



# Pharmaceutical Sector Scan

---

Part of Component 1 of MeTA Baseline Assessments

Part II - Data Forms

Country: **ZAMBIA**

Data Collected By: **ANGELA TAYLOR Bsc Pharm;**  
**CHIDADZA DAKA Dip Pharm; KAMBUZA RUWE Dip**  
**Pharm; MALIWA MUSHIKITA Dip Pharm**

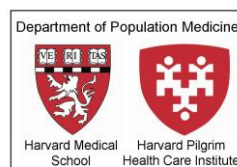
Data Collection Start Date: **02/06/2010**

Data Collection End Date: **22/06/2010**

WHO Harvard Collaborating Center in Pharmaceutical Policy

On behalf of

The Medicines Transparency Alliance



## **Table of Contents**

1. Country Profile: Demographic and Socioeconomic Indicators .....	3
2. Country Profile: Mortality and Causes of Death.....	4
3. Country Profile: Health Care Expenditures.....	5
4. Country Profile: Health Personnel, Infrastructure, and Primary Health Care.....	6
5. Medicines Policy and Regulatory Framework.....	7
6. Medicines Market at Retail Price.....	8
7. Medicines Financing: Government Expenditures and Health Insurance.....	9
8. Medicines Financing: Public Programs Providing Free Medicines.....	10
9. Medicines Financing: Patient Fees and Copayments.....	10
10. Medicines Trade: Intellectual Property Laws .....	11
11. Medicines Trade: Registration.....	11
12. Medicines Trade: Manufacturing .....	12
13. Medicines Trade: Quality Assurance.....	13
14. Medicines Trade: Price Control and Transparency.....	13
15. Medicines Trade: Price Comparison in the Private-for-Profit Sector .....	14
16. Medicines Trade: Consumer Prices of Medicines on HAI Global Core List.....	15
17. Medicines Trade: Promotion and Advertising - Legal and Regulatory Provisions ...	16
18. Medicines Trade: Promotion and Advertising - Code of Conduct and Spending.....	17
19. Medicines Supply System: Selection.....	18
20. Medicines Supply System: Procurement in the Public Sector.....	19
21. Medicines Supply System: Procurement Price of Medicines (HAI Global List) .....	20
22. Medicines Supply System: Distribution .....	21
23. Medicines Access .....	22
24. Medicines Use: National Structures .....	23
25. Medicines Use: Prescribing.....	24
26. Medicines Use: Dispensing.....	25
27. Medicines Use: Pharmaco-vigilance .....	25

**1. Country Profile: Demographic and Socioeconomic Indicators**

Item	Value
<b>Population, mortality, fertility</b>	
1.1 → Population, total (millions)	12,620,000
1.2 Population < 15 years (% of total population)	46
1.3 Population > 60 years (% of total population)	5
1.4 Urban population (% of total population)	35
1.5 Birth rate (births per 1,000 population)	40.42
1.6 Death rate (deaths per 1,000 population)	<25
1.7 Fertility rate, total (births per woman)	5.8%
<b>Economic status</b>	
1.8 GNI per capita (local cur.)	1230 USD
1.9 GDP growth (annual %)	6.3%
1.10 Population living < PPP int. \$1.25 a day (%)	N/A
1.11 Income share held by lowest 20% (%)	0.9%
<b>Education and literacy</b>	
1.12 Adult literacy rate, 15+ years (% of total population)	71%
1.13 Primary school enrollment rate, males (% of male population)	126.72% (95% WHO 2009)
1.14 Primary school enrollment rate, females (% of female population)	125.51% (96% WHO 2009)

**2. Country Profile: Mortality and Causes of Death**

Item	Value
<b><i>Life expectancy and mortality</i></b>	
2.1. Life expectancy at birth (years)	48
2.2. Adult mortality rate [15 to 60 years] (/1,000 population)	515
2.3. Maternal mortality ratio (/100,000 live births)	591
2.4. Neonatal mortality rate (/1,000 live births)	36
2.5. Infant mortality rate (/1,000 live births)	92
2.6. Under 5 mortality rate (/1,000 live births)	148
2.7. Age-standardized mortality rate by non-communicable diseases (/ 100,000 population)	833
2.8. Age-standardized mortality rate by cardiovascular diseases (/ 100,000 population)	389
2.9. Age-standardized mortality rate by cancer (/ 100,000 population)	146
2.10. Mortality rate by HIV/AIDS (/ 100,000 population)	470
2.11. Mortality rate by tuberculosis regardless of HIV status (/ 100,000 population)	18 for HIV negative (2008) 89.1 for HIV positive (2007)
<b><i>Causes of death among children &lt;5 years</i></b>	
2.12. Neonatal (% of deaths)	20.0
2.13. Pneumonia (% of deaths)	15
2.14. Diarrhea (% of deaths)	15
2.15. Measles (% of deaths)	1
2.16. Malaria (% of deaths)	15
2.17. HIV/AIDS (% of deaths)	12
2.18. Other (% of deaths)	17

**3. Country Profile: Health Care Expenditures**

Item	Value
<b><i>Overall health expenditures</i></b>	
3.1. ➡ Total annual per capita expenditure on health	68
3.2. Total expenditure on Health (THE) as % of GDP	6.0
3.3. ➡ Percent of Ministry of Health budget to total government budget (% of total government budget)	15.2
<b><i>Health expenditures by source</i></b>	
3.4. ➡ Annual per capita government expenditure on health (local cur.)	42
3.5. ➡ General Government expenditure on health as percent of total (% of total expenditure on health)	61.8
3.6. Social security expenditure as percent of government on health (% of government expenditure on health)	0.0
3.7. ➡ Annual per capita private expenditures on health (local cur.)	14.9
3.8. Private expenditures as percent of total health expenditures (% of total expenditure on health)	38.2
3.9. ➡ Private out-of-pocket expenditures as percent of total health expenditure (% of total expenditure on health)	74.5
3.10. Premiums for private prepaid health plans as percent of total private health expenditures (% of private expenditure on health)	3.7
3.11. ➡ Population covered by national, social, or private health insurance or other sickness funds (% of total population)	no data compiled or available

## Pharmaceutical Sector Scan - Data Forms

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

Item	Value
<b>Personnel</b>	
4.1. ⇨Physicians (Total)	1729
4.2. Nursing and midwifery personnel (Total)	16455 + 6514
4.3. ⇨Licensed pharmacists (Total)	277
4.4. Other non-pharmacist pharmaceutical personnel (Total)	512 total Pharmacy Technologists
4.5. Community health workers Total	3762
<b>Facilities</b>	
4.6. Hospitals (Total)	99
4.7. Hospital beds (/10,000 population)	19
4.8. ⇨Licensed pharmacies Total	83 total number
<b>Primary Health Care</b>	
4.9. Primary health care units and centers (Total)	1465
4.10. Neonates protected at birth against neonatal tetanus [PAB] (% neonates)	90%
4.11. One-year olds immunized against MCV (% one-year old)	68.8%

## Pharmaceutical Sector Scan - Data Forms

### 5. Medicines Policy and Regulatory Framework

Item	Value
<b>Policy framework</b>	
5.1. National Health Policy exists	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
a. If yes, year updated	1999
5.2. <input checked="" type="checkbox"/> National Medicines Policy official document exists	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
a. <input checked="" type="checkbox"/> If yes, year updated	2005
b. <input checked="" type="checkbox"/> If no, draft NMP document exists	<input type="checkbox"/> Yes <input type="checkbox"/> No
5.3. <input checked="" type="checkbox"/> National Medicines Policy Implementation Plan exists	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
a. <input checked="" type="checkbox"/> If yes, year updated	1997
<b>Regulatory framework</b>	
5.4. <input checked="" type="checkbox"/> Legal provisions exist establishing the powers and responsibility of a medicines regulatory agency	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
5.5. <input checked="" type="checkbox"/> Legal provisions exist for market authorization	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
5.6. WHO certification scheme is required as part of the marketing authorization process	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
5.7. <input checked="" type="checkbox"/> Formal medicines regulatory agency exists	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
a. <input checked="" type="checkbox"/> If yes, number of regulatory staff	13
5.8. <input checked="" type="checkbox"/> Legal provisions exist requiring transparency and accountability and promoting a code of conduct in regulatory work	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
5.9. <input checked="" type="checkbox"/> Formal code of conduct exists that applies to public officials and staff involved in pharmaceutical-related activities	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
5.10. <input checked="" type="checkbox"/> Medicines regulatory agency is actively involved in regional / international harmonization initiatives	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
5.11. <input checked="" type="checkbox"/> Regulatory agency has website	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
a. If yes, URL address is: www.pra.gov.zm	

## Pharmaceutical Sector Scan - Data Forms

---

### 6. Medicines Market at Retail Price

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

Item	Value
6.1. <input checked="" type="checkbox"/> Number of pharmaceutical products registered	4037
6.2. <input checked="" type="checkbox"/> List of registered pharmaceutical products by, ,generic name, license number and license holder is publicly available	<input checked="" type="checkbox"/> Yes <sup>&amp;</sup> <input type="checkbox"/> No
6.3. Total annual market for medicines by value (local cur.)	
6.4. <input checked="" type="checkbox"/> Market share of generic medicines [branded and INN] by value (%)	
6.5. <input checked="" type="checkbox"/> Market share of medicines produced by local manufacturers by value (%)	
6.6. <input checked="" type="checkbox"/> List of top 20 medicines by value is publicly available	<input type="checkbox"/> Yes <sup>&amp;</sup> <input type="checkbox"/> No
6.7. Annual growth rate of total medicines market value (%)	
6.8. Annual growth rate of generic market value (%)	

<sup>&</sup>: If yes, obtain list and append to report

**7. Medicines Financing: Government Expenditures and Health Insurance**

Item	Value
<b>Medicines expenditures</b>	
7.1. ⇒ MOH budget for medicines (local cur.)	ZMK 104,439,307,206
7.2. ⇒ Percent MOH health budget for medicines (%)	9
7.3. ⇒ Total expenditures on health (2007-2008)	ZMK 3,215,990,000
7.4. ⇒ Total medicines expenditures per capita (local cur.)	ZMK 7652
7.5. ⇒ Percent government medicines expenditures (% of total medicines expenditures)	8.3
<b>Health insurance</b>	
7.6. ⇒ National Health Insurance (NHI) exists	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
7.7. ⇒ If yes, NHI provides at least partial medicines coverage	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
7.8. ⇒ Social Health Insurance (SHI) exists	<input type="checkbox"/> Yes <input type="checkbox"/> No
7.9. ⇒ If yes, SHI provides at least partial medicines coverage	<input type="checkbox"/> Yes <input type="checkbox"/> No
7.10. ⇒ Proportion of the population covered by NHI or SHI (% of population)	no data compiled or collected or available
7.11. ⇒ List of medicines reimbursed by NHI or SHI and structure of reimbursement is available	<input type="checkbox"/> Yes <sup>&amp;</sup> <input type="checkbox"/> No

<sup>&</sup>: If yes, obtain list and append to report

**8. Medicines Financing: Public Programs Providing Free Medicines**

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

**9. Medicines Financing: Patient Fees and Copayments**

Item	Value
9.1. <input checked="" type="checkbox"/> Inpatients pay a fee for medicines in public hospitals	XYes No
9.2. <input checked="" type="checkbox"/> Registration/consultation fees are common in public primary care facilities	XYes No
9.3. <input checked="" type="checkbox"/> Dispensing fees are common in public primary care facilities	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
9.4. <input checked="" type="checkbox"/> Medicines are free in public primary care facilities	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
9.5. <input checked="" type="checkbox"/> If not, medicines copayments are used to pay salaries of public health care workers	<input type="checkbox"/> Yes <input type="checkbox"/> No
9.6. <input checked="" type="checkbox"/> Public sector medicines copayments are flat fees	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
a. If yes, fee amount (local cur.)	
9.7. <input checked="" type="checkbox"/> Public sector medicines copayments are percent copayment	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
a. If yes, percent (%)	

## Pharmaceutical Sector Scan - Data Forms

### 10. Medicines Trade: Intellectual Property Laws

Item	Value
10.1. Country has signed international Intellectual Property agreements	<input checked="" type="checkbox"/> Yes <sup>&amp;</sup> <input type="checkbox"/> No

<sup>&</sup>: If yes, obtain list and append to report

### 11. Medicines Trade: Registration

Item	Value
11.1. <input checked="" type="checkbox"/> An explicit and transparent process exists for assessing applications for registration of pharmaceutical products	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
11.2. <input checked="" type="checkbox"/> Functional formal committee exists responsible for assessing applications for registration of products	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
11.3. <input checked="" type="checkbox"/> Conflict of interest declarations required for individuals responsible for approval of registration applications	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
11.4. INN names are used to register medicines	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
11.5. <input checked="" type="checkbox"/> Medicines registration fees exist	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
11.6. If yes, amount per application of a patented product (local cur.)	3,800,000
11.7. If yes, amount per application of a generic product (local cur.)	3,800,000
11.8. <input checked="" type="checkbox"/> A transparent process exists to appeal medicines registration decisions	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
11.9. <input checked="" type="checkbox"/> Medicine samples are tested as part of the registration process	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
11.10. <input checked="" type="checkbox"/> List of registered products is publicly available, identifying originator brands, branded generics, and generics	<input checked="" type="checkbox"/> Yes <sup>&amp;</sup> <input type="checkbox"/> No
11.11. <input checked="" type="checkbox"/> List and application status of products submitted for registration are publicly available	<input type="checkbox"/> Yes <sup>&amp;</sup> <input checked="" type="checkbox"/> No
11.12. Average length of time from submission of a patented product application to decision (average number of days)	Normal registration takes 12-18 months
11.13. Average length of time from submission of a generic product application to decision (average number of days)	normal registration takes 6-1 year

<sup>&</sup>: If yes, obtain list and append to report

## Pharmaceutical Sector Scan - Data Forms

### 12. Medicines Trade: Manufacturing

Item	Value
<b>All manufacturers</b>	
12.1.  List of GMP compliant manufacturing plants with date and results of the latest inspection is available	<input checked="" type="checkbox"/> Yes <sup>&amp;</sup> <input type="checkbox"/> No
12.2.  List of type and number of sanctions following inspections is available	<input checked="" type="checkbox"/> Yes <sup>&amp;</sup> <input type="checkbox"/> No
<b>Domestic manufacturers</b>	
12.3.  Legal provisions exist for licensing domestic manufacturers	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
12.4. Number and list of domestic manufacturers is available	<input checked="" type="checkbox"/> Yes <sup>&amp;</sup> <input type="checkbox"/> No
12.5. Number of domestic manufacturers involved in:	
a. R&D to discover new active substances	None
b. Production of pharmaceutical starting material	None
c. Formulation from pharmaceutical starting material	Yes
d. Repackaging of finished dosage forms	Yes
12.6. Percentage of market share <b>by volume</b> produced by domestic manufacturers (%)	
12.7. Percentage of market share <b>by value</b> produced by domestic manufacturers (%)	
<b>Multinational manufacturers</b>	
12.8.  Legal provisions exist for licensing multinational manufacturers that produce medicines locally	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
12.9.  Legal provisions exist for licensing importers	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
12.10. Number of and list of multinational pharmaceutical companies with a local subsidiary is available	<input type="checkbox"/> Yes <sup>&amp;</sup> <input checked="" type="checkbox"/> No
12.11. Number and list of multinational pharmaceutical companies producing medicines locally is available	<input type="checkbox"/> Yes <sup>&amp;</sup> <input checked="" type="checkbox"/> No

<sup>&</sup>: If yes, obtain list and append to report

## Pharmaceutical Sector Scan - Data Forms

### 13. Medicines Trade: Quality Assurance

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

<sup>&</sup> If yes, obtain list and append to report

### 14. Medicines Trade: Price Control and Transparency

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

<sup>&</sup>: If yes, obtain list and append to report

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

Item	Value
<b>Medicines price comparison in the private for-profit sector (i.e. retail pharmacies)</b>	
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)	survey conducted, data analysis not completed
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 (%)	"

## Pharmaceutical Sector Scan - Data Forms

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

[List all median prices in local currency] →

Medicine, Strength, Formulation	Public Sector		Private For-Profit Sector	
	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. Amitriptyline 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				

## Pharmaceutical Sector Scan - Data Forms

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

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

<sup>&</sup>: If yes, obtain list and append to report

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

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

<sup>&</sup>: If yes, obtain list and append to report

19. Medicines Supply System: Selection

Item	Value
19.1. <input checked="" type="checkbox"/> National standard treatment guidelines (STGs) exist for most common illnesses	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
a. If yes, they are incorporated in a government document	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
b. If yes, year of last update in national STGs	2009
19.2. <input checked="" type="checkbox"/> National essential medicines list (EML) exists.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
a. If yes, number of unique medicine formulations on the national EML	58
b. If yes, frequency of revisions over the past 20 years	2-3 years
c. If yes, year of last update in EML	
d. <input checked="" type="checkbox"/> If yes, process for selecting medicines on the EML are clearly documented and publicly available	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
e. <input checked="" type="checkbox"/> If yes, criteria for selecting medicines on the EML are clearly documented and publicly available	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
f. <input checked="" type="checkbox"/> If yes, list of national EML committee members is publicly available	<input checked="" type="checkbox"/> Yes <sup>&amp;</sup> <input type="checkbox"/> No
g. <input checked="" type="checkbox"/> If yes, conflict of interest declarations are required from members on national EML committee	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
19.3. <input checked="" type="checkbox"/> Explicit criteria for selecting medicines on national EML	<input checked="" type="checkbox"/> Yes <sup>&amp;</sup> <input type="checkbox"/> No
19.4. <input checked="" type="checkbox"/> National medicines formulary manual exists.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
a. If yes, national medicines formulary manual is limited to essential medicines	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. If yes, year of last update in national medicines formulary manual	2005

<sup>&</sup>: If yes, obtain list and append to report

20. Medicines Supply System: Procurement in the Public Sector

Item	Value
20.1. <input checked="" type="checkbox"/> There is a tender board/committee overseeing public procurement that is independent from the procurement office	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
20.2. Public procurement is limited to medicines on the national EML	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
20.3. <input checked="" type="checkbox"/> A functioning process exists to prequalify suppliers for public procurement	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
a. <input checked="" type="checkbox"/> If yes, explicit criteria and procedures exist for prequalification of suppliers	<input checked="" type="checkbox"/> Yes <sup>&amp;</sup> <input type="checkbox"/> No
b. <input checked="" type="checkbox"/> If yes, a list of prequalified suppliers is publicly available	<input type="checkbox"/> Yes <sup>&amp;</sup> <input checked="" type="checkbox"/> No
c. <input checked="" type="checkbox"/> If yes, a list of suppliers who failed to meet pre-qualification standards in the past exists.	<input type="checkbox"/> Yes <sup>&amp;</sup> <input type="checkbox"/> No
20.4. Percent of public sector procurement expenditures in last year awarded by:	data available but not analysed
a. National competitive tenders (%)	
b. International competitive tenders (%)	data available but not analysed
c. Negotiation//direct purchasing (%)	data available but not analysed
20.5. <input checked="" type="checkbox"/> Public sector tenders are publicly available	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
20.6. <input checked="" type="checkbox"/> Winning bids in the public sector are publicly available	<input type="checkbox"/> Yes <input type="checkbox"/> No
20.7. <input checked="" type="checkbox"/> Public sector tenders use a transparent electronic bidding process	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
20.8. <input checked="" type="checkbox"/> Results of quality testing during the procurement process are publicly available	<input type="checkbox"/> Yes <sup>&amp;</sup> <input checked="" type="checkbox"/> No
20.9. Percent of public sector procurement expenditures in last year on:	
a. Medicines on the national EML (%)	10-11%
b. Medicines produced by local manufacturers (%)	15%

<sup>&</sup> If yes, obtain list and append to report

## Pharmaceutical Sector Scan - Data Forms

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

[List all prices in MPR] ⇨

Medicine, Strength, Formulation	Public Sector	
	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. Amitriptyline 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		

**22. Medicines Supply System: Distribution**

Item	Value
<b>All Distributors</b>	
22.1.  National guidelines exist for GDP	<input checked="" type="checkbox"/> Yes <sup>&amp;</sup> <input type="checkbox"/> No
22.2.  List of GDP compliant distributors is available	<input type="checkbox"/> Yes <sup>&amp;</sup> <input checked="" type="checkbox"/> No
<b>Central Medical Store</b>	
22.3. The government supply system department has a CMS	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
22.4. Software tools are available for planning, quantification of needs, and procurement processes	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
22.5.  Software tools are available for management of medicines supply (procurement tracking, expenditure tracking, stock outs and inventory control)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
22.6. Data on months of stock available are routinely collected	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
22.7. Percentage of medicines with at least one stock out in the past year (%)	no data available
22.8.  Routine procedures exist to track the expiry dates of medicines	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
<b>Wholesale market characteristics</b>	
22.9.  Legal provisions exist for licensing wholesalers	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
22.10.  List of wholesalers is publicly available	<input checked="" type="checkbox"/> Yes <sup>&amp;</sup> <input type="checkbox"/> No
22.11.  Number of wholesalers in market	
22.12. National association of wholesalers exists	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
22.13. Number of domestic manufacturers with integrated wholesale activities	3

<sup>&</sup>: If yes, obtain list and append to report

**23. Medicines Access**

Item	Value
<b>Geographic access</b>	
23.1. ⇒ Percentage of patients who travel more than one hour to reach primary care facility (%)	specific survey to capture this not compiled
23.2. ⇒ Percentage of households obtaining medicines for recent illness at a public health care facility (%)	Survey conducted data analysis not completed"
<b>Affordability of medicines</b>	
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 (%)	"
<b>Availability of medicines</b>	
23.7. ⇒ Availability of basket of key medicines in health care facilities (%)	70 -90%
23.8. ⇒ Percentage of prescribed medicines actually dispensed (%)	"
<b>Equity in access</b>	
23.9. ⇒ Percentage of households in lowest socioeconomic (SE) quintile whose monthly medicines expenditures represent 40% or more of discretionary expenditures (%)	"
23.10. ⇒ Percentage of households in lowest 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 in lowest SE quintile (Local cur.)	"

## Pharmaceutical Sector Scan - Data Forms

### 24. Medicines Use: National Structures

Item	Value
24.1. <input checked="" type="checkbox"/> A national program or committee [involving government, civil society, and professional bodies] exists to monitor and promote rational use of medicines	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
24.2. <input checked="" type="checkbox"/> Public education campaigns about rational medicines use have been conducted by the MOH in the previous two years	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
24.3. <input checked="" type="checkbox"/> A written national strategy exists to contain antimicrobial resistance	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
24.4. <input checked="" type="checkbox"/> A national reference laboratory has responsibility to coordinate epidemiological surveillance of antimicrobial resistance	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
24.5. A government department has been assigned to coordinate medicines use policies and promote rational use of medicines	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
<b>INRUD facility indicators</b>	
24.6. <input checked="" type="checkbox"/> Percentage of facilities with copy of national STGs (%)	(mean) 40%
24.7. <input checked="" type="checkbox"/> Percentage of facilities with copies of national EML (%)	(mean) 40%

## Pharmaceutical Sector Scan - Data Forms

### 25. Medicines Use: Prescribing

Item	Value
25.1. <input checked="" type="checkbox"/> Legal provisions exist to govern the licensing and prescribing practice of prescribers and health facilities	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
25.2. <input checked="" type="checkbox"/> Legal provisions exist to restrict dispensing by prescribers	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
25.3. <input checked="" type="checkbox"/> A professional association code of conduct exists governing professional behavior of prescribers	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
25.4. Prescribing by INN name obligatory in:	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
a. Public sector	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
b. Private sector	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
c. Regulations exist requiring hospitals to organize/develop DTCs	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
25.5. Functioning DTCs are present in what percent of	
a. Public referral hospitals (%)	90%
b. Public regional or district hospitals (%)	90%
c. Private hospitals (%)	N/A
<b>INRUD prescribing indicators</b>	
25.6. <input checked="" type="checkbox"/> Average number of medicines per prescription	3
25.7. <input checked="" type="checkbox"/> Percentage of medicines prescribed by INN name (%)	70%
25.8. <input checked="" type="checkbox"/> Percentage of encounters with an antibiotic prescribed (%)	60%
25.9. <input checked="" type="checkbox"/> Percentage of encounters with an injection prescribed (%)	15%
25.10. <input checked="" type="checkbox"/> Percentage of medicines prescribed from EML or formulary (%)	
25.11. Average consultation time (minutes)	10-15
<b>Disease-specific prescribing indicators</b>	
25.12. Percentage of non-pneumonia acute respiratory tract infection (ARI) of any age treated with antibiotics (%)	82%
25.13. Percentage of non-bacterial diarrhea in children under age 5 treated with ORT (%)	100%

## Pharmaceutical Sector Scan - Data Forms

### 26. Medicines Use: Dispensing

Item	Value
26.1. <input checked="" type="checkbox"/> Legal provisions exist to govern licensing and dispensing practice of pharmacists and pharmacy establishments	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
26.2. <input checked="" type="checkbox"/> Legal provisions exist to restrict prescribing by dispensers	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
26.3. <input checked="" type="checkbox"/> A professional association code of conduct exists governing professional behavior of pharmacists	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
26.4. Substitution of generic equivalents is permitted for:	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
a. Public sector dispensers	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
b. Private sector dispensers	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
26.5. <input checked="" type="checkbox"/> Dispensing of antibiotics is not allowed without a prescription	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
26.6. <input checked="" type="checkbox"/> Dispensing of injections is not allowed without a prescription	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
26.7. <input checked="" type="checkbox"/> Dispensing of narcotics, psychotropic drugs and precursors is not allowed without a prescription	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
<b>INRUD dispensing indicators</b>	
26.8. Average dispensing time (minutes)	
26.9. <input checked="" type="checkbox"/> Percentage of prescribed medicines actually dispensed at facility where they were prescribed (%)	86%
26.10. <input checked="" type="checkbox"/> Percentage of dispensed medicines that are adequately labeled (%)	29%
26.11. <input checked="" type="checkbox"/> Percentage of patients who know the correct dosing of all dispensed medicines (%)	83.9%

### 27. Medicines Use: Pharmaco-vigilance

Item	Value
27.1. Legal provisions exist for monitoring adverse drug reactions (ADRs) on a routine basis	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
27.2. A functioning system exists for monitoring ADRs	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
27.3. If yes, number of ADR reports sent to the system in last year	no data