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# 14

## Monitoring medicine prices and availability

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### 14.1 INTRODUCTION

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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.<sup>1</sup>

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<sup>1</sup> <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<sup>1</sup> and HAI Global<sup>2</sup> web sites.

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## **14.2 BACKGROUND**

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### **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

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<sup>1</sup> <http://www.haiafrica.org/>

<sup>2</sup> <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.<sup>1</sup> 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.<sup>2</sup> 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.<sup>3</sup>
- Prescription cost analysis data in the United Kingdom, which provide volumes and prices of prescribed medicines on an individual and aggregate basis.<sup>4</sup>
- EUROMEDSTAT database,<sup>5</sup> which lists retail pharmacy prices (patient prices) of medicines in European countries for individual medicines.
- WHO/HAI Medicine Price Survey database.<sup>6</sup>
- 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).<sup>7</sup> 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<sup>8</sup> monitors ex-manufacturer prices of medicines to construct the pharmaceutical producer price index (pharmaceutical

<sup>1</sup> <http://erc.msh.org/>

<sup>2</sup> <http://www.who.int/hiv/amds/gprm/en/>

<sup>3</sup> <http://www.accessmed-msf.org/>

<sup>4</sup> <http://www.ic.nhs.uk/statistics-and-data-collections/primary-care/prescriptions/prescription-cost-analysis-2006>

<sup>5</sup> <http://www.euromedstat.cnr.it/database/database.asp>

<sup>6</sup> <http://www.haiweb.org/medicineprices>

<sup>7</sup> <http://www.pmprb-cepmb.gc.ca/english/home.asp?x=1>

<sup>8</sup> <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.

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### **14.3 HOW CAN MEDICINE PRICES AND AVAILABILITY BE MONITORED IN RESOURCE-POOR COUNTRIES?**

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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-imburement 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<sup>1</sup> 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,<sup>2</sup> 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.)

<sup>1</sup> Non-random sampling, where the selected units in the sample have an unknown probability of being selected.

<sup>2</sup> 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<sup>1</sup> 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

<sup>1</sup> 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; pharmacoeconomics; 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.**

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## **14.4 OVERVIEW OF A METHODOLOGY FOR ROUTINE MONITORING OF MEDICINE PRICES AND AVAILABILITY AND PILOT TESTING IN THREE COUNTRIES**

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### **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

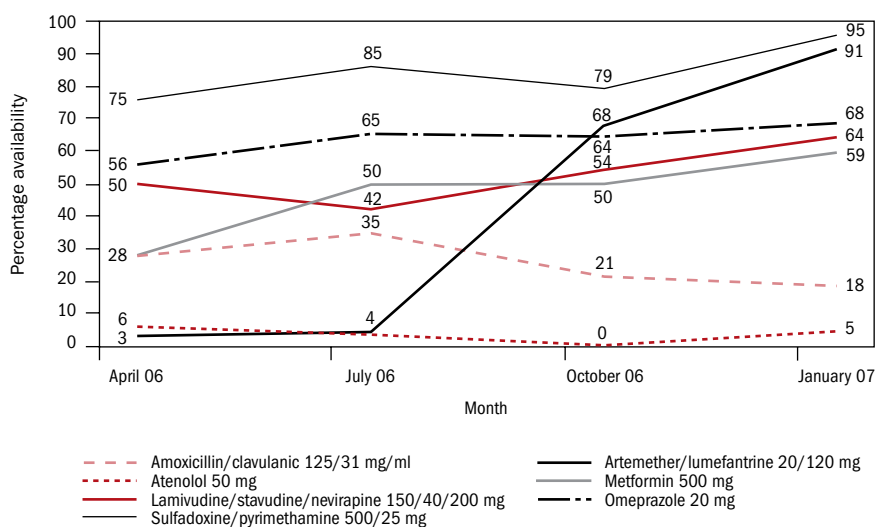
- Two trained public sector pharmacists or pharmaceutical technologists from each of the four provinces visit the facility sites in all three sectors every three months to document prices and availability, using a standardized data collection form.
- Price and availability data are collected every three 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
<b>List A</b> – 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
<b>List B</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.
<b>List C</b> – 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<sup>1</sup> (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.

<sup>1</sup> Based on information found on the Ministry of Health's web site "Directori Hospital Kerajaan" [www.moh.gov.my/hospital.htm](http://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.

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### 14.7 MEDICINE PRICE AND AVAILABILITY MONITORING PROTOCOL – PAKISTAN

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#### 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.**