Annexes

ANNEX 1

Abridged questionnaire on structures and processes of country pharmaceutical situations

IMPORTANT NOTE: To improve the comparability of results across different survey instruments investigating national pharmaceutical policies, the *National Pharmaceutical Sector Form* used in the first edition of the survey methodology has been replaced with an abridged version of the WHO *Questionnaire on structures and processes of country pharmaceutical situations*. (Note that the numbering of the questions has been kept consistent with the full questionnaire). A set of supplementary questions important to the medicine prices and availability survey has been included at the end of the questionnaire.

INTRODUCTION

The *Questionnaire on structures and processes of country pharmaceutical situations* is a basic assessment tool that provides a rapid means of obtaining information on the existing infrastructure and key processes of the pharmaceutical sector. The WHO asks all Member States to respond to the Questionnaire every four years in order to have up-to-date data on country, regional and global pharmaceutical situations as well as to enable comparisons over time.

THE COORDINATOR AND RESPONDENTS

In order to complete the Questionnaire, it is likely that you will need to gather data from a number of departments/divisions within the Ministry of Health, such as those responsible for policy, procurement and supply, financing, etc., as well as other ministries and agencies, including the Medicines Regulatory Authority, the Quality Control Laboratory, the department/agency responsible for trade and patents, the association/ministry responsible for training, etc. Which ministries, departments and agencies will need to be consulted will depend on the division of responsibilities in your country.

INSTRUCTIONS

- Provide your full name, position and contact details at the top of the Questionnaire so that we may contact you for any clarifications.
- Identify appropriate persons to complete each section of the questionnaire. Suggestions on which ministries, departments, agencies, etc. may be able to contribute to each section are provided at the beginning of the section.
- At the end of the questionnaire, include a list of all respondents contributing to the Questionnaire together with their contact details and the sections to which they contributed.
- When providing statistical information, please use national/local sources (e.g. local health statistical yearbook, drug accounts, information from the Medicines Regulatory Authority, etc) if available. Utilize the most recent statistics.
- Make sure that the responses are as accurate as possible using available resources and calling upon knowledgeable respondents. In some cases, where exact figures are unavailable, it may be necessary to give your best estimate.
- Answer all the questions. Use "DK" or "Don't Know" if you simply cannot provide/obtain the appropriate response/information.
- Explanations of the questions and definitions of terms and concepts used in the *Questionnaire* are provided in the right-most column of the questionnaire. If you require further clarification on any of the questions asked or the definitions used and/or more information on appropriate sources of information, please contact WHO (medicineprices@who.int).

Please forward the entire completed questionnaire to HAI (info@haiweb.org) or WHO (medicineprices@who.int) together with the final survey data (*Workbook*) and report. Where available, please also include the:

1. National medicines policy
2. National essential medicines list
3. National standard treatment guidelines
4. Reports of national indicator studies of the pharmaceutical situation, rational use and/or access to medicines

Please note that in submitting this data to HAI or WHO, the data will also be forwarded to the WHO Medicines Policy and Standards/Technical Cooperation for Essential Drugs and Traditional Medicine (PSM/TCM) department.

ABRIDGED QUESTIONNAIRE: STRUCTURES & PROCESSES OF COUNTRY PHARMACEUTICAL SITUATIONS

Country: Date (dd/mm/yyyy) :

Name of coordinator/principal respondent : E-mail address :

Position : Postal address :

Questions	Responses	Explanations
1. NATIONAL MEDICINES (DRUGS) POLICY (NMP)		
Please consult the health ministry, medicines regulatory authority and/or medicine service in answering the questions in this section.		
1.1 Is there a National Medicines Policy (NMP) document? *If no, skip to 2.*	Yes No Don't know	A national medicines (drug) policy document is a written expression of the government's medium to long term goals and priorities for the pharmaceutical sector and the main strategies for attaining them.
a) If yes, is it an official or draft document?	Official Draft Don't know	Mark "official" if the NMP document has been endorsed or officially adopted by the government otherwise mark "draft".
b) What year was it last updated?	Year	Indicate the year of last update whether the document is still in draft form or has been officially adopted.
1.2 Is there an NMP implementation plan that sets activities, responsibilities, budget and timeline?	Yes No Don't know	
a) If yes, when was it last updated?	Year	
2. REGULATORY SYSTEM		
Please consult the medicines regulatory authority in answering the questions in this section. Specific information regarding medicines tested for quality control purposes and monitoring of adverse drug reactions may need to be obtained from the quality control laboratory or the responsible agency/department.		
Regulatory authority		
2.2 Is there an existing formal medicines regulatory authority?	Yes No Don't know	This question is asking if there is a formal regulatory body with existing staff and a specific budget for conducting relevant medicines (drug) regulatory functions. Mark "no" if medicines regulatory functions, such as registration and licensing, are performed on an ad-hoc basis by an office, group or department that performs other pharmaceutical service functions, such as supply management and procurement.
2.3 What are the sources of funding for the medicines regulatory authority:		
Regular budget from the government:	Yes No Don't know	
Fees from registration of medicines:	Yes No Don't know	
Other:	Yes No Don't know	

Questions		Responses	Explanations
2.4	Are there legal provisions requiring transparency and accountability and promoting a code of conduct in regulatory work?	Yes No Don't know	This question is asking whether there are legal provisions (or legislation) requiring the regulatory authority to: – Define its policies and procedures in writing and publish the written documentation, – Give reasons for decisions to affected parties, – Account for its conduct and actions to individuals or groups and ultimately to the public, and – Follow a code of conduct in conducting its regulatory functions.
2.6	Is there a medicines regulatory authority website providing publicly accessible information on any of the following: legislation, regulatory procedures, prescribing information (such as indications, counterindications, side effects, etc.), authorised companies, and/or approved medicines?	Yes No Don't know	
Marketing authorization			
2.7	Are there legal provisions for marketing authorization?	Yes No Don't know	This question is asking if there are legal provisions (or legislation) that describe the legal conditions under which marketing authorization should be conducted. Marketing authorization is an official document issued by the medicines regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality and/or after registration of a product for marketing.
2.8	How many medicinal products have been approved to be marketed? (*count total number of unique dosage forms and strengths*)	Number	Tablets, capsules, injections, elixirs and suppositories should be counted in different strengths. For example, if Paracetamol (Brand X) 250 mg and 500 mg have been approved to be marketed, they count as two medicinal products because they are two unique strengths. Paracetamol (Brand Y) 250 mg and 500 mg are another two unique products.
2.9	Is a list of all registered products publicly accessible?	Yes No Don't know	Registered products are medicine products that have been evaluated for quality, safety and efficacy and thence authorised for marketing. In order to be publicly accessible, it should be available on the web or to anyone contacting the responsible authority.

Questions	Responses	Explanations
Licensing		
2.14 Are there legal provisions for licensing of the following:		This question is asking if there are legal provisions (or legislation) that describe the legal conditions under which manufacturers, wholesalers and distributors and importers and exporters are subjected to evaluation against a set of requirements and issued a permit to operate (license) authorising them to undertake specific activities.
Manufacturers:	☐ Yes ☐ No ☐ Don't know	
Wholesalers or distributors:	☐ Yes ☐ No ☐ Don't know	A wholesaler is a company that buys goods from a manufacturer or importer and sells them to retailers. The wholesaler may be an agent for one company only or deal with products from several companies. Manufacturers may also be wholesalers for their own products. In some countries, pharmacies may also have a wholesaler license. Distributors include wholesalers, retail pharmacies and medicine outlets.
Importers or exporters of medicines:	☐ Yes ☐ No ☐ Don't know	
Quality control		
2.19 Is there a quality management system in place?	☐ Yes ☐ No ☐ Don't know	This question is asking if there is an officially defined protocol for ensuring the quality of medicines, including testing of medicines to be registered, collection and testing of samples, reporting results, corrective actions to be taken when poor results are found and preventative measures to be taken to reduce future incidence of poor results.
2.20 Are medicine samples tested for the following regulatory purposes:		
Medicines registration:	☐ Yes ☐ No ☐ Don't know	
Post-marketing surveillance:	☐ Yes ☐ No ☐ Don't know	Post-marketing surveillance is testing medicine samples to assess the quality of medicines that have already been licensed for public use.
2.22 What is the total number of samples quality tested in the last calendar year?	Number ☐	This should include all samples tested whether in a quality assurance laboratory within the country or outside the country.
2.23 What is the total number of samples tested in the last calendar year that failed to meet quality standards?	Number ☐	This should include all samples tested that failed to meet quality standards whether the testing was done in a quality assurance laboratory within the country or outside the country.
2.24 Are there regulatory procedures to ensure quality control of imported medicines?	☐ Yes ☐ No ☐ Don't know	This question is asking if there are standard operating procedures for ensuring the quality of imported medicine, such as reviewing dossiers, product evaluation and testing of imported medicine products. This may include donated medicines.

Questions		Responses	Explanations
Dispensing and prescribing			
2.30	Are there legal provisions for the following:		This question is asking if there are legal provisions (or legislation) that describe the legal conditions under which prescribers and the practice of pharmacy are licensed. Licensing is a system that subjects all persons to evaluation against a set of requirements before they may be authorized to prescribe medicines/practice pharmacy. It may include issuing an official permit and granting authorization to prescribe medicines/practice pharmacy by either the governing authority or the body regulating the exercise of the profession.
	Licensing and practice of prescribers:	Yes No Don't know	
	Licensing and practice of pharmacy:	Yes No Don't know	
2.31	Is prescribing by generic name obligatory in the:		A generic name (international non-proprietary name – INN) is a non-proprietary or approved name rather than a proprietary or brand name under which a generic medicine is marketed. If prescribing by generic name is obligatory then prescribers are required to prescribe by generic name.
	Public sector:	Yes No Don't know	
	Private sector:	Yes No Don't know	
2.32	Is generic substitution permitted at:		Generic substitution is the practice of substituting a product, whether marketed under a trade name or generic name, by an equivalent product, usually a cheaper one, containing the same active ingredient at the dispensing level. Mark "yes" if either generic substitution is required or if the dispenser is allowed to make a generic substitution in at least some instances.
	Public pharmacies:	Yes No Don't know	
	Private pharmacies:	Yes No Don't know	
2.33	Are there incentives to dispense generic medicines at:		Incentives may include dispensing fees or mark-ups which provide financial incentive for dispensers to dispense lower-priced generic medicines
	Public pharmacies:	Yes No Don't know	
	Private pharmacies:	Yes No Don't know	

Questions		Responses		Explanations
Promotion and advertising				
2.34	Are there provisions in the medicines legislation/ regulations covering promotion and/or advertising of medicines?	Yes No Don't know		This question is asking if there are legal provisions (or legislation) that describe the conditions under which the promotion and/or advertisement of medicines may be conducted. Promotion and advertisement are activities that provide health workers and consumers with information about medicine products, particularly with the intent of encouraging health workers and consumers to use a particular product.
3. MEDICINES SUPPLY SYSTEM				
Please consult the agency/department responsible for the procurement and supply of medicines in answering the questions in this section.				
3.1	Is public sector procurement pooled at the national level (i.e. there is centralised procurement for the regions/ provinces)?	Yes No Don't know		Mark "yes" if public sector procurement is centralised and medicines are procured for the entire public sector by a national procurement body even if in some instances, such as cases of stock outages, public sector facilities procure medicines through other means.
3.2	Who is responsible for public sector medicines procurement and distribution:	**Procurement**	**Distribution**	
	Ministry of Health:	Yes No DK	Yes No DK	
	Non-governmental organization (NGO):	Yes No DK	Yes No DK	Mark "yes" if government funds or foreign contributions are allocated to NGOs to procure or distribute medicines for the public sector. Non-governmental organizations (NGOs) are non-governmental, non-profit organizations, networks and voluntary associations including charities, community groups, faith-based organizations, professional associations, academia and trade unions.
	Private institution contracted by the government:	Yes No DK	Yes No DK	Mark "yes" for private institution contracted by the government if the government contracts or makes an agreement with a private entity to procure or distribute medicines for the public sector, e.g. if an agreement is made with a private company to distribute medical items and supplies to public sector district warehouses and health facilities.
	Individual health institutions:	Yes No DK	Yes No DK	
3.3	What type of tender process is used for public sector procurement and what is the percentage of the total cost for each:		**Percentage of total cost**	Competitive tender is a procedure for procuring medicines which puts a number of suppliers into competition. Purchasing is done on the basis of quotations submitted by suppliers in response to a public notice.
	National competitive tender:	Yes No DK	%	National competitive tender is open to all or a limited number of local suppliers only.
	International competitive tender:	Yes No DK	%	International competitive tender is open to all or a limited number of local and international suppliers though sometimes conditions give preference to either local or international suppliers.

Questions		Responses	Explanations
Negotiation/direct purchasing:		Yes No DK _____ %	In negotiation/direct purchasing the buyer approaches one or a small number of suppliers and either buys at the quoted prices or bargains for a specific service arrangement.
3.6	Is public sector procurement limited to medicines on the Essential Medicines List (EML)?	Yes No Don't know	An Essential Medicines List (EML) is a government-approved selective list of medicines or national reimbursement list. Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford.

4. MEDICINES FINANCING

Please consult the budget/ finance division of the health ministry and/or the pharmaceutical supply group in answering the questions in this section. The hospital/health facility service and/or the national social and insurance services may also need to be consulted.

4.1	What is the total public or government expenditure for medicines in US$ for the most recent year for which data are available?	US$ _____ Year _____	This question is asking for the total amount the government has spent on medicines, including government allotment, health ministry expenditure, donor contributions channelled through the government, etc.
4.2	Is there a national policy to provide at least some medicines free of charge (i.e. patients do not pay out-of-pocket for medicines) at public primary care facilities?	Yes No Don't know	If medicines are provided for free but patients must pay service fees, mark "yes" here. If some facilities provide medicines for free but there is not a consistent national policy that applies to all primary public health facilities, mark "no" here. If there is a national policy to provide medicines for free at primary public health facilities, but facilities are not required to abide by the policy and not all facilities provide medicines for free, mark "no" here.
	b) Which of the following types of patients receive medicines for free:		
	Patients who cannot afford them:	Yes No Don't know	
	Children under 5 years of age:	Yes No Don't know	
	Older children:	Yes No Don't know	Mark "yes" if children over 5 years of age receive medicines for free, regardless of the age limit, for example mark "yes" if children under 12 receive medicines for free.
	Pregnant women:	Yes No Don't know	
	Elderly persons:	Yes No Don't know	

Questions		Responses	Explanations
4.3	Which fees are commonly charged in public primary care facilities:		
	Registration/consultation fees:	☐ Yes ☐ No ☐ Don't know	Registration and consultation fees are fees patients must pay for seeing a health professional for a health check-up and/or diagnosis regardless of whether or not medicines are prescribed.
	Dispensing fees:	☐ Yes ☐ No ☐ Don't know	A dispensing fee is a fixed fee that pharmacies are allowed to charge per prescribed item or per prescription instead of or in addition to a percentage mark-up. The dispensing fee is paid to the dispenser and is in addition to the cost of the medicine. Both the dispensing fee and the cost of the medicine may be paid in part or whole by the patient, insurer or government.
	Flat fees for medicines:	☐ Yes ☐ No ☐ Don't know	Mark "yes" if either a flat fee for medicines or a flat fee per medicine item is commonly charged. – A flat fee for medicines is a fee which remains the same irrespective of the number of medicines or the quantity of each medicine dispensed. Thus, for example, a patient receiving 3 medicines would pay the same as one receiving 1 medicine. Also a patient receiving 20 tablets of one medicine would pay the same as a patient receiving 100 tablets each of 2 medicines. – A fee per drug item is a fee where the patient pays one set fee per each medicine irrespective of the number of units (tablets) of that medicine dispensed. Thus, for example, a patient receiving one medicine would pay $1 and a patient receiving 2 medicines would pay $2 and a patient receiving 3 medicines would pay $3 and so on. However, a patient receiving 10 tablets of one medicine would pay the same as a patient receiving 100 tablets of one medicine.
	Flat rate co-payments for medicines:	☐ Yes ☐ No ☐ Don't know	A flat rate co-payment is a fixed amount that a patient must pay either per medicine or per prescription to cover part of the cost of medicines, the other part being paid by an insurer or government.
	Percentage co-payments for medicines:	☐ Yes ☐ No ☐ Don't know	A percentage co-payment is a fixed percentage of the cost of prescribed medicines that a patient must pay to cover part of the cost of medicines, the other part being paid by an insurer or government. The amount a patient pays will depend on the medicine and the number of units of that medicine prescribed.
4.4	Is revenue from fees or the sale of medicines used to pay the salaries or supplement the income of public health personnel in the same facility?	☐ Always ☐ Frequently ☐ Occasionally ☐ Never ☐ Don't know	Mark "yes" if any percentage of collected fees or medicines sales is used to pay salaries, expenses and/or in any way supplement the income of public health personnel in the same facility.

Questions		Responses			Explanations
4.5	Do prescribers dispense medicines?	**Public sector** Always Frequently Occasionally Never Don't know	**Private sector** Always Frequently Occasionally Never Don't know		In answering this question, mark the degree of frequency doctors or other authorised prescribers dispense medicines in the public and private sectors irrespective of laws permitting or disallowing authorised prescribers to dispense medicines.
4.6	What proportion of the population has health insurance?	All Some None DK	All Some None DK		Health insurance is any prepayment scheme for health care costs additional to but excluding subsidies funded through the health ministry budget. The purpose of questions 4.6 and 4.7 are to identify how much protection the population has against exposure to the cost of medicines at the time people are sick. This includes: – Prepaid financing and – Public funding through the (prepaid) health ministry budget.
4.7	Are medicines covered by health insurance?	All Some None DK	All Some None DK		
4.8	Is there a policy covering medicine prices that applies to the public sector, the private sector, or non-governmental organisations?	**Public sector** Yes No DK	**Private sector** Yes No DK	**NGO** Yes No DK	In some countries, NGOs, such as faith-based missions, provide non-profit or not-for-profit health services. The third column should be completed by ticking any policies applicable to this sector. Non-governmental organizations (NGO) are non-governmental non-profit organizations, networks and voluntary associations including charities, community groups, faith-based organizations, professional associations, academia and trade unions.
	a) If yes, which of the following policies covering medicine prices apply:				
	Maximum wholesale mark-up:	Yes No DK	Yes No DK	Yes No DK	A wholesale mark-up is a certain percentage added to a purchasing price to cover the cost and profit of the wholesaler.
	Maximum retail mark-up:	Yes No DK	Yes No DK	Yes No DK	A retail mark-up is a certain percentage added to a purchasing price to cover the cost and profit of the retailer.
	Duty on imported raw pharmaceutical materials:	Yes No DK	Yes No DK	Yes No DK	A duty/tax on imported raw pharmaceutical materials is a fee assessed by customs or other responsible national authority on imported starting materials, reagents, intermediates, process aids, and solvents intended for use in the production of intermediates or active pharmaceutical ingredients.
	Duty on imported finished pharmaceutical products:	Yes No DK	Yes No DK	Yes No DK	A duty/tax on imported finished pharmaceutical products is a fee assessed by customs or other responsible national authority on medicinal products that require no further processing and are already in their final containers.

Questions		Responses			Explanations
4.9	Is a national medicine prices monitoring system for retail/patient prices in place?	**Public sector** ☐ Yes ☐ No ☐ DK	**Private sector** ☐ Yes ☐ No ☐ DK	**NGO** ☐ Yes ☐ No ☐ DK	A national medicine prices monitoring system for retail/patient prices is any means of regularly tracking and comparing over time retail/patient medicine prices in the public, private and/or NGO sectors.
4.10	Are there regulations mandating retail/patient medicine price information to be made publicly accessible?	☐ Yes ☐ No ☐ DK	☐ Yes ☐ No ☐ DK	☐ Yes ☐ No ☐ DK	In order for retail/patient medicine price information to be considereds publicly accessible, one or more of the following or similar measures should be taken: prices should be available on the web or to anyone contacting the responsible authority, prices should be periodically published in national newspapers or official publications, prices should be posted in health facilities/pharmacies, etc.
4.11	Are there official written guidelines on medicine donations that provide rules and regulations for donors and provide guidance to the public, private and/or NGO sectors on accepting and handling donated medicines?	☐ Yes ☐ No ☐ DK	☐ Yes ☐ No ☐ DK	☐ Yes ☐ No ☐ DK	Countries may have differing definitions for medicine donations which may include not only products but also monetary gifts earmarked for a particular product from a named source (e.g. manufacturer, organization or other country).

6. RATIONAL USE OF MEDICINES

Please consult the health ministry (hospital division), professional bodies and/or the education ministry in answering the questions in this section.

6.1	Is there a national Essential Medicines List (EML)?	☐ Yes ☐ No ☐ Don't know	A national Essential Medicines List is a government-approved selective list of medicines or national reimbursement list from which most prescriptions should be made. Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness.
	a) If yes, how many unique medicine formulations does the national EML contain?	Number ☐	Count similar formulations registered or approved as different products as one formulation, for example Brand X 500 mg Paracetamol tablets and Brand Y 500 mg Paracetamol tablets are counted as one formulation whereas Brand X 250 mg Paracetamol tablets and Brand X 500 mg Paracetamol tablets are counted as two formulations.
	c) When was the national EML last updated?	Year ☐	
	d) Is the national EML being used in the following:		Mark "yes" if the EML is currently being used.
	Public sector procurement:	☐ Yes ☐ No ☐ Don't know	
	Public insurance reimbursement:	☐ Yes ☐ No ☐ Don't know	
	Private insurance reimbursement:	☐ Yes ☐ No ☐ Don't know	

	Questions	Responses			Explanations
	e) Is there a committee responsible for the selection of products on the national EML?	☐ Yes ☐ No ☐ Don't know			This refers to a formally recognised committee with members of different expertise and from different agencies/organizations.
6.2	Are the following types of standard treatment guidelines (STG) produced by the health ministry for major conditions?	**National STG** ☐ Yes ☐ No ☐ DK	**Hospital level STG** ☐ Yes ☐ No ☐ DK	**Primary care STG** ☐ Yes ☐ No ☐ DK	Mark "yes" if the health ministry or similar national authority produces a collection of treatment guidelines covering prevalent/common disease conditions in the country for use at the national, hospital or primary care levels. If treatment guidelines are produced separately for each disease/condition or organ system, mark "no".
	a) If yes, when were the STGs last updated?	Year _____	Year _____	Year _____	
6.16	How frequently are the following types of medicines sold over the counter without any prescription:				This question is asking how often antibiotics and injections which require a prescription to be dispensed are sold without a prescription, regardless of laws prohibiting such practice.
	Antibiotics:	☐ Always ☐ Frequently ☐ Occasionally ☐ Never ☐ Don't know			
	Injections:	☐ Always ☐ Frequently ☐ Occasionally ☐ Never ☐ Don't know			

SUPPLEMENTARY QUESTIONS FOR MEDICINE PRICES AND AVAILABILITY SURVEY

Questions	Responses	Explanations
1. Retail		
S1.1 How many licensed private retail medicine outlets are there in the country?	Number	"Licensed" refers to medicine outlets that are subjected to evaluation against a set of requirements and issued a permit to operate (license).
S1.2 What proportion of patients access medicines through: a) public/government sector b) formal private sector c) Other: specify: d) Other: specify:	a) % b) % c) % d) %	The formal private sector refers to licensed medicine retail outlets and licensed retail drug stores. Common other sectors include non-government organizations, mission health facilities, or dispensing doctors.
S1.3 Are there public medicine outlets which sell medicines in public health facilities?	Yes No Don't know	
S1.4 Are there private pharmacies which sell medicines in public health facilities?	Yes No Don't know	
2. Medicines financing		
S2.1 What proportion of medicines by volume are imported?	% Year	
S2.2 What proportion of medicines by value are imported?	% Year	
3. Medicines supply system		
S3.1 Are there regulations for local preference in public procurement?	Yes No Don't know	Local preference purchasing means that domestic companies will be preferred even if their prices are not the lowest.
4. Regulatory authority		
S4.1 Do the fees charged for the registration of medicines differ between:		
a) Originator brands and generic equivalents	Yes No Don't know	
b) Imported and locally produced medicines	Yes No Don't know	
5. Medicine pricing policies		
S5.1 Does the government set the price of some/all originator brand products?	Yes No Don't know	
a) If yes, please describe how this is done (e.g. direct price controls, international reference pricing):		Direct price controls refers to price-setting using a pricing formula, e.g. production costs + a % margin. International reference pricing refers to comparing prices to those in other countries.
S5.2 Does the government set the price of some/all generic products?	Yes No Don't know	

Questions	Responses	Explanations
a) If yes, please describe how this is done (e.g. direct price controls, national reference pricing):		National reference pricing refers to setting prices by comparing the prices of similar medicines (by molecule or therapeutic class; originator brand or generics) on the national market.
S5.3 Are prices set in the private sector for medicines on the national Essential Medicines List?	Yes No No national EML	This question is asking whether price-setting is limited to medicines on the national EML.
S5.4 Are prices of medicines set as part of market authorization?	Yes No Don't know	Marketing authorization is an official document issued by the medicines regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality and/or after registration of a product for marketing.
6. Other		
S6.1 Of the medicines included in the survey, are there any which are patent protected or only available as the originator brand product (i.e. single source products)?	Yes No Don't know	
a) If yes, please specify which medicines:		
S6.2 Please provide the website address (URL) of any websites that publish the following information:		
a) Pharmaceutical legislation	a)	
b) Standard treatment guidelines	b)	
c) Regulatory procedures	c)	
d) Prescribing information	d)	
e) Licensed manufacturers	e)	
f) Medicines approved for marketing	f)	
g) List of registered products	g)	
h) Medicine prices (procurement or patient)	h)	

List of respondents

Name	Position	Address	E mail	Section(s) completed

Comments about indicators and values

Item number	Comment

ANNEX 2

Example of a letter of endorsement

MEDICINE PRICE AND AVAILABILITY SURVEY

To whom it may concern

Mr/Ms/Dr ..... (title and name of survey manager) of ..... (organization) will be undertaking a survey of medicine prices and availability in ..... (area or districts) in ..... (month in which study will be undertaken). This requires the collection of price information at a sample of retail pharmacies and other medicine outlets, as well as the collection of information on price composition at different points in the supply chain, from manufacturer to consumer.

The survey follows methods promoted by the World Health Organization and Health Action International and is designed to help identify ways of improving the affordability of medicines in ..... (name of country). Supporting ..... (survey manager) in this work are ..... (Advisory Committee member names and designations).

We understand that the results will be publicly available by ..... (likely date for completion of report) and that complete anonymity of individual pharmacies and medicine outlets will be assured. A prior appointment will be made with each pharmacy to be visited at a date and time convenient to staff.

On behalf of ..... (Ministry of Health or Pharmacy Association), I would be grateful if you would provide full access to the information needed for this survey.

Signed

Designation

Place

Date

ANNEX 3

Trainers' guide for training area supervisors, data collectors and data entry personnel

INTRODUCTION

This trainer's guide has been developed for a training workshop that instructs area supervisors, data collectors and data entry personnel in conducting the Medicine Prices and Availability survey. While area supervisors and data collectors should be trained together, survey managers may choose to train their data entry personnel separately. In such cases appropriate modification to the training agenda and materials will be necessary. It should be noted that this guide does not cover training on the price components element of the Medicine Prices and Availability survey, as this is generally a separate activity with different personnel who may or may not require training.

The aim of the trainer's guide is to provide guidance to survey managers in conducting a training workshop for their survey personnel, including:

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

Sample presentations, handouts and exercises are also available to accompany this guide. The guide should be read alongside *Chapter 4: Training area supervisors, data collectors and data entry personnel*, of the survey manual.

This trainer's guide and materials have been developed based on experience in conducting training workshops for the survey. The training plan described in this guide uses a range of activities (e.g. presentations, exercises) to cover different learning styles and preferences, and to promote recall of training material. In particular, the data collection pilot test is an essential element of the workshop as participants will "learn by doing" and get hands-on experience in visiting medicine outlets and collecting data.

This guide should serve as an example only; the training plan and accompanying materials (i.e. presentations, handouts and exercises) will need to be adapted to fit the specificities of each survey. Considerations should include the level of experience of survey personnel, the specific objectives of the survey, any deviations from the standard methodology, and logistics issues (e.g. data collection pilot test must be conducted at the most convenient time for pharmacy staff). You, as the only person directly in contact with your specific audience and having the knowledge

about the actual situation, will need to adapt the training content to your specific needs, in order to reach your objectives.

The trainer's guide is divided into modules according to the training agenda. Each module outlines the objectives of the training session, instructions for training activities to be conducted, materials required, and the key messages that should be emphasized.

This trainer's guide is a work in progress; we welcome your input and suggestions (contact HAI at: info@haiweb.org).

TRAINING OBJECTIVES

Overall training objective:

To provide area supervisors, data collectors and data entry personnel with the knowledge and skills required to carry out the medicine prices and availability survey in an accurate and reliable manner.

Specific learning objectives:

Upon completion of the training, participants should:

1. Be familiar with the key aspects of the survey and how it is conducted
2. Understand their roles and responsibilities in the survey, including specific tasks, timelines and reporting requirements
3. Understand the critical content required to do their job effectively and possess the skills required to undertake each of their activities
4. Be aware of common issues which may arise during survey activities, and troubleshooting/problem-solving strategies
5. Recognize the intrinsic value of good-quality data and be motivated to ensure data quality as part of their activities

NOTE: The overall objectives of the survey should be linked to the personal objectives of survey personnel to increase the relevance of the training and the commitment to rigorous application of the methodology. For example, will the experience gained in conducting the survey be beneficial in future career development? Are survey personnel MoH staff that can relate to the financial benefits of, for example, lowering procurement prices?

Training format:

3-day workshop at central level (see agenda)

Participants:

Area supervisors, data collectors, data entry personnel

Materials required

Trainer's material

- Trainer's guide
- Powerpoint slides/transparencies
- Flip chart and paper
- Markers

Learner's material

- Name card for each participant
- Training agenda for each participant
- Copy of presentations for each participant
- Handouts and exercises for each participant
- 2 Medicine Price Data Collection forms per participant
- Note pad, pen, calculator, clipboard for each participant
- 1 computer per data collection team (area supervisor and their data collectors), plus 1 for data entry personnel

All training materials must be reviewed and adapted to your survey before use. In particular, sample presentations require careful review as not all information / instructions are likely to be relevant to your survey.

SAMPLE TRAINING AGENDA

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

DAY 1

WELCOME, SURVEY OBJECTIVES AND TRAINING OVERVIEW

Objectives:

- To present the survey objectives and demonstrate the value of carrying out a medicine prices and availability survey
- To provide an overview of the training workshop
- To set a cooperative, non-threatening learning environment
- To promote positive group dynamics and interaction

Instructions:

1. **Welcome participants to the workshop (~ 30 minutes)**. If participants do not know each other, ask them to briefly introduce themselves to the group, e.g. by providing their name; role in the survey; background/relevant experience; and an interesting non-work fact about themselves. Again, if participants do not know each other, ask them to write their names on name cards and place them on their desk/table so that they are visible to the other participants.
2. **Conduct a group brainstorming exercise (~ 40 minutes)**. Ask participants to brainstorm on the reasons why some people do not have access to the medicines they need. Encourage participants to give as many ideas as possible, and record all responses on a flip chart. Continue until ideas are exhausted.

   Tip: write the question on the top of the flip chart to keep participants focused.

Expected responses:

- Medicines are not available at health centres/pharmacies
- Prices are too high
- Poverty – people cannot afford to buy medicines
- People have to travel too far to access medicines
- Government does not provide medicines for free
- Medicines are of poor quality, so people don't bother to buy them

Review the responses and ask participants how they know that these problems exist. Expected responses include: personal or professional experience, information in the media, intuition or other.

Conclusion to be drawn: "although we all know that access to medicines is a problem, we need reliable evidence to understand what the specific problems are how best to improve the situation, and to make a case for change. Collecting data on medicine prices, availability and affordability is therefore a key step in improving access to medicines in the country".

3. **Introduce the survey and review the training objectives, agenda and format (~ 20 minutes)**. A sample presentation, "Introduction to survey and training workshop" is provided on the CD-ROM.

   The training agenda should be copied and distributed to participants. The ground rules for the workshop should be written on a flip chart and posted in the workshop venue.

Materials required:

- Flip charts with 1) training objectives and 2) ground rules that can be posted in room for duration of workshop
- Name cards for each participant
- Copy of training agenda for each participant
- Handout of presentation: "Introduction to the medicine prices and availability survey and training workshop", for each participant

Key messages:

- Each participant brings valuable experience to the survey that will help it to run smoothly
- The medicine prices and availability survey is an important activity in improving access to affordable medicines

OVERVIEW OF SURVEY METHODOLOGY

Objectives:

- To provide an overview of the survey methodology so participants can see where their activities fit in the "big picture"
- To familiarize survey personnel with key aspects of the survey methodology and important terminology (e.g. survey areas, medicine outlets, originator brand, lowest-priced generic)
- To familiarize participants with their respective roles and responsibilities in the survey

Instructions:

1. **Present an overview of the survey methodology and introduce the roles and responsibilities of each type of survey personnel (1.5–2 hours)**. A sample presentation, "Overview of the medicine prices and availability survey methodology" is provided on the CD-ROM.

The sample presentation provided must be modified to fit the specificities of your survey. For example, the names of survey areas, sectors to be surveyed, and number of survey medicines, must be added/amended as appropriate.

Materials required:

- Handout of presentation: "Overview of the medicine prices and availability survey methodology", for each participant

Key messages:

- Data collection will take place in 6 areas of the country ("survey areas")
- Medicine outlets from the public, private and if applicable, "other" sectors, will be surveyed

- A total of 50 medicines are surveyed
- For each medicine, data are collected on 2 products: the originator brand, identified centrally before data collection, and on the lowest-priced generic equivalent found at each medicine outlet
- Data on the price and availability of medicines is obtained by data collectors during visits to pre-selected medicine outlets
- During the survey, data collectors will enter data into Medicine Price Data Collection forms. At the end of the survey, data from the forms will be entered into the electronic survey workbook by data entry personnel
- Each member of the survey personnel has an equal role to play in ensuring the success of the survey

DATA COLLECTION PROCEDURES

Objectives:

- To teach participants the protocol for planning data collection and visiting medicine outlets
- To identify the common problems encountered during data collection and how to address them

Instructions:

1. **Present the procedures for 1) preparing for data collection, and 2) conducting data collection (~ 1 hour)**. Be very clear about the specific activities to be undertaken by area supervisors versus data collectors. A sample presentation, "Data collection procedures" is provided on the CD-ROM.
2. **Conduct a small group exercise (~ 30 minutes)**. Divide participants into groups of 3-4 people. Ask them to make a list of things they can do to promote a positive interaction with staff at medicine outlets (5-7 minutes). Collect responses on a flip chart.

Expected responses:

- Be prepared so that data collection is as efficient as possible and staff do not lose time
- Do not visit during peak hours
- If customers arrive, allow the pharmacist to serve them before continuing the survey
- Be polite, respectful and professional
- Use letters of introduction and endorsement to give credibility to the survey
- Dress professionally
- Present the objective of the survey: to improve access to affordable medicines
- Remind staff that individual medicine outlets will not be identified in the results

Materials required:

- Handout of presentation: "Data collection procedures", for each participant
- Instruction sheets for area supervisors and data collectors

Key messages:

- Area supervisors must fully prepare for data collection visits before sending data collectors into the field. This includes scheduling all data collection visits and confirming appointments the day before.
- Data collectors must have all materials with them on each day of data collection. They must have a written schedule of visit to avoid missing any appointments
- Both data collectors and area supervisors are responsible for verifying the completeness, legibility and reliability of data collection forms. Data collectors should check forms before leaving the medicine outlet, while area supervisors should check forms at the end of each day of fieldwork
- Area supervisors must validate data collection at 1 public outlet and 1 private outlet per survey area and check their results against those of data collectors

COMPLETING THE MEDICINE PRICES DATA COLLECTION FORM

Objectives:

- To familiarize participants with the Medicine Price Data Collection form and teach them how to complete it correctly
- To present the "Rules for Data Collection"

1. **Introduce participants to the Medicine Price Data Collection form (~ 45 minutes)**. Distribute a blank Medicine Price Data Collection form to each participant. Go through the list of medicines on the form and give a brief description of their use. Highlight any "tricky" medicines that might cause difficulties during data collection, e.g. retard formulations, medicines commonly available in different dosage forms or strengths, concentrations that can be expressed in different ways (i.e. paracetamol syrup 120mg/5ml is equivalent to 24mg/ml), etc.

   For each medicine, the form contains two rows: one for the originator brand and one for the lowest-price generic. Remind participants of the difference between the originator brand and generic equivalent.

   Originator brand – original pharmaceutical product that was first authorized for marketing.

   Generic equivalent – all products other than the originator brand that contain the same active ingredient (substance), whether marketed under another brand name or the generic name.

2. **Explain each column of the data collection form and how to complete it (~ 1 hour)**. Highlight special cases (e.g. medicine is out of stock, medicine is provided free of charge) and how to handle them. A sample presentation, "Completing the Medicine Price Data Collection form" is provided on the CD-ROM. It presents each column of the data collection form and provides instructions on how to complete it, followed by an example.

Note: This presentation contains animation; not all information on the slide will appear at once. This allows you to control when participants receive information; for example, you may wish to explain the instructions before showing an example. You can make additional information on the slide appear by hitting the Enter key on your keyboard. Practise using animated slides before the workshop!

3. **Conduct an individual exercise: "Spot the mistakes" (~ 45 minutes)**. A Medicine Price Data Collection form, available on the CD ROM, has been completed with some common mistakes. Distribute one form per person and ask participants to identify the mistakes (15 minutes). Review the results as a group: working row by row, ask participants to identify any mistakes. Highlight any mistakes that they do not identify.

Materials required:

- Blank Medicine Price Data Collection form for each participant
- Handout of presentation: "Completing the Medicine Price Data Collection form", for each participant
- Instruction sheet on Completing the Medicine Price Data Collection form
- Spot the mistakes exercise

Key messages:

The "rules" of data collection:

- Collect data for every medicine on the form
- NO substitution of other medicines, strengths or forms
- The originator brand is still the originator if it is produced by a subsidiary company (e.g. manufactured for Pfizer by Dr Reddy)
- The LPG cannot be the originator brand
- The LPG is the generic product with the lowest unit price
- If multiple generics are available for an individual medicine and they have different pack sizes, you need to calculate the unit prices to identify the LPG
- Only record a medicine as available if you actually see it
- Out-of-stock medicines are unavailable
- If multiple pack sizes are available, record the price of the recommended pack size or the closest, higher pack size
- Record the full price of the medicine even if the patient only pays a part of the full price, but note the patient price in the Comments column
- Flat fees and non-universal discounts are not entered
- Prices for out-of-stock medicines are not entered
- Do not record 'special discounts' available only to certain groups of patients. However, record discounted prices that apply to all patients.
- If some medicines are available for free or for a fixed fee, their availability must still be recorded, with a note in the Comments column

DAY 2

REVIEW OF DAY 1

Objectives:

- To recall and embed the learning from Day 1
- To clarify any misunderstanding

Instructions:

1. **Conduct a "memory quiz" exercise (~ 1 hour)**. Working individually, ask participants to write down as many important points about data collection as they can remember (20 minutes). Instruct them to think specifically about 1) data collection procedures and 2) completing the Medicine Price Data Collection form.

   Tip: you could also ask participants to answer the following questions:

   What instructions would you give a data collector who was about to begin visiting medicine outlets?

   What are the key points to remember in completing the Medicine Price Data Collection form?

   Once participants have had a chance to work individually, collect responses from the group. Ask each participant for one response at a time, and make sure all participants have answered before moving to a second "round". Write down responses on two separate flip charts: 1) data collection procedures and 2) completing the Medicine Price Data Collection form. Continue collecting responses until ideas are exhausted.

   Expected responses should relate to the key messages from the Data Collection Procedures and Completing the Medicine Price Data Collection Form sessions. Review the lists and add any key ideas that were not provided by participants.

Materials:

- Flip chart and markers

Key messages:

- There are many things to keep in mind when collecting data
- To collect accurate data, data collectors must pay strict attention to the details and double check their forms to make sure no mistakes have been made
- If you have any uncertainly about data collection contact your area supervisor before leaving the medicine outlet

INSTRUCTIONS FOR DATA COLLECTION PILOT TEST

Objectives:

- To provide participants with a clear understanding of the objectives and instructions for the data collection pilot test
- To provide information on the logistics of conducting the pilot test

Instructions:

1. **Explain the purpose of the pilot test (~ 5 minutes)**.
   - To practise visiting medicine outlets, collecting data and completing the Medicine Price Data Collection form before starting the actual survey
   - To identify any data collection issues specific to the medicines in this survey
   - To identify any uncertainties or questions about data collection that require further review
2. **Provide instructions for conducting the data collection pilot test (~ 15 minutes)**:
   - During the pilot test you will visit two medicine outlets (1 public and 1 private) and collect data using the Medicine Price Data Collection form
   - You will visit medicine outlets in your data collection teams, i.e. each area supervisor and his/her data collectors count as one team

     Notes to trainer: large data collection teams (i.e. > 5 people) will need to be split into two groups. Each member of the data entry personnel will have to be allocated to a data collection team, preferably the teams with the fewest survey personnel
   - Data should be collected in exactly the same way as in the real survey, using the same procedures and instructions covered in training yesterday
   - The pilot medicine outlets are expecting your visits. Introduce yourselves in the same way as you would in the real survey
   - Take turns asking the pharmacist about individual medicines, BUT, each participant should fill in his/her own data collection forms (1 per medicine outlet)
   - You can bring reference materials (handouts, instruction sheets, notes) with you
   - If you are unsure of anything, or have any questions, write them down for discussion later on EVEN IF you solve the problem yourself/as a team
   - In addition to collecting data, area supervisors should also supervise and watch out for common mistakes, for example, information collected on the wrong strength or dosage form. Correct any mistakes and note any uncertainties for clarification during the training workshop

     Notes to trainer: It may be necessary to hold a preliminary pilot test with area supervisors to ensure they are sufficiently knowledgeable about th survey protocol to supervise data collectors and identify mistakes
   - After the pilot test is completed, we will have a debriefing on your experiences

- The data you collect will be used in future sessions; make sure it is complete and legible

3. **Provide information on the logistics of the data collection pilot test (~ 10 minutes), including**:
   - Transport arrangements
   - Start and end times – stress that there should be ample time to collect data at the two medicine outlets, so no need to rush
   - Name of pilot sites, address, contact person, time of visit (prepare a schedule for each team)
   - Contingency plan: contact information of survey manager in case there is a problem

Tips:

- Be available during the pilot test to respond to any questions or problems
- Make sure pilot sites are nearby and easy to locate (provide a map if necessary)
- Have a few medicine outlets ready as back-ups in case in case pilot sites no longer want to participate
- Accompany a team that has shown limited understanding of data collection procedures

Materials:

- A schedule for each team with the name of pilot sites, address, contact person, time of visit
- 2 Medicine Price Data Collection forms per participant
- Pens, notepads, clipboards, calculators for each participant
- One mobile phone per team

Key messages:

- Data should be collected in exactly the same way as in the real survey
- Each participant should complete their own forms: one per facility
- Any uncertainties or questions should be recorded
- This is your only chance to practise before starting the survey; it is more important to complete the forms well than to finish quickly

PILOT TEST

Objectives:

- To provide data collectors with an opportunity to practise data collection activities in medicine outlets
- To identify any areas which require clarification or improvement and address them before the survey begins

During the pilot test, participants visit medicine outlets, collect data and complete the Medicine Price Data Collection form, in exactly the same way they would during the survey. Each participant should complete a Medicine Price Data Collection form for each of the 2 outlets they visit (see previous module, Instructions for Pilot Test).

Do not send more than 5 survey personnel (e.g. 1 area supervisor and 4 data collectors) to a pilot site. If survey teams consist of larger numbers of personnel, they will need to be split into smaller groups for the pilot test.

UNIT PRICE CALCULATIONS

Objectives:

- To provide participants with experience in calculating unit prices

Instructions:

1. **Unit price calculation by participants (~ 45 minutes – 1 hour)**

   As participants to calculate the unit price for each medicine product on the Medicine Price Data Collection forms they completed during the pilot test:

   - Unit price is the price per pill, ml, dose
   - For each product, divide the Price of Pack Found (Column H) by the Pack Size Found (Column G)
   - Retain four digits after the decimal point
   - Enter the calculated unit prices in Column I of the data collection form
   - Any unit prices calculated during data collection to identify the lowest priced generics should be double checked

   Note: Depending on the number of medicines surveyed, participants may not have time to calculate unit prices for both sets of data they collected during the pilot test. If time runs short, ask participants to finish unit price calculations as "homework" and bring them to the workshop the next day.

Materials:

- Medicine Price Data Collection forms completed during the pilot test
- Calculators for each participant

Key messages:

- Unit price is the price per tablet, capsule, ml, dose
- Retain four digits after the decimal point

PILOT TEST DEBRIEF

Objectives:

To discuss participants' impressions of the data collection process, and to identify and address any problems encountered.

Instructions:

1. **Conduct a group discussion (~ 1.5 hours)**. Ask participants to report back on their experiences during the pilot test. Specifically,
   - What went well?
   - What was the most difficult?
   - Any uncertainties with data?
   - Anything unexpected?

   You may wish to prompt the group to discuss the following topics:

   — Finding the pharmacy

   — Pharmacist's attitude

   — Finding the right products – right strength, dosage form, pack size

   — Identifying the lowest-priced generic product

   — Determining availability

   — Calculating unit price

Record any questions or uncertainties about data collection on a flip chart. Provide solutions, or depending on the nature of the questions, solicit possible solutions from the group. Be sure to record the solutions on the flip chart next to the original question/problem.

Finish the discussion by asking each participant to name the most valuable thing they learned from the pilot test.

Materials:

- Flip chart
- Notes taken during the pilot test

Key messages:

- Questions and uncertainties are almost sure to arise during data collection.
- Data collectors should always check with their area supervisor, and area supervisors with the survey manager, if there are any problems or uncertainties.

DAY 3

REVIEW OF DAY 2

Objectives:

- To recall and embed the learning from Day 2
- To build motivation for collecting data in a reliable way

Instructions:

1. **Describe any changes made to the Medicine Price Data Collection form based on results of the pilot test (~ 15 minutes)**. If possible distribute a copy of the final Medicine Price Data Collection form to each participant.
2. **Conduct a group brainstorm (~ 45 minutes)**. Ask participants to brainstorm on the possible mistakes that can be made during data collection (15 minutes). Record responses on a flip chart. Continue until ideas are exhausted. You may wish to prompt participants by asking for mistakes related to product identification, availability, pack size and price.

   Expected responses:

   - the originator brand appears in a generic row
   - the lowest-priced generic is identified as the product with the lowest pack price
   - wrong strength
   - dosage form not as specified (example: nasal spray instead of inhaler, tablet instead of ampoule/vial)
   - related but not equivalent substance
   - price entered without indicating whether medicine was available
   - medicine was not actually available – price taken from price list during temporary stock-out
   - price recorded of pack which is not the closest to recommended pack size
   - discount was applied to recorded price but discount was not available to all patients
   - discount mentioned in comment, but not clear if the price recorded was pre-discount or post-discount
   - price was actually a flat dispensing fee, not true price
   - price included injection fee
   - paper form not filled out completely or illegible
   - unit price calculated incorrectly

   Conclude the exercise by summarizing the key messages below.

Materials:

- Flip chart and markers

Key messages:

- There are many possible errors that can be made during data collection.
- To collect accurate data, data collectors must pay strict attention to the details and bring any questions or uncertainties to the attention of their area supervisor
- It is essential that data are checked:
  - — By data collectors before leaving facility
  - — By area supervisors at the end of each day of data collection

DATA ENTRY

Objectives:

- To familiarize participants with the electronic survey Workbook used for data entry and analysis
- To teach participants how to enter data from completed Medicine Price Data Collection forms

Instructions:

Participants should work in their data collection teams as they did during the pilot test. One computer, with the electronic survey workbook file loaded and opened, should be available for each team. As this session is particularly relevant to the two data entry personnel, it is recommended that they work together on one computer so that they get as much practise using the workbook as possible.

1. **Present the survey workbook and instructions for data entry (~ 1 hour)**. A sample presentation, "Data entry" is provided on the CD-ROM. If you are using a computer with a projector, you should have both the presentation and the workbook open so that you can switch back and forth between the two. As you present various aspects of the workbook and data entry procedures, switch to the workbook and demonstrate to participants how it works. Encourage participants to follow along on their computer and try various workbook functions.
2. **Conduct a data entry exercise (~ 2 hours)**. Collect the data collection forms completed during the pilot test and redistribute them so that data collection teams do not have their own forms. Instruct teams to enter the data on the forms, including the medicine outlet identifying information on the first page of the form. They should enter data on the appropriate Field Data Consolidation page, depending on whether the data are from the public sector or the private sector. Depending on the size of the groups, the first participant should enter data for the first 10 medicines, the second participant should enter data for the next 10 medicines, and so on, until all the data from the medicine outlet are entered. They should then use the double entry function of the workbook to enter the same data (i.e. from the same data collection form) a second time. Participants should enter data for different medicines than those they entered the first time (i.e. a participant should not enter the same medicines both times). Results should be checked and corrected using the double entry function.

   Note: Summary data will not be displayed in the workbook unless an exchange rate has been entered on the Reference Prices page and the minimum number of prices required for calculating of median price ratios has been set to "1" on the Field Data Consolidation pages.

Tip: As participants are entering data you should circulate and assist with any difficulties. Some issues may be encountered (e.g. data illegible or ambiguous) that will provide an opportunity to highlight the importance of rigorous data collection techniques.

Materials:

- Handout of presentation: "Data entry", for each participant
- Computers (1 per data collection team, plus 1 for data entry personnel) loaded with the electronic survey *Workbook Part I* that has been customized to the survey (e.g. survey medicines, sectors to be surveyed)
- Medicine Price Data Collection forms completed during the pilot test

Key messages:

- Illegible or ambiguous data on the Medicine Price Data Collection forms will lead to difficulty in data entry, delays caused by re-checking of data, and sometimes return visits to medicine outlets to confirm data
- Do not try to interpret illegible or ambiguous data, rather bring this to the attention of the survey manager
- Entering long columns of prices can lead to a substantial number of errors. All data must be entered twice and verified using the double entry function of the workbook
- Do not enter "0"s for medicines that were not available (i.e. no price data on the Medicine Price Data Collection form)

CHECKING WORKBOOK DATA

Objectives:

- To demonstrate the importance of checking workbook data
- To instruct participants on how to check data that have been entered into the workbook

Instructions:

1. **Present the possible causes of data errors in the survey Workbook, and the three ways that Workbook data is checked: 1) double entry, 2) data checker, and 3) manual check (~ 30 minutes)**. A sample presentation, "Data quality and checking" is provided on the CD-ROM. In particular, spend time demonstrating the data checker function of the Workbook. As in the Data Entry module, it is useful to have the workbook projected onto a screen/wall that is visible to all participants as you demonstrate the data checker.

2. **Conduct a data checking exercise (~ 1.5 hours)**.

   During this exercise, participants will check data contained in the Data Checking workbook that has been pre-loaded onto each computer (~ 1 hour). The Data Checking workbook, available on the CD-ROM, contains intentional mistakes that participants will identify during the exercise. Participants will continue to work in their data collection teams. They should open the Data Checking work-

book saved on their computers and check the data by first running the data checker and then conducting a manual check of the data. Any suspicious data should be noted.

At the end of the exercise conduct a group debriefing (~ 30 minutes). Ask participants the following questions, taking care to solicit responses from each of the teams:

- Were any mistakes or suspicious data identified by the data checker? If so, what are some examples?

  Expected responses: LPG price was higher than OB price; minimum price was very low compared to others in the row, maximum price was very high compared to others in the row; spread between minimum and maximum price was very wide; median price ratio was very high/low in international terms.

- Were any mistakes or suspicious data identified through manual checking? If so, what are some examples?

  Expected responses: some identifying information missing for medicine outlets; unit prices not entered to 4 decimal places; strange unit prices that turned out to be data entry mistakes

- Were you able to correct or confirm data by consulting the Medicine Price Data Collection form?

Conclude that data entry problems can sometimes be resolved by consulting the original Medicine Price Data Collection form, but ambiguous data on the form itself is a data collection issue that will require further follow up – these issues must be brought to the attention of the survey manager.

Materials:

- Handout of presentation: ““Data quality and checking”, for each participant
- Computers (1 per data collection team, plus 1 for data entry personnel)
- Data Checking workbook that has been pre-loaded onto each computer

Key messages:

- Even though data are checked multiple times throughout data collection, there may still be mistakes after data entry due to:

  — unidentified data collection mistakes

  — data entry errors

- Before submitting the workbook to the survey manager, data must be checked both manually and using the data checker function
- Identifying questionable data is not useful unless issues are resolved – notify the survey manager of anything suspicious

LOGISTICS FOR DATA COLLECTION

Objectives:

To inform survey personnel of the next steps and logistics related to data collection

Instructions:

1. **Provide instructions on the logistical aspects of the survey, including next steps following the workshop (~ 1 hour)**.

   The information provided in this session will depend on whether 1) the survey sample has already been identified and confirmed, in which case data collection will begin on a specific date soon after the training workshop; or 2) the survey sample has yet to be identified and confirmed, in which case the start date of data collection is still to be determined.

   In the either case, next steps will usually involve a meeting between area supervisors and their data collectors in which data collectors will be given their data collection schedules, materials and any final instructions. In the first case data collectors can be given the date, time and location of the meeting, while in the second case they will need to wait to be contacted by their area supervisor. In some cases schedules and materials can be distributed to data collectors at the training workshop for initiation of fieldwork directly after the workshop.

   Survey personnel should be provided with the following logistic information, or should be told how and when they will receive this information:

   - Start date for data collection
   - Allocation of data collectors into teams
   - Meeting times and locations for data collection teams
   - Transport (and accommodation where required) arrangements
   - Time/location of end-of-day meetings during data collection
   - Communications when in the field
   - Distribution of Medicine Price Data Collection forms and other materials

   Information on compensation, per diems, and transportation costs should always be covered as part of this session.

Materials:

- Handout for each data collection team with the contact information of data collectors, the area supervisor and survey manager, as well as any other logistical information (e.g. scheduled meeting time).

Key messages:

- Each participant should be aware of their immediate instructions following the workshop, e.g. initiate data collection on X date/time, await contact from area supervisor/survey manager, attend meeting on X date/time.

FINAL COMMENTS, EVALUATION OF WORKSHOP

Objectives:

- To thank participants for their contribution to the workshop
- To give participants the opportunity to provide feedback on the workshop

Instructions:

Close the workshop by providing any final comments or instructions, thanking participants, and distributing a workshop evaluation form for completion (~ 30 minutes).

You should end the workshop by thanking participants for their active participation and reminding them of the importance of the medicine prices and availability survey to which they are contributing.

Distributing an evaluation form for the training workshop is also recommended so that participants can provide feedback on the learning process. A sample evaluation form is provided on the CD-ROM.

Materials:

Training workshop evaluation form for each participant

Key messages:

- Reliable data is needed to identify strategies for improving access to affordable medicines
- Each participant has an equal role to play in ensuring the success of the survey

ANNEX 4

Example of a letter of introduction from the survey manager

MEDICINE PRICE AND AVAILABILITY SURVEY .... (PLACE AND DATES)

To whom it may concern

By this letter I would like to introduce to you ……. (name of area supervisor) and his/her team (details attached), as they begin to collect information from registered pharmacies and other medicine outlets on the price and availability of selected medicines in your area.

This work is in accordance with methods promoted by the World Health Organization and Health Action International and endorsed by ……. (Ministry of Health and/or Pharmacy Association). The results will be made publicly available and the anonymity of individual pharmacies and individual respondents will be strictly maintained.

This work should contribute to better knowledge about retail price differences, both in the country and internationally. It should also help us to understand how these prices are determined and how we might better control them. As you are aware, the price of medicines is of great importance to all people.

The survey team's work consists of interviewing staff at a preselected sample of medicine outlets about the prices and availability of 50 important medicines. Each outlet visit will probably take about two hours and we will try to ensure that the timing of the visit is convenient for you and your staff. Interviewers have specifically been asked to avoid arriving at peak times, when the outlet is busiest.

Should you need further information or have questions about this survey, please contact me directly. I would be grateful for every assistance you can provide to ……. area supervisor) and his/her team in carrying out their work.

Signed

Designation

Place

Date

Attachments:

- Full contact details of survey manager and commissioning organization
- Names of all data collectors in survey area
- Planned schedule of dates and times of visits to medicine outlets
- Names and designations of Advisory Committee members
- Copy of letter(s) of endorsement

ANNEX 5

Checklist for manual check of survey data

As described in Chapter 7, the following checklist can be used as a guide in conducting a manual verification of survey data once it has been entered into the *Workbook*.

Home page:

- Has the country name been selected?
- If the survey is being conducted as a state or provincial survey, has the state or province been identified?
- Have any other sectors been identified?
- Has the first day of data collection been entered?
- Have the survey areas been identified?

International Medicine Reference Price Data page:

- Is the exchange rate correctly entered (commercial buying rate on the first day of data collection)? Is it entered the correct way round (1US = XX local currency)?
- Is the name of the local currency entered?
- Does the date of the exchange rate coincide with the first day of data collection?
- Has the source of the exchange rate entered?
- If a different reference source (other than MSH) is being used, is the name of that source entered?
- Has the appropriate regional core list of medicines been uploaded?
- Are all the supplementary medicine names spelt correctly?
- In Column G: Core List, are supplementary medicines listed as 'no' and global and regional core medicines as 'yes'?
- Are the unit prices of the reference source accurately entered (for MSH: check year and enter median unit prices for suppliers – only use the median buyer price if there is no supplier price)?

- If two medicines are listed with different strengths or dose forms, have they been given unique names in column C (for example, amoxicillin tabs and amoxicillin suspension)?
- For each medicine, has the minimum level of public sector facility where the medicine is expected to be available been entered into Column O?

Field Data Consolidation: Medicine Procurement Prices page:

- Have the procurement ID, agency name (abbreviated) and date been entered?
- Has the number of orders required for median price data set to <1? Note: if procurement prices have been collected from many public facilities then the number should be set to <4.
- Are the unit prices entered correctly – to at least four decimal places, and without currency symbols? If there is no unit price then the cell should be left blank.

Field Data Consolidation: Patient Prices pages:

- Have the outlet study ID, region and distance from population centre been entered for each facility?
- On the public sector patient prices page, has the level of care of each public health facility been entered as 1 (primary), 2 (secondary) and 3 (tertiary)?
- Has the number of prices required for median price data set to <4?
- Are the unit prices entered correctly – to at least four decimal places, and without currency symbols? If there is no unit price then the cell should be left blank.
- When medicines were found but were provided to patients for free or for a fixed fee, has "F" been entered into the appropriate cell of the Patient price consolidation page?
- If no survey medicines were found in a given medicine outlet, has Row 10 been switched to "1" so that this outlet is still included in the analysis?

Standard Treatment Affordability page:

- Has the *daily* wage of the lowest paid unskilled government worker been entered in cell J6 (in local currency, but with no currency symbols)?
- For non-standard treatments:
  - — has the name of the condition been entered?
  - — is the treatment duration appropriate (duration for chronic conditions should be 30 days)?
  - — is the total number of units per treatment appropriate?

Price Components: Data Entry page:

- Are full descriptions entered for each example (sector, generic or originator brand, imported or locally produced, etc.)?
- Are examples included for all variations found in the country?

- Is it clear whether the example is based on real component costs or a hypothetical case?
- For each add-on costs, has the charge status (Value, Not found), charge basis (percentage or fixed fee), and amount of charge been entered?
- For percentage charges, has the base price to which the charge is applied been correctly identified?
- Have any discrepancies (e.g. Stage 2 selling price does not match Stage 3 procurement price) been verified?

ANNEX 6

Price Components Interview Guide

Table A6 lists the key informants commonly interviewed during Price Components central data collection. For each informant, the principal objectives of the interview are listed. It is important to keep these objectives in mind during the interview to ensure that the necessary information is obtained. Also listed are sample questions to ask during each interview. Note that not all types of interviewees listed may be appropriate for your country, and that not all questions will be appropriate.

In conducting the price components survey, it is important to double and even triple check the data obtained during interviews. All informants may not have the same understanding of the medicine supply chain and its associated costs, and some informants may not be aware of the most up-to-date information. This might include you, the researcher!

In addition to the specific questions presented in Table A6 below, you may wish to ask the following questions of many, if not all, of your informants:

- Are the final prices of some/all medicines controlled? If so, what are the regulations?
- Are there maximum wholesale and/or retail mark-ups? Do these apply to the public, private, other sectors?
- What are the taxes applied to medicines in the public, private and other sectors? Are any sectors or medicines exempt?
- How do mark-ups and other add-on costs differ for originator brand and generic medicines? How do they differ for imported and locally-produced medicines?

Note that some questions appear twice, namely once on each side of a transaction, in order to double check all data.

Table A6 Key informants for central data collection, interview objectives and sample questions

Informant	Objectives	Sample questions
Ministry of Health, Policy and Planning Branch	Obj 1: Determine the size of the medicine budget, what costs it covers in addition to medicines, and the population served. Obj 2: Determine the various means by which patients obtain pharmaceuticals. Obj 3: Determine whether there are user fees/cost recovery systems in the public sector. Obj 4: Obtain an overview of the process and rules of public procurement.	▪ Is there an essential medicines list? If yes, how many medicines are included? Does the list vary by level? Who develops it? How often is it reviewed? ▪ What is the medicines budget? Are quality control testing, overhead and distribution costs covered in the medicine budget, or are these a separate budget line? ▪ Are medicines free in the public sector? ▪ Are there policies for the use of generic products in the public and private sectors (e.g. generic substitution)? ▪ What are the taxes/tariffs applied to medicines in the public, private and other sectors? Are any sectors or medicines exempt? Where are exemptions documented? (Law number...) ▪ Does the government regulate mark-ups in the public distribution chain? If yes, please indicate rates for central medical stores, regional stores and public medicine outlets. ▪ Does the government control medicine prices in the public, private and/or other sectors? prices? If so, what are the regulations (e.g. maximum selling price)? Are prices enforced and by whom? ▪ How is public procurement conducted? Is public procurement limited to registered essential medicines? ▪ How is quality control testing conducted in the public sector? Do you have your own QC laboratory? What are the quality assurance requirements for local purchases? How much is spent on QA testing? Does this cost come out of the drug procurement budget? ▪ How are distribution and storage managed in the public sector? How are costs budgeted? ▪ Is there a pharmacy board? Does the pharmacy board collect a fee on pharmaceuticals? Do fees differ between generic equivalents and originator brands, and/or between imported and locally-produced products? ▪ Is there a government regulated dispensing fee? If yes, please describe the fee and how it is applied.
Procurement office – public and other sectors	Obj 1: Obtain an overview of the process and rules of public procurement. Obj 2: Identify how the administrative costs of procurement are covered (i.e. medicine budget or other government budget).	▪ What are the steps in public sector procurement? Do hospitals purchase any medicines directly? ▪ Is public sector procurement centralized, or decentralized to regional stores or individual health facilities? ▪ What are the technical requirements for procurement? Are WHO prequalification and/or Good Manufacturing Practices certification part of the technical requirements for procured products? ▪ What type of tendering process is used for public procurement? What is the procurement cycle? How are funds allocated, and how/when are funds made available? Are there ever delays in accessing funds? ▪ How is the procurement price determined? ▪ Do you procure all the medicines used in public sector facilities, or are some obtained from vertical programmes, local purchase, or other? If yes, what percentage are you supplying? How do you select the medicines that you will procure? How do facilities obtain medicines that are not procured centrally? ▪ What percentage of publicly procured medicines are locally produced? Is there a policy that provides preference to locally manufactured medicines? ▪ Of the medicines procured, approximately what proportion are originator brands? ▪ How often do stock-outs occur in the central/regional medical stores?

Informant	Objectives	Sample questions
		▪ How are these handled? How much was spent on emergency orders last year? ▪ What is this year's procurement budget? Does this cover additional costs such as medical stores' overhead, transport to health facilities, quality control testing? ▪ Who is responsible for distribution to public facilities? How are medicines transported and stored? ▪ What finance charges and fees are imposed by the bank on the procurement of pharmaceuticals (e.g. letter of credit, purchase of foreign exchange, contingency fee)?
Central/regional stores – public and other sectors[1]	Obj 1: Identify distribution routes for medicines in the public sector. Obj 2: Determine the overall availability of medicines, and assess whether the medicine budget matches population need.	▪ How are medicines delivered to central stores? How are they distributed to regional stores/health facilities? Is transport outsourced to a private company or handled by the central/regional stores? ▪ Is transport paid from the medicine procurement budget or from another budget? ▪ How often do you have stock-outs? How are stock-outs handled? ▪ What are your overhead expenses? What are your handling charges? Who covers these costs? ▪ Do you ever purchase medicines directly from the manufacturer? Who else do you purchase from? ▪ Is there a pharmacy board? Does the pharmacy board collect a fee on pharmaceuticals? Do fees differ between generic and originator brands, and/or between imported and locally-produced products? ▪ Does the government regulate mark-ups in the public distribution chain? If yes, please indicate rates for central medical stores, regional stores and public medicine outlets.
Government pricing authority (if one exists)	Obj 1: Determine what, if any, regulations are in place to control medicine prices. Obj 2: Identify any differences in pricing structures, e.g. for generics vs. originator brands; imported vs. locally manufactured, public sector vs. private sector.	▪ Are the final prices of some/all medicines controlled (e.g. maximum selling price)? How is information on a controlled price communicated (e.g. printed on box)? ▪ If there are maximum selling prices, how are these determined? Is there a pricing formula? Is it the same for all medicines/sectors? Please explain the pricing formula (taxes, mark-ups, etc.). ▪ Are there maximum wholesale and/or retail mark-ups? If so, to which sectors do these apply (public, private, other sectors)? ▪ Is there a Value Added Tax and/or General Services Tax on pharmaceuticals? If yes, to which sectors (public, private and/or other sectors) does it apply? Are any medicines exempt from VAT/GST? Are any other taxes or tariffs levied on medicines? ▪ Are there maximum profit margins for various participants in the supply chain? ▪ Are rebates and/or discounts common? How do they work?
Drug regulatory authority/drug control agency	Obj 1: Obtain an overview of the medicine registration process and how it impacts the availability of generics in the market. Obj 2: Identify quality assurance testing protocols and enforcement methods. Obj 3: Identify any fees collected for quality control testing.	▪ What fees (e.g. registration) are collected, and what are they used for? ▪ Do registration fees differ between generic equivalents and originator brands? What is the relative cost to register a generic equivalent or an originator brand? [NOTE: For the purposes of this survey, registration fees are not a price component – see page 141 ▪ What products are tested for quality? How many batches are tested? Do you have your own quality control lab, or is testing outsourced? How do you check that quality control protocols are followed? ▪ Is QA testing conducted for the public sector only, or for other sectors? ▪ What is the cost of quality control testing (samples and testing)? How is this cost covered (medicine procurement budget or separate budget)?

[1] May be same informant as for procurement.

Informant	Objectives	Sample questions
		▪ What is the importer's mark-up? Does this include transport to wholesalers/central stores? Are there other middlemen involved in the importation/supply of medicines (e.g. a clearing and forwarding agent)? If so, what are their mark-ups? ▪ If medicine prices are regulated, how are regulations enforced?
Quality control (QC) laboratory used by public sector	Obj 1: To understand the process of quality testing in the public sector and its associated costs	▪ How is quality testing conducted? What medicines are tested? What is the sampling protocol (e.g. every batch, random batches)? What happens when medicines do not meet standards? ▪ What is the approximate budget for QC testing? Does this match the cost of testing? ▪ How long does QC testing take? How are medicines stored/handled while testing is underway (e.g. quarantined at central medical stores until QC report is issued)?
Importers, customs officers, Ministry of Trade NB: Importer need not specialize in medicines	Obj 1: Determine how medicines are imported. Obj 2: Collect data on the charges related to the importation of medicines. Obj 3: Identify the importer's mark-up.	▪ What are the routes (e.g. air, land, sea) and major entry points (e.g. ports) by which medicines are imported? How is the logistics line divided (e.g. international freight vs local transport from border), and what is charged? ▪ How long does it take to clear an import order? What fees are incurred while an order waits to clear (e.g. storage, insurance, wharfage)? Importer: is it possible to pay more to get shipments to clear faster? ▪ What are the fees for international inspection (pre-shipment inspection (e.g. SGS) and in-country inspection)? ▪ What are the charges (e.g. port fee, port insurance, customs, stamp fee) incurred at the receiving port? ▪ Is there an import tariff on pharmaceuticals? Are any medicines/sectors/programmes exempted from the import tariff? ▪ What finance charges and fees are imposed by the bank on the procurement of pharmaceuticals (e.g. letter of credit, purchase of foreign exchange, contingency fee)? ▪ Does the government set a maximum importer's mark-up? If yes, what is the rate? ▪ Importer: what are charges for local transport: a) from the border to the import warehouse; b) from the import warehouse to the wholesaler/central stores? Who is responsible for these charges? Ministry of Trade: ▪ What percentage of medicines on the market are imported?
Manufacturer's association	Obj 1: Develop an understanding of the pricing structures of locally manufactured medicines Obj 2. Determine the distribution routes and associated costs for locally manufactured medicines Obj 3: Understand the cost differentials between imported and locally manufactured medicines	▪ What percentage (by volume or by value) of medicines are locally manufactured? What proportion of these are consumed locally (vs exported)? ▪ Is there a policy of preferential purchasing for locally manufactured medicines? ▪ Who are the major manufacturers of locally produced medicines? Are they stand alone manufacturers or subsidiaries of MNCs? ▪ For locally manufactured medicines, where are production facilities located and how are medicines distributed across the country? ▪ Does the government regulate medicine prices in the private sector? What are the regulations? How are they enforced? ▪ How do manufacturers determine the prices of generic and originator brand medicines? ▪ What is the pricing structure (e.g. taxes, mark-ups) for locally produced medicines? How does this differ from the pricing structure of imported medicines?

Informant	Objectives	Sample questions
Transport companies	Obj 1: Determine the costs and fees for local transport at each Stage of the supply chain. Obj 2: Compare the costs of the transport system in the public sector with those of the private sector.	▪ What are the charges for the local transport of medicines: – from the border to the import warehouse – from the import warehouse to the wholesaler/central stores – from the wholesaler to the retailer? ▪ Who is responsible for these charges? ▪ Are there any special requirements for the safe and timely delivery of medicines (e.g. refrigerated trucks, seasonal constraints)? ▪ Are there any additional (unofficial) charges that contribute to the cost of transport (e.g. roadblocks)?
Tax consultant	Obj 1: Understand the regulations for import tariffs. Obj 2: Identify if sales taxes exist and if so, how are they applied. Obj 3: Determine whether any other taxes or tariffs are levied on medicines. Obj 4: Determine whether any tax exemptions exist.	▪ May I photocopy chapter 30 (and 29 if applicable) of the International Harmonized Tariff Schedule? ▪ Is there a Value Added Tax and/or General Services Tax on pharmaceuticals? If yes, to which sectors (public, private and/or other sectors) does it apply? Are any medicines exempt from VAT/GST? ▪ How is VAT applied and reimbursed? Who is the ultimate payer? ▪ Are any other taxes or tariffs levied on medicines (excise tax, city sales tax, defence levy)? Are any medicines, sectors or programs eligible for tax exemptions? ▪ Can we work through an example of a medicine moving through the supply chain to see how and when various taxes are applied? ▪ Are there any tax refunds or abatements?
Ministry of Finance, Central Bank	Obj 1: Understand how public sector procurement funding operates.	▪ How does the Ministry of Health central procurement office access funds for medicine procurement? What is the time frame for requesting/releasing funds? ▪ What finance charges and fees are imposed by the bank on the procurement of pharmaceuticals (e.g. letter of credit, purchase of foreign exchange, contingency fee)?
Large bank in urban centre	Obj 1: Understand the banking system as it applies to foreign currency transactions for the importation of medicines.	▪ What are the fees involved in foreign currency transactions (e.g. letter of credit, telex charges, purchase of foreign exchange, foreign currency account)? ▪ If there are contingency fees, what do these cover? ▪ How are changes in exchange rate handled?
Pharmacists' association, individual pharmacists	Obj 1: Confirm the charges and mark-ups between the wholesale and retail levels of the supply chain. Obj 2: Identify any other government policies that impact private sector pharmacy practice.	▪ Who pays for the cost of transporting medicines from the wholesale warehouse to the retail outlet? ▪ How are wholesale and retail mark-ups determined? Are overhead and transport costs included in the wholesale/retail mark-ups? ▪ Are wholesaler and/or retailer margins regulated in the private sector? If so, what are the rates? ▪ Does the government control medicine prices in the private sector? If so, what are the regulations? How are they enforced? ▪ Is there a government regulated dispensing fee? If yes, what is the fee and how is it applied? ▪ Are discounts or rebates commonly offered to pharmacies? If so, are these being offered by the manufacturer, the wholesaler, or both? ▪ Who can be a wholesaler or retailer? What training is required? What, if any, restrictions does the government impose?

Informant	Objectives	Sample questions
Pharmacy board/ Pharmacists' council (office which accredits pharmacists and pharmacies)	Obj 1: Determine the roles and responsibilities of the pharmacy board. Obj 2: Identify any fees the pharmacy board collects on medicines. Obj 3: Obtain the pharmacist's perspective on the respective margins and viability of various actors in the supply chain.	▪ What are the roles and responsibilities of the pharmacy board/ pharmacists' council? ▪ Are any fees collected? If so, from whom? How are the fees used? Do fees differ between generic equivalents and originator brands, and/or between imported and locally produced products? ▪ How are wholesale and retail mark-ups determined? ▪ Are wholesaler and/or retailer margins regulated in the private sector? If so, what are the regulations? Do government-set mark-ups match what is found in practice? ▪ Does the government control medicine prices in the private sector? If so, what are the regulations? How are they enforced? ▪ Are discounts or rebates commonly offered to pharmacies? If so, are these being offered by the manufacturer, the wholesaler, or both?
WHO	Obj 1: Obtain a general overview of pharmaceutical policy and practices. Obj 2: Compare pharmaceutical policies and practices with other countries in the region. Obj 3: Confirm central information collected at the Ministry of Health and elsewhere.	▪ What is the government's medicine budget? What percentage of the population buy their medicines through out-of-pocket expenditures? ▪ What is the approximate contribution of each sector (public, private, other(s)) to the pharmaceutical market? ▪ Are medicines free in the public sector? Does the public sector use a cost recovery system? ▪ Are the final prices of some/all medicines controlled? Are wholesale and/or retail mark-ups regulated? In what sectors do these price regulations apply (public, private, other sectors)? ▪ Is there a sales tax on medicines? Are some medicines/sectors/ programmes exempt? ▪ Are there policies for the use of generic products in the public and/or private sector (e.g. generic substitution)?

ANNEX 7

Price components data collection form

Name of data collector:		
Region:		
Sector:		
Name/code of dispensing outlet:		
Product name, dosage, strength:		
Manufacturer:		
Pack size:		
Product type:	☐ originator brand	☐ generic
Production:	☐ imported	☐ locally produced
Type of data:	☐ field	☐ hypothetical

Any additional information about target medicine:

Stage 1	Type of charge	Charge basis	Price to which charge is applied	Amount of charge	Comments
	Manufacturers selling price	price			
	Insurance and freight				
	CIF				

Stage 2: Landed price	Type of charge	Charge status	Charge basis	Price to which charge is applied	Amount of charge	Comments

Source:

Stage 3: Wholesaler or medical store	Type of charge	Charge status	Charge basis	Price to which charge is applied	Amount of charge	Comments
	Procure price	value				

Source:

Stage 4: Retailer or dispensary	Type of charge	Charge status	Charge basis	Price to which charge is applied	Amount of charge	Comments
	Procure price	value				

Stage 5: Dispensed price	Type of charge	Charge status	Charge basis	Price to which charge is applied	Amount of charge	Comments
	Selling price	value				

Example:

Stage 2: Landed price	Type of charge	Charge status	Charge basis	Price to which charge is applied	Amount of charge	Comments
	Inspection	*V*	*Fee*	*MSP +IF*	*$200*	*Minimum charge on all shipments less than $5000*
	Port charges	*NF*				
	Importer's mark-up	*V*	*%*	*Cumulative sub-total*	*3%*	
	Pharmacy board	*V*	*%*	*Cumulative Sub-total*	*1%*	

ANNEX 8

International comparison of MPRs: adjustment for reference price year, inflation/deflation and purchasing power parity

As described in Chapter 10, the following adjustments can be used to improve the comparability of procurement price data (Option 1) and patient price data (Option 2) for international comparisons.

The large majority of surveys conducted to date have used MSH prices as the standard set of international reference prices to which median local prices are compared. As such, the adjustment instructions provided below assume the use of MSH prices; similar adjustments would also be needed if other reference prices are used.

OPTION 1: CORRECTING ONLY FOR MSH REFERENCE YEAR AND INFLATION/DEFLATION, I.E. FOR ADJUSTMENT OF PROCUREMENT PRICE DATA

1. Pick a base year for comparison

It is suggested that you use the same year as your survey using the same MSH reference prices e.g. if a survey was conducted in 2008 using 2007 MSH reference prices, 2008 should be chosen as the base year. However, if the bulk of the studies were done in one particular year, it is best to pick that year as the base year and adjust other results to that year. Note: this will result in some changes to MPRs calculated in your survey.

2. Convert MPR back to country-specific prices

a. Multiply the MPR by the appropriate MSH reference price to get the price in U.S. dollars (USD)

b. Multiply (2a) times the relevant currency exchange rate used in the survey to obtain the local currency unit price.

3. Convert local currency to US dollars

Divide the local currency value from (2b) by the relevant country specific official exchange rate for US dollars in the year the country survey was conducted. The period average exchange rate for the relevant survey year should be used, when available. If unavailable, use the end of period exchange rate.

4. Adjust for inflation/deflation

This is only for studies NOT conducted in the base year to adjust the country specific prices to account for deflation or inflation using the GDP deflator for the time difference between when the study was conducted to the base year chosen.

If the country CPI in the survey year is INFLATED (higher) compared to that of the base year, then the medicine prices need to be DEFLATED to base year prices (use a1 below). If the country CPI in the survey year is DEFLATED (lower) compared to that of the base year, then the medicine prices need to be INFLATED to base year prices (use a2 below).

$$\text{a1. Deflation factor} = \left[1 - \left(\frac{SurveyYearUSCPI - BaseYearUSCPI}{BaseYearUSCPI}\right)\right]$$

$$\text{a2. Inflation factor} = \left[1 + \left(\frac{BaseYearUSCPI - SurveyYearUSCPI}{BaseYearUSCPI}\right)\right]$$

b. Multiply (4a1 or 4a2) times the price from (3) above

5. Recalculate MPR

Divide adjusted country prices from (3) or (4) above by the MSH reference price **from the year prior to the base year**.

Notes

1. Sources of official conversion rate for US dollars: IMF: International Financial Statistics http://ifs.apdi.net/imf/ImfBrowser.aspx?PDF=y&type=ct; UNECE Economic Statistics http://w3.unece.org/pxweb/DATABASE/STAT/2-ME/6-MEER/6-MEER.asp
2. In Option 1, CPIs for the United States of America (USCPIs) are used to adjust for inflation/deflation. Source of U.S. CPI data: IMF: World Economic Outlook Database. http://www.imf.org/external/pubs/ft/weo/2007/01/data/index.aspx
3. If the survey was conducted in the base year, there is no need for step 4 adjustment for GDP deflator. Use the value calculated in step 3 and skip to step 4.
4. No need to adjust MSH reference prices for PPP as 1 USD is equivalent to 1 international dollar (PPP implied conversion rate for USD = 1)
5. These instructions will result you calculating a different MPR for your own survey because you will have inflated/deflated your local medicine prices to the base year.

Example: Yemen (survey conducted in 2006); amitriptyline 25mg tab/cap, lowest priced generic, public sector procurement price (original MPR = 1.38)

The MPR for amitriptyline 25mg tablets in the survey conducted in 2006 was measured as 1.38. This is to be compared to other surveys and so needs to be adjusted for MSH reference year and inflation.

STEP	CALCULATION
1. Choose base year	2004 (for purposes of demonstration)
2a. Convert MPR to USD	MSH price for amitriptyline 25mg tab for 2005 = $0.0049
	1.38 x 0.0049 = $0.0068
2b. Convert to local currency	Exchange rate used in survey: $1 = YER197.56
	$0.0068 x 197.56 = 1.34 yemeni rials per tablet
3. Convert to USD using standard exchange rate	1.34 yemeni rials per tablet/197.049 = $0.0068
4. Adjust for deflation	US CPI for 2006 = 117.069, US CPI for 2004 = 109.703
	Deflation factor $= \left[1 - \left(\frac{SurveyYearUSCPI - BaseYearUSCPI}{BaseYearUSCPI}\right)\right]$
	= [1 – ((117.069 – 109.703) / 109.703)]
	= 0.933
	0.933 x 0.0068 = 0.0063 USD
5. Recalculate MPR	MSH price for 2003 = $0.0076
	0.0063 / 0.0076 = 0.83

OPTION 2: STANDARDIZED CURRENCY CONVERSION PLUS PURCHASE POWER PARITY (PPP) , I.E. FOR ADJUSTMENT OF PATIENT PRICE DATA

1. Pick a base year for comparison

It is suggested that you use the same year as your survey using the same MSH reference prices e.g. if a survey was conducted in 2008 using 2007 MSH reference prices, 2008 should be chosen as the base year. However, if the bulk of the studies were done in one particular year, it is best to pick that year as the base year and adjust other results to that year. Note: this will result in some changes to MPRs calculated in your survey.

2. Convert MPR back to country-specific prices

a. Multiply the MPR by the appropriate MSH reference price to get the price in U.S. dollars (USD)

b. Multiply (2a) times the relevant currency exchange rate used in the survey to obtain the local currency unit price.

3. Adjust for inflation/deflation

This is only for studies NOT conducted in the base year to adjust the country specific prices to account for deflation or inflation using the GDP deflator for the time difference between when the study was conducted to the base year chosen.

If the country CPI in the survey year is INFLATED (higher) compared to that of the base year, then the medicine prices need to be DEFLATED to base year prices (use a1 below). If the country CPI in the survey year is DEFLATED (lower) compared to that of the base year, then the medicine prices need to be INFLATED to base year prices (use a2 below).

$$\text{a1. Deflation factor} = \left[1 - \left(\frac{SurveyYearCPI - BaseYearCPI}{BaseYearCPI}\right)\right]$$

$$\text{a2. Inflation factor} = \left[1 + \left(\frac{BaseYearCPI - SurveyYearCPI}{BaseYearCPI}\right)\right]$$

b. Multiply (3a1 or 3a2) times the price from (2) above

4. Adjust for country wealth in international dollars (using PPP):

Divide price in local currency from (3) above by the relevant country specific "Implied Purchase Power Parity" (PPP) conversion rate in the base year.

5. Recalculate MPR

Divide adjusted country prices from (3) or (4) above by the MSH reference price **from the year prior to the base year**.

Notes:

1. In Option 2, CPIs for the survey country are used to adjust for inflation/deflation. Source of National CPI data: IMF: World Economic Outlook Database http://www.imf.org/external/pubs/ft/weo/2007/01/data/index.aspx
2. Source of PPP data: IMF: World Economic Outlook Database http://www.imf.org/external/pubs/ft/weo/2007/01/data/index.aspx
3. If the survey was conducted in the base year, there is no need for step 4 adjustment for GDP deflator. Use the value calculated in step 3 and skip to step 4.
4. No need to adjust MSH reference prices for PPP as 1 USD is equivalent to 1 international dollar (PPP implied conversion rate for USD = 1).
5. These instructions will result you calculating a different MPR for your own survey because you will have inflated/deflated your local medicine prices to the base year.

Example: Yemen (survey conducted in 2006); aciclovir 200mg tab/cap, originator brand, private pharmacies (original MPR = 19.11)

The MPR for aciclovir 200mg tablets in the survey conducted in 2006 was measured as 19.11. This is to be compared to other surveys and so needs to be adjusted from inflation and purchasing power parity.

STEP	CALCULATION
1. Choose base year	2004 (for purposes of demonstration)
2a. Convert MPR to USD	MSH price for aciclovir 200mg tab for 2005 = $0.049
	19.11 x 0.049 = $0.936
2b. Convert to local currency	Exchange rate used in survey: $1 = YER197.56
	$0.936 x 197.56 = 184.99 yemeni rials per tablet
3. Adjust for deflation	CPI for 2006 = 213.028, CPI for 2004 = 156.632
	$\text{Deflation factor} = \left[1 - \left(\frac{SurveyYearCPI - 2004CPI}{BaseYearCPI}\right)\right]$
	= [1 – ((213.028 – 156.632) / 156.632)]
	= 0.640
	0.640 x 184.99 = 118.39 local currency (adjusted for inflation)
4. Adjust for PPP	PPP factor for 2004 = 137.332
	118.39 / 137.332 = 0.862 international dollars
5. Recalculate MPR	MSH price for 2003 = $0.0696
	0.862 / 0.0969 = 8.90