
3

Preparation

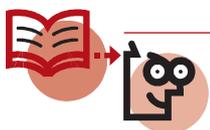
You may begin detailed planning of the survey after attaining a thorough understanding of the national pharmaceutical sector and obtaining the necessary human, technical and financial resources required to carry it out.

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 HAI¹ or WHO² 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 HAI² or WHO³ 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.


CAUTION

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:

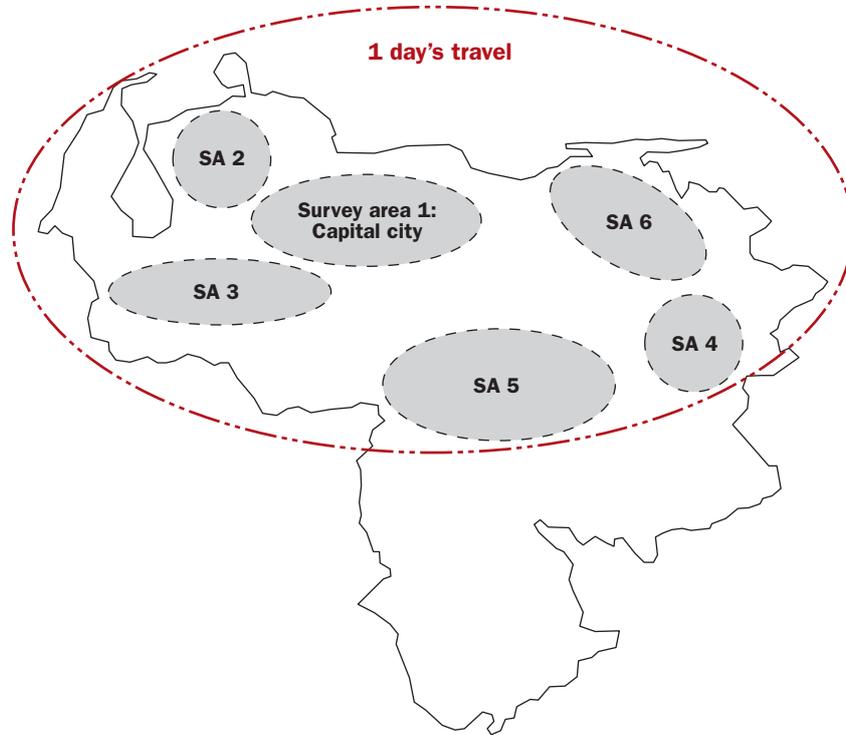
- Divide the administrative areas that can be reached within one day from the major urban centre into groups according to population density (e.g. urban, rural, periurban).
- Randomly select survey areas from each group, allocating the number of survey areas to each group roughly according to the proportion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

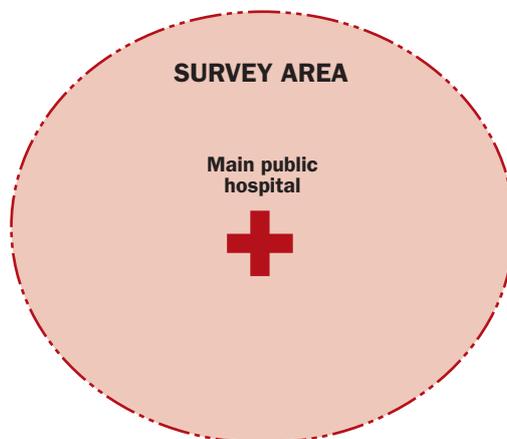


Experience from over 50 studies confirms the importance of following the recommendations on survey design and sampling carefully. Selecting a smaller sample size severely weakens the data's reliability.

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.

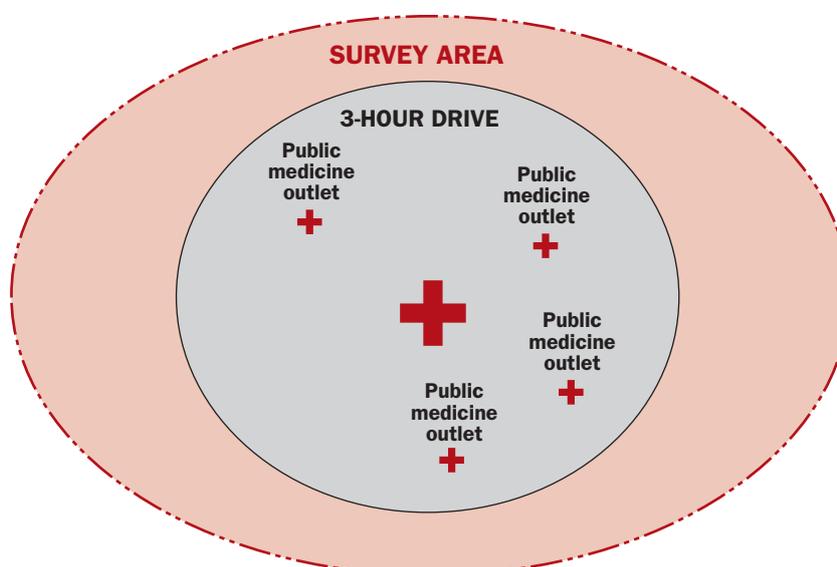


To facilitate data collection visits, all medicine outlets should be within three hours' travel of the main public hospital in each survey area. However, if travel conditions significantly limit the distance that can be covered in that time, the limitations on maximum travel time can be relaxed, resources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

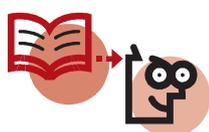
STEP 3: Select four public sector outlets in each survey area.

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.

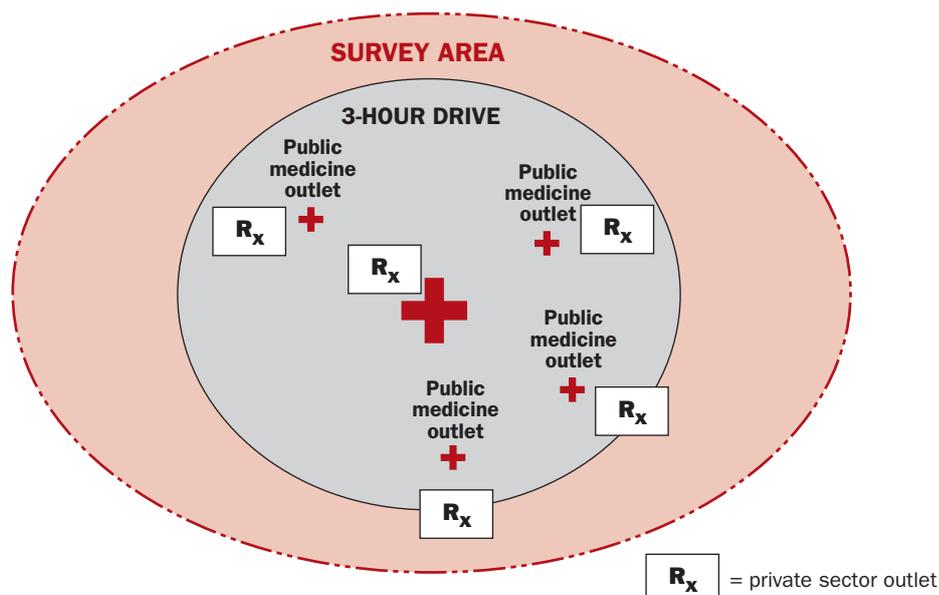
STEP 5: Select five private sector medicine outlets in each survey area.

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.

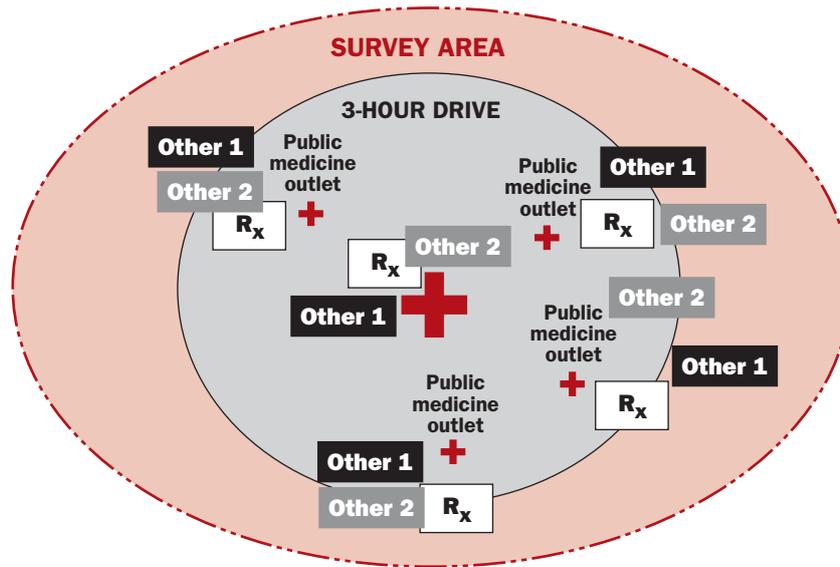
STEP 7: Select five medicine outlets for each 'other' sector in each survey area.

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.

**CAUTION**

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 site¹ 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 site² 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.

CAUTION

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 site² 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) prices² 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 Workbook1.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>

CAUTION

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 HAI¹ or WHO² 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 recommended	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 the 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*.

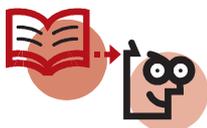
Column F: Pack size recommended

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	<i>generics only</i>
	Lowest-priced generic	<i>Amitriptyline</i>	<i>Pharma</i>	Yes	100	1000	970.00	0.9700/tab	
Amoxicillin cap/tab 500 mg	Originator brand	Amoxil	GSK	No	21			/tab	<i>generics only</i>
	Lowest-priced generic	<i>Amoxicillin</i>	<i>Ratio-pharma</i>	Yes	21	500	2407.00	4.8140/tab	
Atenolol cap/tab 50mg	Originator brand	Tenormin	Astra Zeneca	No	60			/tab	<i>Not on EML</i>
	Lowest-priced generic			No	60			/tab	<i>Not on EML</i>

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.