Pharmaceutical Sector Scan Framework

Draft

Overview of Key Pharmaceutical Sector Data

WHO Harvard Collaborating Center in Pharmaceutical Policy
On behalf of
The Medicines Transparency Alliance

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Symbols and Glossary

⇨	Indicates priority data for MeTA
⇨	Indicates data collected in the WHO Level I survey
&	If a list of data is available, obtain it and append to report

ADR	Adverse Drug Reaction
AIDS	Acquired Immunodeficiency Syndrome
ARI	Acute Respiratory Infection
CIF	Cost, Insurance, and Freight
CMS	Central Medical Store
EM	Essential Medicine
EML	Essential Medicines List
DTC	Drug and Therapeutic Committee
GDP	Gross Domestic Product Good Distribution Practices
GF	Global Fund
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
GNI	Gross National Income
HAI	Health Action International
HIV	Human Immunodeficiency Virus
IHSN	International Household Survey Network
IMS	Intercontinental Marketing Services
INN	International Non-proprietary Name
INRUD	International Network for the Rational Use of Drugs
IP	Intellectual Property
Local Cur.	Local Currency
MCV	Measles Containing Vaccine
MeTA	Medicines Transparency Alliance
MOH	Ministry of Health
MPR	Median Price Ratio (from WHO-HAI Medicine Price Survey)
MSP	Manufacturer's Selling Price
N/A	Not Applicable
NHA	National Health Accounts
NGO	Non-Governmental Organization

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NHI	National Health Insurance
OOP	Out-Of-Pocket
OTC	Over The Counter
ORT	Oral Rehydration Therapy
PAB	Protection-At-Birth
PPP	Purchasing Power Parity
QA	Quality Assurance
QC	Quality Control
Rx	Prescription
R&D	Research and Development
SES	Socio Economic Status
SHI	Social Health Insurance
SOP	Standard Operating Procedures
STG	Standard Treatment Guidelines
TRIPS	Trade Related Aspects of Intellectual Property Rights
VAT	Value Added Tax
WHO	World Health Organization
WHS	World Health Survey
WMS	World Medicines Situation
WTO	World Trade Organization

Definitions

Originator brand	A product distributed under patent name either directly by the company holding the patent or under license to another company
Branded generic	A generic product sold under a non-INN name
Good Distribution Practices	As established by the WHO Expert Committee on Specifications for Pharmaceutical Preparations[1]
Generic	A generic product sold under an INN name
Key Medicines	Refers to medicines selected to be on the list of the national basket of key medicines
Legal provisions	Existing laws pertaining to a component of the pharmaceutical sector
National Health Insurance	State funded health insurance through MOH or national health services
Private Sector	Includes private for-profit and not-for-profit sectors, unless specified otherwise
Social Health Insurance	Generally characterized by independent or quasi-independent insurance funds, a reliance on mandatory earmarked payroll contributions (usually from individuals and employers), and a clear link between these contributions and the right to a defined package for health benefits. [(In Gottret, P. E., & Schieber, G. (2006). *Health financing revisited: A practitioner's guide*. Washington, DC: World Bank]
Traditional Medicine	Traditional medicine is the sum total of the knowledge, skills, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness.

Introduction

The Pharmaceutical Sector Scan is intended to assemble a core set of existing information about a country's pharmaceutical sector and to highlight key information gaps. It will assess how medicines for primary care are supplied and used. Medicines for hospital inpatient care, while important, are not the focus of this sector scan. Data on primary care medicines may already exist in a variety of different government and private sector institutions or they may have been reported in previous national or international surveys.

The Pharmaceutical Sector Scan will assist national MeTA stakeholder groups in their efforts to improve transparency in the pharmaceutical sector and to set priorities for future activities. Collating a large body of relevant information about medicines in a standardized, user-friendly format will facilitate systematic analysis and point to areas where key information gaps exist.

To complete the Pharmaceutical Sector Scan, individuals designated by the MeTA stakeholder group or the MeTA Secretariat will scan a range of public and private sector institutions to assemble existing country-level data, assess their validity, flag inconsistencies between sources, and provide the most up-to-date summary of existing information. The information in the sector scan will be saved in a structured set of tables, organized by topic.

Section 1 outlines the recommended step-by-step method for collecting data.

Section 2 provides a series of forms for presenting key data in a structured format. Forms are classified according to the following domains:

1. Country Profile
2. Medicines Policy and Regulatory Framework
3. Medicines Market
4. Medicines Financing
5. Medicines Trade
6. Medicines Supply System
7. Medicines Access
8. Medicines Use

Each form starts with an **introductory list of data sources** listing possible national and international sources that may be consulted to complete the form. The main part of the form is a **data table** where the numbered items of interest are listed in the first column. The majority of items are yes/no statements for which check boxes are provided in the 'value' column. The other items indicate the expected unit for the response (e.g., %, or value in local currency) in parenthesis. At the bottom of each form, the sources and year of data for each item in the table should be documented, one source per row. Each listed source may apply to multiple items in the table: each item should be identified by its unique number.

Notes at the end of the document provide background information and website addresses of some possible international sources of pharmaceutical sector data. These sources may be useful for obtaining some of the data needed for the Pharmaceutical Sector Scan. Data

from these sources may not be as up-to-date as data available within a country, and in some cases, the data from international sources may not be accurate.

I. Methodology

The Pharmaceutical Sector Scan is intended to collect, organize, and synthesize important pharmaceutical sector data for review by the national MeTA stakeholder group. Before implementing the Scan, the national MeTA Council should consolidate the list of data to be collected by deciding whether to expand the list presented in this document.

The pharmaceutical sector is diverse and its organization and institutions differ from country to country. The sector frequently includes many independent and sometimes overlapping public, private, mission, and other non-governmental institutions that set policy for, operate, or evaluate pharmaceutical sector structures, processes, and results. Each of these institutions is a potential source of data for the pharmaceutical sector scan.

Once all of the possible national sources of data have been indentified, the team will proceed to contact key people and departments at each of these national institutions to identify which of the target items of data they may have. The quality of the collected data should be carefully assessed before completing summary tables in Section 2.

Step 1
A good first step in conducting the sector scan will be for the national team to review the contents of all the presentation forms to get a better understanding of the full scope of the data to be collected. This will make it easier to carry out subsequent tasks.

Step 2
After the review, the team should identify which data are already available from international sources, and enter the most recent available data into draft data presentation forms. These data should be considered provisional until they are verified by a national source.

Step 3
In order to work efficiently, the team should look through all of the data collection forms and list all of the possible data elements that might be found in specific national institutions, such as the MOH Bureau of Planning, the Drug Regulatory Authority, or the National Manufacturers Association. Then, working through a contact in each institution, identify the departments or systems in which different types of data might be kept. Document the data collection process and all of the institutions and people contacted for future reference.

Step 4
Obtain copies of the source materials that provide any of the data for the sector scan, documenting their location or institutional source. These materials will be of many types, including:

- Legislative proceedings or public announcements
- Published or unpublished reports or papers
- Databases or data repositories
- Website URLs

Step 5

From the source materials, extract the individual items of data needed to complete all of the summary presentation forms displayed in Section 2, including any additional data that have been added by the MeTA Council. At the bottom of each form, list the sources that were used to answer each item, where the data was found in the source, and the year to which the data correspond. If some data are only available by personal communication, document the name of the person providing the information and the date of the communication.

Step 6

After the sector scan is complete, prepare a short report to accompany the forms, summarizing in one or two paragraphs or bullet points the key findings and gaps in each domain. Highlight key issues for the MeTA stakeholder group to consider during its review and priority setting process.

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II. Presentation of Key Data

1. Country Profile: Demographic and Socioeconomic Indicators

Possible sources: MOH, Ministry of Planning, National Bureau of Statistics, WHOSIS[2], WHO Global InfoBase[3], World Bank Annual Development Report[4], WHO National Macroeconomics Report[5]

Item	Value
Population, mortality, fertility	
1.1 ⇨Population, total (millions)	
1.2 Population < 15 years (% of total population)	
1.3 Population > 60 years (% of total population)	
1.4 Urban population (% of total population)	
1.5 Birth rate (births per 1,000 population)	
1.6 Death rate (deaths per 1,000 population)	
1.7 Fertility rate, total (births per woman)	
Economic status	
1.8 GNI per capita (local cur.)[6]	
1.9 GDP growth (annual %)	
1.10 Population living < PPP int. $1 a day (%)	
1.11 Income share held by lowest 20% (%)	
Education and literacy	
1.12 Adult literacy rate, 15+ years (% of total population)	
1.13 Primary school enrollment rate, males (% of male population)	
1.14 Primary school enrollment rate, females (% of female population)	

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments

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2. Country Profile: Mortality and Causes of Death

Samia Saad 9/24/09 4:06 PM
Comment: All of this is useful from contextual point of view-should it all be highlighted?

Wilbert Bannenberg 9/24/09 4:27 PM
Comment: Not a priority for this routine sector scan.

Possible sources: MOH, Ministry of Planning, National Bureau of Statistics, WHOSIS[2], WHO Global InfoBase[3], World Bank Annual Development Report[4], WHO National Macroeconomics Report[5], WHO National Health Accounts[7]

Item	Value
Life expectancy and mortality	
2.1. Life expectancy at birth (years)	
2.2. Adult mortality rate [15 to 60 years] (/1,000 population)	
2.3. Maternal mortality ratio (/100,000 live births)	
2.4. Neonatal mortality rate (/1,000 live births)	
2.5. Infant mortality rate (/1,000 live births)	
2.6. Under 5 mortality rate (/1,000 live births)	
2.7. Age-standardized mortality rate by non-communicable diseases (/ 100,000 population)	
2.8. Age-standardized mortality rate by cardiovascular diseases (/ 100,000 population)	
2.9. Age-standardized mortality rate by cancer (/ 100,000 population)	
2.10. Mortality rate by HIV/AIDS (/ 100,000 population)	
2.11. Mortality rate by tuberculosis regardless of HIV status (/ 100,000 population)	
Causes of death among children <5 years	
2.12. Neonatal (% of deaths)	
2.13. Pneumonia (% of deaths)	
2.14. Diarrhea (% of deaths)	
2.15. Measles (% of deaths)	
2.16. Malaria (% of deaths)	
2.17. HIV/AIDS (% of deaths)	
2.18. Other (% of deaths)	

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Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments

3. Country Profile: Health Care Expenditures

Possible sources: MOH, Ministry of Finances, Ministry of Planning, National Bureau of Statistics, WHOSIS[2], WHO Global InfoBase[3], World Bank Annual Development Report[4], WHO National Macroeconomics Report[5], WHO National Health Accounts[7], WHO Global Burden of Disease and Risk Factors Data Base[8], Demographic and Health Surveys[9], World Bank Health and Nutrition Data Base[10]

Item	Value
Overall health expenditures	
3.1. ⇨Total annual per capita expenditure on health (local cur.)[6]	
3.2. Health expenditures as percent of GDP (% of gross domestic product)	
3.3. ⇨Percent of Ministry of Health budget to total government budget (% of total government budget)	
Health expenditures by source	
3.4. ⇨Annual per capita government expenditure on health (local cur.)[6]	
3.5. ⇨Government annual expenditure on health as percent of total (% of total expenditure on health)	
3.6. Social security expenditure as percent of government on health (% of government expenditure on health)	
3.7. ⇨Annual per capita private expenditures on health (local cur.)[6]	
3.8. Private expenditures as percent of total health expenditures (% of total expenditure on health)	
3.9. ⇨Private out-of-pocket expenditures as percent of total health expenditure (% of total expenditure on health)	
3.10. Premiums for private prepaid health plans as percent of total private health expenditures (% of private expenditure on health)	
3.11. ⇨Population covered by national, social, or private health insurance or other sickness funds (% of total population)	

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments

4. Country Profile: Health Personnel, Infrastructure, and Primary Health Care

Possible sources: MOH, Ministry of Finances, Ministry of Labor, Ministry of Planning, National Bureau of Statistics, WHOSIS[2], WHO Global InfoBase[3], World Bank Annual Development Report[4], WHO National Health Accounts[7], WHO Global Burden of Disease

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and Risk Factors Data Base[8], Demographic and Health Surveys[9], World Bank Health and Nutrition Data Base[10]

Item	Value
Personnel	
4.1. ⇨Physicians (/10,000 population)	
4.2. Nursing and midwifery personnel (/10,000 population)	
4.3. ⇨Licensed pharmacists (/10,000 population)	
4.4. Other non-pharmacist pharmaceutical personnel (/10,000 population)	
4.5. Community health workers (/10,000 population)	
Facilities	
4.6. Hospitals (/10,000 population)	
4.7. Hospital beds (/10,000 population)	
4.8. ⇨Licensed pharmacies (/10,000 population)	
Primary Health Care	
4.9. Primary health care units and centers (/10,000 population)	
4.10. Neonates protected at birth against neonatal tetanus [PAB] (% neonates)	
4.11. One-year olds immunized against MCV (% one-year old)	

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments

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5. Medicines Policy and Regulatory Framework

Possible sources: National legislative proceedings, MOH, Medicines Regulatory Agency, WHO Level I Survey 2003[11] and 2007, WHO Evaluation of Pharmaceutical Regulations[12], WHO Good Governance for Medicines Project[13]

Item	Value
Policy framework	
5.1. ⇨ National Health Policy exists	☐Yes ☐No
a. ⇨If yes, year updated	
5.2. ⇨ ⇨National Medicines Policy official document exists	☐Yes ☐No
a. ⇨⇨If yes, year updated	
b. ⇨⇨ If no, draft NMP document exists	☐Yes ☐No
5.3. ⇨⇨ National Medicines Policy Implementation Plan exists	☐Yes ☐No
a. ⇨⇨If yes, year updated	
Regulatory framework	
5.4. ⇨ ⇨Legal provisions exist establishing the powers and responsibility of a medicines regulatory agency	☐Yes ☐No
5.5. ⇨ ⇨Legal provisions exist for market authorization	☐Yes ☐No
5.6. ⇨ WHO certification scheme is required as part of the marketing authorization process	☐Yes ☐No
5.7. ⇨ ⇨Formal medicines regulatory agency exists	☐Yes ☐No
a. ⇨If yes, number of regulatory staff	
5.8. ⇨ ⇨Legal provisions exist requiring transparency and accountability and promoting a code of conduct in regulatory work	☐Yes ☐No
5.9. ⇨ ⇨Formal code of conduct exists that applies to public officials and staff involved in pharmaceutical-related activities	☐Yes ☐No
5.10. ⇨ ⇨ Medicines regulatory agency is actively involved in regional/international harmonization initiatives	☐Yes ☐No
5.11. ⇨⇨ Regulatory agency has website a. If yes, URL address is: ___________________________	☐Yes ☐No

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments

6. Medicines Market at Retail Price

In this section, “medicines market” refers to public, private, and not-for-profit markets.

Possible sources: National legislative proceedings, MOH, Medicines Regulatory Agency, Ministry of Trade, National Bureau of Statistics, Manufacturer associations, Importer or wholesaler records, WHO Level I Survey 2003[11] and 2007, IMS country reports[14], WHO World Medicines Situation[15]

Item	Value
6.1. ⇨ ⇨Number of medicines registered	
6.2. ⇨List of registered medicines by therapeutic class, patent status, patent expiry and registration dates is publicly available	☐Yes[&] ☐No
6.3. Total annual market for medicines by value (local cur.)[6]	
6.4. ⇨ Market share of generic medicines [branded and INN] by value (%)	
6.5. ⇨ Market share of medicines produced by local manufacturers by value (%)	
6.6. ⇨List of top 20 medicines by value is publicly available	☐Yes[&] ☐No
6.7. Annual growth rate of total medicines market value (%)	
6.8. Annual growth rate of generic market value (%)	

&: If yes, obtain list and append to report

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments

7. Medicines Financing: Government Expenditures and Health Insurance

Possible sources: MOH, National or Social Health Insurance, WHO National Health Accounts[7], WHO Level I Survey 2003[11] and 2007, WHO World Medicines Situation[15]

Item	Value
Medicines expenditures	
7.1. ⇨MOH budget for medicines (local cur.)[6]	
7.2. ⇨Percent MOH health budget for medicines (%)	
7.3. ⇨ ⇨Total medicines expenditures (local cur.)[6]	
7.4. ⇨Total medicines expenditures per capita (local cur.)[6]	
7.5. ⇨Percent government medicines expenditures (% of total medicines expenditures)	
7.6. ⇨Percent private medicines expenditures (% of total medicines expenditures)	
Health insurance	
7.7. ⇨National Health Insurance (NHI) exists	☐Yes ☐No
7.8. ⇨If yes, NHI provides at least partial medicines coverage	☐Yes ☐No
7.9. ⇨Social Health Insurance (SHI) exists	☐Yes ☐No
7.10. ⇨If yes, SHI provides at least partial medicines coverage	☐Yes ☐No
7.11. ⇨Proportion of the population covered by NHI or SHI (% of population)	
7.12. ⇨List of medicines reimbursed by NHI or SHI and structure of reimbursement is available	☐Yes[&] ☐No

&: If yes, obtain list and append to report

Wilbert Bannenberg 9/24/09 4:33 PM
Comment: Do we have a definition as to difference between national vs. social health insurance?

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments

8. Medicines Financing: Public Programs Providing Free Medicines

Possible sources: MOH, National or Social Health Insurance, WHO National Health Accounts[7], WHO Level I Survey 2003[11] and 2007, WHO World Medicines Situation[15]

Item	Value
8.1. ⇨ ⇨There is a official government program for obtaining free medicines	☐Yes ☐No
8.2. ⇨⇨If yes, medicines are available free-of-charge for: a. ⇨Patients who cannot afford them	☐Yes ☐No
b. ⇨Children under 5	☐Yes ☐No
c. ⇨Pregnant women	☐Yes ☐No
d. ⇨Elderly persons	☐Yes ☐No
8.3. ⇨⇨If yes, the following types of medicines are free: a. ⇨All	☐Yes ☐No
b. Malaria medicines	☐Yes ☐No
c. Tuberculosis medicines	☐Yes ☐No
d. Sexually transmitted diseases medicines	☐Yes ☐No
e. HIV/AIDS medicines	☐Yes ☐No
8.4. ⇨⇨If yes, medicines are free a. ⇨At public health care facilities	☐Yes ☐No
b. ⇨Through insurance program membership	☐Yes ☐No

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments

9. Medicines Financing: Patient Fees and Copayments

Possible sources: MOH, National or Social Health Insurance, WHO National Health Accounts[7], WHO Level I Survey 2003[11] and 2007, WHO World Medicines Situation[15]

Item	Value
9.1. ⇨Inpatients pay a fee for medicines in public hospitals	☐Yes ☐No
9.2. ⇨⇨ Registration/consultation fees are common in public primary care facilities	☐Yes ☐No
9.3. ⇨ ⇨Dispensing fees are common in public primary care facilities	☐Yes ☐No
9.4. ⇨Medicines are free in public primary care facilities	☐Yes ☐No
9.5. ⇨⇨ If not, medicines copayments are used to pay salaries of public health care workers	☐Yes ☐No
9.6. ⇨ ⇨Public sector medicines copayments are flat fees	☐Yes ☐No
a. If yes, fee amount (local cur.)[6]	
9.7. ⇨ ⇨Public sector medicines copayments are percent copayment	☐Yes ☐No
a. If yes, percent (%)	

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments

10. Medicines Trade: Intellectual Property Laws

Possible sources: Ministry of Trade, National Patent Office, WTO[16]

Item	Value
10.1. Country has signed international IP agreements	☐Yes[&] ☐No

&: If yes, obtain list and append to report

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Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments

11. Medicines Trade: Registration

Possible sources: MOH, Medicines Regulatory Agency, WHO Level I Survey 2003[11]and 2007, WHO Evaluation of Pharmaceutical Regulations[12]

Item	Value
11.1. ⇨An explicit and transparent process exists for assessing applications for registration of pharmaceutical products	☐Yes ☐No
11.2. ⇨⇨Functional formal committee exists responsible for assessing applications for registration of products	☐Yes ☐No
11.3. ⇨Conflict of interest declarations required for individuals responsible for approval of registration applications	☐Yes ☐No
11.4. ⇨ INN names are used to register medicines	☐Yes ☐No
11.5. ⇨⇨Medicines registration fees exist	☐Yes ☐No
11.6. If yes, amount per application of a patented product (local cur.)[6]	
11.7. If yes, amount per application of a generic product (local cur.)[6]	
11.8. ⇨A transparent process exists to appeal medicines registration decisions	☐Yes ☐No
11.9. ⇨⇨ Medicine samples are tested as part of the registration process	☐Yes ☐No
11.10. ⇨⇨ List of registered products is publicly available, identifying originator brands, branded generics, and generics	☐Yes[&] ☐No
11.11. ⇨List and application status of products submitted for registration are publicly available	☐Yes[&] ☐No
11.12. Average length of time from submission of a patented product application to decision (average number of days)	
11.13. Average length of time from submission of a generic product application to decision (average number of days)	

&: If yes, obtain list and append to report

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments

Item Number(s)	Source, Location, & Year	Comments

12. Medicines Trade: Manufacturing

Possible sources: MOH, Medicines Regulatory Agency, Ministry of Labor, Ministry of Trade, National Manufacturer Associations, Pharmacist Associations, International Manufacturer Associations[17], WHO Level I Survey 2003[11]and 2007

Item	Value
All manufacturers	
12.1. ⇨List of GMP compliant manufacturing plants with date and results of the latest inspection is available	☐Yes[&] ☐No
12.2. ⇨List of type and number of sanctions following inspections is available	☐Yes[&] ☐No
Domestic manufacturers	
12.3. ⇨ ⇨Legal provisions exist for licensing domestic manufacturers	☐Yes ☐No
12.4. Number and list of domestic manufacturers is available	☐Yes[&] ☐No
12.5. Number of domestic manufacturers involved in: a. R&D to discover new active substances	
b. Production of pharmaceutical starting material	
c. Formulation from pharmaceutical starting material	
d. Repackaging of finished dosage forms	
12.6. Percentage of market share **by volume** produced by domestic manufacturers (%)	
12.7. Percentage of market share **by value** produced by domestic manufacturers (%)	
Multinational manufacturers	
12.8. ⇨ ⇨Legal provisions exist for licensing multinational manufacturers that produce medicines locally	☐ Yes ☐No
12.9. ⇨⇨ Legal provisions exist for licensing importers	☐ Yes ☐No
12.10. Number of and list of multinational pharmaceutical companies with a local subsidiary is available	☐Yes[&] ☐No
12.11. Number and list of multinational pharmaceutical companies producing medicines locally is available	☐Yes[&] ☐No

&: If yes, obtain list and append to report

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments

13. Medicines Trade: Quality Assurance

Possible sources: MOH, Medicines Regulatory Agency, WHO Level I Survey 2003[11]and 2007, WHO Evaluation of Pharmaceutical Regulations[12], Pharmaceutical Security Institute[18]

Item	Value
13.1. ⇨ ⇨Legal provisions exist to inspect premises and collect samples	☐ Yes ☐No
13.2. ⇨⇨Legal provisions exist for detecting and combating counterfeit medicines	☐ Yes ☐No
13.3. ⇨⇨Legal provisions exist to ensure quality control of imported medicines	☐ Yes ☐No
13.4. ⇨Legal provisions exist to ensure quality control of locally produced medicines	☐ Yes ☐No
13.5. ⇨ ⇨Total number of samples tested for quality in past year, [including samples tested at importation, for registration, or sampled from market]	
13.6. ⇨ ⇨Total number of above samples that failed quality testing in past year	
13.7. ⇨List is publicly available giving detailed results of quality testing in past year	☐Yes[&] ☐No

& If yes, obtain list and append to report

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14. Medicines Trade: Price Control and Transparency

Possible sources: MOH, Medicines Regulatory Agency, Wholesalers, Retailers, Health Insurance Agencies, IMS[14], WHO Level I Survey 2003[11] and 2007, WHO Evaluation of Pharmaceutical Regulations[12], WHO/HAI Surveys[19]

Item	Value
Legal or regulatory provisions for medicines price control	
14.1. ⇨Legal or regulatory provisions exist for setting a. ⇨⇨Manufacturer selling price	☐ Yes ☐No
b. ⇨⇨Maximum wholesale markup	☐ Yes ☐No
c. ⇨⇨Maximum retail markup	☐ Yes ☐No
d. ⇨⇨Duty on imported raw materials	☐ Yes ☐No
e. ⇨⇨Duty on imported finished products	☐ Yes ☐No
f. ⇨⇨VAT or other taxes on medicines	☐ Yes ☐No
14.2. Legal or regulatory provisions for controlling medicines prices vary for different types of medicines	☐ Yes ☐No
Medicines price transparency	
14.3. ⇨ ⇨Government runs an active national medicine price monitoring system for retail prices	☐ Yes ☐No
14.4. ⇨ ⇨Regulations exist mandating that retail medicine price information should be publicly accessible	☐ Yes ☐No
14.5. ⇨Consumer price of medicines on the list of top 20 medicines is publicly available	☐Yes[&] ☐No

&: If yes, obtain list and append to report

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments

15. Medicines Trade: Price Comparison in the Private-for-Profit Sector

Samia Saad 7/31/09 4:57 PM
Comment: Not sure how valuable a median or aggregate data is going to be .Table 16 is more important.

Wilbert Bannenberg 9/24/09 4:19 PM
Comment: This will allow us to benchmark countries amongst themselves

Possible sources: MOH, Medicines Regulatory Agency, Wholesalers, Retailers, Health Insurance Agencies, IMS[14], WHO Level I Survey 2003[11]and 2007, WHO Evaluation of Pharmaceutical Regulations[12], WHO/HAI Surveys[19]

Item	Value
Medicines price comparison in the private for-profit sector (i.e. retail pharmacies)	
15.1. For a basket of 14 medicines on the global core list of WHO-HAI Pricing Survey, ratio of median MPR to international procurement reference prices for: a. Originator brand products (Median MPR)	
b. Lowest price generics (Median MPR)	
15.2. Median manufacturer selling price (CIF) as percent of retail price for a basket of key medicines (%)	
15.3. Median wholesaler selling price as percent of retail price for a basket of key medicines (%)	
15.4. Median pharmacist mark-up or dispensing fee as percent of retail price for a basket of key medicines (%)	
15.5. Median VAT and other taxes and duties as percent of retail price for a basket of key medicines (%)	

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments

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16. ⇨Medicines Trade: Consumer Prices of Medicines on HAI Global Core List

Possible sources: WHO/HAI Survey[19]

[List all median prices in local currency]

	Public Sector		Private For-Profit Sector	
Medicine, Strength, Formulation	**Originator**	**Low price generic**	**Originator**	**Low price generic**
16.1. Salbutamol 0.1mg/dose Inhaler				
16.2. Glibenclamide 5 mg Cap/tab				
16.3. Atenolol 50 mg Cap/tab				
16.4. Captopril 25 mg Cap/tab				
16.5. Simvastatin 20 mg Cap/tab				
16.6. Amitryptyline 25 mg Cap/tab				
16.7. Ciprofloxacin 500 mg Cap/tab				
16.8. Co-trimoxazole 8 + 40 mg/ml Susp.				
16.9. Amoxicillin 500 mg Cap/tab				
16.10. Ceftriaxone 1 g/ vial Injection				
16.11. Diazepam 5 mg Cap/tab				
16.12. Diclofenac 50 mg Cap/tab				
16.13. Paracetamol 24 mg/ml Susp.				
16.14. Omeprazole 20 mg Cap/tab				

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments

17. Medicines Trade: Promotion and Advertising - Legal and Regulatory Provisions

Possible sources: MOH, Medicines Regulatory Agency, National Manufacturer Associations, Consumer Associations, NGOs, Public Procurement Agencies, International Manufacturer Associations[17], WHO/HAI[19]

Item	Value
17.1. ➪ ➪Legal provisions exist to control the promotion and/or advertising of prescription medicines	☐ Yes ☐No
17.2. ➪Legal provisions exist to make direct advertising to the public illegal	☐ Yes ☐No
17.3. ➪Legal provisions exist to control gifts from the pharmaceutical industry to prescribers	☐ Yes ☐No
17.4. ➪ ➪Regulatory pre-approval is required for medicines advertisements and/or promotional materials	☐ Yes ☐No
17.5. ➪Regulatory committee exists for controlling medicines advertising and promotion	☐ Yes ☐No
a. ➪If yes, committee procedures are clearly documented and publicly available	☐ Yes ☐No
b. ➪If yes, list of committee members is publicly available	☐Yes[&] ☐No
c. ➪If yes, members must declare conflicts of interest	☐ Yes ☐No
17.6. ➪Standard Operating Procedures (SOP) exist governing the behavior of public procurement agencies in their interactions with sales representatives/wholesalers	☐ Yes ☐No
17.7. ➪Reports of complaints regarding promotional practices are publicly available	☐ Yes ☐No
17.8. ➪Number of violations and sanctions related to legal provisions controlling advertising of medicines	

&: If yes, obtain list and append to report

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments

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18. Medicines Trade: Promotion and Advertising - Code of Conduct and Spending

Possible sources: MOH, Medicines Regulatory Agency, National Manufacturer Associations, consumer Associations, NGOs, Public Procurement Agencies, International Manufacturer Associations[17], WHO/HAI[19]

Item	Value
Code of conduct	
18.1. ⇨A professional code of conduct exists to limit gifts that physicians can accept from the pharmaceutical industry	☐ Yes ☐No
18.2. ⇨A national code of conduct exists concerning advertising and promotion of medicines by pharmaceutical manufacturers	☐ Yes ☐No
a. ⇨If yes, the code of conduct applies to domestic manufacturers only, multinational manufacturers operating locally only, or both (Circle which applies)	Domestic, Multinational, Both
b. ⇨If yes, adherence to the code is voluntary	☐ Yes ☐No
c. ⇨If yes, code contains a formal process for complaints and sanctions	☐ Yes ☐No
d. ⇨If yes, list of complaints and sanctions for the last two years is publicly available	☐Yes[&] ☐No
Promotion and Advertising Spending	
18.3. ⇨Pharmaceutical companies are required to report their promotion and advertising budget in taxes disclosures	☐ Yes ☐No

&: If yes, obtain list and append to report

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments

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19. Medicines Supply System: Selection

Possible sources: MOH, Health Insurance Agencies, WHO Level I Survey 2003[11]and 2007

Item	Value
19.1. ⇨ ⇨National standard treatment guidelines (STGs) exist for most common illnesses	☐ Yes ☐No
a. If yes, they are incorporated in a government document	☐ Yes ☐No
b. ⇨ If yes, year of last update in national STGs	
19.2. ⇨ ⇨National essential medicines list (EML) exists.	☐ Yes ☐No
a. ⇨ If yes, number of unique medicine formulations on the national EML	
b. If yes , frequency of revisions over the past 20 years	
c. ⇨ If yes , year of last update in EML	
d. ⇨If yes, process for selecting medicines on the EML are clearly documented and publicly available	☐ Yes ☐No
e. ⇨If yes, criteria for selecting medicines on the EML are clearly documented and publicly available	☐ Yes ☐No
f. ⇨If yes, list of national EML committee members is publicly available	☐Yes[&] ☐No
g. ⇨If yes, conflict of interest declarations are required from members on national EML committee	☐ Yes ☐No
19.3. ⇨Explicit criteria for selecting medicines on national EML	☐Yes[&] ☐No
19.4. ⇨⇨ National medicines formulary manual exists.	☐ Yes ☐No
a. ⇨ If yes , national medicines formulary manual is limited to essential medicines	☐ Yes ☐No
b. ⇨ If yes ,year of last update in national medicines formulary manual	

&: If yes, obtain list and append to report

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments

20. Medicines Supply System: Procurement in the Public Sector

Possible sources: MOH, Government Procurement Agency, Public Hospitals and Dispensaries, WHO Level I Survey 2003[11]and 2007, WHO/HAI Surveys[19], IMS[14]

Item	Value
20.1. ⇨⇨ There is a tender board/committee overseeing public procurement that is independent from the procurement office	☐ Yes ☐No
20.2. ⇨ Public procurement is limited to medicines on the national EML	☐ Yes ☐No
20.3. ⇨A functioning process exists to prequalify suppliers for public procurement	☐ Yes ☐No
a. ⇨If yes, explicit criteria and procedures exist for prequalification of suppliers	☐Yes[&] ☐No
b. ⇨If yes, a list of prequalified suppliers is publicly available	☐Yes[&] ☐No
c. ⇨If yes, a list of suppliers who failed to meet pre-qualification standards in the past exists.	☐Yes[&] ☐No
20.4. Percent of public sector procurement expenditures in last year awarded by: a. ⇨ National competitive tenders (%)	
b. ⇨ International competitive tenders (%)	
c. ⇨ Negotiation//direct purchasing (%)	
20.5. ⇨Public sector tenders are publicly available	☐ Yes ☐No
20.6. ⇨Winning bids in the public sector are publicly available	☐ Yes ☐No
20.7. ⇨Public sector tenders use a transparent electronic bidding process	☐ Yes ☐No
20.8. ⇨Results of quality testing during the procurement process are publicly available	☐Yes[&] ☐No
20.9. Percent of public sector procurement expenditures in last year on: a. Medicines on the national EML (%)	
b. Medicines produced by local manufacturers (%)	

& If yes, obtain list and append to report

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments

21. ⇨Medicines Supply System: Procurement Price of Medicines (HAI Global List)

Possible source: WHO/HAI Surveys[19]

[List all prices in MPR]

	Public Sector	
Medicine, Strength, Formulation	**Originator**	**Low price generic**
21.1. Salbutamol 0.1mg/dose Inhaler		
21.2. Glibenclamide 5 mg Cap/tab		
21.3. Atenolol 50 mg Cap/tab		
21.4. Captopril 25 mg Cap/tab		
21.5. Simvastatin 20 mg Cap/tab		
21.6. Amitryptyline 25 mg Cap/tab		
21.7. Ciprofloxacin 500 mg Cap/tab		
21.8. Co-trimoxazole 8 + 40 mg/ml Susp.		
21.9. Amoxicillin 500 mg Cap/tab		
21.10. Ceftriaxone 1 g/ vial Injection		
21.11. Diazepam 5 mg Cap/tab		
21.12. Diclofenac 50 mg Cap/tab		
21.13. Paracetamol 24 mg/ml Susp.		
21.14. Omeprazole 20 mg Cap/tab		

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments

22. Medicines Supply System: Distribution

Possible sources: MOH, Ministry of Trade, Pharmacists Associations, WHO Level I Survey 2003[11]and 2007, WHO mapping medicines supply and distribution project (ongoing), MeTA mapping

Item	Value
All Distributors	
22.1. ⇨National guidelines exist for GDP	☐Yes[&] ☐No
22.2. ⇨List of GDP compliant distributors is available	☐Yes[&] ☐No
Central Medical Store	
22.3. The government supply system department has a CMS	☐ Yes ☐No
22.4. Software tools are available for planning, quantification of needs, and procurement processes	☐ Yes ☐No
22.5. ⇨Software tools are available for management of medicines supply (procurement tracking, expenditure tracking, stock outs and inventory control)	☐ Yes ☐No
22.6. Data on months of stock available are routinely collected	☐ Yes ☐No
22.7. Percentage of medicines with at least one stock out in the past year (%)	
22.8. ⇨Routine procedures exist to track the expiry dates of medicines	☐ Yes ☐No
Wholesale market characteristics	
22.9. ⇨⇨ Legal provisions exist for licensing wholesalers	☐ Yes ☐No
22.10. ⇨List of wholesalers is publicly available	☐Yes[&] ☐No
22.11. ⇨Number of wholesalers in market	
22.12. National association of wholesalers exists	☐ Yes ☐No
22.13. Number of domestic manufacturers with integrated wholesale activities	

&: If yes, obtain list and append to report

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments

23. Medicines Access

Possible sources: MOH, Medicines Regulatory Agency, WHO Level II Survey, WHO Medicines Survey (ongoing), INRUD Indicators[20], World Health Survey[21], International Household Survey Network[22]

Item	Value
Geographic access	
23.1. ⇨Percentage of patients who travel more than one hour to reach primary care facility (%)	
23.2. ⇨Percentage of households obtaining medicines for recent illness at a public health care facility (%)	
Affordability of medicines	
23.3. ⇨Number of days' wages of the lowest paid government worker for standard treatment with cotrimoxazole for a child respiratory infection	
23.4. ⇨Number of days' wages of the lowest paid government worker for standard treatments with atenolol for hypertension	
23.5. ⇨Number of days' wages of the lowest paid government worker for monthly standard treatment with simvastatin for hypercholesterolemia	
23.6. ⇨Percentage of households obtaining free medicines at public health care facilities (%)	
Availability of medicines	
23.7. ⇨Availability of basket of key medicines in health care facilities (%)	
23.8. ⇨Percentage of prescribed medicines actually dispensed (%)	
Equity in access	
23.9. ⇨Percentage of households by socioeconomic (SE) quintile whose monthly medicines expenditures represent 40% or more of discretionary expenditures (%)	
23.10. ⇨Percentage of households by SE quintile with a chronically ill member who requires medicines but having no medicines at home (%)	
23.11. ⇨Average monthly cost of medicines for the most frequent chronic disease in households by SE quintile (Local cur.)[6]	

Samia Saad 7/31/09 3:46 PM
Comment: Unless a household survey is performed there will be good info on this!

Wilbert Bannenberg 9/24/09 4:28 PM
Comment: So be it…

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments

24. Medicines Use: National Structures

Possible sources: MOH, Professional organizations, NGOs, WHO Level II Survey, WHO Level I Survey 2003[11]and 2007, INRUD indicators[20]

Item		Value
24.1.	⇨⇨ A national program or committee [involving government, civil society, and professional bodies] exists to monitor and promote rational use of medicines	☐ Yes ☐No
24.2.	⇨⇨ Public education campaigns about rational medicines use have been conducted by the MOH in the previous two years	☐ Yes ☐No
24.3.	⇨ ⇨A written national strategy exists to contain antimicrobial resistance	☐ Yes ☐No
24.4.	⇨⇨ A national reference laboratory has responsibility to coordinate epidemiological surveillance of antimicrobial resistance	☐ Yes ☐No
24.5.	A government department has been assigned to coordinate medicines use policies and promote rational use of medicines	☐ Yes ☐No
INRUD facility indicators		
24.6.	⇨Percentage of facilities with copy of national STGs (%)	
24.7.	⇨Percentage of facilities with copies of national EML (%)	

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments

25. Medicines Use: Prescribing

Possible sources: MOH, Professional organizations, NGOs, WHO Level I Survey 2003[11]and 2007, WHO Level II Survey, INRUD indicators[20], WHO Level II survey

Item	Value
25.1. ⇨⇨ Legal provisions exist to govern the licensing and prescribing practice of prescribers and health facilities	☐ Yes ☐No
25.2. ⇨Legal provisions exist to restrict dispensing by prescribers	☐ Yes ☐No
25.3. ⇨A professional association code of conduct exists governing professional behavior of prescribers	☐ Yes ☐No
25.4. Prescribing by INN name obligatory in: a. ⇨ Public sector	☐ Yes ☐No
b. ⇨ Private sector	☐ Yes ☐No
c. ⇨ Regulations exist requiring hospitals to organize/develop DTCs	☐ Yes ☐No
25.5. Functioning DTCs are present in what percent of a. ⇨ Public referral hospitals (%)	
b. ⇨ Public regional or district hospitals (%)	
c. Private hospitals (%)	
INRUD prescribing indicators	
25.6. ⇨Average number of medicines per prescription	
25.7. ⇨Percentage of medicines prescribed by INN name (%)	
25.8. ⇨Percentage of encounters with an antibiotic prescribed (%)	
25.9. ⇨Percentage of encounters with an injection prescribed (%)	
25.10. ⇨Percentage of medicines prescribed from EML or formulary (%)	
25.11. Average consultation time (minutes)	
Disease-specific prescribing indicators	
25.12. Percentage of non-pneumonia acute respiratory tract infection (ARI) of any age treated with antibiotics (%)	
25.13. Percentage of non-bacterial diarrhea in children under age 5 treated with ORT (%)	

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments

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26. Medicines Use: Dispensing

Possible sources: MOH, Professional organizations, NGOs, WHO Level II Survey, WHO Level I Survey 2003[11]and 2007, INRUD indicators[20], WHO Level II survey

Item	Value
26.1. ⇨ ⇨Legal provisions exist to govern licensing and dispensing practice of pharmacists and pharmacy establishments	☐ Yes ☐No
26.2. ⇨Legal provisions exist to restrict prescribing by dispensers	☐ Yes ☐No
26.3. ⇨A professional association code of conduct exists governing professional behavior of pharmacists	☐ Yes ☐No
26.4. Substitution of generic equivalents is permitted for: a. ⇨ Public sector dispensers	☐ Yes ☐No
b. ⇨ Private sector dispensers	☐ Yes ☐No
26.5. ⇨⇨ Dispensing of antibiotics is not allowed without a prescription	☐ Yes ☐No
26.6. ⇨ ⇨Dispensing of injections is not allowed without a prescription	☐ Yes ☐No
26.7. ⇨⇨ Dispensing of narcotics, psychotropic drugs and precursors is not allowed without a prescription	☐ Yes ☐No
INRUD dispensing indicators	
26.8. Average dispensing time (minutes)	
26.9. ⇨Percentage of prescribed medicines actually dispensed at facility where they were prescribed (%)	
26.10. ⇨Percentage of dispensed medicines that are adequately labeled (%)	
26.11. ⇨Percentage of patients who know the correct dosing of all dispensed medicines (%)	

⇨: Indicates data collected in the WHO Level I survey

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments

27. Medicines Use: Pharmaco-vigilance

Possible sources: MOH, Medicines Regulatory Agency, WHO Level I Survey 2003[11]and 2007, WHO Evaluation of Pharmaceutical Regulations[12], Uppsala WHO Collaborating Center[23]

Item	Value
27.1. Legal provisions exist for monitoring adverse drug reactions (ADRs) on a routine basis	☐ Yes ☐No
27.2. A functioning system exists for monitoring ADRs	☐ Yes ☐No
27.3. If yes, number of ADR reports sent to the system in last year	

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments

Possible National Sources of Key Data

1. Government Procurement Agency
2. Manufacturer Associations
3. Medicines Regulatory Agency
4. Ministry of Finances
5. Ministry of Health
6. Ministry of Labor
7. Ministry of Planning
8. Ministry of Trade
9. Mission Hospitals
10. National Bureau of Statistics
11. National or Social Health Insurance Agency
12. Non-Governmental Organizations
13. Private Health Insurers
14. Professional Organizations: physicians, pharmacists, nurses
15. Public Hospitals and Dispensaries

Possible International Sources of Key Data

[1] **WHO Expert Committee on Specifications for Pharmaceutical Preparations**

Good Distribution Practices are described in Technical Report Series, No. 937, Annex 5, 2006

http://www.who.int/medicines/publications/pharmprep/en/index.html

[2] **WHO Statistical Information System (WHOSIS)**

http://www.who.int/whosis/en/index.html

Provides recent and comprehensive health data on all of the 193 WHO Member States. The data, selected on the basis of quality and availability, relevance to global health, and comparability across member nations, cover over 50 core health indicators, which are organized into six major areas: mortality and burden of disease, health service coverage, risk factors, health system inputs, differentials in health outcome and coverage, as well as basic socio-demographic statistics. These are published in the World Health Statistics that is released in May of each year.

Data exist for all seven MeTA pilot countries.

[3] **WHO Global InfoBase**

http://www.who.int/infobase/report.aspx

The WHO Global InfoBase is a data warehouse that collects stores and displays information on chronic diseases and their risk factors for all WHO member states.

Data exist for all MeTA pilot countries.

[4] **World Bank Development Report**

http://siteresources.worldbank.org/INTWDR2009/Resources/4231006-1225840759068/WDR09_22_SWDIweb.pdf

The World Bank development report 2009 provides recent values for most country profile indicators.

[5] **National Macroeconomics and Health Report**

http://www.who.int/macrohealth/en/

National Macroeconomic and Health Reports provide data on health status, health systems, health care financing, and an analysis of costs of health care and investment plan.

A 2005 Report of the Ghana Macroeconomics and Health Initiative exists.

[6] **Conversion of Local Currency in $US**

http://www.oanda.com/convert/fxhistory

Provides a useful tool for converting local currency in $US.

[7] **WHO National Health Accounts**

http://www.who.int/nha/en/

National Health Accounts (NHA) provides evidence to monitor trends in health spending for all sectors, public and private, different health care activities, providers, diseases, population groups and regions in a country, intended to help in developing national strategies for effective health financing and in raising additional funds for health. Information can be used to make financial projections of a country's health system requirements and compare their own experiences with the past or with those of other countries.

Data until 2005 (last revision in 2007) exist for all MeTA pilot countries. However some data may be much older. That is why it is important to document the date of data collection for each data point included in the sector scan.

[8] **WHO Global Burden of Disease and Risk Factors database**

http://www.who.int/healthinfo/bod/en/index.html

Statistical estimates of mortality and burden of disease (DALYs) by cause for the world, regions and WHO Member States. Estimates of Healthy Life Expectancy (HALE) and Life Expectancy for WHO Member States; latest documentation, methods, results and projections for the Global Burden of Disease; manuals, resources and software for carrying out national burden of disease studies.

[9] **Demographic and Health Surveys (DHS)**

http://www.measuredhs.com/aboutsurveys/start.cfm

DHS supports a range of data collection options tailored to fit specific monitoring and evaluation needs of host countries.

Demographic and Health Surveys (DHS)

Provide data for a wide range of monitoring and impact evaluation indicators in the areas of population, health, and nutrition.

AIDS Indicator Surveys (AIS)

Provide countries with a standardized tool to obtain indicators for the effective monitoring of national HIV/AIDS programs.

Service Provision Assessment (SPA) Surveys

Provides information about the characteristics of health and family planning services available in a country.

Key Indicators Survey (KIS)

Provides monitoring and evaluation data for population and health activities in small areas—regions, districts, catchment areas—that may be targeted by an individual project, although they can be used in nationally representative surveys as well.

Other Quantitative Surveys

Includes biomarker collection, geographic data collection, and benchmarking surveys.

Qualitative Research

Provides informed answers to questions that lie outside the purview of standard quantitative approaches.

Data for many of these surveys exist for MeTA countries. Details can be found at: http://www.measuredhs.com/aboutsurveys/search/.

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[10] **World Bank Health and Nutrition Data Base (HNPStats)**

http://web.worldbank.org/WBSITE/EXTERNAL/TOPICS/EXTHEALTHNUTRITIONANDPOPULATION/EXTDATASTATISTICSHNP/EXTHNPSTATS/0,,menuPK:3237172~pagePK:64168427~piPK:64168435~theSitePK:3237118,00.html

The World Bank's comprehensive database of Health, Nutrition and Population (HNP) statistics makes a variety of national and international data sources available in one location, compiles World Bank data on health, nutrition and population, adopts an analysis-friendly format that enables flexible access and custom-tailored reports, and provides links to a large number of websites of international agencies and country statistical offices.

Data exist for all MeTA pilot countries.

[11] **WHO Level I Pharmaceutical Assessment**

http://www.who.int/medicines/areas/technical_cooperation/supply_management/AssessMonit/en/index.html

To monitor the progress and consequently improve the global medicines situation, WHO/TCM has developed a system of indicators that measures key aspects of a country's pharmaceutical situation. A standard methodology allows over time progress monitoring as well as comparisons across facilities, districts and countries. The process of pharmaceutical monitoring and assessment uses a hierarchical approach with three groups of indicators: Level I, Level II and Level III. Standardized key informant questionnaires (Level I) assess the structures and processes related to medicines in a country legislation and regulations; quality control of medicines; essential medicines lists; supply systems; financing; production; rational use; and protection of intellectual property rights. Level II facility and household surveys medicines assess, product quality, and rational use (see MeTA Assessment Component E). Level III tools measure specific components of the pharmaceutical sector, health system, or national medicines policy in more depth. Examples include the WHO/HAI medicines price surveys (see MeTA Assessment Component E).

Level I data from 1999 and 2003 exist for all seven MeTA pilot countries.

All Level I data revised in 2007 are available upon request

[12] **WHO Multi-Country Study on Effective Drug Regulation**

http://www.who.int/medicinedocs/en/d/Js2300e/#Js2300e.17.

The aim of this 10-country study was to assess drug regulation performance in selected countries using a standardized study guide, and to document the results so that other countries may learn from them.

The standardized study guide assesses drug regulation in general and specific drug regulatory functions (licensing, inspection and surveillance, product assessment and registration, adverse drug reaction monitoring, clinical trials, control of drug promotion and advertising, drug quality control laboratory).

Uganda is a MeTA pilot country included in the 2002 report

Data until 2005 (last revision in 2007) exist for all MeTA pilot countries. However some data may be much older. That is why it is important to document the date of data collection for each data point included in the sector scan.

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[13] **WHO Ethical Infrastructure for Good Governance**

http://www.who.int/medicines/areas/policy/goodgovernance/home/en/

Guided by WHO's Medicines Strategy 2004-2007 and launched in late 2004, the Good Governance for Medicines programme's goal is to raise awareness of abuse in the public pharmaceutical sector and to promote good governance. Participating countries complete a standardized Good Governance Assessment Tool on the level of transparency and vulnerability to corruption in the public pharmaceutical sector. The Assessment Tool evaluates medicines registration, control of medicines promotion, inspections of establishments, selection of essential medicines, procurement, and distribution.

Data exist for the following MeTA pilot countries: Ghana, Jordan, Philippines, Zambia

[14] **IMS Pharmaceutical Market Assessment Data**

http://www.imshealth.com/portal/site/imshealth

IMS agreed to share data on request

Data exist in Peru and the Philippines, and possible other MeTA pilot countries.

[15] **WHO World Medicines Situation (WMS)**

http://www.who.int/medicinedocs/index.fcgi?sid=zNnGhaRZ9ee80ca600000000476162bf&a=d&c=medicinedocs&d=Js6160e

The statistical Annex to the 2004 WMS contains country-level data on production, trade, sales, expenditures (1995 and 2000), and data from the 1999 world drug survey.

Data exist for all MeTA pilot countries

Data will be updated in 2009

[16] **World Trade Organization**

http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm

[17] **International Manufacturer Associations**

http://www.ifpma.org/aboutus

[18] **Pharmaceutical Security Institute**

http://www.psi-inc.org/index.cfm

[19] **WHO/HAI Medicine Price Surveys**

http://www.haiweb.org/medicineprices/

In May 2003 Health Action International (HAI) and the World Health Organization (Department of Medicine Policy and Standards) published a working draft of a manual to collect and analyse the prices people pay for a selection of important medicines across sectors and regions in a country, as well as medicine availability, treatment affordability and all price components in the supply chain (taxes, mark-ups etc.). The results of over 50 surveys are currently available in the web-based database, along with survey reports and other information.

WHO/HAI surveys were conducted in the following MeTA pilot countries: Ghana (May 2002, October 2004), Jordan (May 2004), Kyrgyzstan (February 2005), Peru (May 2002, September 2005), Philippines (June 2002, February 2005), and Uganda (April 2004).

Reports for the pricing surveys conducted in African countries can be found at:
http://www.afro.who.int/edp/publications/afro_essential_medicine_price_indicator_2007.pdf

In addition to price surveys, WHO/HAI provides information about promotion of medicines at:
http://www.drugpromo.info

[20] **INRUD**

The International Network for Rational Use of Drugs (INRUD) was established in 1989 to design, test, and disseminate effective strategies to improve the way drugs are prescribed, dispensed, and used, with a particular emphasis on resource poor countries.

http://www.inrud.org/

[21] **WHO World Health Survey (WHS)**

http://www.who.int/healthinfo/survey/en/

The WHS was conducted in 70 countries in 2002. In 52 countries, household expenditures for health care including medicines, and individual respondents' need for and access to care were assessed.

Surveys with household expenditures information exist for the following MeTA pilot countries: Ghana, Philippines and Zambia (Zambia data to be verified).

[22] **International Household Survey Network (IHSN)**

http://surveynetwork.org/home/

The IHSN is a partnership of international organizations seeking to improve the availability, quality and use of survey data in developing countries. This informal network was established as a recommendation of the Marrakech Action Plan for Statistics. The Central Survey Catalogue allows searching for surveys conducted in countries by type of survey and country.

Income and expenditure surveys are available in all MeTA pilot countries except Ghana.

[23] **Uppsala WHO Collaborating Centre**

http://www.who-umc.org