of pharmaceutical price levels might be constructed using pharmaceutical purchasing power parities (PPP) based on surveys of prices of baskets of medicines conducted periodically.

Examples include:

- Canadian Patented Medicine Prices Review Board (PMPRB).[7] PMPRB monitors trends in the prices of patented medicines in Canada and in seven comparator countries to regulate the prices of these medicines.
- The United States Bureau of Labor Statistics[8] monitors ex-manufacturer prices of medicines to construct the pharmaceutical producer price index (pharmaceutical

[1] http://erc.msh.org/
[2] http://www.who.int/hiv/amds/gprm/en/
[3] http://www.accessmed-msf.org/
[4] http://www.ic.nhs.uk/statistics-and-data-collections/primary-care/prescriptions/prescription-cost-analysis-2006
[5] http://www.euromedstat.cnr.it/database/database.asp
[6] http://www.haiweb.org/medicineprices
[7] http://www.pmprb-cepmb.gc.ca/english/home.asp?x=1
[8] http://www.bls.gov/home.htm

PPI) and retail pharmacy price to develop the pharmaceutical consumer price index (pharmaceutical CPI) for both prescription and non-prescription medicines.

14.3 HOW CAN MEDICINE PRICES AND AVAILABILITY BE MONITORED IN RESOURCE-POOR COUNTRIES?

The methodology to be used in setting up a national medicine price monitoring system will greatly depend on the proposed system's specific objectives. Depending on such objectives, different sampling approaches, data collection methods and statistical analyses might be needed.

The primary objectives of conducting a regular medicine price monitoring will usually be:

- to inform consumers and purchasers about current prices of specific medicines; and
- to inform policy-makers, managers of health systems and the public about price changes and trends over time.

Specific objectives may include:

1. Provide the evidence-base to support decision-making on pharmaceutical policies and regulations intended to improve affordability and availability of medicines in a country (these decisions may range from decisions on selection and procurement through inclusion in reimbursement schemes to price controls or adjustments in pricing policies).
2. Monitor the progress of pharmaceutical policy implementation or intervention intended to influence prices and/or availability of medicines at various levels.
3. Evaluate the impact of a pharmaceutical policy or interventions on medicine prices, availability and affordability.
4. Participate in international price comparison efforts that can:
   a. support decision-making on reference pricing used in price controls, based on regional/international price level indices;
   b. enable calculation of PPPs to compare real pharmaceutical expenditures between countries and at subregional and regional levels; and/or
   c. help monitor the impact of intellectual property rights-related policies and international trade policies on medicine price and availability in a country.
5. Support advocacy approaches for increasing access to medicines and transparency around medicine pricing, and supply reliable and up-to-date information on medicine price trends to government, civil society, health professionals, donor partners and the pharmaceutical industry.

14.3.1 What prices to monitor?

Commonly, three different prices are the focus of interest, but depending on the health system, a country may want to monitor additional prices.

14.3.2 Ex-factory or ex-manufacturer price

Monitoring of ex-manufacturer price and calculating a producer price index can be important in countries with significant domestic pharmaceutical production

capacity, where local industry supplies most of the domestic demand. In addition, countries that regulate medicine prices based on reference pricing or use ex-factory prices when negotiating price at the time of registration or for inclusion of medicine in a national health insurance re-imbursement scheme may want to monitor price changes in ex-manufacturer prices as well. However, these prices are notoriously difficult to collect and often have little relation to actual production costs or final prices paid by patients, governments or other payers.

14.3.3 Procurement price

Developing countries with central procurement agencies may be interested in monitoring changes in procurement prices to assess the efficiency of their national procurement systems in terms of prices. In decentralized medicine supply systems, changes in either the procurement price or the wholesale price can be important to monitor movements of these prices as well as the efficiency and transparency of such supply systems. In developing countries, where faith-based organizations play an important role in the procurement and supply of medicines, it may be equally important to monitor their procurements (purchase and selling prices) and compare them with the public-health system.

14.3.4 Private sector patient price

Changes in private sector patient prices are often the highest priority to monitor in many developing countries since patients frequently have to pay out of pocket for the full retail price in the private sector (e.g. pharmacies, drug stores). Private sector patient price usually includes all the components of the price system mark-ups, distribution costs, professional fees and taxation. Various discounts might be applied to different types of products and different types of patients (e.g. insured, pensioners).

14.3.5 Public sector patient price

In most countries, governments supply medicines through the public sector. In countries where patients have to pay the full cost of medicines provided through government, municipality or other local authority health facilities, it is important to include these prices in routine monitoring.

In some countries, medicines in the public sector are free, or patients have to pay a standard (fixed) fee that may or may not include consultation costs. Where medicines are available for free or for a fixed fee, it is still crucial to monitor availability in the public sector.

14.3.6 Prices paid by patients at other access points

In cases where alternative access points are significant sources of medicines for the population, there can be various other price changes that one may want to monitor and compare to either the retail pharmacy price index or other price indices. These may include:

- prices of medicines sold by dispensing doctors;
- prices paid for medicines in nongovernmental or faith-based, not-for-profit health facilities and/or medicine outlets.

14.3.7 Important methodological considerations

As stated before, the final methodology of any national medicine price monitoring system will have to be carefully designed to serve the selected specific objectives and provide accurate, reliable information on price changes.

At the same time, resource constraints may not allow developing countries to use the most optimal and comprehensive sampling or data collection methods. Thus, there is a need to consider the minimum methodological characteristics that are required to measure medicine price changes accurately when limited resources are available.

Approach A

In some countries, the government statistical agency may already conduct regular product price surveys to compute CPI or PPI and/or have reliable accounting/auditing systems that can provide consistent data on medicine prices from procurement agencies, medical reimbursement claim databases, pharmaceutical expenditure and consumption databases, etc. In these cases, it can be useful to investigate how a monitoring system can be set up to extract necessary data from the information available or how these systems can be extended to collect additional medicine price information at little additional cost. Individual countries are likely to have unique systems in place that will require specific solutions for collecting and compiling medicine price information. Therefore, detailed recommendations are not given here. Depending on the type of data collected, calculation of changes in price trends in time should be based on sound, relevant statistical analysis.

Approach B

If it is not possible to connect data collection to existing information systems because these are not available or not reliable, it will be necessary to design an independent medicine price monitoring data collection method. The following major points should help guide discussions on important characteristics of such systems.

14.3.8 Basic matters to consider

A. Product selection

1. Main principle: Prices of a fixed representative basket of medicines.
2. Sampling: non-probability sampling[1] for medicine selection can be justified; potential selection criteria may include public health importance/therapeutic value, "best-sellers or high consumption items, highest value (expenditure/procurement value) based on ABC analysis,[2] prescription or non-prescription status, originator brands or generic, etc.
3. Sample size: The minimum number of medicines in the basket to make it representative will have to be determined based on the monitoring system's objectives (e.g. essential medicines only, top 50 most-sold medicines, specific classes, global/regional core medicines from pricing survey, etc.)

[1] Non-random sampling, where the selected units in the sample have an unknown probability of being selected.

[2] In ABC analysis, items are valued (item cost multiplied by quantity issued/consumed in period) with the results grouped into three bands: "A" – items that typically account for 70% of total value; "B" – around 20% of total value, and "C" – the remaining 10% of total value.

4. Product description, minimum requirements: active ingredient with the international nonproprietary name (INN), dosage form and strength, dosage form type, such as extended release, if applicable, package size.
5. Product type for each medicine: e.g. lowest-priced product only, lowest-priced product and originator brand, all products.

B. Data sources selection

1. Data source selection: Depending on the type of medicine price, the data source might be:
   a. central, i.e. manufacturer's selling price, procurement price, health insurance claim database, with voluntary or mandatory reporting of price data of a selected basket of medicines to the medicine price monitoring authority;
   b. outlet-based, i.e. point-of-purchase data collection in retail pharmacies, government health facilities, dispensing doctors surgery, mission hospitals, etc; and
   c. at the medicines regulatory authority during the verification of proforma invoices.
2. Data source sampling (mainly in case of outlet-based price collection): Probability sampling[1] is recommended where relevant sampling frames are available, e.g. up-to-date registry of private retail pharmacies, list of government health facilities, registry of dispensing doctors. However, often due to the limited resources (number of data collectors, transport costs, area coverage, lack of up-to-date registries) it is necessary to apply a non-probability sampling method. This can be a tailor made sampling frame, such as the one used in the WHO/HAI medicine prices and availability surveys (i.e. limited number of regions, urban centres selected with clustering facilities around large public health hospitals).
3. The inclusion of black-market or informal sector medicine outlets is not recommended since the quality of products may vary greatly (illegally imported, counterfeits, etc.) and price data obtained can bias price changes due to variance of quality or black-market currency changes.

C. Price collection method

1. Frequency: The desired frequency of price collection may vary by type of price data (e.g. central procurement price may be collected annually if contracts are awarded on a yearly basis), and on how frequently the prices to be observed change (stable inflation exchange rates vs hyperinflation). Again, practicalities of available resources may affect whether monthly, quarterly, biannual or annual price collection can be performed.
2. Collection procedure: Data collection procedures should be consistent with those used in the medicine prices and availability survey (Chapter 6). The price collector should obtain the price that patients would actually pay. As in the survey, data collectors will need specific instructions on how to deal with discounts and package size variations, etc. An important requirement is to develop a clear data collection form, including accurate product descriptions (see above). Data collection can be conducted on a printed form or in electronic format stored on hand-held

[1] Any method of selection of a sample based on the theory of probability; at any stage of the operation of selection the probability of any set of units being selected must be known. Also known as 'random sampling'.

computers (personal digital assistants). All the quality assurance techniques used in the survey, e.g. data quality checks in the field and validation, should also be used with monitoring.

3. Collection technique: A wide variety of methods can be employed, depending on their suitability for the local environment.

   — In the case of central data collection from manufacturers and procurement agencies, etc., data may be submitted in pre-formatted spreadsheets by e-mail or online through the Internet by way of a password-protected secure web site, by fax, mail, etc.

   — When collecting patient prices, visits to medicine outlets by trained data collectors and physical checking of price tags or invoices/receipts is the most accurate way of recording actual prices paid by patients.

   — Data collectors could include public-health officials, pharmacists, technicians, NGO representatives, consumers or others.

   — Alternative techniques, such as price collection by mail, phone, e-mail, fax, SMS text messages, online submission by outlets through a secure web site or from controlled national retail price lists, price lists issued for government facilities or price lists of major pharmacy chains, will require verification by random visits to actual pharmacy or medical outlets.

D. Price data transmission, quality assurance

Prices collected by data collectors in outlets may be reported to a central office of the medicine price monitoring agency through submission of printed data collection forms by mail, fax, e-mail (scanned) or electronically from a hand-held computer. Appropriate auditing and data-cleaning procedures at the central office will need to be developed. These will need to be conducted as early as possible in the collection and compilation processes in case it is necessary to return to the outlets for verification.

E. Data analysis

For each set of monitoring data, data analysis for individual medicines should include per cent availability, median unit price and ranges (i.e. minimums/maximums or quintiles), and affordability for specific treatments (number of days wages of the lowest-paid government worker needed to purchase a course of treatment). Summary data across medicines, i.e. mean per cent availability and median of median unit prices, can also be analysed. Analysis should be conducted by sector and, where appropriate, by location (i.e. urban and rural).

Since the objective of medicine price and availability monitoring is to investigate changes over time, it is important to conduct time series analyses once multiple rounds of monitoring have been done. For example, the per cent availability or median unit price of individual medicines can be graphed over time to illustrate trends. Per cent changes in availability and price, from baseline and from the last round of monitoring, can also be reported.

A more advanced method of data analysis is the use of price indices to compare rates of price changes of medicines to rates of price changes of consumer goods. There are numerous mathematical formulae employed in constructing price index calculations. Price indices based on fixed baskets of products may use different calculation methods, such as Lowe indices, the Laspeyres index, the Paasche index and

the Young index. The input of a qualified statistician, economist or health economist is required in deciding what methods should be used in calculating a price index.

F. Publishing and information dissemination on medicine price and price changes

Since one of the principal aims of any medicine price monitoring system is to increase transparency about medicine prices, this step is a crucial part of the programme. The specific objectives of a medicine price-monitoring programme will determine:

- What results to report (level of details)
- The title of the report
- Who the audiences are
- Which presentation format to use
- What dissemination techniques to use (media, electronic Internet, free bulletin, reports, etc.)
- Timeliness

G. Other issues

There can be numerous other issues that a medicine-price monitoring system will have to consider, such as:

- Organization and management of the medicine-price monitoring unit.
- Use of the advisory committee. Such a committee should include members with in-depth understanding of: medicine selection and analysis of utilization; pharmacoeceonomics; pharmaceutical procurement and distribution; pharmaceutical policy development; and creation of advocacy tools. This knowledge will be vital to supporting the development of the methodology, analysis and interpretation, and dissemination of results.
- Necessary human, technical and financial resources, including a qualified data analyst, statistician and data collection manager.
- Training.
- Quality assurance, to ensure validity of data collected and consistency of data analysis.
- Data security must be ensured from the outset to allow long-term availability and analysis of data.
- Periodic review and update of the methodology, for example:
  - — How to include newer medicines
  - — Replacement of outlets due to unresponsiveness
  - — Frequency of updating weights (if using indices)

A medicine price and availability monitoring system should follow a rigorously designed methodology to provide accurate, reliable and timely information on medicine price movements over time.

Government involvement in medicine price and availability monitoring can facilitate data collection and help to ensure long-term sustainability.

14.4 OVERVIEW OF A METHODOLOGY FOR ROUTINE MONITORING OF MEDICINE PRICES AND AVAILABILITY AND PILOT TESTING IN THREE COUNTRIES

14.4.1 Background

Following the development and application of the WHO/HAI survey methodology for measuring medicine prices and availability, survey managers expressed the need for a simple and inexpensive price-monitoring tool to complement and serve as a continuation of the broader survey. At a meeting of project members in December 2004, it was agreed that a survey using the WHO/HAI methodology should be repeated every three to five years as an integral part of national policy, but countries should also be encouraged to establish a system for regular price, availability and affordability monitoring. A monitoring framework was developed at this meeting and was subsequently used for developing a proposed methodology.

14.4.2 Overview of proposed methodology

The main features of the proposed methodology for medicine prices and availability monitoring were:

- Establishing a small, central coordinating office (manager, data-entry person and analyst).
- Selecting a target sample size of 80 facilities (i.e. 40 public and 40 private sector medicine outlets) to serve as sentinel monitoring sites, with the number of facilities from urban and rural areas roughly proportional to the population they represent. Facilities from a third sector (e.g. church missions) should be added, where appropriate.
- Monitoring a total of 30 medicines: 10 medicines per month, on a three-month rotation, i.e. minimum of four price data points for each medicine per year.
- The medicines to be monitored are based on the core list used in the comprehensive WHO/HAI survey, adapted to national conditions.
- Only data for the lowest-priced product will be collected (pack price, pack size, unit price, product name and manufacturer).
- Monthly data collection using a simple, sustainable method, e.g. e-mail, fax, phone or mail (no data collectors or area supervisors).
- Comparing medicine price variations to price variations for some basic consumer commodities, e.g. a dozen eggs, a kilogram of sugar or 500 grams of salt.
- Analysis of availability and the affordability of pre-selected standard treatments for the lowest-paid unskilled government worker.
- Data entered in automated Excel spreadsheets.
- Brief standard monthly reports prepared showing median unit prices, ranges and variation over the last three months, affordability and availability.
- Annual report showing monthly information for each sector, as well as annual median unit prices and per cent changes from 0 (baseline) to 12 months.
- Annual review of medicine selection and rotation of sentinel sites.

The full methodology is available on the CD-ROM that accompanies this manual.

14.4.3 Pilot testing

Pilot testing of the proposed monitoring methodology has been undertaken in three countries, i.e. Kenya, Malaysia and Pakistan. In all three countries, written protocols were developed before initiating the medicine price monitoring system. A summary of each protocol is provided below.

14.5 MEDICINE PRICE AND AVAILABILITY MONITORING PROTOCOL – KENYA (UPDATED JUNE 2007)

Lead organizations: HAI Africa, Ministry of Health and WHO

Objectives

- To document the availability and price variations of selected medicines within the private and mission sectors.
- To document the availability and price (in facilities where service/treatment fees are not packaged) of selected medicines in the public sector.
- To monitor the affordability of treatment for a selected list of common diseases for ordinary Kenyans.
- To monitor procurement prices in the public sector and to compare them to internationally accepted reference prices.
- To inform consumers, policy-makers, donors and other stakeholders on a quarterly basis of the cost of selected medicines.

Sectors

Medicines prices will be surveyed in three sectors: public, private and mission.

Regions

The facilities to be surveyed are grouped within four of Kenya's eight provinces (namely Coast, Eastern, Nairobi and Rift Valley). These four were chosen as a realistic representation of the country's socioeconomic, epidemiological and geographical diversity.

Sampling

- 24 facilities (eight facilities each from public, private and mission) are selected for each of the four regions to be surveyed for the entire year. The total number of facilities being surveyed, therefore, will be 96.
- In each province, to survey facilities representing the public sector, the four main provincial hospitals are selected, plus district or subdistrict hospitals.
- Private sector facilities are selected specifically among retail chemists in urban areas (e.g. not including private hospital pharmacies) but may include private clinic pharmacies in rural areas if there are no rural retail chemists. These private facilities are selected purposively within 5 km of each of the selected public facilities, while using the official list of registered pharmacies from the Pharmacy and Poisons Board.
- The mission sector facilities are purposively selected from the Mission for Essential Drugs and Supplies (MEDS) facilities, with specific targeting of facilities

with similar characteristics to public sector equivalents (e.g. mission hospitals of similar size and capacity to the provincial, district and subdistrict hospitals in the region).

- Given the expanse of some of Kenya's provinces, the purposive sampling method (considering convenience and logistics) is used to ensure that the data collectors can get reliable access.

Medicines selection

- A total of 36 medicines.
- The selection was based on the methodology's core list and Kenya's Essential Medicines List. The epidemiology and most commonly available medicines for Kenya's public health issues were also considered. Finally, for inclusion in the study, the medicines are registered with the Pharmacy and Poisons Board.

Data collection

- Two trained public sector pharmacists or pharmaceutical technologists from each of the four provinces visit the facility sites in all three sectors every three months to document prices and availability, using a standardized data collection form.
- Price and availability data are collected every three months for all 36 medicines. For each medicine the lowest-priced product that is available with the recommended pack size is monitored.

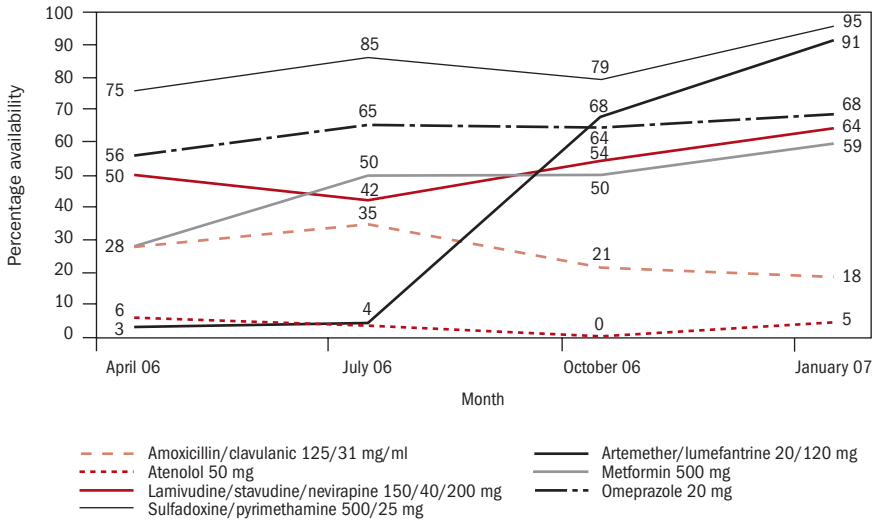
Reporting and dissemination

- Every three months a short report is generated, reflecting exceptional and relevant findings from the data collected. These findings may include availability of medicines in all three sectors, prices of selected medicines and any significant per cent variation from previous months, and affordability calculations for treatment of common diseases. Regional/geographical and intersectoral comparisons may be made. Further analysis may be carried out on disease-specific conditions (e.g. malaria) or for certain classes of medicines (e.g. chronic disease medicines). Availability analyses may also be carried out using standard public sector facility medicines lists.
- The reports are disseminated by e-mail and post; they are accessible on the HAI Africa and HAI Global web sites. The target audience includes pharmacies, civil society organizations (CSOs) and NGOs, private clinics, retail pharmacies, public hospitals, mission sites, procurement agencies, consumers, government officials and policy-makers, the health professional organizations and societies, and the donors of the health sector that are supporting procurement of medicines.

Results

Several rounds of medicine price and availability monitoring have been conducted, which has allowed for the tracking of availability and prices over time. An example is provided in Fig. 14.1, which shows the differences in the public sector availability of selected medicines between April 2006 and January 2007.

Fig. 14.1 Trends in availability in April, July, October 2006 and January 2007 in the public sector facilities surveyed



14.6 MEDICINE PRICE AND AVAILABILITY MONITORING PROTOCOL – MALAYSIA

Lead organization: The Pharmaceutical Services Division, Ministry of Health

Objectives

The primary objective of the medicine price monitoring system in Malaysia is to inform health policy-makers, health professionals and consumers about medicines prices, changes in prices, availability and affordability of selected medicines.

Group of medicine	Specific objectives of price monitoring
List A – commonly used prescription and non-prescription medication for the treatment of prevalent conditions in Malaysia	1. To monitor prices that patients pay and follow trends in price changes and affordability over time, and to monitor availability both in the private and the public sector
List B – patented medicines recently registered in Malaysia that are not yet included in the Formulary of the Ministry of Health	2. To monitor procurement prices and availability of these patented (single-source) products in the private sector and rate of price changes before and after patented medicines included in Formulary of the Ministry of Health Malaysia.
List C – specialty medicines (oncology, transplant, etc.)	3. To monitor procurement prices and follow trends in price changes for these usually expensive and often single-source products

Sectors

Public sector facilities (secondary and tertiary government hospitals, and main university hospitals) and private sector health facilities (officially registered private retail pharmacies and private hospitals).

Regions

Health facilities will be grouped for comparison based on geographical location as being in West Malaysia (urban) or East Malaysia (rural).

Sampling

Monitoring of List A medicines:

- Public sector: 40 hospitals out of a total 123 government hospitals[1] (32%) in 14 states were selected to be included in the price monitoring system.
  - — 20 hospitals in West Malaysia: One main general hospital/state was selected, then another tertiary or secondary hospital from each state with the highest number of hospitals existing was added (i.e. larger states are represented by two or three hospitals).
  - — 20 hospitals in East Malaysia: All tertiary hospitals were included from Sabah and Sarawak, and additional tertiary and secondary hospitals were selected by regions.
- Private sector: 40 private retail pharmacies.
  - — **West Malaysia:** Private retail pharmacies are selected randomly within a 5 km radius of each of the selected government hospitals.
  - — **East Malaysia:** Private retail pharmacies are randomly selected within 10 km radius of each of the selected government hospitals or the nearest available private pharmacy is selected if there is none within the 10 km radius.

Monitoring of List B & C medicines:

Before patented medicines included in the Ministry of Health Formulary: identify the seven largest specialized private hospitals and three University teaching hospitals for procurement price monitoring.

After patented medicines included in Ministry of Health Formulary: initiate monitoring in 10 additional large, specialist government hospitals.

Medicines selection

- List A. Commonly used medicines for regular monitoring of prices paid by patients (30 medicines)
  - — Inclusion criteria: frequently used in Malaysia for treatment of prevalent conditions, included in either Malaysian Essential Medicines List, Formulary of Ministry of Health or in WHO/HAI core monitoring list, can be either prescription or non-prescription medicines, commonly stocked by both in private retail pharmacies and government hospital pharmacies.
  - — Exclusion criteria: injectables and psychotropic medications, because due to restrictions only a few private pharmacies would stock these items.
- List B. Newly registered medicines (not in MOH Formulary) for monitoring of procurement prices (20 medicines)
- List C. Oncology medicines for monitoring of procurement prices (10 medicines)

Data collection

- Hospital pharmacists and pharmacy inspectors in each state will collect data both in private and public sectors.

[1] Based on information found on the Ministry of Health's web site "Directori Hospital Kerajan" www.moh.gov.my/hospital.htm

- List A medicines: prices and availability information will be collected every three months.
- List B & C medicines: procurement prices will be collected every six months.

Reporting and dissemination

- A short, one-to-two page report prepared every three months, summarizing median, minimum, maximum prices, availability, affordability of selected therapies, and percentage of price changes per sector and location.
- Target audiences: all government hospitals, all participating retail pharmacies, Malaysian Pharmaceutical Society (inclusion in their news bulletin), other professional societies, Malaysian Consumer Association.

14.7 MEDICINE PRICE AND AVAILABILITY MONITORING PROTOCOL – PAKISTAN

Lead organization: The Network for Consumer Protection

Objectives

To inform health policy-makers, health professionals and consumers about medicines prices, changes in prices, availability and affordability of selected medicines in both the public and private health sector. The specific objectives are:

- to monitor prices that patients pay and follow trends in price changes and affordability in time for a selected group of commonly used prescription and non-prescription medication for treating prevalent conditions in Pakistan;
- to monitor availability of these indicator medicines both in the private and the public sector; and
- to monitor procurement prices of indicator medicines in the public sector and the rate of price changes in time.

Sectors

The sectors are: public facilities (secondary and tertiary government hospitals, rural health centres and basic health units) and private retail pharmacies.

Regions

The regions are the two most densely populated provinces, i.e. Punjab and Sindh.

Sampling

- Health facilities will be grouped for comparison based on geographical location as located in either urban or rural areas.
  - — Health facilities (public or private pharmacy), located in specified cities, or metropolitan centres within the provinces, will be designated as urban facilities; and
  - — private pharmacy outlets, any Tehsil hospitals (TH) rural health centres (RHC) or basic health units (BHU) located in villages/mouza/deh or other rural areas (i.e. at least 30 km away from nearest city/town will be designated as rural facilities and analysed as subgroups accordingly.

- Due to limited resources allowing only a small sample size, a non-probability sampling is applied, i.e. a quota sampling based on population data was used to determine the sample size for each province, then convenience sampling is used to select major city centres and accessible rural areas. Since Punjab constitutes 56% of the country's population and Sindh 23%, health facilities for the pilot study are selected proportionally to population size in these provinces.
- Though most of Pakistan's population – approximately 65% – lives in rural areas, due to the potential difficulties of transport and finding suitable rural facilities, the number of rural facilities – a total of 37 – is lower than the number of urban facilities – a total of 53 – to enable the establishment of a pilot study with limited resources.
- A total of 90 facilities, 39 government health facilities (where medicines are free) and 51 private pharmacies.

Medicines selection

- A total of 30 medicines, with data collected on the lowest-priced generic product.
- Inclusion criteria: frequently used in Pakistan for treatment of prevalent conditions, included in either Pakistan Essential Medicines List or Formulary of Ministry of Health or in WHO/HAI core monitoring list; it can be either prescription or non-prescription medicines, commonly stocked by both in private retail pharmacies and government hospital pharmacies.
- Exclusion criteria: illegally marketed medicines without official registration by the Drug Controller in Pakistan.

Data collection

- Data will be collected by trained personnel within each district
- Baseline and quarterly data collection: at the beginning of the pilot study and every three months following, the full set of data on prices and availability for all 30 medicines in both private and public sector is collected.
- Procurement prices are collected every six months in government health facilities only.

Reporting and dissemination

- A short, one-to-two page report prepared every three months, summarizing median, minimum maximum prices, availability and affordability of selected therapies, and percentage of price changes by sector and by location.
- Target audiences: The Network membership, Ministry of Health and Provincial Headquarters, Pakistan Pharmaceutical Society (inclusion in their news bulletin), other professional societies, general practitioners, physicians and other medical specialties, paramedical and allied professions, procurement agencies, policy-makers, universities, academia and WHO/HAI.

14.8 RESULTS OF PILOT STUDIES

Each pilot study made significant modifications to the proposed monitoring system with respect to one or more of the following:

Selection of medicines: The selection of medicines was greatly customized to reflect common disease, prescribing and usage patterns. Advisory groups within the countries played an important role in selecting the most relevant medicines that were expected to be found in both public and private sector facilities.

Selection of facilities: Malaysia and Pakistan opted to monitor availability and medicine prices in secondary and tertiary health-care level facilities since the selected list of medicines are expected to be found in these types of institutions only. Kenya included lower-level health-care facilities since it wanted to get a full picture of availability of medicines across all types of health facilities. The number of facilities and their location also varied from the originally recommended 20 public urban + 20 public rural + 20 private urban + 20 private rural type facilities.

Data collection method: All three countries chose the active data collection method as opposed to the recommended passive voluntary reporting originally recommended.

As a result of the above modifications, the computerized workbooks had to be individualized for each country to conduct data-appropriate data analysis.

Baseline and data collections have been completed in all countries and data entry and cleaning is in progress for additional time points in Kenya and Malaysia. Results confirmed some of the low availability of essential medicines previously found in the public sector in Kenya and Pakistan. In the case of Malaysia, since only higher-level facilities were selected, the availability of surveyed medicines was adequate. In addition to measuring median unit prices for surveyed medicine, some additional comparisons were made to compare sectors. For example, in Kenya this showed that prices were similar or even higher in the mission sector compared to the private retail pharmacies.

Medicine price monitoring managers reported little difficulties with data collection and analysis since this was highly customized according to country situations. However, long-term sustainability may be more challenging with the resource-intensive protocols applied in the pilot countries as compared with the protocol that had originally been proposed.

The need for pilot countries to customize the proposed monitoring methodology to their country circumstances suggests that a standardized methodology for medicine price and availability monitoring may be an approach that is neither feasible nor optimal. As such, future work is focusing on the development of general guidelines and minimum standards as well as subsequent testing of these tools in additional pilot countries. The CD-ROM that accompanies this manual contains these guidelines. Please review these prior to planning a monitoring system in your country.

Experiences from the pilot studies showed that each country required a significant level of customization of the methodology and sustainability was mainly possible when monitoring was linked or embedded in the routine work of government-employed health-care workers.

15

Next steps in the WHO/HAI Project on Medicine Prices and Availability

Substantial progress has been made since the inception of the WHO/HAI Project on Medicine Prices and Availability in 2001. In the project's first phase, which was reported on in the *Essential Drugs Monitor*, No. 33,[1] an innovative standardized methodology for measuring medicine prices, availability, affordability and price components was developed and tested. This methodology has since become an internationally recognized gold standard for medicine price measurement in resource-poor settings.

In the project's second phase, covered in issue 35 of the *Essential Drugs Monitor*,[1] technical assistance was provided to ministries of health, consumer organizations, university researchers and others to undertake national and state medicine price and availability surveys. To date, over 50 surveys have been conducted in countries covering every WHO region. By posting survey results in a publicly accessible database, price transparency has been improved. Other Phase II activities included further validating the survey methodology; investigating the causes of gross price variations in a number of countries; comparative analyses of medicine prices, availability and affordability by region and disease groups; and preliminary work on routine medicine price and availability monitoring systems.

Despite these achievements, much remains to be done. In particular, governments that wish to take action to improve medicine availability and affordability require additional support in identifying, implementing and evaluating policy and programme interventions. As such, Phase III of the project will focus on building capacity to advocate for, develop, implement and evaluate evidence-based medicine price policies. This will include the actions outlined in the sections below.

15.1 UNDERTAKING RESEARCH TO INFORM POLICY INTERVENTIONS RELATED TO MEDICINE PRICING, AVAILABILITY AND AFFORDABILITY

The medicine prices and availability survey is an effective tool for identifying issues related to medicine prices, availability and affordability. However, additional research is sometimes needed to determine the right policy and programme interventions to tackle these issues. In Phase III, additional research will be conducted, e.g.

[1] http://www.who.int/medicines/publications/monitor/en/index.html

- developing and testing minimum standards/core principles for routine monitoring of medicine prices and availability;
- making comparative analyses of medicine prices, affordability and availability, and price components across regions and disease areas; and
- measuring total treatment costs, including diagnostics, doctor's visits, etc., in different therapeutic areas.

15.2 EVALUATE POLICY INTERVENTIONS AND EXPAND THE EVIDENCE BASE ON EFFECTIVE POLICIES FOR LOWERING MEDICINE PRICES, INCREASING AVAILABILITY AND IMPROVING AFFORDABILITY

Policy options for reducing medicine prices, increasing availability and improving affordability, particularly in resource-poor settings, will be reviewed and evaluated. The results will be used to develop a user-friendly information series that describes various policies, outlines their pros and cons and provides practical guidance on their design, implementation and enforcement.

In Phase III, the project will also support the development and implementation of national policies aimed at reducing medicine prices, increasing availability and/or improving affordability, e.g. through regional and national policy workshops.

15.3 TO IMPLEMENT AND EVALUATE ADVOCACY STRATEGIES AIMED AT STIMULATING NATIONAL, REGIONAL AND GLOBAL ACTION TO INCREASE THE AVAILABILITY OF AFFORDABLE MEDICINES

Phase III activities to support advocacy on medicine prices, availability and affordability include:

- providing support to countries for developing and implementing advocacy strategies to address the key issues identified in pricing surveys;
- further developing the HAI web site as a communications tool for policy and advocacy work; and
- undertaking regional and global advocacy activities, such as a global conference on medicine prices to promote transparency in medicine prices and stimulate public debate on medicine prices and affordability issues.

MEDICINE PRICING MATTERS

HAI

IMPROVING THE AVAILABILITY AND AFFORDABILITY OF ESSENTIAL MEDICINES

Focus on pricing policies

EMRO ministers confront high prices

As new research methods are developed and evidence is generated on effective advocacy strategies and policy options for improving medicine prices, availability and affordability, it is anticipated that a 3rd edition of the survey manual will be developed to provide additional guidance in these areas.

There is a substantial amount of work underway at national, regional and international levels to not only measure but, most importantly, to lower medicine prices and improve medicine availability and affordability. To share successes and lessons learnt, and

keep informed of new developments, HAI and WHO are publishing a project bulletin *Medicine Pricing Matters* on a quarterly basis. It aims to highlight pricing work around the globe and some of the work of the WHO/ HAI *Project on Medicine Prices and Availability*. The bulletin is available on the HAI web site.[1] Contact HAI[2] to be placed on the mailing list.

[1] http://www.haiweb.org/medicineprices/
[2] info@haiweb.org

Glossary

Active pharmaceutical ingredient (API)
The chemical substance responsible for a product's effect. In this manual, it is called "substance".

Affordability
The cost of treatment in relation to peoples' income. In this survey, the daily wage of the lowest-paid unskilled national government worker is used for comparison with the cost of a defined course of treatment for a specific condition.

Brand name
Name given to a pharmaceutical product by the manufacturer: e.g. Valium is the originator brand name (also called trade name) for diazepam. The use of this name is reserved exclusively to its owner as opposed to the generic name e.g. diazepam.

Brand names may also be used for generic products; they are then often called "branded generics". These brand names are different from innovator brand names. See Generic medicine.

Cost, insurance, freight (CIF)
Shipping term meaning the seller must pay the costs, insurance and freight charges necessary to bring the goods to the port of destination.

Dispensing fee
Normally a fixed fee that pharmacies are allowed to charge per prescribed item instead of or in addition to a percentage mark-up. The fee more accurately reflects the work involved in dispensing a prescription; a percentage mark-up makes profit dependent on the sale of expensive medicines.

Dosage form
The administration form of the completed pharmaceutical product: e.g. tablet, capsule, suspension, injection. Also called dose form or dosing unit.

Drug
See Medicine.

Essential medicines
Essential medicines are intended to be available within the context of functioning health systems at all times, in adequate quantities, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual

and community can afford. The WHO Model List of Essential Medicines (WHOML) is intended to be flexible and adaptable to many different situations; the precise definition of the medicines that are regarded as essential remains a national responsibility.

Free on board (FOB)

Shipping term meaning the buyer must pay all costs and insurance against risks of damage once goods are loaded for shipping.

Generic medicine

A pharmaceutical product usually intended to be interchangeable with the originator brand product, manufactured without a licence from the originator manufacturer and marketed after the expiry of patent or other exclusivity rights.

Generic medicines are marketed either under a nonproprietary name (INN), for example diazepam or occasionally another approved name, rather than under a proprietary or brand name. However, they are also quite frequently marketed under brand names, often called "branded generics". Many different branded generic products of the same medicine can be on the market in a country along with the originator brand product.

The manual Marketing Authorization of Pharmaceutical Products with Special Reference to Multi-source (Generic) Products (WHO/DMP/RGS/98.5) defines and uses the term "multi-source pharmaceutical product" for generic products. This includes even an originator brand for which the patent has expired. This definition of a generic is used in some countries, but this manual distinguishes between originator brand, regardless of its patent status, and lowest-priced generic equivalents.

Innovator brand

See Originator pharmaceutical product/originator brand

Note: in the first edition of this manual the originator brand was referred to as the innovator brand. This was changed in the second edition primarily to clarify that the product was the original (normally patented) one worldwide.

International Nonproprietary Name (INN)

A common, generic name selected by designated experts for the unambiguous identification of a new pharmaceutical substance. The selection process is based on a procedure and guiding principles adopted by the World Health Assembly. INNs are recommended for worldwide use. This manual uses INNs.

The system was introduced by WHO in 1950 as a means of identifying each pharmaceutical substance or active pharmaceutical ingredient by a unique name that is universally accessible as public property (non-proprietary). It is often identical to the generic name: e.g. diazepam. A brand name (trade name) should not be derived from the INN name.

More information is available on the WHO website: http://www.who.int/medicines/services/inn/en/index.html

Interchangeable pharmaceutical products

Products within a therapeutic class, but with different active ingredients are interchangeable if they have equivalent therapeutic effect.

Mark-up
A certain percentage added to a purchasing price to cover the cost and profit of the distributor, wholesaler,retailer, medical store etc.

Marketing authorization
An official document issued by a competent medicines regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality. “Registration” is another term used for this purpose.

Median
There are three ways of expressing the average value: mean, median and mode. The mean is simply the sum of the values divided by the number of values. The median is the value that divides the distribution in half. If the observations are arranged in increasing order, the median is the middle observation. The median is a useful descriptive measure if there is an asymmetrical distribution of the data or there are one or two extremely high or low values, which would make the mean unrepresentative of the majority of the data.

The median is correctly used with the interquartile range to summarise markedly non-normally distributed (asymmetrical) data. See Percentile.

Medicine
Any dosage form containing a substance approved for the prevention and treatment of disease. The term “medicine” is increasingly used to distinguish it from a drug as a substance that is misused. See also Pharmaceutical product.

Medicine outlet
A term sometimes used to describe a shop that is not owned or run by a pharmacist and that has a limited licence. However, in this survey “medicine outlet” is used more broadly to identify any place in which medicines are sold, including private retail pharmacies, outpatient pharmacies/dispensaries in public and NGO health facilities etc.

MSH (Management Sciences for Health) reference prices
MSH issues an annual International Drug Price Indicator Guide (http://erc.msh.org). It lists twice types of prices:

- supplier prices: prices offered by not-for-profit and for-profit suppliers to developing countries for multi-source generically equivalent products. Most supplier prices do not include insurance and transportation charges.
- buyer prices: these are usually government international competitive bidding, or tender, prices. They are actual prices obtained by the organizations listed, and usually do include insurance and transportation charges.

In both lists, the number of suppliers listed for each product may vary. For each product, a mean and a median unit price is calculated. The median price is used in this manual as the international reference price. The tender price is used only for products that have no supplier price.

Multi-source product
See Generic medicine.

Originator brand premium
The difference in price between the originator brand and a generic equivalent (in this case the lowest-priced generic equivalent).

Originator pharmaceutical product/originator brand

Generally the product that was first authorized world wide for marketing (normally as a patented product) on the basis of the documentation of its efficacy, safety and quality, according to requirements at the time of authorization: e.g. Valium. The originator product always has a brand name; this name may, however, vary between countries.

Some substances (eg. prednisolone and isoniazid) are so old that no originator can be identified and the patent was probably never claimed. In these cases you only survey the lowest priced generic equivalent.

Patent

A title granted by public authorities that confers a temporary monopoly for the exploitation of an invention upon the person who reveals it, furnishes a sufficiently clear and full description of it, and claims this monopoly.

Patient co-payments

Payments by patients of a fixed amount per prescribed medicine, even if reimbursed.

Percentile

The range of values containing the central half of the observations: that is, the range between the 25th and 75th percentiles (the range including the values that are up to 25% higher or down to 25% lower than the median) is called the interquartile range. It is used with the median value to report data that are markedly non-normally distributed.

Pharmaceutical equivalence

Medicines with identical amounts of the same active ingredient in the same dosage form and route of administration, that meet the standards of strength, quality, purity and identity.

Pharmaceutical product

Any medicine intended for human use, presented in its finished dosage form that is subject to control by pharmaceutical legislation (registered). A product may be sold under a brand name (e.g. Valium) or under the generic name (e.g. diazepam).

Procurement price

The price paid by the government, wholesalers, retailers and other purchasers to procure medicines. Different prices may be paid for the same product by a public sector purchaser, such as the Ministry of Health, the medicine outlet that supplies the medicine to the patient, and the individual who purchases the medicine.

Rebate

Pharmacies may receive a bulk refund from a wholesaler, based on sales of a particular product or total purchases from that wholesaler over a particular period of time. It does not affect the price the patient pays, but the retailer's profits will be higher.

Retailer

A company that sells goods to consumers. In the pharmaceutical sector, the retailer is the pharmacy or any other medicine outlet.

Many low- and middle-income countries have at least two different types of shops in which medicines can be purchased: pharmacies with a registered pharmacist and drug stores, chemists or medicine outlets with paramedical staff or lay people.

Retail mark-up
A percentage added to the purchasing price to cover the retailer's costs and profit.

Standard deviation
The standard deviation measures how spread out a set of data is around the average (mean) value. Normally, about two-thirds of the values in a set of data will fall within one standard deviation above or below the average, and only one in 20 will fall more than two standard deviations above or below the average.

When you get a very low standard deviation about the mean it indicates that the majority of the values are close to the mean (little spread) thus the mean is a good indicator for the sample as a whole. Conversely, when there is a large standard deviation there is a lot of spread and the value of the mean as an indicator is reduced, as a lot of observations are going to be a long way off the mean.

Substance
See Active pharmaceutical ingredient.

Trade name
See Brand name.

Trade-Related Aspects of Intellectual Property Rights (TRIPS)
An agreement annexed to the World Trade Organization convention aimed at strengthening and harmonizing aspects of the protection of intellectual property at the global level. It includes trademarks and patents as well as other forms of intellectual property.

Wholesaler
A company that buys goods from a manufacturer or importer and sells it to retailers.

The number of wholesalers in the pharmaceutical sector varies between countries, from one state wholesaler to more than 500. The wholesaler may be an agent for one company only or deal with products from several companies. Manufacturers may also be wholesalers for their own products. In some countries, pharmacies may also have a wholesaler licence.

Wholesale mark-up
A percentage added to the purchasing price to cover the wholesaler's costs and profit.

Annexes

Annex 1 Abridged questionnaire on structures and processes of country pharmaceutical situations

Annex 2 Example of a letter of endorsement

Annex 3 Trainer's Guide for training area supervisors, data collectors and data entry personnel

Annex 4 Example of a letter of introduction from the survey manager

Annex 5 Checklist for manual check of survey data

Annex 6 Price Components Interview Guide

Annex 7 Price Components Data Collection Form

Annex 8 International comparison of MPRs: adjustment for reference price year, inflation/deflation and purchasing power parity

ANNEX 1

Abridged questionnaire on structures and processes of country pharmaceutical situations

IMPORTANT NOTE: To improve the comparability of results across different survey instruments investigating national pharmaceutical policies, the *National Pharmaceutical Sector Form* used in the first edition of the survey methodology has been replaced with an abridged version of the WHO *Questionnaire on structures and processes of country pharmaceutical situations*. (Note that the numbering of the questions has been kept consistent with the full questionnaire). A set of supplementary questions important to the medicine prices and availability survey has been included at the end of the questionnaire.

INTRODUCTION

The *Questionnaire on structures and processes of country pharmaceutical situations* is a basic assessment tool that provides a rapid means of obtaining information on the existing infrastructure and key processes of the pharmaceutical sector. The WHO asks all Member States to respond to the Questionnaire every four years in order to have up-to-date data on country, regional and global pharmaceutical situations as well as to enable comparisons over time.

THE COORDINATOR AND RESPONDENTS

In order to complete the Questionnaire, it is likely that you will need to gather data from a number of departments/divisions within the Ministry of Health, such as those responsible for policy, procurement and supply, financing, etc., as well as other ministries and agencies, including the Medicines Regulatory Authority, the Quality Control Laboratory, the department/agency responsible for trade and patents, the association/ministry responsible for training, etc. Which ministries, departments and agencies will need to be consulted will depend on the division of responsibilities in your country.

INSTRUCTIONS

- Provide your full name, position and contact details at the top of the Questionnaire so that we may contact you for any clarifications.
- Identify appropriate persons to complete each section of the questionnaire. Suggestions on which ministries, departments, agencies, etc. may be able to contribute to each section are provided at the beginning of the section.
- At the end of the questionnaire, include a list of all respondents contributing to the Questionnaire together with their contact details and the sections to which they contributed.
- When providing statistical information, please use national/local sources (e.g. local health statistical yearbook, drug accounts, information from the Medicines Regulatory Authority, etc) if available. Utilize the most recent statistics.
- Make sure that the responses are as accurate as possible using available resources and calling upon knowledgeable respondents. In some cases, where exact figures are unavailable, it may be necessary to give your best estimate.
- Answer all the questions. Use "DK" or "Don't Know" if you simply cannot provide/obtain the appropriate response/information.
- Explanations of the questions and definitions of terms and concepts used in the *Questionnaire* are provided in the right-most column of the questionnaire. If you require further clarification on any of the questions asked or the definitions used and/or more information on appropriate sources of information, please contact WHO (medicineprices@who.int).

Please forward the entire completed questionnaire to HAI (info@haiweb.org) or WHO (medicineprices@who.int) together with the final survey data (*Workbook*) and report. Where available, please also include the:

1. National medicines policy
2. National essential medicines list
3. National standard treatment guidelines
4. Reports of national indicator studies of the pharmaceutical situation, rational use and/or access to medicines

Please note that in submitting this data to HAI or WHO, the data will also be forwarded to the WHO Medicines Policy and Standards/Technical Cooperation for Essential Drugs and Traditional Medicine (PSM/TCM) department.

ABRIDGED QUESTIONNAIRE: STRUCTURES & PROCESSES OF COUNTRY PHARMACEUTICAL SITUATIONS

Country: Date (dd/mm/yyyy) :

Name of coordinator/principal respondent : E-mail address :

Position : Postal address :

Questions	Responses	Explanations
1. NATIONAL MEDICINES (DRUGS) POLICY (NMP)		
Please consult the health ministry, medicines regulatory authority and/or medicine service in answering the questions in this section.		
1.1 Is there a National Medicines Policy (NMP) document? *If no, skip to 2.*	Yes No Don't know	A national medicines (drug) policy document is a written expression of the government's medium to long term goals and priorities for the pharmaceutical sector and the main strategies for attaining them.
a) If yes, is it an official or draft document?	Official Draft Don't know	Mark "official" if the NMP document has been endorsed or officially adopted by the government otherwise mark "draft".
b) What year was it last updated?	Year	Indicate the year of last update whether the document is still in draft form or has been officially adopted.
1.2 Is there an NMP implementation plan that sets activities, responsibilities, budget and timeline?	Yes No Don't know	
a) If yes, when was it last updated?	Year	
2. REGULATORY SYSTEM		
Please consult the medicines regulatory authority in answering the questions in this section. Specific information regarding medicines tested for quality control purposes and monitoring of adverse drug reactions may need to be obtained from the quality control laboratory or the responsible agency/department.		
Regulatory authority		
2.2 Is there an existing formal medicines regulatory authority?	Yes No Don't know	This question is asking if there is a formal regulatory body with existing staff and a specific budget for conducting relevant medicines (drug) regulatory functions. Mark "no" if medicines regulatory functions, such as registration and licensing, are performed on an ad-hoc basis by an office, group or department that performs other pharmaceutical service functions, such as supply management and procurement.
2.3 What are the sources of funding for the medicines regulatory authority:		
Regular budget from the government:	Yes No Don't know	
Fees from registration of medicines:	Yes No Don't know	
Other:	Yes No Don't know	

Questions		Responses	Explanations
2.4	Are there legal provisions requiring transparency and accountability and promoting a code of conduct in regulatory work?	Yes No Don't know	This question is asking whether there are legal provisions (or legislation) requiring the regulatory authority to: – Define its policies and procedures in writing and publish the written documentation, – Give reasons for decisions to affected parties, – Account for its conduct and actions to individuals or groups and ultimately to the public, and – Follow a code of conduct in conducting its regulatory functions.
2.6	Is there a medicines regulatory authority website providing publicly accessible information on any of the following: legislation, regulatory procedures, prescribing information (such as indications, counterindications, side effects, etc.), authorised companies, and/or approved medicines?	Yes No Don't know	
Marketing authorization			
2.7	Are there legal provisions for marketing authorization?	Yes No Don't know	This question is asking if there are legal provisions (or legislation) that describe the legal conditions under which marketing authorization should be conducted. Marketing authorization is an official document issued by the medicines regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality and/or after registration of a product for marketing.
2.8	How many medicinal products have been approved to be marketed? (*count total number of unique dosage forms and strengths*)	Number	Tablets, capsules, injections, elixirs and suppositories should be counted in different strengths. For example, if Paracetamol (Brand X) 250 mg and 500 mg have been approved to be marketed, they count as two medicinal products because they are two unique strengths. Paracetamol (Brand Y) 250 mg and 500 mg are another two unique products.
2.9	Is a list of all registered products publicly accessible?	Yes No Don't know	Registered products are medicine products that have been evaluated for quality, safety and efficacy and thence authorised for marketing. In order to be publicly accessible, it should be available on the web or to anyone contacting the responsible authority.

Questions	Responses	Explanations
Licensing		
2.14 Are there legal provisions for licensing of the following:		This question is asking if there are legal provisions (or legislation) that describe the legal conditions under which manufacturers, wholesalers and distributors and importers and exporters are subjected to evaluation against a set of requirements and issued a permit to operate (license) authorising them to undertake specific activities.
Manufacturers:	☐ Yes ☐ No ☐ Don't know	
Wholesalers or distributors:	☐ Yes ☐ No ☐ Don't know	A wholesaler is a company that buys goods from a manufacturer or importer and sells them to retailers. The wholesaler may be an agent for one company only or deal with products from several companies. Manufacturers may also be wholesalers for their own products. In some countries, pharmacies may also have a wholesaler license. Distributors include wholesalers, retail pharmacies and medicine outlets.
Importers or exporters of medicines:	☐ Yes ☐ No ☐ Don't know	
Quality control		
2.19 Is there a quality management system in place?	☐ Yes ☐ No ☐ Don't know	This question is asking if there is an officially defined protocol for ensuring the quality of medicines, including testing of medicines to be registered, collection and testing of samples, reporting results, corrective actions to be taken when poor results are found and preventative measures to be taken to reduce future incidence of poor results.
2.20 Are medicine samples tested for the following regulatory purposes:		
Medicines registration:	☐ Yes ☐ No ☐ Don't know	
Post-marketing surveillance:	☐ Yes ☐ No ☐ Don't know	Post-marketing surveillance is testing medicine samples to assess the quality of medicines that have already been licensed for public use.
2.22 What is the total number of samples quality tested in the last calendar year?	Number ☐	This should include all samples tested whether in a quality assurance laboratory within the country or outside the country.
2.23 What is the total number of samples tested in the last calendar year that failed to meet quality standards?	Number ☐	This should include all samples tested that failed to meet quality standards whether the testing was done in a quality assurance laboratory within the country or outside the country.
2.24 Are there regulatory procedures to ensure quality control of imported medicines?	☐ Yes ☐ No ☐ Don't know	This question is asking if there are standard operating procedures for ensuring the quality of imported medicine, such as reviewing dossiers, product evaluation and testing of imported medicine products. This may include donated medicines.

Questions		Responses	Explanations
Dispensing and prescribing			
2.30	Are there legal provisions for the following:		This question is asking if there are legal provisions (or legislation) that describe the legal conditions under which prescribers and the practice of pharmacy are licensed. Licensing is a system that subjects all persons to evaluation against a set of requirements before they may be authorized to prescribe medicines/practice pharmacy. It may include issuing an official permit and granting authorization to prescribe medicines/practice pharmacy by either the governing authority or the body regulating the exercise of the profession.
	Licensing and practice of prescribers:	Yes No Don't know	
	Licensing and practice of pharmacy:	Yes No Don't know	
2.31	Is prescribing by generic name obligatory in the:		A generic name (international non-proprietary name – INN) is a non-proprietary or approved name rather than a proprietary or brand name under which a generic medicine is marketed. If prescribing by generic name is obligatory then prescribers are required to prescribe by generic name.
	Public sector:	Yes No Don't know	
	Private sector:	Yes No Don't know	
2.32	Is generic substitution permitted at:		Generic substitution is the practice of substituting a product, whether marketed under a trade name or generic name, by an equivalent product, usually a cheaper one, containing the same active ingredient at the dispensing level. Mark "yes" if either generic substitution is required or if the dispenser is allowed to make a generic substitution in at least some instances.
	Public pharmacies:	Yes No Don't know	
	Private pharmacies:	Yes No Don't know	
2.33	Are there incentives to dispense generic medicines at:		Incentives may include dispensing fees or mark-ups which provide financial incentive for dispensers to dispense lower-priced generic medicines
	Public pharmacies:	Yes No Don't know	
	Private pharmacies:	Yes No Don't know	

Questions		Responses		Explanations
Promotion and advertising				
2.34	Are there provisions in the medicines legislation/ regulations covering promotion and/or advertising of medicines?	Yes No Don't know		This question is asking if there are legal provisions (or legislation) that describe the conditions under which the promotion and/or advertisement of medicines may be conducted. Promotion and advertisement are activities that provide health workers and consumers with information about medicine products, particularly with the intent of encouraging health workers and consumers to use a particular product.
3. MEDICINES SUPPLY SYSTEM				
Please consult the agency/department responsible for the procurement and supply of medicines in answering the questions in this section.				
3.1	Is public sector procurement pooled at the national level (i.e. there is centralised procurement for the regions/ provinces)?	Yes No Don't know		Mark "yes" if public sector procurement is centralised and medicines are procured for the entire public sector by a national procurement body even if in some instances, such as cases of stock outages, public sector facilities procure medicines through other means.
3.2	Who is responsible for public sector medicines procurement and distribution:	**Procurement**	**Distribution**	
	Ministry of Health:	Yes No DK	Yes No DK	
	Non-governmental organization (NGO):	Yes No DK	Yes No DK	Mark "yes" if government funds or foreign contributions are allocated to NGOs to procure or distribute medicines for the public sector. Non-governmental organizations (NGOs) are non-governmental, non-profit organizations, networks and voluntary associations including charities, community groups, faith-based organizations, professional associations, academia and trade unions.
	Private institution contracted by the government:	Yes No DK	Yes No DK	Mark "yes" for private institution contracted by the government if the government contracts or makes an agreement with a private entity to procure or distribute medicines for the public sector, e.g. if an agreement is made with a private company to distribute medical items and supplies to public sector district warehouses and health facilities.
	Individual health institutions:	Yes No DK	Yes No DK	
3.3	What type of tender process is used for public sector procurement and what is the percentage of the total cost for each:		**Percentage of total cost**	Competitive tender is a procedure for procuring medicines which puts a number of suppliers into competition. Purchasing is done on the basis of quotations submitted by suppliers in response to a public notice.
	National competitive tender:	Yes No DK	_____ %	National competitive tender is open to all or a limited number of local suppliers only.
	International competitive tender:	Yes No DK	_____ %	International competitive tender is open to all or a limited number of local and international suppliers though sometimes conditions give preference to either local or international suppliers.

Questions	Responses	Explanations
Negotiation/direct purchasing:	Yes No DK _____ %	In negotiation/direct purchasing the buyer approaches one or a small number of suppliers and either buys at the quoted prices or bargains for a specific service arrangement.
3.6 Is public sector procurement limited to medicines on the Essential Medicines List (EML)?	Yes No Don't know	An Essential Medicines List (EML) is a government-approved selective list of medicines or national reimbursement list. Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford.

4. MEDICINES FINANCING

Please consult the budget/ finance division of the health ministry and/or the pharmaceutical supply group in answering the questions in this section. The hospital/health facility service and/or the national social and insurance services may also need to be consulted.

4.1	What is the total public or government expenditure for medicines in US$ for the most recent year for which data are available?	US$ _____ Year _____	This question is asking for the total amount the government has spent on medicines, including government allotment, health ministry expenditure, donor contributions channelled through the government, etc.
4.2	Is there a national policy to provide at least some medicines free of charge (i.e. patients do not pay out-of-pocket for medicines) at public primary care facilities?	Yes No Don't know	If medicines are provided for free but patients must pay service fees, mark "yes" here. If some facilities provide medicines for free but there is not a consistent national policy that applies to all primary public health facilities, mark "no" here. If there is a national policy to provide medicines for free at primary public health facilities, but facilities are not required to abide by the policy and not all facilities provide medicines for free, mark "no" here.
	b) Which of the following types of patients receive medicines for free:		
	Patients who cannot afford them:	Yes No Don't know	
	Children under 5 years of age:	Yes No Don't know	
	Older children:	Yes No Don't know	Mark "yes" if children over 5 years of age receive medicines for free, regardless of the age limit, for example mark "yes" if children under 12 receive medicines for free.
	Pregnant women:	Yes No Don't know	
	Elderly persons:	Yes No Don't know	

Questions		Responses	Explanations
4.3	Which fees are commonly charged in public primary care facilities:		
	Registration/consultation fees:	☐ Yes ☐ No ☐ Don't know	Registration and consultation fees are fees patients must pay for seeing a health professional for a health check-up and/or diagnosis regardless of whether or not medicines are prescribed.
	Dispensing fees:	☐ Yes ☐ No ☐ Don't know	A dispensing fee is a fixed fee that pharmacies are allowed to charge per prescribed item or per prescription instead of or in addition to a percentage mark-up. The dispensing fee is paid to the dispenser and is in addition to the cost of the medicine. Both the dispensing fee and the cost of the medicine may be paid in part or whole by the patient, insurer or government.
	Flat fees for medicines:	☐ Yes ☐ No ☐ Don't know	Mark "yes" if either a flat fee for medicines or a flat fee per medicine item is commonly charged. – A flat fee for medicines is a fee which remains the same irrespective of the number of medicines or the quantity of each medicine dispensed. Thus, for example, a patient receiving 3 medicines would pay the same as one receiving 1 medicine. Also a patient receiving 20 tablets of one medicine would pay the same as a patient receiving 100 tablets each of 2 medicines. – A fee per drug item is a fee where the patient pays one set fee per each medicine irrespective of the number of units (tablets) of that medicine dispensed. Thus, for example, a patient receiving one medicine would pay $1 and a patient receiving 2 medicines would pay $2 and a patient receiving 3 medicines would pay $3 and so on. However, a patient receiving 10 tablets of one medicine would pay the same as a patient receiving 100 tablets of one medicine.
	Flat rate co-payments for medicines:	☐ Yes ☐ No ☐ Don't know	A flat rate co-payment is a fixed amount that a patient must pay either per medicine or per prescription to cover part of the cost of medicines, the other part being paid by an insurer or government.
	Percentage co-payments for medicines:	☐ Yes ☐ No ☐ Don't know	A percentage co-payment is a fixed percentage of the cost of prescribed medicines that a patient must pay to cover part of the cost of medicines, the other part being paid by an insurer or government. The amount a patient pays will depend on the medicine and the number of units of that medicine prescribed.
4.4	Is revenue from fees or the sale of medicines used to pay the salaries or supplement the income of public health personnel in the same facility?	☐ Always ☐ Frequently ☐ Occasionally ☐ Never ☐ Don't know	Mark "yes" if any percentage of collected fees or medicines sales is used to pay salaries, expenses and/or in any way supplement the income of public health personnel in the same facility.

Questions		Responses		Explanations
4.5	Do prescribers dispense medicines?	**Public sector** Always Frequently Occasionally Never Don't know	**Private sector** Always Frequently Occasionally Never Don't know	In answering this question, mark the degree of frequency doctors or other authorised prescribers dispense medicines in the public and private sectors irrespective of laws permitting or disallowing authorised prescribers to dispense medicines.
4.6	What proportion of the population has health insurance?	All Some None DK	All Some None DK	Health insurance is any prepayment scheme for health care costs additional to but excluding subsidies funded through the health ministry budget. The purpose of questions 4.6 and 4.7 are to identify how much protection the population has against exposure to the cost of medicines at the time people are sick. This includes: – Prepaid financing and – Public funding through the (prepaid) health ministry budget.
4.7	Are medicines covered by health insurance?	All Some None DK	All Some None DK	
4.8	Is there a policy covering medicine prices that applies to the public sector, the private sector, or non-governmental organisations?	**Public sector** Yes No DK	**Private sector** Yes No DK	**NGO** Yes No DK	In some countries, NGOs, such as faith-based missions, provide non-profit or not-for-profit health services. The third column should be completed by ticking any policies applicable to this sector. Non-governmental organizations (NGO) are non-governmental non-profit organizations, networks and voluntary associations including charities, community groups, faith-based organizations, professional associations, academia and trade unions.
	a) If yes, which of the following policies covering medicine prices apply:				
	Maximum wholesale mark-up:	Yes No DK	Yes No DK	Yes No DK	A wholesale mark-up is a certain percentage added to a purchasing price to cover the cost and profit of the wholesaler.
	Maximum retail mark-up:	Yes No DK	Yes No DK	Yes No DK	A retail mark-up is a certain percentage added to a purchasing price to cover the cost and profit of the retailer.
	Duty on imported raw pharmaceutical materials:	Yes No DK	Yes No DK	Yes No DK	A duty/tax on imported raw pharmaceutical materials is a fee assessed by customs or other responsible national authority on imported starting materials, reagents, intermediates, process aids, and solvents intended for use in the production of intermediates or active pharmaceutical ingredients.
	Duty on imported finished pharmaceutical products:	Yes No DK	Yes No DK	Yes No DK	A duty/tax on imported finished pharmaceutical products is a fee assessed by customs or other responsible national authority on medicinal products that require no further processing and are already in their final containers.

Questions		Responses			Explanations
4.9	Is a national medicine prices monitoring system for retail/patient prices in place?	**Public sector** ☐ Yes ☐ No ☐ DK	**Private sector** ☐ Yes ☐ No ☐ DK	**NGO** ☐ Yes ☐ No ☐ DK	A national medicine prices monitoring system for retail/patient prices is any means of regularly tracking and comparing over time retail/patient medicine prices in the public, private and/or NGO sectors.
4.10	Are there regulations mandating retail/patient medicine price information to be made publicly accessible?	☐ Yes ☐ No ☐ DK	☐ Yes ☐ No ☐ DK	☐ Yes ☐ No ☐ DK	In order for retail/patient medicine price information to be considereds publicly accessible, one or more of the following or similar measures should be taken: prices should be available on the web or to anyone contacting the responsible authority, prices should be periodically published in national newspapers or official publications, prices should be posted in health facilities/pharmacies, etc.
4.11	Are there official written guidelines on medicine donations that provide rules and regulations for donors and provide guidance to the public, private and/or NGO sectors on accepting and handling donated medicines?	☐ Yes ☐ No ☐ DK	☐ Yes ☐ No ☐ DK	☐ Yes ☐ No ☐ DK	Countries may have differing definitions for medicine donations which may include not only products but also monetary gifts earmarked for a particular product from a named source (e.g. manufacturer, organization or other country).

6. RATIONAL USE OF MEDICINES

Please consult the health ministry (hospital division), professional bodies and/or the education ministry in answering the questions in this section.

6.1	Is there a national Essential Medicines List (EML)?	☐ Yes ☐ No ☐ Don't know	A national Essential Medicines List is a government-approved selective list of medicines or national reimbursement list from which most prescriptions should be made. Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness.
	a) If yes, how many unique medicine formulations does the national EML contain?	Number ☐	Count similar formulations registered or approved as different products as one formulation, for example Brand X 500 mg Paracetamol tablets and Brand Y 500 mg Paracetamol tablets are counted as one formulation whereas Brand X 250 mg Paracetamol tablets and Brand X 500 mg Paracetamol tablets are counted as two formulations.
	c) When was the national EML last updated?	Year ☐	
	d) Is the national EML being used in the following:		Mark "yes" if the EML is currently being used.
	Public sector procurement:	☐ Yes ☐ No ☐ Don't know	
	Public insurance reimbursement:	☐ Yes ☐ No ☐ Don't know	
	Private insurance reimbursement:	☐ Yes ☐ No ☐ Don't know	

	Questions	Responses			Explanations
	e) Is there a committee responsible for the selection of products on the national EML?	☐ Yes ☐ No ☐ Don't know			This refers to a formally recognised committee with members of different expertise and from different agencies/organizations.
6.2	Are the following types of standard treatment guidelines (STG) produced by the health ministry for major conditions?	**National STG** ☐ Yes ☐ No ☐ DK	**Hospital level STG** ☐ Yes ☐ No ☐ DK	**Primary care STG** ☐ Yes ☐ No ☐ DK	Mark "yes" if the health ministry or similar national authority produces a collection of treatment guidelines covering prevalent/common disease conditions in the country for use at the national, hospital or primary care levels. If treatment guidelines are produced separately for each disease/condition or organ system, mark "no".
	a) If yes, when were the STGs last updated?	Year _____	Year _____	Year _____	
6.16	How frequently are the following types of medicines sold over the counter without any prescription:				This question is asking how often antibiotics and injections which require a prescription to be dispensed are sold without a prescription, regardless of laws prohibiting such practice.
	Antibiotics:	☐ Always ☐ Frequently ☐ Occasionally ☐ Never ☐ Don't know			
	Injections:	☐ Always ☐ Frequently ☐ Occasionally ☐ Never ☐ Don't know			

SUPPLEMENTARY QUESTIONS FOR MEDICINE PRICES AND AVAILABILITY SURVEY

Questions	Responses	Explanations
1. Retail		
S1.1 How many licensed private retail medicine outlets are there in the country?	Number	"Licensed" refers to medicine outlets that are subjected to evaluation against a set of requirements and issued a permit to operate (license).
S1.2 What proportion of patients access medicines through: a) public/government sector b) formal private sector c) Other: specify: d) Other: specify:	a) % b) % c) % d) %	The formal private sector refers to licensed medicine retail outlets and licensed retail drug stores. Common other sectors include non-government organizations, mission health facilities, or dispensing doctors.
S1.3 Are there public medicine outlets which sell medicines in public health facilities?	Yes No Don't know	
S1.4 Are there private pharmacies which sell medicines in public health facilities?	Yes No Don't know	
2. Medicines financing		
S2.1 What proportion of medicines by volume are imported?	% Year	
S2.2 What proportion of medicines by value are imported?	% Year	
3. Medicines supply system		
S3.1 Are there regulations for local preference in public procurement?	Yes No Don't know	Local preference purchasing means that domestic companies will be preferred even if their prices are not the lowest.
4. Regulatory authority		
S4.1 Do the fees charged for the registration of medicines differ between:		
a) Originator brands and generic equivalents	Yes No Don't know	
b) Imported and locally produced medicines	Yes No Don't know	
5. Medicine pricing policies		
S5.1 Does the government set the price of some/all originator brand products?	Yes No Don't know	
a) If yes, please describe how this is done (e.g. direct price controls, international reference pricing):		Direct price controls refers to price-setting using a pricing formula, e.g. production costs + a % margin. International reference pricing refers to comparing prices to those in other countries.
S5.2 Does the government set the price of some/all generic products?	Yes No Don't know	

Questions	Responses	Explanations
a) If yes, please describe how this is done (e.g. direct price controls, national reference pricing):		National reference pricing refers to setting prices by comparing the prices of similar medicines (by molecule or therapeutic class; originator brand or generics) on the national market.
S5.3 Are prices set in the private sector for medicines on the national Essential Medicines List?	☐ Yes ☐ No ☐ No national EML	This question is asking whether price-setting is limited to medicines on the national EML.
S5.4 Are prices of medicines set as part of market authorization?	☐ Yes ☐ No ☐ Don't know	Marketing authorization is an official document issued by the medicines regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality and/or after registration of a product for marketing.
6. Other		
S6.1 Of the medicines included in the survey, are there any which are patent protected or only available as the originator brand product (i.e. single source products)?	☐ Yes ☐ No ☐ Don't know	
a) If yes, please specify which medicines:		
S6.2 Please provide the website address (URL) of any websites that publish the following information:		
a) Pharmaceutical legislation	a)	
b) Standard treatment guidelines	b)	
c) Regulatory procedures	c)	
d) Prescribing information	d)	
e) Licensed manufacturers	e)	
f) Medicines approved for marketing	f)	
g) List of registered products	g)	
h) Medicine prices (procurement or patient)	h)	

List of respondents

Name	Position	Address	E mail	Section(s) completed

Comments about indicators and values

Item number	Comment

ANNEX 2

Example of a letter of endorsement

MEDICINE PRICE AND AVAILABILITY SURVEY

To whom it may concern

Mr/Ms/Dr ..... (title and name of survey manager) of ..... (organization) will be undertaking a survey of medicine prices and availability in ..... (area or districts) in ..... (month in which study will be undertaken). This requires the collection of price information at a sample of retail pharmacies and other medicine outlets, as well as the collection of information on price composition at different points in the supply chain, from manufacturer to consumer.

The survey follows methods promoted by the World Health Organization and Health Action International and is designed to help identify ways of improving the affordability of medicines in ..... (name of country). Supporting ..... (survey manager) in this work are ..... (Advisory Committee member names and designations).

We understand that the results will be publicly available by ..... (likely date for completion of report) and that complete anonymity of individual pharmacies and medicine outlets will be assured. A prior appointment will be made with each pharmacy to be visited at a date and time convenient to staff.

On behalf of ..... (Ministry of Health or Pharmacy Association), I would be grateful if you would provide full access to the information needed for this survey.

Signed

Designation

Place

Date

ANNEX 3

Trainers' guide for training area supervisors, data collectors and data entry personnel

INTRODUCTION

This trainer's guide has been developed for a training workshop that instructs area supervisors, data collectors and data entry personnel in conducting the Medicine Prices and Availability survey. While area supervisors and data collectors should be trained together, survey managers may choose to train their data entry personnel separately. In such cases appropriate modification to the training agenda and materials will be necessary. It should be noted that this guide does not cover training on the price components element of the Medicine Prices and Availability survey, as this is generally a separate activity with different personnel who may or may not require training.

The aim of the trainer's guide is to provide guidance to survey managers in conducting a training workshop for their survey personnel, including:

- how a training programme can be conducted,
- what basic steps should be followed,
- what material should be covered, and
- training activities and aids that can be used

Sample presentations, handouts and exercises are also available to accompany this guide. The guide should be read alongside *Chapter 4: Training area supervisors, data collectors and data entry personnel*, of the survey manual.

This trainer's guide and materials have been developed based on experience in conducting training workshops for the survey. The training plan described in this guide uses a range of activities (e.g. presentations, exercises) to cover different learning styles and preferences, and to promote recall of training material. In particular, the data collection pilot test is an essential element of the workshop as participants will "learn by doing" and get hands-on experience in visiting medicine outlets and collecting data.

This guide should serve as an example only; the training plan and accompanying materials (i.e. presentations, handouts and exercises) will need to be adapted to fit the specificities of each survey. Considerations should include the level of experience of survey personnel, the specific objectives of the survey, any deviations from the standard methodology, and logistics issues (e.g. data collection pilot test must be conducted at the most convenient time for pharmacy staff). You, as the only person directly in contact with your specific audience and having the knowledge

about the actual situation, will need to adapt the training content to your specific needs, in order to reach your objectives.

The trainer's guide is divided into modules according to the training agenda. Each module outlines the objectives of the training session, instructions for training activities to be conducted, materials required, and the key messages that should be emphasized.

This trainer's guide is a work in progress; we welcome your input and suggestions (contact HAI at: info@haiweb.org).

TRAINING OBJECTIVES

Overall training objective:

To provide area supervisors, data collectors and data entry personnel with the knowledge and skills required to carry out the medicine prices and availability survey in an accurate and reliable manner.

Specific learning objectives:

Upon completion of the training, participants should:

1. Be familiar with the key aspects of the survey and how it is conducted
2. Understand their roles and responsibilities in the survey, including specific tasks, timelines and reporting requirements
3. Understand the critical content required to do their job effectively and possess the skills required to undertake each of their activities
4. Be aware of common issues which may arise during survey activities, and troubleshooting/problem-solving strategies
5. Recognize the intrinsic value of good-quality data and be motivated to ensure data quality as part of their activities

NOTE: The overall objectives of the survey should be linked to the personal objectives of survey personnel to increase the relevance of the training and the commitment to rigorous application of the methodology. For example, will the experience gained in conducting the survey be beneficial in future career development? Are survey personnel MoH staff that can relate to the financial benefits of, for example, lowering procurement prices?

Training format:

3-day workshop at central level (see agenda)

Participants:

Area supervisors, data collectors, data entry personnel

Materials required

Trainer's material

- Trainer's guide
- Powerpoint slides/transparencies
- Flip chart and paper
- Markers

Learner's material

- Name card for each participant
- Training agenda for each participant
- Copy of presentations for each participant
- Handouts and exercises for each participant
- 2 Medicine Price Data Collection forms per participant
- Note pad, pen, calculator, clipboard for each participant
- 1 computer per data collection team (area supervisor and their data collectors), plus 1 for data entry personnel

All training materials must be reviewed and adapted to your survey before use. In particular, sample presentations require careful review as not all information / instructions are likely to be relevant to your survey.

SAMPLE TRAINING AGENDA

DAY 1	
8:30–10:00	Welcome, survey objectives and training overview
10:00–10:15	**BREAK**
10:15–12:00	Overview of survey methodology
	• Key aspects of survey design
	• Roles and responsibilities of personnel
12:00–13:00	**LUNCH**
13:00–14:30	Data collection procedures
	• Preparation for data collection
	• Procedures – before, during and after medicine outlet visits
	• At the end of data collection
14:30–14:45	**BREAK**
14:45–17:15	Completing the Medicine Prices Data Collection form
	• Instructions for completing the form
	• Key rules to remember
DAY 2	
8:30–9:30	Review of Day 1
9:30–10:00	Instructions for data collection pilot test
10:00–15:00	Data collection pilot test (includes lunch break)
	• Data collection at one private and one public medicine outlet
15:00–15:15	**BREAK**
15:15–16:00	Unit price calculation
16:00–17:30	Debrief of data collection pilot test
DAY 3	
8:30–9:30	Review of Day 2
9:30–10:30	Data entry
	• How to enter unit price data into the survey workbook
	• How to conduct double entry and check results
10:30–10:45	**BREAK**
10:45–12:45	Data entry
	• Entry of data collected during pilot test
12:45–13:45	**LUNCH**
13:45–15:45	Checking workbook data
	• Using the workbook's data checker function
	• Manual checking of workbook data
15:45–16:00	**BREAK**
16:00–17:00	Logistics for data collection
	• Next steps
17:00–17:30	Final comments, evaluation of workshop

DAY 1

WELCOME, SURVEY OBJECTIVES AND TRAINING OVERVIEW

Objectives:

- To present the survey objectives and demonstrate the value of carrying out a medicine prices and availability survey
- To provide an overview of the training workshop
- To set a cooperative, non-threatening learning environment
- To promote positive group dynamics and interaction

Instructions:

1. **Welcome participants to the workshop (~ 30 minutes)**. If participants do not know each other, ask them to briefly introduce themselves to the group, e.g. by providing their name; role in the survey; background/relevant experience; and an interesting non-work fact about themselves. Again, if participants do not know each other, ask them to write their names on name cards and place them on their desk/table so that they are visible to the other participants.
2. **Conduct a group brainstorming exercise (~ 40 minutes)**. Ask participants to brainstorm on the reasons why some people do not have access to the medicines they need. Encourage participants to give as many ideas as possible, and record all responses on a flip chart. Continue until ideas are exhausted.

   Tip: write the question on the top of the flip chart to keep participants focused.

Expected responses:

- Medicines are not available at health centres/pharmacies
- Prices are too high
- Poverty – people cannot afford to buy medicines
- People have to travel too far to access medicines
- Government does not provide medicines for free
- Medicines are of poor quality, so people don't bother to buy them

Review the responses and ask participants how they know that these problems exist. Expected responses include: personal or professional experience, information in the media, intuition or other.

Conclusion to be drawn: "although we all know that access to medicines is a problem, we need reliable evidence to understand what the specific problems are how best to improve the situation, and to make a case for change. Collecting data on medicine prices, availability and affordability is therefore a key step in improving access to medicines in the country".

3. **Introduce the survey and review the training objectives, agenda and format (~ 20 minutes)**. A sample presentation, "Introduction to survey and training workshop" is provided on the CD-ROM.

   The training agenda should be copied and distributed to participants. The ground rules for the workshop should be written on a flip chart and posted in the workshop venue.

Materials required:

- Flip charts with 1) training objectives and 2) ground rules that can be posted in room for duration of workshop
- Name cards for each participant
- Copy of training agenda for each participant
- Handout of presentation: "Introduction to the medicine prices and availability survey and training workshop", for each participant

Key messages:

- Each participant brings valuable experience to the survey that will help it to run smoothly
- The medicine prices and availability survey is an important activity in improving access to affordable medicines

OVERVIEW OF SURVEY METHODOLOGY

Objectives:

- To provide an overview of the survey methodology so participants can see where their activities fit in the "big picture"
- To familiarize survey personnel with key aspects of the survey methodology and important terminology (e.g. survey areas, medicine outlets, originator brand, lowest-priced generic)
- To familiarize participants with their respective roles and responsibilities in the survey

Instructions:

1. **Present an overview of the survey methodology and introduce the roles and responsibilities of each type of survey personnel (1.5–2 hours)**. A sample presentation, "Overview of the medicine prices and availability survey methodology" is provided on the CD-ROM.

The sample presentation provided must be modified to fit the specificities of your survey. For example, the names of survey areas, sectors to be surveyed, and number of survey medicines, must be added/amended as appropriate.

Materials required:

- Handout of presentation: "Overview of the medicine prices and availability survey methodology", for each participant

Key messages:

- Data collection will take place in 6 areas of the country ("survey areas")
- Medicine outlets from the public, private and if applicable, "other" sectors, will be surveyed

- A total of 50 medicines are surveyed
- For each medicine, data are collected on 2 products: the originator brand, identified centrally before data collection, and on the lowest-priced generic equivalent found at each medicine outlet
- Data on the price and availability of medicines is obtained by data collectors during visits to pre-selected medicine outlets
- During the survey, data collectors will enter data into Medicine Price Data Collection forms. At the end of the survey, data from the forms will be entered into the electronic survey workbook by data entry personnel
- Each member of the survey personnel has an equal role to play in ensuring the success of the survey

DATA COLLECTION PROCEDURES

Objectives:

- To teach participants the protocol for planning data collection and visiting medicine outlets
- To identify the common problems encountered during data collection and how to address them

Instructions:

1. **Present the procedures for 1) preparing for data collection, and 2) conducting data collection (~ 1 hour)**. Be very clear about the specific activities to be undertaken by area supervisors versus data collectors. A sample presentation, "Data collection procedures" is provided on the CD-ROM.
2. **Conduct a small group exercise (~ 30 minutes)**. Divide participants into groups of 3-4 people. Ask them to make a list of things they can do to promote a positive interaction with staff at medicine outlets (5-7 minutes). Collect responses on a flip chart.

Expected responses:

- Be prepared so that data collection is as efficient as possible and staff do not lose time
- Do not visit during peak hours
- If customers arrive, allow the pharmacist to serve them before continuing the survey
- Be polite, respectful and professional
- Use letters of introduction and endorsement to give credibility to the survey
- Dress professionally
- Present the objective of the survey: to improve access to affordable medicines
- Remind staff that individual medicine outlets will not be identified in the results

Materials required:

- Handout of presentation: "Data collection procedures", for each participant
- Instruction sheets for area supervisors and data collectors

Key messages:

- Area supervisors must fully prepare for data collection visits before sending data collectors into the field. This includes scheduling all data collection visits and confirming appointments the day before.
- Data collectors must have all materials with them on each day of data collection. They must have a written schedule of visit to avoid missing any appointments
- Both data collectors and area supervisors are responsible for verifying the completeness, legibility and reliability of data collection forms. Data collectors should check forms before leaving the medicine outlet, while area supervisors should check forms at the end of each day of fieldwork
- Area supervisors must validate data collection at 1 public outlet and 1 private outlet per survey area and check their results against those of data collectors

COMPLETING THE MEDICINE PRICES DATA COLLECTION FORM

Objectives:

- To familiarize participants with the Medicine Price Data Collection form and teach them how to complete it correctly
- To present the "Rules for Data Collection"

1. **Introduce participants to the Medicine Price Data Collection form (~ 45 minutes)**. Distribute a blank Medicine Price Data Collection form to each participant. Go through the list of medicines on the form and give a brief description of their use. Highlight any "tricky" medicines that might cause difficulties during data collection, e.g. retard formulations, medicines commonly available in different dosage forms or strengths, concentrations that can be expressed in different ways (i.e. paracetamol syrup 120mg/5ml is equivalent to 24mg/ml), etc.

   For each medicine, the form contains two rows: one for the originator brand and one for the lowest-price generic. Remind participants of the difference between the originator brand and generic equivalent.

   Originator brand – original pharmaceutical product that was first authorized for marketing.

   Generic equivalent – all products other than the originator brand that contain the same active ingredient (substance), whether marketed under another brand name or the generic name.

2. **Explain each column of the data collection form and how to complete it (~ 1 hour)**. Highlight special cases (e.g. medicine is out of stock, medicine is provided free of charge) and how to handle them. A sample presentation, "Completing the Medicine Price Data Collection form" is provided on the CD-ROM. It presents each column of the data collection form and provides instructions on how to complete it, followed by an example.

Note: This presentation contains animation; not all information on the slide will appear at once. This allows you to control when participants receive information; for example, you may wish to explain the instructions before showing an example. You can make additional information on the slide appear by hitting the Enter key on your keyboard. Practise using animated slides before the workshop!

3. **Conduct an individual exercise: "Spot the mistakes" (~ 45 minutes)**. A Medicine Price Data Collection form, available on the CD ROM, has been completed with some common mistakes. Distribute one form per person and ask participants to identify the mistakes (15 minutes). Review the results as a group: working row by row, ask participants to identify any mistakes. Highlight any mistakes that they do not identify.

Materials required:

- Blank Medicine Price Data Collection form for each participant
- Handout of presentation: "Completing the Medicine Price Data Collection form", for each participant
- Instruction sheet on Completing the Medicine Price Data Collection form
- Spot the mistakes exercise

Key messages:

The "rules" of data collection:

- Collect data for every medicine on the form
- NO substitution of other medicines, strengths or forms
- The originator brand is still the originator if it is produced by a subsidiary company (e.g. manufactured for Pfizer by Dr Reddy)
- The LPG cannot be the originator brand
- The LPG is the generic product with the lowest unit price
- If multiple generics are available for an individual medicine and they have different pack sizes, you need to calculate the unit prices to identify the LPG
- Only record a medicine as available if you actually see it
- Out-of-stock medicines are unavailable
- If multiple pack sizes are available, record the price of the recommended pack size or the closest, higher pack size
- Record the full price of the medicine even if the patient only pays a part of the full price, but note the patient price in the Comments column
- Flat fees and non-universal discounts are not entered
- Prices for out-of-stock medicines are not entered
- Do not record 'special discounts' available only to certain groups of patients. However, record discounted prices that apply to all patients.
- If some medicines are available for free or for a fixed fee, their availability must still be recorded, with a note in the Comments column

DAY 2

REVIEW OF DAY 1

Objectives:

- To recall and embed the learning from Day 1
- To clarify any misunderstanding

Instructions:

1. **Conduct a "memory quiz" exercise (~ 1 hour)**. Working individually, ask participants to write down as many important points about data collection as they can remember (20 minutes). Instruct them to think specifically about 1) data collection procedures and 2) completing the Medicine Price Data Collection form.

   Tip: you could also ask participants to answer the following questions:

   What instructions would you give a data collector who was about to begin visiting medicine outlets?

   What are the key points to remember in completing the Medicine Price Data Collection form?

   Once participants have had a chance to work individually, collect responses from the group. Ask each participant for one response at a time, and make sure all participants have answered before moving to a second "round". Write down responses on two separate flip charts: 1) data collection procedures and 2) completing the Medicine Price Data Collection form. Continue collecting responses until ideas are exhausted.

   Expected responses should relate to the key messages from the Data Collection Procedures and Completing the Medicine Price Data Collection Form sessions. Review the lists and add any key ideas that were not provided by participants.

Materials:

- Flip chart and markers

Key messages:

- There are many things to keep in mind when collecting data
- To collect accurate data, data collectors must pay strict attention to the details and double check their forms to make sure no mistakes have been made
- If you have any uncertainly about data collection contact your area supervisor before leaving the medicine outlet

INSTRUCTIONS FOR DATA COLLECTION PILOT TEST

Objectives:

- To provide participants with a clear understanding of the objectives and instructions for the data collection pilot test
- To provide information on the logistics of conducting the pilot test

Instructions:

1. **Explain the purpose of the pilot test (~ 5 minutes)**.
   - To practise visiting medicine outlets, collecting data and completing the Medicine Price Data Collection form before starting the actual survey
   - To identify any data collection issues specific to the medicines in this survey
   - To identify any uncertainties or questions about data collection that require further review
2. **Provide instructions for conducting the data collection pilot test (~ 15 minutes)**:
   - During the pilot test you will visit two medicine outlets (1 public and 1 private) and collect data using the Medicine Price Data Collection form
   - You will visit medicine outlets in your data collection teams, i.e. each area supervisor and his/her data collectors count as one team

     Notes to trainer: large data collection teams (i.e. > 5 people) will need to be split into two groups. Each member of the data entry personnel will have to be allocated to a data collection team, preferably the teams with the fewest survey personnel
   - Data should be collected in exactly the same way as in the real survey, using the same procedures and instructions covered in training yesterday
   - The pilot medicine outlets are expecting your visits. Introduce yourselves in the same way as you would in the real survey
   - Take turns asking the pharmacist about individual medicines, BUT, each participant should fill in his/her own data collection forms (1 per medicine outlet)
   - You can bring reference materials (handouts, instruction sheets, notes) with you
   - If you are unsure of anything, or have any questions, write them down for discussion later on EVEN IF you solve the problem yourself/as a team
   - In addition to collecting data, area supervisors should also supervise and watch out for common mistakes, for example, information collected on the wrong strength or dosage form. Correct any mistakes and note any uncertainties for clarification during the training workshop

     Notes to trainer: It may be necessary to hold a preliminary pilot test with area supervisors to ensure they are sufficiently knowledgeable about th survey protocol to supervise data collectors and identify mistakes
   - After the pilot test is completed, we will have a debriefing on your experiences

- The data you collect will be used in future sessions; make sure it is complete and legible

3. **Provide information on the logistics of the data collection pilot test (~ 10 minutes), including**:
   - Transport arrangements
   - Start and end times – stress that there should be ample time to collect data at the two medicine outlets, so no need to rush
   - Name of pilot sites, address, contact person, time of visit (prepare a schedule for each team)
   - Contingency plan: contact information of survey manager in case there is a problem

Tips:

- Be available during the pilot test to respond to any questions or problems
- Make sure pilot sites are nearby and easy to locate (provide a map if necessary)
- Have a few medicine outlets ready as back-ups in case in case pilot sites no longer want to participate
- Accompany a team that has shown limited understanding of data collection procedures

Materials:

- A schedule for each team with the name of pilot sites, address, contact person, time of visit
- 2 Medicine Price Data Collection forms per participant
- Pens, notepads, clipboards, calculators for each participant
- One mobile phone per team

Key messages:

- Data should be collected in exactly the same way as in the real survey
- Each participant should complete their own forms: one per facility
- Any uncertainties or questions should be recorded
- This is your only chance to practice before starting the survey; it is more important to complete the forms well than to finish quickly

PILOT TEST

Objectives:

- To provide data collectors with an opportunity to practise data collection activities in medicine outlets
- To identify any areas which require clarification or improvement and address them before the survey begins

During the pilot test, participants visit medicine outlets, collect data and complete the Medicine Price Data Collection form, in exactly the same way they would during the survey. Each participant should complete a Medicine Price Data Collection form for each of the 2 outlets they visit (see previous module, Instructions for Pilot Test).

Do not send more than 5 survey personnel (e.g. 1 area supervisor and 4 data collectors) to a pilot site. If survey teams consist of larger numbers of personnel, they will need to be split into smaller groups for the pilot test.

UNIT PRICE CALCULATIONS

Objectives:

- To provide participants with experience in calculating unit prices

Instructions:

1. **Unit price calculation by participants (~ 45 minutes – 1 hour)**

   As participants to calculate the unit price for each medicine product on the Medicine Price Data Collection forms they completed during the pilot test:

   - Unit price is the price per pill, ml, dose
   - For each product, divide the Price of Pack Found (Column H) by the Pack Size Found (Column G)
   - Retain four digits after the decimal point
   - Enter the calculated unit prices in Column I of the data collection form
   - Any unit prices calculated during data collection to identify the lowest priced generics should be double checked

   Note: Depending on the number of medicines surveyed, participants may not have time to calculate unit prices for both sets of data they collected during the pilot test. If time runs short, ask participants to finish unit price calculations as "homework" and bring them to the workshop the next day.

Materials:

- Medicine Price Data Collection forms completed during the pilot test
- calculators for each participant

Key messages:

- Unit price is the price per tablet, capsule, ml, dose
- Retain four digits after the decimal point

PILOT TEST DEBRIEF

Objectives:

To discuss participants' impressions of the data collection process, and to identify and address any problems encountered.

Instructions:

1. **Conduct a group discussion (~ 1.5 hours)**. Ask participants to report back on their experiences during the pilot test. Specifically,
   - What went well?
   - What was the most difficult?
   - Any uncertainties with data?
   - Anything unexpected?

   You may wish to prompt the group to discuss the following topics:

   — Finding the pharmacy

   — Pharmacist's attitude

   — Finding the right products – right strength, dosage form, pack size

   — Identifying the lowest-priced generic product

   — Determining availability

   — Calculating unit price

Record any questions or uncertainties about data collection on a flip chart. Provide solutions, or depending on the nature of the questions, solicit possible solutions from the group. Be sure to record the solutions on the flip chart next to the original question/problem.

Finish the discussion by asking each participant to name the most valuable thing they learned from the pilot test.

Materials:

- Flip chart
- Notes taken during the pilot test

Key messages:

- Questions and uncertainties are almost sure to arise during data collection.
- Data collectors should always check with their area supervisor, and area supervisors with the survey manager, if there are any problems or uncertainties.

DAY 3

REVIEW OF DAY 2

Objectives:

- To recall and embed the learning from Day 2
- To build motivation for collecting data in a reliable way

Instructions:

1. **Describe any changes made to the Medicine Price Data Collection form based on results of the pilot test (~ 15 minutes)**. If possible distribute a copy of the final Medicine Price Data Collection form to each participant.
2. **Conduct a group brainstorm (~ 45 minutes)**. Ask participants to brainstorm on the possible mistakes that can be made during data collection (15 minutes). Record responses on a flip chart. Continue until ideas are exhausted. You may wish to prompt participants by asking for mistakes related to product identification, availability, pack size and price.

   Expected responses:

   - the originator brand appears in a generic row
   - the lowest-priced generic is identified as the product with the lowest pack price
   - wrong strength
   - dosage form not as specified (example: nasal spray instead of inhaler, tablet instead of ampoule/vial)
   - related but not equivalent substance
   - price entered without indicating whether medicine was available
   - medicine was not actually available – price taken from price list during temporary stock-out
   - price recorded of pack which is not the closest to recommended pack size
   - discount was applied to recorded price but discount was not available to all patients
   - discount mentioned in comment, but not clear if the price recorded was pre-discount or post-discount
   - price was actually a flat dispensing fee, not true price
   - price included injection fee
   - paper form not filled out completely or illegible
   - unit price calculated incorrectly

   Conclude the exercise by summarizing the key messages below.

Materials:

- Flip chart and markers

Key messages:

- There are many possible errors that can be made during data collection.
- To collect accurate data, data collectors must pay strict attention to the details and bring any questions or uncertainties to the attention of their area supervisor
- It is essential that data are checked:
  - — By data collectors before leaving facility
  - — By area supervisors at the end of each day of data collection

DATA ENTRY

Objectives:

- To familiarize participants with the electronic survey Workbook used for data entry and analysis
- To teach participants how to enter data from completed Medicine Price Data Collection forms

Instructions:

Participants should work in their data collection teams as they did during the pilot test. One computer, with the electronic survey workbook file loaded and opened, should be available for each team. As this session is particularly relevant to the two data entry personnel, it is recommended that they work together on one computer so that they get as much practise using the workbook as possible.

1. **Present the survey workbook and instructions for data entry (~ 1 hour)**. A sample presentation, "Data entry" is provided on the CD-ROM. If you are using a computer with a projector, you should have both the presentation and the workbook open so that you can switch back and forth between the two. As you present various aspects of the workbook and data entry procedures, switch to the workbook and demonstrate to participants how it works. Encourage participants to follow along on their computer and try various workbook functions.
2. **Conduct a data entry exercise (~ 2 hours)**. Collect the data collection forms completed during the pilot test and redistribute them so that data collection teams do not have their own forms. Instruct teams to enter the data on the forms, including the medicine outlet identifying information on the first page of the form. They should enter data on the appropriate Field Data Consolidation page, depending on whether the data are from the public sector or the private sector. Depending on the size of the groups, the first participant should enter data for the first 10 medicines, the second participant should enter data for the next 10 medicines, and so on, until all the data from the medicine outlet are entered. They should then use the double entry function of the workbook to enter the same data (i.e. from the same data collection form) a second time. Participants should enter data for different medicines than those they entered the first time (i.e. a participant should not enter the same medicines both times). Results should be checked and corrected using the double entry function.

   Note: Summary data will not be displayed in the workbook unless an exchange rate has been entered on the Reference Prices page and the minimum number of prices required for calculating of median price ratios has been set to "1" on the Field Data Consolidation pages.

Tip: As participants are entering data you should circulate and assist with any difficulties. Some issues may be encountered (e.g. data illegible or ambiguous) that will provide an opportunity to highlight the importance of rigorous data collection techniques.

Materials:

- Handout of presentation: "Data entry", for each participant
- Computers (1 per data collection team, plus 1 for data entry personnel) loaded with the electronic survey *Workbook Part I* that has been customized to the survey (e.g. survey medicines, sectors to be surveyed)
- Medicine Price Data Collection forms completed during the pilot test

Key messages:

- Illegible or ambiguous data on the Medicine Price Data Collection forms will lead to difficulty in data entry, delays caused by re-checking of data, and sometimes return visits to medicine outlets to confirm data
- Do not try to interpret illegible or ambiguous data, rather bring this to the attention of the survey manager
- Entering long columns of prices can lead to a substantial number of errors. All data must be entered twice and verified using the double entry function of the workbook
- Do not enter "0"s for medicines that were not available (i.e. no price data on the Medicine Price Data Collection form)

CHECKING WORKBOOK DATA

Objectives:

- To demonstrate the importance of checking workbook data
- To instruct participants on how to check data that have been entered into the workbook

Instructions:

1. **Present the possible causes of data errors in the survey Workbook, and the three ways that Workbook data is checked: 1) double entry, 2) data checker, and 3) manual check (~ 30 minutes)**. A sample presentation, "Data quality and checking" is provided on the CD-ROM. In particular, spend time demonstrating the data checker function of the Workbook. As in the Data Entry module, it is useful to have the workbook projected onto a screen/wall that is visible to all participants as you demonstrate the data checker.
2. **Conduct a data checking exercise (~ 1.5 hours)**.

   During this exercise, participants will check data contained in the Data Checking workbook that has been pre-loaded onto each computer (~ 1 hour). The Data Checking workbook, available on the CD-ROM, contains intentional mistakes that participants will identify during the exercise. Participants will continue to work in their data collection teams. They should open the Data Checking work-

book saved on their computers and check the data by first running the data checker and then conducting a manual check of the data. Any suspicious data should be noted.

At the end of the exercise conduct a group debriefing (~ 30 minutes). Ask participants the following questions, taking care to solicit responses from each of the teams:

- Were any mistakes or suspicious data identified by the data checker? If so, what are some examples?

  Expected responses: LPG price was higher than OB price; minimum price was very low compared to others in the row, maximum price was very high compared to others in the row; spread between minimum and maximum price was very wide; median price ratio was very high/low in international terms.

- Were any mistakes or suspicious data identified through manual checking? If so, what are some examples?

  Expected responses: some identifying information missing for medicine outlets; unit prices not entered to 4 decimal places; strange unit prices that turned out to be data entry mistakes

- Were you able to correct or confirm data by consulting the Medicine Price Data Collection form?

Conclude that data entry problems can sometimes be resolved by consulting the original Medicine Price Data Collection form, but ambiguous data on the form itself is a data collection issue that will require further follow up – these issues must be brought to the attention of the survey manager.

Materials:

- Handout of presentation: ""Data quality and checking", for each participant
- Computers (1 per data collection team, plus 1 for data entry personnel)
- Data Checking workbook that has been pre-loaded onto each computer

Key messages:

- Even though data are checked multiple times throughout data collection, there may still be mistakes after data entry due to:

  — unidentified data collection mistakes

  — data entry errors

- Before submitting the workbook to the survey manager, data must be checked both manually and using the data checker function
- Identifying questionable data is not useful unless issues are resolved – notify the survey manager of anything suspicious

LOGISTICS FOR DATA COLLECTION

Objectives:

To inform survey personnel of the next steps and logistics related to data collection

Instructions:

1. **Provide instructions on the logistical aspects of the survey, including next steps following the workshop (~ 1 hour)**.

   The information provided in this session will depend on whether 1) the survey sample has already been identified and confirmed, in which case data collection will begin on a specific date soon after the training workshop; or 2) the survey sample has yet to be identified and confirmed, in which case the start date of data collection is still to be determined.

   In the either case, next steps will usually involve a meeting between area supervisors and their data collectors in which data collectors will be given their data collection schedules, materials and any final instructions. In the first case data collectors can be given the date, time and location of the meeting, while in the second case they will need to wait to be contacted by their area supervisor. In some cases schedules and materials can be distributed to data collectors at the training workshop for initiation of fieldwork directly after the workshop.

   Survey personnel should be provided with the following logistic information, or should be told how and when they will receive this information:

   - Start date for data collection
   - Allocation of data collectors into teams
   - Meeting times and locations for data collection teams
   - Transport (and accommodation where required) arrangements
   - Time/location of end-of-day meetings during data collection
   - Communications when in the field
   - Distribution of Medicine Price Data Collection forms and other materials

   Information on compensation, per diems, and transportation costs should always be covered as part of this session.

Materials:

- Handout for each data collection team with the contact information of data collectors, the area supervisor and survey manager, as well as any other logistical information (e.g. scheduled meeting time).

Key messages:

- Each participant should be aware of their immediate instructions following the workshop, e.g. initiate data collection on X date/time, await contact from area supervisor/survey manager, attend meeting on X date/time.

FINAL COMMENTS, EVALUATION OF WORKSHOP

Objectives:

- To thank participants for their contribution to the workshop
- To give participants the opportunity to provide feedback on the workshop

Instructions:

Close the workshop by providing any final comments or instructions, thanking participants, and distributing a workshop evaluation form for completion (~ 30 minutes).

You should end the workshop by thanking participants for their active participation and reminding them of the importance of the medicine prices and availability survey to which they are contributing.

Distributing an evaluation form for the training workshop is also recommended so that participants can provide feedback on the learning process. A sample evaluation form is provided on the CD-ROM.

Materials:

Training workshop evaluation form for each participant

Key messages:

- Reliable data is needed to identify strategies for improving access to affordable medicines
- Each participant has an equal role to play in ensuring the success of the survey

ANNEX 4

Example of a letter of introduction from the survey manager

MEDICINE PRICE AND AVAILABILITY SURVEY .... (PLACE AND DATES)

To whom it may concern

By this letter I would like to introduce to you ……. (name of area supervisor) and his/her team (details attached), as they begin to collect information from registered pharmacies and other medicine outlets on the price and availability of selected medicines in your area.

This work is in accordance with methods promoted by the World Health Organization and Health Action International and endorsed by ……. (Ministry of Health and/or Pharmacy Association). The results will be made publicly available and the anonymity of individual pharmacies and individual respondents will be strictly maintained.

This work should contribute to better knowledge about retail price differences, both in the country and internationally. It should also help us to understand how these prices are determined and how we might better control them. As you are aware, the price of medicines is of great importance to all people.

The survey team's work consists of interviewing staff at a preselected sample of medicine outlets about the prices and availability of 50 important medicines. Each outlet visit will probably take about two hours and we will try to ensure that the timing of the visit is convenient for you and your staff. Interviewers have specifically been asked to avoid arriving at peak times, when the outlet is busiest.

Should you need further information or have questions about this survey, please contact me directly. I would be grateful for every assistance you can provide to ……. area supervisor) and his/her team in carrying out their work.

Signed

Designation

Place

Date

Attachments:

- Full contact details of survey manager and commissioning organization
- Names of all data collectors in survey area
- Planned schedule of dates and times of visits to medicine outlets
- Names and designations of Advisory Committee members
- Copy of letter(s) of endorsement

ANNEX 5

Checklist for manual check of survey data

As described in Chapter 7, the following checklist can be used as a guide in conducting a manual verification of survey data once it has been entered into the *Workbook*.

Home page:

- Has the country name been selected?
- If the survey is being conducted as a state or provincial survey, has the state or province been identified?
- Have any other sectors been identified?
- Has the first day of data collection been entered?
- Have the survey areas been identified?

International Medicine Reference Price Data page:

- Is the exchange rate correctly entered (commercial buying rate on the first day of data collection)? Is it entered the correct way round (1US = XX local currency)?
- Is the name of the local currency entered?
- Does the date of the exchange rate coincide with the first day of data collection?
- Has the source of the exchange rate entered?
- If a different reference source (other than MSH) is being used, is the name of that source entered?
- Has the appropriate regional core list of medicines been uploaded?
- Are all the supplementary medicine names spelt correctly?
- In Column G: Core List, are supplementary medicines listed as 'no' and global and regional core medicines as 'yes'?
- Are the unit prices of the reference source accurately entered (for MSH: check year and enter median unit prices for suppliers – only use the median buyer price if there is no supplier price)?

- If two medicines are listed with different strengths or dose forms, have they been given unique names in column C (for example, amoxicillin tabs and amoxicillin suspension)?
- For each medicine, has the minimum level of public sector facility where the medicine is expected to be available been entered into Column O?

Field Data Consolidation: Medicine Procurement Prices page:

- Have the procurement ID, agency name (abbreviated) and date been entered?
- Has the number of orders required for median price data set to <1? Note: if procurement prices have been collected from many public facilities then the number should be set to <4.
- Are the unit prices entered correctly – to at least four decimal places, and without currency symbols? If there is no unit price then the cell should be left blank.

Field Data Consolidation: Patient Prices pages:

- Have the outlet study ID, region and distance from population centre been entered for each facility?
- On the public sector patient prices page, has the level of care of each public health facility been entered as 1 (primary), 2 (secondary) and 3 (tertiary)?
- Has the number of prices required for median price data set to <4?
- Are the unit prices entered correctly – to at least four decimal places, and without currency symbols? If there is no unit price then the cell should be left blank.
- When medicines were found but were provided to patients for free or for a fixed fee, has "F" been entered into the appropriate cell of the Patient price consolidation page?
- If no survey medicines were found in a given medicine outlet, has Row 10 been switched to "1" so that this outlet is still included in the analysis?

Standard Treatment Affordability page:

- Has the *daily* wage of the lowest paid unskilled government worker been entered in cell J6 (in local currency, but with no currency symbols)?
- For non-standard treatments:
  - — has the name of the condition been entered?
  - — is the treatment duration appropriate (duration for chronic conditions should be 30 days)?
  - — is the total number of units per treatment appropriate?

Price Components: Data Entry page:

- Are full descriptions entered for each example (sector, generic or originator brand, imported or locally produced, etc.)?
- Are examples included for all variations found in the country?

- Is it clear whether the example is based on real component costs or a hypothetical case?
- For each add-on costs, has the charge status (Value, Not found), charge basis (percentage or fixed fee), and amount of charge been entered?
- For percentage charges, has the base price to which the charge is applied been correctly identified?
- Have any discrepancies (e.g. Stage 2 selling price does not match Stage 3 procurement price) been verified?

ANNEX 6

Price Components Interview Guide

Table A6 lists the key informants commonly interviewed during Price Components central data collection. For each informant, the principal objectives of the interview are listed. It is important to keep these objectives in mind during the interview to ensure that the necessary information is obtained. Also listed are sample questions to ask during each interview. Note that not all types of interviewees listed may be appropriate for your country, and that not all questions will be appropriate.

In conducting the price components survey, it is important to double and even triple check the data obtained during interviews. All informants may not have the same understanding of the medicine supply chain and its associated costs, and some informants may not be aware of the most up-to-date information. This might include you, the researcher!

In addition to the specific questions presented in Table A6 below, you may wish to ask the following questions of many, if not all, of your informants:

- Are the final prices of some/all medicines controlled? If so, what are the regulations?
- Are there maximum wholesale and/or retail mark-ups? Do these apply to the public, private, other sectors?
- What are the taxes applied to medicines in the public, private and other sectors? Are any sectors or medicines exempt?
- How do mark-ups and other add-on costs differ for originator brand and generic medicines? How do they differ for imported and locally-produced medicines?

Note that some questions appear twice, namely once on each side of a transaction, in order to double check all data.

Table A6 Key informants for central data collection, interview objectives and sample questions

Informant	Objectives	Sample questions
Ministry of Health, Policy and Planning Branch	Obj 1: Determine the size of the medicine budget, what costs it covers in addition to medicines, and the population served. Obj 2: Determine the various means by which patients obtain pharmaceuticals. Obj 3: Determine whether there are user fees/cost recovery systems in the public sector. Obj 4: Obtain an overview of the process and rules of public procurement.	▪ Is there an essential medicines list? If yes, how many medicines are included? Does the list vary by level? Who develops it? How often is it reviewed? ▪ What is the medicines budget? Are quality control testing, overhead and distribution costs covered in the medicine budget, or are these a separate budget line? ▪ Are medicines free in the public sector? ▪ Are there policies for the use of generic products in the public and private sectors (e.g. generic substitution)? ▪ What are the taxes/tariffs applied to medicines in the public, private and other sectors? Are any sectors or medicines exempt? Where are exemptions documented? (Law number...) ▪ Does the government regulate mark-ups in the public distribution chain? If yes, please indicate rates for central medical stores, regional stores and public medicine outlets. ▪ Does the government control medicine prices in the public, private and/or other sectors? prices? If so, what are the regulations (e.g. maximum selling price)? Are prices enforced and by whom? ▪ How is public procurement conducted? Is public procurement limited to registered essential medicines? ▪ How is quality control testing conducted in the public sector? Do you have your own QC laboratory? What are the quality assurance requirements for local purchases? How much is spent on QA testing? Does this cost come out of the drug procurement budget? ▪ How are distribution and storage managed in the public sector? How are costs budgeted? ▪ Is there a pharmacy board? Does the pharmacy board collect a fee on pharmaceuticals? Do fees differ between generic equivalents and originator brands, and/or between imported and locally-produced products? ▪ Is there a government regulated dispensing fee? If yes, please describe the fee and how it is applied.
Procurement office – public and other sectors	Obj 1: Obtain an overview of the process and rules of public procurement. Obj 2: Identify how the administrative costs of procurement are covered (i.e. medicine budget or other government budget).	▪ What are the steps in public sector procurement? Do hospitals purchase any medicines directly? ▪ Is public sector procurement centralized, or decentralized to regional stores or individual health facilities? ▪ What are the technical requirements for procurement? Are WHO prequalification and/or Good Manufacturing Practices certification part of the technical requirements for procured products? ▪ What type of tendering process is used for public procurement? What is the procurement cycle? How are funds allocated, and how/when are funds made available? Are there ever delays in accessing funds? ▪ How is the procurement price determined? ▪ Do you procure all the medicines used in public sector facilities, or are some obtained from vertical programmes, local purchase, or other? If yes, what percentage are you supplying? How do you select the medicines that you will procure? How do facilities obtain medicines that are not procured centrally? ▪ What percentage of publicly procured medicines are locally produced? Is there a policy that provides preference to locally manufactured medicines? ▪ Of the medicines procured, approximately what proportion are originator brands? ▪ How often do stock-outs occur in the central/regional medical stores?

Informant	Objectives	Sample questions
		▪ How are these handled? How much was spent on emergency orders last year? ▪ What is this year's procurement budget? Does this cover additional costs such as medical stores' overhead, transport to health facilities, quality control testing? ▪ Who is responsible for distribution to public facilities? How are medicines transported and stored? ▪ What finance charges and fees are imposed by the bank on the procurement of pharmaceuticals (e.g. letter of credit, purchase of foreign exchange, contingency fee)?
Central/regional stores – public and other sectors[1]	Obj 1: Identify distribution routes for medicines in the public sector. Obj 2: Determine the overall availability of medicines, and assess whether the medicine budget matches population need.	▪ How are medicines delivered to central stores? How are they distributed to regional stores/health facilities? Is transport outsourced to a private company or handled by the central/regional stores? ▪ Is transport paid from the medicine procurement budget or from another budget? ▪ How often do you have stock-outs? How are stock-outs handled? ▪ What are your overhead expenses? What are your handling charges? Who covers these costs? ▪ Do you ever purchase medicines directly from the manufacturer? Who else do you purchase from? ▪ Is there a pharmacy board? Does the pharmacy board collect a fee on pharmaceuticals? Do fees differ between generic and originator brands, and/or between imported and locally-produced products? ▪ Does the government regulate mark-ups in the public distribution chain? If yes, please indicate rates for central medical stores, regional stores and public medicine outlets.
Government pricing authority (if one exists)	Obj 1: Determine what, if any, regulations are in place to control medicine prices. Obj 2: Identify any differences in pricing structures, e.g. for generics vs. originator brands; imported vs. locally manufactured, public sector vs. private sector.	▪ Are the final prices of some/all medicines controlled (e.g. maximum selling price)? How is information on a controlled price communicated (e.g. printed on box)? ▪ If there are maximum selling prices, how are these determined? Is there a pricing formula? Is it the same for all medicines/sectors? Please explain the pricing formula (taxes, mark-ups, etc.). ▪ Are there maximum wholesale and/or retail mark-ups? If so, to which sectors do these apply (public, private, other sectors)? ▪ Is there a Value Added Tax and/or General Services Tax on pharmaceuticals? If yes, to which sectors (public, private and/or other sectors) does it apply? Are any medicines exempt from VAT/GST? Are any other taxes or tariffs levied on medicines? ▪ Are there maximum profit margins for various participants in the supply chain? ▪ Are rebates and/or discounts common? How do they work?
Drug regulatory authority/drug control agency	Obj 1: Obtain an overview of the medicine registration process and how it impacts the availability of generics in the market. Obj 2: Identify quality assurance testing protocols and enforcement methods. Obj 3: Identify any fees collected for quality control testing.	▪ What fees (e.g. registration) are collected, and what are they used for? ▪ Do registration fees differ between generic equivalents and originator brands? What is the relative cost to register a generic equivalent or an originator brand? [NOTE: For the purposes of this survey, registration fees are not a price component – see page 141 ▪ What products are tested for quality? How many batches are tested? Do you have your own quality control lab, or is testing outsourced? How do you check that quality control protocols are followed? ▪ Is QA testing conducted for the public sector only, or for other sectors? ▪ What is the cost of quality control testing (samples and testing)? How is this cost covered (medicine procurement budget or separate budget)?

[1] May be same informant as for procurement.

Informant	Objectives	Sample questions
		▪ What is the importer's mark-up? Does this include transport to wholesalers/central stores? Are there other middlemen involved in the importation/supply of medicines (e.g. a clearing and forwarding agent)? If so, what are their mark-ups? ▪ If medicine prices are regulated, how are regulations enforced?
Quality control (QC) laboratory used by public sector	Obj 1: To understand the process of quality testing in the public sector and its associated costs	▪ How is quality testing conducted? What medicines are tested? What is the sampling protocol (e.g. every batch, random batches)? What happens when medicines do not meet standards? ▪ What is the approximate budget for QC testing? Does this match the cost of testing? ▪ How long does QC testing take? How are medicines stored/handled while testing is underway (e.g. quarantined at central medical stores until QC report is issued)?
Importers, customs officers, Ministry of Trade NB: Importer need not specialize in medicines	Obj 1: Determine how medicines are imported. Obj 2: Collect data on the charges related to the importation of medicines. Obj 3: Identify the importer's mark-up.	▪ What are the routes (e.g. air, land, sea) and major entry points (e.g. ports) by which medicines are imported? How is the logistics line divided (e.g. international freight vs local transport from border), and what is charged? ▪ How long does it take to clear an import order? What fees are incurred while an order waits to clear (e.g. storage, insurance, wharfage)? Importer: is it possible to pay more to get shipments to clear faster? ▪ What are the fees for international inspection (pre-shipment inspection (e.g. SGS) and in-country inspection)? ▪ What are the charges (e.g. port fee, port insurance, customs, stamp fee) incurred at the receiving port? ▪ Is there an import tariff on pharmaceuticals? Are any medicines/sectors/programmes exempted from the import tariff? ▪ What finance charges and fees are imposed by the bank on the procurement of pharmaceuticals (e.g. letter of credit, purchase of foreign exchange, contingency fee)? ▪ Does the government set a maximum importer's mark-up? If yes, what is the rate? ▪ Importer: what are charges for local transport: a) from the border to the import warehouse; b) from the import warehouse to the wholesaler/central stores? Who is responsible for these charges? Ministry of Trade: ▪ What percentage of medicines on the market are imported?
Manufacturer's association	Obj 1: Develop an understanding of the pricing structures of locally manufactured medicines Obj 2. Determine the distribution routes and associated costs for locally manufactured medicines Obj 3: Understand the cost differentials between imported and locally manufactured medicines	▪ What percentage (by volume or by value) of medicines are locally manufactured? What proportion of these are consumed locally (vs exported)? ▪ Is there a policy of preferential purchasing for locally manufactured medicines? ▪ Who are the major manufacturers of locally produced medicines? Are they stand alone manufacturers or subsidiaries of MNCs? ▪ For locally manufactured medicines, where are production facilities located and how are medicines distributed across the country? ▪ Does the government regulate medicine prices in the private sector? What are the regulations? How are they enforced? ▪ How do manufacturers determine the prices of generic and originator brand medicines? ▪ What is the pricing structure (e.g. taxes, mark-ups) for locally produced medicines? How does this differ from the pricing structure of imported medicines?

Informant	Objectives	Sample questions
Transport companies	Obj 1: Determine the costs and fees for local transport at each Stage of the supply chain. Obj 2: Compare the costs of the transport system in the public sector with those of the private sector.	▪ What are the charges for the local transport of medicines: – from the border to the import warehouse – from the import warehouse to the wholesaler/central stores – from the wholesaler to the retailer? ▪ Who is responsible for these charges? ▪ Are there any special requirements for the safe and timely delivery of medicines (e.g. refrigerated trucks, seasonal constraints)? ▪ Are there any additional (unofficial) charges that contribute to the cost of transport (e.g. roadblocks)?
Tax consultant	Obj 1: Understand the regulations for import tariffs. Obj 2: Identify if sales taxes exist and if so, how are they applied. Obj 3: Determine whether any other taxes or tariffs are levied on medicines. Obj 4: Determine whether any tax exemptions exist.	▪ May I photocopy chapter 30 (and 29 if applicable) of the International Harmonized Tariff Schedule? ▪ Is there a Value Added Tax and/or General Services Tax on pharmaceuticals? If yes, to which sectors (public, private and/or other sectors) does it apply? Are any medicines exempt from VAT/GST? ▪ How is VAT applied and reimbursed? Who is the ultimate payer? ▪ Are any other taxes or tariffs levied on medicines (excise tax, city sales tax, defence levy)? Are any medicines, sectors or programs eligible for tax exemptions? ▪ Can we work through an example of a medicine moving through the supply chain to see how and when various taxes are applied? ▪ Are there any tax refunds or abatements?
Ministry of Finance, Central Bank	Obj 1: Understand how public sector procurement funding operates.	▪ How does the Ministry of Health central procurement office access funds for medicine procurement? What is the time frame for requesting/releasing funds? ▪ What finance charges and fees are imposed by the bank on the procurement of pharmaceuticals (e.g. letter of credit, purchase of foreign exchange, contingency fee)?
Large bank in urban centre	Obj 1: Understand the banking system as it applies to foreign currency transactions for the importation of medicines.	▪ What are the fees involved in foreign currency transactions (e.g. letter of credit, telex charges, purchase of foreign exchange, foreign currency account)? ▪ If there are contingency fees, what do these cover? ▪ How are changes in exchange rate handled?
Pharmacists' association, individual pharmacists	Obj 1: Confirm the charges and mark-ups between the wholesale and retail levels of the supply chain. Obj 2: Identify any other government policies that impact private sector pharmacy practice.	▪ Who pays for the cost of transporting medicines from the wholesale warehouse to the retail outlet? ▪ How are wholesale and retail mark-ups determined? Are overhead and transport costs included in the wholesale/retail mark-ups? ▪ Are wholesaler and/or retailer margins regulated in the private sector? If so, what are the rates? ▪ Does the government control medicine prices in the private sector? If so, what are the regulations? How are they enforced? ▪ Is there a government regulated dispensing fee? If yes, what is the fee and how is it applied? ▪ Are discounts or rebates commonly offered to pharmacies? If so, are these being offered by the manufacturer, the wholesaler, or both? ▪ Who can be a wholesaler or retailer? What training is required? What, if any, restrictions does the government impose?

Informant	Objectives	Sample questions
Pharmacy board/ Pharmacists' council (office which accredits pharmacists and pharmacies)	Obj 1: Determine the roles and responsibilities of the pharmacy board. Obj 2: Identify any fees the pharmacy board collects on medicines. Obj 3: Obtain the pharmacist's perspective on the respective margins and viability of various actors in the supply chain.	▪ What are the roles and responsibilities of the pharmacy board/ pharmacists' council? ▪ Are any fees collected? If so, from whom? How are the fees used? Do fees differ between generic equivalents and originator brands, and/or between imported and locally produced products? ▪ How are wholesale and retail mark-ups determined? ▪ Are wholesaler and/or retailer margins regulated in the private sector? If so, what are the regulations? Do government-set mark-ups match what is found in practice? ▪ Does the government control medicine prices in the private sector? If so, what are the regulations? How are they enforced? ▪ Are discounts or rebates commonly offered to pharmacies? If so, are these being offered by the manufacturer, the wholesaler, or both?
WHO	Obj 1: Obtain a general overview of pharmaceutical policy and practices. Obj 2: Compare pharmaceutical policies and practices with other countries in the region. Obj 3: Confirm central information collected at the Ministry of Health and elsewhere.	▪ What is the government's medicine budget? What percentage of the population buy their medicines through out-of-pocket expenditures? ▪ What is the approximate contribution of each sector (public, private, other(s)) to the pharmaceutical market? ▪ Are medicines free in the public sector? Does the public sector use a cost recovery system? ▪ Are the final prices of some/all medicines controlled? Are wholesale and/or retail mark-ups regulated? In what sectors do these price regulations apply (public, private, other sectors)? ▪ Is there a sales tax on medicines? Are some medicines/sectors/ programmes exempt? ▪ Are there policies for the use of generic products in the public and/or private sector (e.g. generic substitution)?

ANNEX 7

Price components data collection form

Name of data collector:		
Region:		
Sector:		
Name/code of dispensing outlet:		
Product name, dosage, strength:		
Manufacturer:		
Pack size:		
Product type:	☐ originator brand	☐ generic
Production:	☐ imported	☐ locally produced
Type of data:	☐ field	☐ hypothetical

Any additional information about target medicine:

Stage 1	Type of charge	Charge basis	Price to which charge is applied	Amount of charge	Comments
	Manufacturers selling price	price			
	Insurance and freight				
	CIF				

Stage 2: Landed price	Type of charge	Charge status	Charge basis	Price to which charge is applied	Amount of charge	Comments

Source:

Stage 3: Wholesaler or medical store	Type of charge	Charge status	Charge basis	Price to which charge is applied	Amount of charge	Comments
	Procure price	value				

Source:

Stage 4: Retailer or dispensary	Type of charge	Charge status	Charge basis	Price to which charge is applied	Amount of charge	Comments
	Procure price	value				

Stage 5: Dispensed price	Type of charge	Charge status	Charge basis	Price to which charge is applied	Amount of charge	Comments
	Selling price	value				

Example:

Stage 2: Landed price	Type of charge	Charge status	Charge basis	Price to which charge is applied	Amount of charge	Comments
	Inspection	*V*	*Fee*	*MSP +IF*	*$200*	*Minimum charge on all shipments less than $5000*
	Port charges	*NF*				
	Importer's mark-up	*V*	*%*	*Cumulative sub-total*	*3%*	
	Pharmacy board	*V*	*%*	*Cumulative Sub-total*	*1%*	

ANNEX 8

International comparison of MPRs: adjustment for reference price year, inflation/deflation and purchasing power parity

As described in Chapter 10, the following adjustments can be used to improve the comparability of procurement price data (Option 1) and patient price data (Option 2) for international comparisons.

The large majority of surveys conducted to date have used MSH prices as the standard set of international reference prices to which median local prices are compared. As such, the adjustment instructions provided below assume the use of MSH prices; similar adjustments would also be needed if other reference prices are used.

OPTION 1: CORRECTING ONLY FOR MSH REFERENCE YEAR AND INFLATION/DEFLATION, I.E. FOR ADJUSTMENT OF PROCUREMENT PRICE DATA

1. Pick a base year for comparison

It is suggested that you use the same year as your survey using the same MSH reference prices e.g. if a survey was conducted in 2008 using 2007 MSH reference prices, 2008 should be chosen as the base year. However, if the bulk of the studies were done in one particular year, it is best to pick that year as the base year and adjust other results to that year. Note: this will result in some changes to MPRs calculated in your survey.

2. Convert MPR back to country-specific prices

a. Multiply the MPR by the appropriate MSH reference price to get the price in U.S. dollars (USD)

b. Multiply (2a) times the relevant currency exchange rate used in the survey to obtain the local currency unit price.

3. Convert local currency to US dollars

Divide the local currency value from (2b) by the relevant country specific official exchange rate for US dollars in the year the country survey was conducted. The period average exchange rate for the relevant survey year should be used, when available. If unavailable, use the end of period exchange rate.

4. Adjust for inflation/deflation

This is only for studies NOT conducted in the base year to adjust the country specific prices to account for deflation or inflation using the GDP deflator for the time difference between when the study was conducted to the base year chosen.

If the country CPI in the survey year is INFLATED (higher) compared to that of the base year, then the medicine prices need to be DEFLATED to base year prices (use a1 below). If the country CPI in the survey year is DEFLATED (lower) compared to that of the base year, then the medicine prices need to be INFLATED to base year prices (use a2 below).

$$\text{a1. Deflation factor} = \left[1 - \left(\frac{SurveyYearUSCPI - BaseYearUSCPI}{BaseYearUSCPI}\right)\right]$$

$$\text{a2. Inflation factor} = \left[1 + \left(\frac{BaseYearUSCPI - SurveyYearUSCPI}{BaseYearUSCPI}\right)\right]$$

b. Multiply (4a1 or 4a2) times the price from (3) above

5. Recalculate MPR

Divide adjusted country prices from (3) or (4) above by the MSH reference price **from the year prior to the base year**.

Notes

1. Sources of official conversion rate for US dollars: IMF: International Financial Statistics http://ifs.apdi.net/imf/ImfBrowser.aspx?PDF=y&type=ct; UNECE Economic Statistics http://w3.unece.org/pxweb/DATABASE/STAT/2-ME/6-MEER/6-MEER.asp
2. In Option 1, CPIs for the United States of America (USCPIs) are used to adjust for inflation/deflation. Source of U.S. CPI data: IMF: World Economic Outlook Database. http://www.imf.org/external/pubs/ft/weo/2007/01/data/index.aspx
3. If the survey was conducted in the base year, there is no need for step 4 adjustment for GDP deflator. Use the value calculated in step 3 and skip to step 4.
4. No need to adjust MSH reference prices for PPP as 1 USD is equivalent to 1 international dollar (PPP implied conversion rate for USD = 1)
5. These instructions will result you calculating a different MPR for your own survey because you will have inflated/deflated your local medicine prices to the base year.

Example: Yemen (survey conducted in 2006); amitriptyline 25mg tab/cap, lowest priced generic, public sector procurement price (original MPR = 1.38)

The MPR for amitriptyline 25mg tablets in the survey conducted in 2006 was measured as 1.38. This is to be compared to other surveys and so needs to be adjusted for MSH reference year and inflation.

STEP	CALCULATION
1. Choose base year	2004 (for purposes of demonstration)
2a. Convert MPR to USD	MSH price for amitriptyline 25mg tab for 2005 = $0.0049
	1.38 x 0.0049 = $0.0068
2b. Convert to local currency	Exchange rate used in survey: $1 = YER197.56
	$0.0068 x 197.56 = 1.34 yemeni rials per tablet
3. Convert to USD using standard exchange rate	1.34 yemeni rials per tablet/197.049 = $0.0068
4. Adjust for deflation	US CPI for 2006 = 117.069, US CPI for 2004 = 109.703
	Deflation factor $= \left[1 - \left(\frac{SurveyYearUSCPI - BaseYearUSCPI}{BaseYearUSCPI}\right)\right]$
	= [1 – ((117.069 – 109.703) / 109.703)]
	= 0.933
	0.933 x 0.0068 = 0.0063 USD
5. Recalculate MPR	MSH price for 2003 = $0.0076
	0.0063 / 0.0076 = 0.83

OPTION 2: STANDARDIZED CURRENCY CONVERSION PLUS PURCHASE POWER PARITY (PPP) , I.E. FOR ADJUSTMENT OF PATIENT PRICE DATA

1. Pick a base year for comparison

It is suggested that you use the same year as your survey using the same MSH reference prices e.g. if a survey was conducted in 2008 using 2007 MSH reference prices, 2008 should be chosen as the base year. However, if the bulk of the studies were done in one particular year, it is best to pick that year as the base year and adjust other results to that year. Note: this will result in some changes to MPRs calculated in your survey.

2. Convert MPR back to country-specific prices

a. Multiply the MPR by the appropriate MSH reference price to get the price in U.S. dollars (USD)

b. Multiply (2a) times the relevant currency exchange rate used in the survey to obtain the local currency unit price.

3. Adjust for inflation/deflation

This is only for studies NOT conducted in the base year to adjust the country specific prices to account for deflation or inflation using the GDP deflator for the time difference between when the study was conducted to the base year chosen.

If the country CPI in the survey year is INFLATED (higher) compared to that of the base year, then the medicine prices need to be DEFLATED to base year prices (use a1 below). If the country CPI in the survey year is DEFLATED (lower) compared to that of the base year, then the medicine prices need to be INFLATED to base year prices (use a2 below).

a1. Deflation factor $= \left[1 - \left(\frac{SurveyYearCPI - BaseYearCPI}{BaseYearCPI}\right)\right]$

a2. Inflation factor $= \left[1 + \left(\frac{BaseYearCPI - SurveyYearCPI}{BaseYearCPI}\right)\right]$

b. Multiply (3a1 or 3a2) times the price from (2) above

4. Adjust for country wealth in international dollars (using PPP):

Divide price in local currency from (3) above by the relevant country specific "Implied Purchase Power Parity" (PPP) conversion rate in the base year.

5. Recalculate MPR

Divide adjusted country prices from (3) or (4) above by the MSH reference price **from the year prior to the base year**.

Notes:

1. In Option 2, CPIs for the survey country are used to adjust for inflation/deflation. Source of National CPI data: IMF: World Economic Outlook Database http://www.imf.org/external/pubs/ft/weo/2007/01/data/index.aspx
2. Source of PPP data: IMF: World Economic Outlook Database http://www.imf.org/external/pubs/ft/weo/2007/01/data/index.aspx
3. If the survey was conducted in the base year, there is no need for step 4 adjustment for GDP deflator. Use the value calculated in step 3 and skip to step 4.
4. No need to adjust MSH reference prices for PPP as 1 USD is equivalent to 1 international dollar (PPP implied conversion rate for USD = 1).
5. These instructions will result you calculating a different MPR for your own survey because you will have inflated/deflated your local medicine prices to the base year.

Example: Yemen (survey conducted in 2006); aciclovir 200mg tab/cap, originator brand, private pharmacies (original MPR = 19.11)

The MPR for aciclovir 200mg tablets in the survey conducted in 2006 was measured as 19.11. This is to be compared to other surveys and so needs to be adjusted from inflation and purchasing power parity.

STEP	CALCULATION
1. Choose base year	2004 (for purposes of demonstration)
2a. Convert MPR to USD	MSH price for aciclovir 200mg tab for 2005 = $0.049
	19.11 x 0.049 = $0.936
2b. Convert to local currency	Exchange rate used in survey: $1 = YER197.56
	$0.936 x 197.56 = 184.99 yemeni rials per tablet
3. Adjust for deflation	CPI for 2006 = 213.028, CPI for 2004 = 156.632
	$\text{Deflation factor} = \left[1 - \left(\frac{\textit{SurveyYearCPI} - \textit{2004CPI}}{\textit{BaseYearCPI}}\right)\right]$
	= [1 – ((213.028 – 156.632) / 156.632)]
	= 0.640
	0.640 x 184.99 = 118.39 local currency (adjusted for inflation)
4. Adjust for PPP	PPP factor for 2004 = 137.332
	118.39 / 137.332 = 0.862 international dollars
5. Recalculate MPR	MSH price for 2003 = $0.0696
	0.862 / 0.0969 = 8.90

This manual and accompanying workbook and tools result from a widely felt need for greater transparency on prices in the global medicines marketplace. The difficulty in finding reliable information on medicine prices and availability - and therefore in analysing their components - hinders governments in constructing sound medicine pricing policies or evaluating their impact.

In 2003, the World Health Organization and Health Action International published the first edition of *Medicine prices – a new approach to measurement*. The manual provided a draft methodology and tools for conducting reliable medicine prices and availability surveys in a standardized way, thereby facilitating national and international comparisons. More than 50 surveys have now been conducted worldwide, and the wealth of experience gained has led to a number of improvements in this second edition of the manual. The survey methodology has been refined based on the lessons learnt to date, and new methodologies and tools have been developed in the areas of price component surveys and routine monitoring of medicine prices and availability. As gathering evidence is only a first step in improving access to affordable treatment, the new edition provides more guidance on policy options and lines of action. Along with an updated version of the automated data workbook, a CD-ROM of survey tools, resources and background materials is included to ensure that the manual and accompanying software are as user-friendly as possible.

The WHO/HAI methodology has already proved to be an invaluable tool for many governments, nongovernmental organizations, international agencies, researchers, health professionals and civil society groups working to improve the availability and affordability of medicines. The aim of *Measuring medicine prices, availability, affordability and price components* is to provide guidance on the collection of sound evidence on which to base policies related to medicine pricing.