

# FINAL REPORT

## **Pharmaceutical Sector Scan Framework** **Overview of Key Pharmaceutical Sector Data**

**Philippines**

**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
AO yyyy-xxx	Administrative Order No. xxx series of yyyy
ARI	Acute Respiratory Infection
ASEAN	Association of Southeast Asian Nations
BFAD	Bureau of Food and Drug
CIF	Cost, Insurance, and Freight
CMS	Central Medical Store
DBM	Department of Budget and Management
DOH	Department of Health
DTC	Drug and Therapeutic Committee
DTI	Department of Trade and Industry
EM	Essential Medicine
EML	Essential Medicines List
FDA	Food and Drug Administration
FHSIS	Field Health Services System
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
IRR	Implementing Rules and Regulations
LGU	Local Government Units
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
NDHS	National Demographics Health Survey
NFP	National Family Planning Survey
NHA	National Health Accounts
NGO	Non-Governmental Organization
NHI	National Health Insurance
NSO	National Statistics Office
OOP	Out-Of-Pocket
OTC	Over The Counter
ORT	Oral Rehydration Therapy
PAB	Protection-At-Birth
PHAP	Pharmaceutical and Healthcare Association of the Philippines
PMA	Philippine Medical Association
PNHA	Philippine National Health Accounts
PPhA	Philippine Pharmacists Association
PPP	Purchasing Power Parity
QA	Quality Assurance
QC	Quality Control
RA	Republic Act
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 <sup>1</sup>
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). <i>Health financing revisited: A practitioner's guide</i> . 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

Access to essential medicines is a basic human right. It is also one of the elements of the Primary Health Care Approach drafted in the Alma Ata Declaration (1978). However, people are denied of their right to access to essential medicines by confluence of factors affecting the availability and affordability of medicines in the market. Nearly two billion people cannot get the medicines they need. This translates to one in three of the world population living in the developing world without access to basic medicines either because the cost is too exorbitant or the medicines are not readily available in the local health centers or pharmacies.<sup>(1)</sup> This grim scenario is compounded by the presence of counterfeit drugs in the market, unethical and irrational drug use and lack of transparency and accountability in the medicine industry.

Disclosing good quality and robust information about medicines remains one of the main objectives of MeTA. MeTA Philippines in particular is involved in overcoming barriers to transparency and accountability by forging a consensus on standards of transparency through a multi-stakeholder process. Through this process, data disclosure on the four key areas, namely (1) medicines quality and registration; (2) availability; (3) price and (4) promotion can be accomplished. Subsequently, these core set of data can be translated into public friendly information. In the long run, MeTA aims to make medicines more accessible to indigent people by having a unified approach in identifying and solving the problems appropriate to the country setting.<sup>(1)</sup>

Though the Philippine pharmaceutical industry is valued at a hundred billion pesos, it only represents 4% of the market share in the Asia-Pacific which only makes up 8% of the global pharmaceutical market.<sup>(2)</sup> The industry is not involved in research and development of manufacturing new drugs and chemicals. It just

relies heavily on global initiatives of research-based foreign companies. Filipino pharmaceutical companies engage only on manufacturing or importing generic products of off-patent drugs. For the longest time, the lack of transparency in medicine pricing remains a very contentious issue. Thus, through this framework, transparency on medicine pricing would be assessed.

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, 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.

It is through this Pharmaceutical Sector Scan that a core set of existing information about a country's pharmaceutical sector would be identified and key information gaps highlighted. It is intended to assist national MeTA stakeholder groups in their efforts to improve transparency in the pharmaceutical sector and to set priorities for future activities. Through this large body of relevant information about medicines, systematic analysis on key information gaps can be identified and recommendation be derived.

## I. Methodology

A standardized, user-friendly data collection tool and methodology developed by the Harvard Group helped in the systematic collection and analysis of data.

The information in the sector scan was placed in a structured set of tables, organized into 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

A team composed of medical doctors scanned existing country-level data, assessed their validity, flagged inconsistencies between sources, and provided the most up-to-date summary of existing information. The data collection form has the following format:

1. **Introductory list of data sources**
2. The **data table**
3. The **sources** and year of data for each item in the table

Sources included background information and website addresses of some possible international sources of pharmaceutical sector data. 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.

Once identified, copies of the source materials were obtained that provided 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

The research team reviewed the data already available from international sources, and entered the most recent available data into draft data presentation forms. The data were considered provisional until they were verified by a national source. Once all of the possible national sources of data were identified, key resource persons were contacted for interview regarding incomplete or vague data. These persons were:

- Dr. Robert So, Head Executive Assistant, Department of Health
- Ms. Regina Obligacion, FDRO III, Food and Drug Association
- Mr. Reiner Gloor, PHAP Executive Director
- Dr. Dennis Batangan, Investigator of WHO Level II Survey
- Dr. Douglas Ball, Investigator of HAI Global Price List/Procurement Price Survey
- Atty. Estanislao Granados, Executive director, Department of Budget and Management
- Ms. Minda Marie Gugol, OIC, Department of Health Central Office Bids and Awards Committee

Responses from these interviews were compiled and included into the data sets for the study. From this a draft was created containing all the collected data. Sessions were conducted with the team and the resource persons above to discuss and confirm the data collected.

At the bottom of each form, the sources that were used to answer each item were listed, including where and when the data was collected. If some data were only available by personal communication, the name of the person providing the information and the date of the communication were listed.

After the sector scan is complete, a short report was prepared to accompany the forms, summarizing in one or two paragraphs or bullet points the key findings and gaps in each domain.

All available data dated January 31, 2010 or earlier were searched for inclusion in the study.

## II. Presentation of Key Data

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

**Actual sources:** National Statistics Office 2007 (1.1, 1.5, 1.6), CIA World Factbook 2007 (1.2, 1.5, 1.6, 1.7, 1.12), WHO World Health Statistics 2009 (1.3, 1.4, 1.8, 1.10, 1.12), World Bank (1.8, 1.9, 1.11), National Demographic Health Survey 2008 (1.2, 1.3, 1.5, 1.6), Asian Development Bank & Philippines Fact Sheet December 2008 (1.9)

Item	Value
<b>Population, mortality, fertility</b>	
1.1 Population, total (millions)	88.574M (NSO 2007) 2010 estimate at 94M (NSO 2006)
1.2 Population < 15 years (% of total population)	35.2% (CIA 2009) 35.7% (NDHS 2008)
1.3 Population > 60 years (% of total population)	6% (WHO 2009) 4.8% (NDHS 2008)
1.4 Urban population (% of total population)	64% (WHO 2009)
1.5 Birth rate (births per 1,000 population)	22.80 (NSO 2007) 26.01 (CIA 2009) 23.4 (NDHS 2008)
1.6 Death rate (deaths per 1,000 population)	5.48 (NSO 2007) 5.15 (CIA 2009)
1.7 Fertility rate, total (births per woman)	2.8 (NDHS 2008) 3.27 (2009 estimate)
<b>Economic status</b>	
1.8 GNI per capita (local cur.)	PhP 80268.86 (WHO 2009) PhP 91267.78 (World Bank 2008)
1.9 GDP growth (annual %)	4.6% (ADB 2008) 3.84% (World Bank 2008)
1.10 Population living < PPP int. \$1 a day (%)	22.6% (WHO 2009)
1.11 Income share held by lowest 20% (%)	5.44% (World Bank 2009)
<b>Education and literacy</b>	
1.12 Adult literacy rate, 15+ years (% of total population)	92.6% (WHO 2007) 93.4% (CIA 2007)
1.13 Primary school enrollment rate, males (% of male population)	90%
1.14 Primary school enrollment rate, females (% of female population)	92%

**Document source of each item and year collected:**

<b>Item Number(s)</b>	<b>Source, Location, &amp; Year</b>	<b>Comments</b>
1.1	National Statistics Office, <a href="http://www.census.gov.ph">http://www.census.gov.ph</a> , 2009 National Statistics Office, <a href="http://www.census.gov.ph/data/sectordata/popproj_tab1r.html">http://www.census.gov.ph/data/sectordata/popproj_tab1r.html</a> , 2006	Data collected 2007  Estimate done December 2006.
1.2	CIA World Factbook, <a href="https://www.cia.gov/library/publications/the-world-factbook/index.html">https://www.cia.gov/library/publications/the-world-factbook/index.html</a> , 2007 National Demographic Health Survey 2008, <a href="http://www.measuredhs.com/pubs/pdf/FR224/FR224.pdf">http://www.measuredhs.com/pubs/pdf/FR224/FR224.pdf</a> , 2009	
1.3, 1.4	WHO World Health Statistics 2009, <a href="http://www.who.int/whosis/whostat/EN_WHS09_Full.pdf">http://www.who.int/whosis/whostat/EN_WHS09_Full.pdf</a> , 2009 National Demographic Health Survey 2008, <a href="http://www.measuredhs.com/pubs/pdf/FR224/FR224.pdf">http://www.measuredhs.com/pubs/pdf/FR224/FR224.pdf</a> , 2009	Data collected 2007
1.5, 1.6, 1.7	CIA World Factbook, <a href="https://www.cia.gov/library/publications/the-world-factbook/index.html">https://www.cia.gov/library/publications/the-world-factbook/index.html</a> , 2009 National Demographic Health Survey 2008, <a href="http://www.measuredhs.com/pubs/pdf/FR224/FR224.pdf">http://www.measuredhs.com/pubs/pdf/FR224/FR224.pdf</a> , 2009	
1.8	WHO World Health Statistics 2009, <a href="http://www.who.int/whosis/whostat/EN_WHS09_Full.pdf">http://www.who.int/whosis/whostat/EN_WHS09_Full.pdf</a> , 2009  World Bank World Development Indicators, <a href="http://datafinder.worldbank.org/gni-per-capita-ppp">http://datafinder.worldbank.org/gni-per-capita-ppp</a> , 2008	The original data is 3430 PPP int. \$. PPP conversion rate used is 23.402 PhP – 1US\$  The World Bank data based on current 2008 prices states a value of around 3900 PPP int. \$.
1.9	Asian Development Bank and the Philippines Fact Sheet December 2008 <a href="http://www.adb.org/Documents/Fact_Sheets/PHI.pdf">http://www.adb.org/Documents/Fact_Sheets/PHI.pdf</a> World Bank Data Finder, <a href="http://datafinder.worldbank.org/gdp-growth-annual">http://datafinder.worldbank.org/gdp-growth-annual</a> , 2008	World Bank Data is of 2008
1.10	WHO World Health Statistics 2009, <a href="http://www.who.int/whosis/whostat/EN_WHS09_Full.pdf">http://www.who.int/whosis/whostat/EN_WHS09_Full.pdf</a> , 2009	Data collected 2007
1.11	World Development Indicators Database, <a href="http://www.worldbank.org/data/countrydata/countrydata.html">www.worldbank.org/data/countrydata/countrydata.html</a> , 2009	Data collected 2008
1.12	CIA World Factbook 2009, <a href="https://www.cia.gov/library/publications/the-world-factbook/index.html">https://www.cia.gov/library/publications/the-world-factbook/index.html</a> , 2009 WHO World Health Statistics 2009, <a href="http://www.who.int/whosis/whostat/EN_WHS09_Full.pdf">http://www.who.int/whosis/whostat/EN_WHS09_Full.pdf</a> , 2009	

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

**Actual source:** WHO World Health Statistics 2009 (2.1-2.18), CIA World Factbook 2009 (2.1), National Family Planning Survey (2.3), National Demographic Health Survey 2008 (2.4, 2.5, 2.6)

Item	Value
<b>Life expectancy and mortality</b>	
2.1. Life expectancy at birth (years)	71 (WHO 2009) 71 (CIA 2009)
2.2. Adult mortality rate [15 to 60 years] (/1,000 population)	178 (WHO 2009)
2.3. Maternal mortality ratio (/100,000 live births)	162 (NFP 2006)
2.4. Neonatal mortality rate (/1,000 live births)	16 (NDHS 2008)
2.5. Infant mortality rate (/1,000 live births)	23 (WHO 2009) 25 (NDHS 2008)
2.6. Under 5 mortality rate (/1,000 live births)	28 (WHO 2009) 34 (NDHS 2008)
2.7. Age-standardized mortality rate by non-communicable diseases (/100,000 population)	620 (WHO 2009)
2.8. Age-standardized mortality rate by cardiovascular diseases (/100,000 population)	320 (WHO 2009)
2.9. Age-standardized mortality rate by cancer (/100,000 population)	93 (WHO 2009)
2.10. Mortality rate by HIV/AIDS (/ 100,000 population)	<10 (WHO 2009)
2.11. Mortality rate by tuberculosis regardless of HIV status (/100,000 population)	41.3 (WHO 2009)
<b>Causes of death among children &lt;5 years</b>	
2.12. Neonatal (% of deaths)	37.5 (WHO 2009)
2.13. Pneumonia (% of deaths)	13.0 (WHO 2009)
2.14. Diarrhea (% of deaths)	14.3 (WHO 2009)
2.15. Measles (% of deaths)	0.1 (WHO 2009)
2.16. Malaria (% of deaths)	0.1 (WHO 2009)
2.17. HIV/AIDS (% of deaths)	0.0 (WHO 2009)
2.18. Other (% of deaths)	31.6 (WHO 2009)

### Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
2.1-2.18	WHO World Health Statistics 2009, <a href="http://www.who.int/whosis/whostat/EN_WHS09_Full.pdf">http://www.who.int/whosis/whostat/EN_WHS09_Full.pdf</a> , 2009	Data collected 2007
2.1	CIA world factbook, 2009 est. <a href="https://www.cia.gov/cia/publications/factbook/">https://www.cia.gov/cia/publications/factbook/</a>	
2.11	WHO World Health Statistics 2009, <a href="http://www.who.int/whosis/whostat/EN_WHS09_Full.pdf">http://www.who.int/whosis/whostat/EN_WHS09_Full.pdf</a> , 2009	Mortality rates for both HIV-negative and HIV-positive individuals were added.
2.3	National Family Planning Survey, <a href="http://www.ncrfw.gov.ph/index.php/statistics-on-filipino-women/14-factsheets-on-filipino-women/74-statistics-fs-filipino-women-health-family-planning">http://www.ncrfw.gov.ph/index.php/statistics-on-filipino-women/14-factsheets-on-filipino-women/74-statistics-fs-filipino-women-health-family-planning</a> , 2006	
2.4, 2.5, 2.6	National Demographic Health Survey 2008, <a href="http://www.measuredhs.com/pubs/pdf/FR224/FR224.pdf">http://www.measuredhs.com/pubs/pdf/FR224/FR224.pdf</a> , 2009	

### 3. Country Profile: Health Care Expenditures

**Actual sources:** Philippine National Health Accounts 2006 (3.1, 3.2, 3.4, 3.5, 3.6, 3.7, 3.8, 3.9), WHO World Health Statistic 2009 (3.1, 3.2, 3.4, 3.5, 3.6, 3.7, 3.8, 3.10), Department of Budget and Management (3.3), National Demographic Health Survey 2008 (3.11)

Item	Value
<b>Overall health expenditures</b>	
3.1. Total annual per capita expenditure on health (local cur.)	2478.32 (WHO 2009) 2596 (PNHA 2006)
3.2. Health expenditures as percent of GDP (% of gross domestic product)	3.8% (WHO 2009) 3.7% (PNHA 2006)
3.3. Percent of Department of Health budget to total government budget (% of total government budget)	2.53% (DBM 2009) PhilHealth not included
<b>Health expenditures by source</b>	
3.4. Annual per capita government expenditure on health (local cur.)	810.22 (WHO 2009) 603 (PNHA 2006)
3.5. Government annual expenditure on health as percent of total (% of total expenditure on health)	32.9% (WHO 2009) 23.2% (PHNA 2006)
3.6. Social security expenditure as percent of government on health (% of government expenditure on health)	25.8% (WHO 2009) 37.1% (PHNA 2006)
3.7. Annual per capita private expenditures on health (local cur.)	PhP 1662.95 (WHO 2009) PhP 1743 (PNHA 2006)
3.8. Private expenditures as percent of total health expenditures (% of total expenditure on health)	67.1% (WHO 2009) 67.1% (PHNA 2006)
3.9. Private out-of-pocket expenditures as percent of total health expenditure (% of total expenditure on health)	56.9% (PNHA 2006)
3.10. Premiums for private prepaid health plans as percent of total private health expenditures (% of private expenditure on health)	9.7% (WHO 2009)
3.11. Population covered by national, social, or private health insurance or other sickness funds (% of total population)	42% (NDHS 2008)

**Document source of each item and year collected:**

Item Number(s)	Source, Location, & Year	Comments
3.1	WHO World Health Statistic 2009, <a href="http://www.who.int/whosis/whostat/EN_WHS09_Full.pdf">http://www.who.int/whosis/whostat/EN_WHS09_Full.pdf</a> , 2009  Philippine National Health Accounts 2006, National Statistical Coordination Board (NSCB), sent via e-mail by Dr. Alberto G. Romualdez, 2006	Value as of 2006; US dollar-peso conversion Php 47.66-USD 1.00 (Nov. 8-10, 2009)
3.2	WHO World Health Statistic 2009, <a href="http://www.who.int/whosis/whostat/EN_WHS09_Full.pdf">http://www.who.int/whosis/whostat/EN_WHS09_Full.pdf</a> , 2009  Philippine National Health Accounts 2006, National Statistical Coordination Board (NSCB), sent via e-mail by Dr. Alberto G. Romualdez, 2006	
3.3	Republic Act No. 9524: General Appropriations Act FY 2009, <a href="http://www.dbm.gov.ph/GAA09/SUM2009.pdf">http://www.dbm.gov.ph/GAA09/SUM2009.pdf</a> , 2009	Includes Office of Secretary, Commission on Population, National Nutrition Council, budgetary support to government corporations under Department of Health  DOH Budget: Php 29.6 Billion  Total Gov't Budget: Php 1,170 Billion
3.4	WHO World Health Statistic 2009, <a href="http://www.who.int/whosis/whostat/EN_WHS09_Full.pdf">http://www.who.int/whosis/whostat/EN_WHS09_Full.pdf</a> , 2009  Philippine National Health Accounts 2006, National Statistical Coordination Board (NSCB), sent via e-mail by Dr. Alberto G. Romualdez, 2006	Value as of 2006; US dollar-peso conversion Php 47.66-USD 1.00 (Nov. 8-10, 2009)
3.5	WHO World Health Statistic 2009, <a href="http://www.who.int/whosis/whostat/EN_WHS09_Full.pdf">http://www.who.int/whosis/whostat/EN_WHS09_Full.pdf</a> , 2009  Philippine National Health Accounts 2006, National Statistical Coordination Board (NSCB), sent via e-mail by Dr. Alberto G. Romualdez, 2006	General government expenditure on health as % of total health expenditure.
3.6	WHO World Health Statistic 2009, <a href="http://www.who.int/whosis/whostat/EN_WHS09_Full.pdf">http://www.who.int/whosis/whostat/EN_WHS09_Full.pdf</a> , 2009  Philippine National Health Accounts 2006, National Statistical Coordination Board (NSCB), sent via e-mail by Dr. Alberto G. Romualdez, 2006	The value is derived from the ff: data Note: Total national government health expenditure registered 52,467 (in million pesos) in 2006. Social insurance in 2006 amounted to 19,458 (in million pesos)
3.7	WHO World Health Statistic 2009, <a href="http://www.who.int/whosis/whostat/EN_WHS09_Full.pdf">http://www.who.int/whosis/whostat/EN_WHS09_Full.pdf</a> , 2009  Philippine National Health Accounts 2006, National Statistical Coordination Board (NSCB), sent via e-mail by Dr. Alberto G. Romualdez, 2006	Value as of 2006; US dollar-peso conversion Php 47.66-USD 1.00 (Nov. 8-10, 2009)
3.8	WHO World Health Statistic 2009, <a href="http://www.who.int/whosis/whostat/EN_WHS09_Full.pdf">http://www.who.int/whosis/whostat/EN_WHS09_Full.pdf</a> , 2009  Philippine National Health Accounts 2006, National Statistical Coordination Board (NSCB), sent via e-mail by Dr. Alberto G. Romualdez, 2006	
3.9	Philippine National Health Accounts 2006, National Statistical Coordination Board (NSCB), sent via e-mail by Dr. Alberto G. Romualdez, 2006	
3.10	WHO World Health Statistic 2009, <a href="http://www.who.int/whosis/whostat/EN_WHS09_Full.pdf">http://www.who.int/whosis/whostat/EN_WHS09_Full.pdf</a> , 2005	
3.11	National Demographic Health Survey 2008, <a href="http://www.measuredhs.com/pubs/pdf/FR224/FR224.pdf">http://www.measuredhs.com/pubs/pdf/FR224/FR224.pdf</a> , 2009	Only 42 percent of Filipinos are <i>covered by some form of health insurance</i> . Insurance coverage is highest in Northern Mindanao (68 percent) and lowest in ARMM (18 percent). Coverage is higher in urban areas (49 percent) than in rural areas (35 percent). (NDHS 2008)

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

**Actual sources:** WHO World Health Statistics 2009 (4.1, 4.2, 4.3, 4.7), PHAP (4.4), FHSIS (4.5, 4.9), DOH (4.6), BFAD (4.8), WHO Vaccine Preventable Diseases: Monitoring System 2009 (4.10, 4.11), National Demographic Health Survey 2008 (4.10, 4.11)

Item	Value
<b>Personnel</b>	
4.1. Physicians (/10,000 population)	12 (WHO 2009)
4.2. Nursing and midwifery personnel (/10,000 population)	61 (WHO 2009)
4.3. Licensed pharmacists (/10,000 population)	6 (WHO 2009)
4.4. Other non-pharmacist pharmaceutical personnel (/10,000 population)	~11 (Gloor 2009)
4.5. Community health workers (/10,000 population)	22 (FHSIS 2006)
<b>Facilities</b>	
4.6. Hospitals (/100,000 population)	2 (DOH 2006)
4.7. Hospital beds (/10,000 population)	13 (WHO 2009)
4.8. Licensed pharmacies (/10,000 population)	3 (FDA 2009)
<b>Primary Health Care</b>	
4.9. Primary health care units and centers	
a. Barangay Health Stations (/10,000 population)	2 (FHSIS 2006)
b. Level 1 Hospitals (Private, Infirmary/Primary) (/1,000,000 population)	9 (DOH 2006)
c. Level 2 Hospitals (Private, Primary Care/Hospital) (/1,000,000 population)	8 (DOH 2006)
d. Combined Level 1 and 2 Hospitals (Private, Primary Care) (/100,000 population)	2 (DOH 2006)
4.10. Neonates protected at birth against neonatal tetanus [PAB] (% neonates)	65% (WHO 2009) 75.6% (NDHS 2008)
4.11. One-year olds immunized against MCV (% one-year old)	92% (WHO 2009) 76.2% (NDHS 2008)

**Document source of each item and year collected:**

Item Number(s)	Source, Location, & Year	Comments
4.1-4.3, 4.7	WHO World Health Statistics 2009, <a href="http://www.who.int/whosis/whostat/EN_WHS09_Full.pdf">http://www.who.int/whosis/whostat/EN_WHS09_Full.pdf</a> , 2007	2007 data
4.4	Interview with Mr. Reiner W. Gloor, Executive Director, Pharmaceutical and Health Association of the Philippines, December 14, 2009	Estimated Raw Data: ~100,000 personnel No available data from other Philippine government agencies like Department of Health and Federal Drug Administration (formerly known as BFAD)
4.5	Field Health Services System Data 2007, <a href="http://www2.doh.gov.ph/nec/fhsis/fhsis2007.zip">http://www2.doh.gov.ph/nec/fhsis/fhsis2007.zip</a> , 2007	Raw Data: 199,546 active BHWs.
4.6	DOH list of government and private medical hospitals, <a href="http://www.doh.gov.ph/files/gvtpvthosp_06.pdf">http://www.doh.gov.ph/files/gvtpvthosp_06.pdf</a> , 2006	Data collected 2006 (raw Data 1755)
4.8	Data via e-mail from BFAD c/o Ms. Regina Obligacion, FDRO III, December 2009	Raw Data: 23,859
4.9	Field Health Services System Data 2007, <a href="http://www2.doh.gov.ph/nec/fhsis/fhsis2007.zip">http://www2.doh.gov.ph/nec/fhsis/fhsis2007.zip</a> , 2007  DOH List of Licensed Government & Private Hospitals & other Health Facilities, <a href="http://www.doh.gov.ph/files/gvtpvthosp_06.pdf">http://www.doh.gov.ph/files/gvtpvthosp_06.pdf</a> , 2006	Raw data states 16,219 Barangay Health Stations in the Philippines as of year 2007. Data collected 2006: Level 1 center is described as An emergency hospital that provides initial clinical care and management to patients requiring immediate treatment, as well as primary care on prevalent diseases in the locality. Raw data: 774  Level 2 center is described as Non-departmentalized hospital that provides clinical care and management on the prevalent diseases in the locality. Raw data: 697
4.10, 4.11	WHO, WHO Vaccine Preventable Diseases: Monitoring System 2009 Global Summary, <a href="http://www.who.int/vaccines/globalsummary/immunization/scheduleselect.cfm">http://www.who.int/vaccines/globalsummary/immunization/scheduleselect.cfm</a> , 2009  National Demographic Health Survey 2008, <a href="http://www.measuredhs.com/pubs/pdf/FR224/FR224.pdf">http://www.measuredhs.com/pubs/pdf/FR224/FR224.pdf</a> , 2009	Data collected 2008

## 5. Medicines Policy and Regulatory Framework

**Actual sources:** DOH (5.1, 5.2, 5.3, 5.8, 5.9), BFAD (5.4, 5.5, 5.6, 5.10, 5.11), Ms. Regina Obligacion, FDRO III of BFAD (5.7), ASEAN Consultative Committee for Standards and Quality (ACCSQ) (5.10)

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	<i>Updated regularly / ongoing update</i>
5.2. National Medicines Policy official document exists	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
a. If yes, year updated	<i>Updated regularly / ongoing update</i>
b. If no, draft NMP document exists	<input type="checkbox"/> Yes <input type="checkbox"/> No
5.3. National Medicines Policy Implementation Plan exists	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
a. If yes, year updated	<i>Updated regularly / ongoing update</i>
<b>Regulatory framework</b>	
5.4. Legal provisions exist establishing the powers and responsibility of a medicines regulatory agency	<i>RA 3720 (Food, Drug and Cosmetic Act) RA 9711 (FDA Act of 2009)</i>
5.5. Legal provisions exist for market authorization	<i>RA 3720</i>
5.6. WHO certification scheme is required as part of the marketing authorization process	<i>According to IRR of RA 9502 (Universally Accessible Cheaper and Quality Medicine Act of 2008), imported products only.</i>
5.7. Formal medicines regulatory agency exists	<i>FDA (BFAD)</i>
a. If yes, number of regulatory staff	<i>249 (main office 147, regional offices 102)</i>
5.8. Legal provisions exist requiring transparency and accountability and promoting a code of conduct in regulatory work	<i>DOH AO 2007-042 (Norms of Behavior for Officials and Employees of the Department of Health) Section 12 of Republic Act No. 6713 (Code of Conduct and Ethical Standards for Public Officials and Employees)</i>
5.9. Formal code of conduct exists that applies to public officials and staff involved in pharmaceutical-related activities	<i>DOH AO 2007-042 Section 12 of Republic Act No. 6713 (Code of Conduct and Ethical Standards for Public Officials and Employees)</i>
5.10. Medicines regulatory agency is actively involved in regional/international harmonization initiatives	<i>Member of ASEAN Consultative Committee for Standards and Quality</i>
5.11. Regulatory agency has website	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
a. If yes, URL address is: _____	<i><a href="http://www.bfad.gov.ph">http://www.bfad.gov.ph</a></i>

**Document source of each item and year collected:**

Item Number(s)	Source, Location, & Year	Comments
5.1	Overview of the Philippine Health System and the Implementation Framework for Health Reforms, <a href="http://www.doh.gov.ph/phs/handbook.doc">http://www.doh.gov.ph/phs/handbook.doc</a> , 2005	Formulated from the Medium-Term Philippine Development Plan 2004-2010.
5.1a	Interview with Dr. Robert So, Head Executive Assistant, Department of Health, November 23, 2009	
5.2, 5.3	Memorandum Order No. 133, Malacañang, <a href="http://www.doh.gov.ph/files/pdf_mo133_malacañang.pdf">http://www.doh.gov.ph/files/pdf_mo133_malacañang.pdf</a> , 1987  Administrative Order No. 46 s. 1988, <a href="http://www.doh.gov.ph/files/pdf_ao46_1988.pdf">http://www.doh.gov.ph/files/pdf_ao46_1988.pdf</a> , 1988  DOH Department Order No. 32, 1994, <a href="http://www.doh.gov.ph/files/pdf_do32_1994.pdf">http://www.doh.gov.ph/files/pdf_do32_1994.pdf</a> , 1994	Department Order No. 32 updates the National Drug Policy
5.2a, 5.3a	Interview with Dr. Robert So, Chief Executive Assistant, Department of Health, November 23, 2009	
5.4	Republic Act 3720, <a href="http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=691">http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=691</a> , 1963  <i>Chapter II Section 4</i>  <i>To carry out the provisions of this Act, there is hereby created an office to be called the Food and Drug Administration in the Department of Health. Said Administration shall be under the Office of the Secretary and shall have the following functions, powers and duties"; (RA 3720)</i>  Republic Act 9711, <a href="http://www.senate.gov.ph/republic_acts/ra%209711.pdf">http://www.senate.gov.ph/republic_acts/ra%209711.pdf</a> , 2008	Revised by Executive Order 175 in 1987  Republic Act 9711 further strengthens the BFAD, transforming into the FDA.
5.5	Republic Act 3720, <a href="http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=691">http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=691</a> , 1963  <i>Chapter II Section 2</i>  <i>It is hereby declared the policy of the State to insure safe and good quality of food, drug and cosmetic, and to regulate the production, sale and traffic of the same to protect the health of the people." (RA 3720)</i>	Revised by Executive Order 175 in 1987
5.6	Joint DOH-DTI-IPO-BFAD Administrative Order No. 2008-01: The Implementing Rules and Regulation of RA 9502, <a href="http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=1234">http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=1234</a> , 2008  <i>"Chapter XIII, Rule 74. Quality Assurance of Drugs. The BFAD shall take the necessary steps to ensure that all drugs authorized for marketing in the country shall conform to international standards for the content, purity and quality of pharmaceutical products as established in the International Pharmacopoeia: Provided, That imported products in finished dosage forms, should be certified under the World Health Organization (WHO) certification scheme on the quality of pharmaceutical products moving in international commerce: Provided, further, That the registration for multi-source pharmaceutical products should conform to the WHO guidelines on registration requirements to establish interchangeability. (32)" (IRR of RA 9502)</i>	
5.7	Republic Act 3720, <a href="http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=691">http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=691</a> , 1963	Revised by Executive Order 175 in 1987
5.7a	Data via e-mail from BFAD c/o Ms. Regina Obligacion, FDRO III, December 2009	
5.8	Department of Health Administrative Order No. 42 s. 2007, <a href="http://www.doh.gov.ph/files/ao2007-0042.pdf">http://www.doh.gov.ph/files/ao2007-0042.pdf</a> , 2007  Section 12 of Republic Act No. 6713, otherwise known as the "Code of Conduct and Ethical Standards for Public Officials and Employees", <a href="http://www.csc.gov.ph/cscweb/RA6713b.html">http://www.csc.gov.ph/cscweb/RA6713b.html</a>	Rule V is dedicated to transparency
5.9	Department of Health Administrative Order No. 42 s. 2007, <a href="http://www.doh.gov.ph/files/ao2007-0042.pdf">http://www.doh.gov.ph/files/ao2007-0042.pdf</a> , 2007  Section 12 of Republic Act No. 6713, otherwise known as the "Code of Conduct and Ethical Standards for Public Officials and Employees", <a href="http://www.csc.gov.ph/cscweb/RA6713b.html">http://www.csc.gov.ph/cscweb/RA6713b.html</a>	The order lists the proper code of conduct for all DOH and BFAD employees.
5.10	ACCSQ Pharmaceutical Product Working Group, <a href="http://www.aseansec.org/14903.htm">http://www.aseansec.org/14903.htm</a> , 2002  <i>"Efforts toward harmonization of ASEAN pharmaceutical regulations were initiated in 1992 through the ASEAN Consultative Committee for Standards and Quality (ACCSQ). The 13th Meeting of the ACCSQ held in March 1999 in Manila, agreed that a Product Working Group on Pharmaceutical (PPWG) be set up, with Malaysia as the lead country. Hence the formation of ACCSQ-PPWG in September 1999 in Kuala Lumpur, Malaysia."</i>  <i>"ASEAN harmonizes pharmaceutical product standards and regulations", <a href="http://balita.ph/2009/05/28/asean-harmonizes-pharmaceutical-product-standards-and-regulations/">http://balita.ph/2009/05/28/asean-harmonizes-pharmaceutical-product-standards-and-regulations/</a>, 2009</i>	The Philippines is a member of ASEAN. Although this web page of the ASEAN has not been updated since late 2002. A recent ACCSQ PPWG meeting was held in the Philippines in May 2009 with the participation of the regulatory agency director.

## 6. Medicines Market at Retail Price

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

**Actual sources:** Ms. Regina Obligacion, FDRO III of BFAD (6.1, 6.2), PHAP Factbook 7<sup>th</sup> ed. (6.3, 6.5, 6.6, 6.7), Mr. Reiner Gloor, Executive Director of PHAP (6.4, 6.8)

Item	Value
6.1. Number of medicines registered	22,981 as of November 2009 (each form/dosage is separately registered)
6.2. List of registered medicines by therapeutic class, patent status, patent expiry and registration dates is publicly available	IPO Philippines (Bureau of Patents), MIMS/PPD Upon request from FDA
6.3. Total annual market for medicines by value (local cur.)	PhP 103.58 billion (PHAP 2008)
6.4. Market share of generic medicines [branded and INN] by value (%)	~40% (Gloor 2009)
6.5. Market share of medicines produced by local manufacturers by value (%)	31.3% (PHAP 2008)
6.6. List of top 20 medicines by value is publicly available	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
6.7. Annual growth rate of total medicines market value (%)	9.88% (PHAP 2008)
6.8. Annual growth rate of generic market value (%)	~15% (Gloor 2009)

&: If yes, obtain list and append to report

### Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
6.1	Data via e-mail from BFAD c/o Ms. Regina Obligacion, FDRO III, December 2009	Does not include food supplements or herbal medications.  The number is an active number and changes daily depending on many factors.
6.2	Data via e-mail from BFAD c/o Ms. Regina Obligacion, FDRO III, December 2009  Intellectual Property Office of the Philippines, <a href="http://www.ipophil.gov.ph">http://www.ipophil.gov.ph</a> , 2009	But may be provided upon presentation of written request and reason/s for requesting the same.  The Bureau of Patents does not list the patent status and expiry.
6.3	Philippine Pharmaceutical Industry Factbook 7 <sup>th</sup> Edition, <a href="http://www.phap.org.ph/images/page/main.factbook/factbook_11_2008.pdf">http://www.phap.org.ph/images/page/main.factbook/factbook_11_2008.pdf</a> , 2008	Based on IMS MAT September 2007
6.4	Interview with Mr. Reiner W. Gloor, Executive Director, Pharmaceutical and Health Association of the Philippines, December 14, 2009	According to Mr. Reiner Gloor, it is estimated at around 40% but the data would best be obtained March 2010 as the market is still unstable after the imposition of the maximum retail price.
6.5	Philippine Pharmaceutical Industry Factbook 7 <sup>th</sup> Edition, <a href="http://www.phap.org.ph/images/page/main.factbook/factbook_11_2008.pdf">http://www.phap.org.ph/images/page/main.factbook/factbook_11_2008.pdf</a> , 2008	Data collected 2007
6.6	Philippine Pharmaceutical Industry Factbook 7 <sup>th</sup> Edition, <a href="http://www.phap.org.ph/images/page/main.factbook/factbook_11_2008.pdf">http://www.phap.org.ph/images/page/main.factbook/factbook_11_2008.pdf</a> , 2008	Top 20 pharmaceutical brands as of 2007
6.7	Philippine Pharmaceutical Industry Factbook 7 <sup>th</sup> Edition, <a href="http://www.phap.org.ph/images/page/main.factbook/factbook_11_2008.pdf">http://www.phap.org.ph/images/page/main.factbook/factbook_11_2008.pdf</a> , 2008	Based on IMS MAT September 2007; Cumulative annual growth rate from 2004-2007: 10.08%
6.8	Interview with Mr. Reiner W. Gloor, Executive Director, Pharmaceutical and Health Association of the Philippines, December 14, 2009	According to Mr. Reiner Gloor, this data would be best obtained March 2010 as the market is still unstable after the imposition of the maximum retail price.

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

**Actual sources:** Philippine National Health Accounts 2005 (7.1, 7.2), Dr. Robert So, Head Executive Assistant of DOH (7.1, 7.2, 7.3, 7.4, 7.5, 7.6), PhilHealth (7.7, 7.8, 7.9, 7.10, 7.11, 7.12), Department of Budget and Management (7.1), National Demographic Health Survey 2008 (7.11)

Item	Value
<b>Medicines expenditures</b>	
7.1. DOH budget for medicines (local cur.)	<i>PhP 4-5 Billion without PhilHealth (DBM 2008)</i> <i>~PhP 12 Billion including PhilHealth (So 2009)</i>
7.2. Percent DOH health budget for medicines (%)	<i>15% (DBM 2008)</i>
7.3. Total medicines expenditures (local cur.)	<i>~PhP 110 billion including supplements (So 2009)</i> <i>~PhP 70-80 billion for pure medicines (Gloor 2010)</i>
7.4. Total medicines expenditures per capita (local cur.)	<i>~PhP 1,222.22</i>
7.5. Percent government medicines expenditures (% of total medicines expenditures)	<i>12% (Using 12-15 Billion [DOH + PhilHealth])</i>
7.6. Percent private medicines expenditures (% of total medicines expenditures)	<i>~88% (So 2009)</i>
<b>Health insurance</b>	
7.7. National Health Insurance (NHI) exists	<i>RA 7875 (National Health Insurance Act of 1995)</i>
7.8. If yes, NHI provides at least partial medicines coverage	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
7.9. Social Health Insurance (SHI) exists	<i>RA 7875 (National Health Insurance Act of 1995)</i>
7.10. If yes, SHI provides at least partial medicines coverage	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
7.11. Proportion of the population covered by NHI or SHI (% of population)	<i>&gt;80% (PhilHealth 2010)</i> <i>38% (NDHS 2008)</i>
7.12. List of medicines reimbursed by NHI or SHI and structure of reimbursement is available	<input checked="" type="checkbox"/> Yes <sup>&amp;</sup> <input type="checkbox"/> No

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

**Document source of each item and year collected:**

Item Number(s)	Source, Location, & Year	Comments
7.1, 7.2, 7.3	<p>Philippine National Health Accounts (2005), official reports, <a href="http://www.nscb.gov.ph/stats/pnha/2005/healthexp.asp">http://www.nscb.gov.ph/stats/pnha/2005/healthexp.asp</a>, 2005</p> <p><a href="http://www.sunstar.com.ph/cagayan-de-oro/health-group-bemoans-paltry-2010-health-budget">http://www.sunstar.com.ph/cagayan-de-oro/health-group-bemoans-paltry-2010-health-budget</a></p> <p>Approximate value collected from interview with Dr. Robert So, Head Executive Assistant, Department of Health, November 23, 2009</p> <p>DOH Budget Appropriation for 2009, <a href="http://www.dbm.gov.ph/NEP09/DOH/DOH.pdf">http://www.dbm.gov.ph/NEP09/DOH/DOH.pdf</a>, 2009</p> <p>Approximate value collected from interview with Mr. Reiner Gloor, Executive Director, Pharmaceutical and Healthcare Association of the Philippines, January 23, 2010</p>	<p>7.1, 7.2, 7.3</p> <p>PhP 4-5 Billion taken from 40% of total DOH MOOE.</p> <p>Estimates from Dr. So includes procurement of medicines and medicines for PhilHealth.</p>
7.4, 7.5, 7.6	<p>Approximate value collected from interview with Dr. Robert So, Head Executive Assistant, Department of Health, November 23, 2009</p>	<p>Item 7.4: Total expenditure (110B) divided by total population (87M)</p> <p>Item 7.5: 13B divided by 110B</p>
7.7, 7.8	<p>Republic Act 7875 - National Health Insurance Act of 1995, <a href="http://www.philhealth.gov.ph/about_us/others/ra7875.pdf">http://www.philhealth.gov.ph/about_us/others/ra7875.pdf</a>, 1995</p>	
7.9, 7.10	<p>Republic Act 7875 - National Health Insurance Act of 1995, <a href="http://www.livinginthephilippines.com/philippines_republic_act_7875s.html">http://www.livinginthephilippines.com/philippines_republic_act_7875s.html</a>, 1995</p>	
7.11	<p>PhilHealth Press Release: PhilHealth achieves universal coverage- February 11, 2010, <a href="http://www.philhealth.gov.ph/media/news/2010/unvrsl_cvrge.htm">http://www.philhealth.gov.ph/media/news/2010/unvrsl_cvrge.htm</a></p> <p>National Demographic Health Survey 2008, <a href="http://www.measuredhs.com/pubs/pdf/FR224/FR224.pdf">http://www.measuredhs.com/pubs/pdf/FR224/FR224.pdf</a>, 2009</p>	<p>According to the PhilHealth press release, 20 million Filipino families representing more than 80 percent of the entire RP population has PhilHealth coverage.</p> <p>Although it is the dominant insurance provider, PhilHealth coverage at the national level remains low (38 percent of the population). More than three-quarters of those covered by PhilHealth are covered by paying members, while 22 percent are covered as indigents. Half of all people covered by PhilHealth are dependents of paying members, while only 29 percent are direct paying members. Similarly, most of those who are covered as indigents are dependents of indigents. (NDHS 2008)</p>
7.12	<p>PhilHealth's Drug Price Reference Index (DPRI), <a href="http://www.doh.gov.ph/files/pharma50_final_dpri.pdf">http://www.doh.gov.ph/files/pharma50_final_dpri.pdf</a>, 2006</p> <p><a href="http://www.philhealth.gov.ph/circulars/index.htm">http://www.philhealth.gov.ph/circulars/index.htm</a> - includes guidelines for reimbursement of different health services</p>	<p>The DPRI lists recommended drug prices</p>

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

**Actual source:** Dr. Robert So, Head Executive Assistant of DOH

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

### Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
8.1	Executive Order No.663, <a href="http://www.doh.gov.ph/files/bakuna01.pdf">http://www.doh.gov.ph/files/bakuna01.pdf</a> , 2007	An example of a program where in pregnant mothers and infants are vaccinated free of charge.
8.2a-d, 8.3a-d	Interview with Dr. Robert So, Head Executive Assistant, Department of Health, November 23, 2009	
8.3e	Interview with Dr. Robert So, Head Executive Assistant, Department of Health, November 23, 2009	Anti-retroviral drugs are free
8.4a	Interview with Dr. Robert So, Head Executive Assistant, Department of Health, November 23, 2009	
8.4b	Interview with Dr. Robert So, Head Executive Assistant, Department of Health, November 23, 2009	Reimbursed by health insurance.

## 9. Medicines Financing: Patient Fees and Copayments

**Actual sources:** Dr. Robert So, Head Executive Assistant of DOH, Anecdotal Experience

Item	Value
9.1. Inpatients pay a fee for medicines in public hospitals	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <i>Depends on the medicine</i>
9.2. Registration/consultation fees are common in public primary care facilities	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
9.3. Dispensing fees are common in public primary care facilities	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
9.4. Medicines are free in public primary care facilities	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
9.5. If not, medicines copayments are used to pay salaries of public health care workers	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
9.6. Public sector medicines copayments are flat fees	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
a. If yes, fee amount (local cur.) <sup>6</sup>	
9.7. Public sector medicines copayments are percent copayment	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
a. If yes, percent (%)	

### Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
9.1	Philippine Health Policy Note: On Improving the Poor's Access to Affordable Drugs (World Bank), <a href="http://www.pcij.org/blog/wp-docs/World_Bank_Notes_on_Improving_Poor's_Access_to_Affordable_Medicines.pdf">http://www.pcij.org/blog/wp-docs/World_Bank_Notes_on_Improving_Poor's_Access_to_Affordable_Medicines.pdf</a> , 2002  Interview with Dr. Robert So, Head Executive Assistant, Department of Health, November 23, 2009	No categorical answer. It depends. Sometimes yes. Sometimes No.
9.2-9.4	Anecdotal experiences of the investigators (Dr. Noel Juban et al. 2009)  Interview with Dr. Robert So, Head Executive Assistant, Department of Health, November 23, 2009	Some local health centers encourage giving "donations" from patients. Some local health centers encourage/suggest replacements for dispensed free medicines.  Dispensing fees should not be done in public primary care facilities.  Medicines are not always free in public primary care facilities. But there are some medicines given for free.

## 10. Medicines Trade: Intellectual Property Laws

**Actual sources:** IIPA, WIPO, Intellectual Property Office of the Philippines

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

**&** If yes, obtain list and append to report

**Document source of each item and year collected:**

Item Number(s)	Source, Location, & Year	Comments
10.1	The Philippines International Intellectual Property Alliance (IIPA) 2009 Special 301 Report On Copyright Protection And Enforcement, <a href="http://www.ipophil.gov.ph/ipenforcement/2009%20IIPA_comments_Philippines.pdf">http://www.ipophil.gov.ph/ipenforcement/2009%20IIPA_comments_Philippines.pdf</a> , 2009  Republic Act 8293 (Intellectual Property Code of the Philippines), <a href="http://www.ipophil.gov.ph/IPCode/IPCodeMain.htm">http://www.ipophil.gov.ph/IPCode/IPCodeMain.htm</a> , 1997  Republic Act 9502 (Cheaper Medicines Act), <a href="http://www.doh.gov.ph/ra/cheaper_drugs">http://www.doh.gov.ph/ra/cheaper_drugs</a> , 2008	
10.1	World Intellectual Property Organization Philippines Data, <a href="http://www.wipo.int/edocs/notdocs/en/convention/treaty_convention_111.html">http://www.wipo.int/edocs/notdocs/en/convention/treaty_convention_111.html</a> , 1980	WIPO Notification No. 111 Convention establishing the World Intellectual Property Organization Ratification by the Republic of the Philippines

## 11. Medicines Trade: Registration

**Actual sources:** BFAD (11.1, 11.2, 11.4, 11.5, 11.9, 11.11), Ms. Regina Obligacion, FDRO III of BFAD (11.3, 11.8, 11.10, 11.12, 11.13)


Item	Value
11.1. An explicit and transparent process exists for assessing applications for registration of pharmaceutical products	<i>DOH AO 1989-066 (Rules and Regulations on the Process of Review and Evaluation of Questioned Drug or Drug Products)</i>  <i>DOH AO 1989-067 (Revised Rules and Regulations on Registration of Pharmaceutical Products)</i>
11.2. Functional formal committee exists responsible for assessing applications for registration of products	<i>BFAD Product Services Division Evaluators/Consultants</i>  <i>BFAD Inspecting and Licensing Division</i>
11.3. Conflict of interest declarations required for individuals responsible for approval of registration applications	<i>DOH AO 2007-042 (Norms of Behavior for Officials and Employees of the Department of Health)</i>
11.4. INN names are used to register medicines	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
11.5. 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.) <sup>6</sup>	<i>PhP 20,000 for 3 years + cost of laboratory analysis</i>

Item	Value
11.7. If yes, amount per application of a generic product (local cur.) <sup>6</sup>	PhP 2,000 (unbranded) or PhP 3,000 (branded) per year + cost of laboratory analysis
11.8. A transparent process exists to appeal medicines registration decisions	-BFAD Bureau Circular No.05 s.1997 -ACTD/ACTR Guidelines -Citizens Charter (Flow chart of drug product registration)
11.9. Medicine samples are tested as part of the registration process	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Tested for quality, purity and other physico-chemical qualities
11.10. List of registered products is publicly available, identifying originator brands, branded generics, and generics	Upon request
11.11. List and application status of products submitted for registration are publicly available	<input checked="" type="checkbox"/> Yes <sup>&amp;</sup> <input type="checkbox"/> No
11.12. Average length of time from submission of a patented product application to decision (average number of days)	180 to 270 days (6 to 9 months)
11.13. Average length of time from submission of a generic product application to decision (average number of days)	90 to 180 days (3 to 6 months)

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

#### Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
11.1	Department of Health Administrative Order No. 66 s. 1989, <a href="http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO66s1989.pdf">http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO66s1989.pdf</a> , 1989  Department of Health Administrative Order No. 67 s. 1989, <a href="http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO67s1989.pdf">http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO67s1989.pdf</a> , 1989	Administrative Order No. 66 details the procedures and specifics when drug products are banned from the market.  Administrative Order No. 67 details the procedures and requirements for registration of drug products.
11.2	The PSD Evaluators are responsible for assessing the application status for product registration. Otherwise, according to Republic Act 3720, <a href="http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=691">http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=691</a> , 1963  "Chapter III, Section 5. The Food and Drug Administration shall have the following Divisions:  "a. Inspection and Licensing Division, which shall have charge of the inspection of food, drug and cosmetic establishment engaged in their manufacture and sale." (RA 3720)	Revised by Executive Order 175 in 1987
11.3	Department of Health Administrative Order No. 42 s. 2007, <a href="http://www.doh.gov.ph/files/ao2007-0042.pdf">http://www.doh.gov.ph/files/ao2007-0042.pdf</a> , 2007  Rule IV Fidelity to Duty, Section 10  "DOH officials and employees shall submit performance reports and other documents required by law such as Statement of Assets and Liabilities and Net worth, Income Tax Returns and other public documents as may be required by the agency" (AO 2007-042)	Although not explicitly stated, conflict of interest statements constitute "other public documents"  Rule VII specifically deals with conflict of interests.

Item Number(s)	Source, Location, & Year	Comments
11.4	<p>Republic Act 6675, <a href="http://www.doh.gov.ph/ra/ra6675">http://www.doh.gov.ph/ra/ra6675</a>, 1988</p> <p><i>Section 3 (11)</i></p> <p><i>“Generic Drugs’ are drugs not covered by patent protection and which are labeled solely by their international non-proprietary or generic name.” (RA 6675)</i></p> <p>BFAD Form No. 8 “Application for Registration of Pharmaceutical Product”, date unknown</p> <p><a href="http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=953">http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=953</a></p> 	Part of registration of a drug involves inputting the INN or generic name.
11.5, 11.6, 11.7	<p>Department of Health Administrative Order No. 67 s. 1989, <a href="http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO67s1989.pdf">http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO67s1989.pdf</a>, 1989</p> <p>Department of Health Administrative Order No. 50 s. 2001, <a href="http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=800">http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=800</a>, 2001</p>	Prices and cost of laboratory analysis are as of December 17, 2001
11.8	<p>Department of Health Administrative Order No. 67 s. 1989, <a href="http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO67s1989.pdf">http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO67s1989.pdf</a>, 1989</p> <p><i>Section 7</i></p> <p><i>“APPEAL. Disapproved application(s) may be appealed to the Secretary of Health for reconsideration.” (AO No. 1989-067)</i></p> <p>Data via e-mail from BFAD c/o Ms. Regina Obligacion, FDRO III, December 2009</p>	<p>The process for appeals follow:</p> <ul style="list-style-type: none"> <li>• BFAD Bureau Circular No.05 s.1997</li> <li>• ACTD/ACTR Guidelines</li> <li>• Citizens Charter (Flow chart of drug product registration)</li> </ul>
11.9	<p>Department of Health Administrative Order No. 67 s. 1989, <a href="http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO67s1989.pdf">http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO67s1989.pdf</a>, 1989</p> <p><i>“4.3. Evaluation by Testing of Submitted Samples</i></p> <p><i>BFAD evaluates submitted samples of drug product. The evaluation shall cover tests for quality, purity and other physico-chemical qualities.” (AO No. 1989-067)</i></p>	

Item Number(s)	Source, Location, & Year	Comments
11.10	Data via e-mail from BFAD c/o Ms. Regina Obligacion, FDRO III, December 2009	It is not publicly available but may be obtained upon presentation of a written request and reason/s for requesting the same.
11.11	<p><a href="http://www.bfad.gov.ph/default.cfm?page_id=1192&amp;parent=0">http://www.bfad.gov.ph/default.cfm?page_id=1192&amp;parent=0</a>, 2009</p> <p>BFAD Website "Frequently Asked Questions", <a href="http://www.bfad.gov.ph/default.cfm?page_id=949&amp;parent=636">http://www.bfad.gov.ph/default.cfm?page_id=949&amp;parent=636</a>, 2009</p> <p>"1. How do we know if a certain product is registered with BFAD?"</p> <p><i>For product registration verification, consumers may contact the Policy, Planning, and Advocacy Division at telephone number 8425606. Consumers are advised to provide details such as the complete product name, registration number, and name of Manufacturer or distributor."</i></p>	<p>List of product applications are available per month starting from July 2009 until September 2009.</p> <p>Application status (approved or rejected) is not available publicly. One may call the BFAD to know the status of the listed products since the details of product name, registration number, and name of Manufacturer/distributor are listed.</p>
11.12 – 11.13	Data via e-mail from BFAD c/o Ms. Regina Obligacion, FDRO III, December 2009	

## 12. Medicines Trade: Manufacturing

**Actual sources:** BFAD (12.1, 12.3, 12.8, 12.9), Ms. Regina Obligacion, FDRO III of BFAD (12.2, 12.5c, 12.5d, 12.8, 12.9, 12.10, 12.11), PHAP Factbook 7<sup>th</sup> ed. (12.4, 12.6, 12.7, 12.10, 12.11), Mr. Reiner Gloor, Executive Director of PHAP (12.5a, 12.5b),

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	<p><i>RA 3720 (Food, Drug and Cosmetic Act)</i></p> <p><i>DOH AO 1989-056 (Revised regulations for the Licensing of Drug Establishments &amp; Outlets)</i></p> <p><i>DOH AO 2005-031 (Guidelines and Procedures for the Issuance of the Principal Certificate of Product Registration and the Listing of Identical Drug Products Based on the Identity of Manufacturer and Pharmaceutical Formulation)</i></p>
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:	0 (Gloor 2009)
a. R&D to discover new active substances	
b. Production of pharmaceutical starting material	0 (Gloor 2009)
c. Formulation from pharmaceutical starting material	89 (FDA 2009)

Item	Value
d. Repackaging of finished dosage forms	13 (FDA 2009)
12.6. Percentage of market share <b>by volume</b> produced by domestic manufacturers (%)	48% (PHAP 2008)
12.7. Percentage of market share <b>by value</b> produced by domestic manufacturers (%)	31% (PHAP 2008)
<b>Multinational manufacturers</b>	
12.8. Legal provisions exist for licensing multinational manufacturers that produce medicines locally	RA 3720 (Food, Drug and Cosmetic Act) DOH AO 1989-056  DOH AO 2004-142 (Bureau of Food and Drug's issuance of Certificate of Product Registration for Foreign Assisted Projects Procurement and Laboratory Testing of Pharmaceutical and Biological Products Procured by and/or delivered to the Department of Health)
12.9. Legal provisions exist for licensing importers	RA 3720 (Food, Drug and Cosmetic Act)  DOH AO 1989-056  DOH AO 2005-031
12.10. Number of and list of multinational pharmaceutical companies with a local subsidiary is available	<input checked="" type="checkbox"/> Yes <sup>&amp;</sup> <input type="checkbox"/> No
12.11. Number and list of multinational pharmaceutical companies producing medicines locally is available	<input checked="" type="checkbox"/> Yes <sup>&amp;</sup> <input type="checkbox"/> No

**&**: If yes, obtain list and append to report

**Document source of each item and year collected:**

Item Number(s)	Source, Location, & Year	Comments
12.1	BFAD List of Establishments with CERTIFICATE OF GOOD MANUFACTURING PRACTICE, <a href="http://www.bfad.gov.ph/default.cfm?page_id=1302&amp;parent=0">http://www.bfad.gov.ph/default.cfm?page_id=1302&amp;parent=0</a> , 2009	As of December 29, 2009; Website not available on some occasions
12.2	Data via e-mail from BFAD c/o Ms. Regina Obligation, FDRO III, December 2009	Type of sanctions: Record of violation, Cease and Decease Order, Revocation of License to Operate
12.3	Department of Health Administrative Order No. 56 s. 1989: Revised Regulations For The Licensing Of Drug Establishments And Outlets, <a href="http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO56s1989.pdf">http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO56s1989.pdf</a> , 1989 <i>"Contains provisions on <b>Standards and Requirements for License to Operate (LTO)</b>: Any entity applying for a license to operate as a drug manufacturer, drug trader or drug distributor shall be required to demonstrate its capacity to perform adequately as such in a manner that satisfactorily assures the safety, efficacy and quality of its drug products."</i> (AO 1989-056)  Department of Health Administrative Order No. 31 s. 2005, <a href="http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=541">http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=541</a> , 2005  The World Medicine Situation Statistical Annex (WHO 2004), <a href="http://www.who.int/medicinedocs/index.fcgi?sid=zNnGhaRZ9ee80ca60000000476162bf&amp;a=d&amp;c=medicinedocs&amp;d=Js6160e">http://www.who.int/medicinedocs/index.fcgi?sid=zNnGhaRZ9ee80ca60000000476162bf&amp;a=d&amp;c=medicinedocs&amp;d=Js6160e</a> , 2004	
12.4	Philippine Pharmaceutical Industry Factbook 7 <sup>th</sup> Edition, <a href="http://www.phap.org.ph/images/page/main.factbook/factbook_11_2008.pdf">http://www.phap.org.ph/images/page/main.factbook/factbook_11_2008.pdf</a> , 2008  Data via e-mail from BFAD c/o Ms. Regina Obligation, FDRO III, December 2009	
12.5a, 12.5b	Interview with Mr. Reiner W. Gloor, Executive Director, Pharmaceutical and Health Association of the Philippines, December 14, 2009	No available data from FDA.  As of present, there are no domestic drug manufacturers involved in R&D in discovering new active substances and producing pharmaceutical starting materials.
12.5c, 12.5d	Data via e-mail from BFAD c/o Ms. Regina Obligation, FDRO III, December 2009	

12.6	Philippine Pharmaceutical Industry Factbook 7 <sup>th</sup> Edition, <a href="http://www.phap.org.ph/images/page/main.factbook/factbook_11_2008.pdf">http://www.phap.org.ph/images/page/main.factbook/factbook_11_2008.pdf</a> , 2008  "Local pharmaceutical companies cumulatively sold 21.36 billion units in the market for a 47.7% share in total actual units sold." (PHAP Factbook)	Expressed in counting units sold in pesos (as of 2007)
12.7	Philippine Pharmaceutical Industry Factbook 7 <sup>th</sup> Edition, <a href="http://www.phap.org.ph/images/page/main.factbook/factbook_11_2008.pdf">http://www.phap.org.ph/images/page/main.factbook/factbook_11_2008.pdf</a> , 2008	Expressed % Share in pesos (as of 2007)
12.8	Republic Act 3720, <a href="http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=691">http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=691</a> , 1963  Department of Health Administrative Order No. 56 s. 1989: Revised Regulations For The Licensing Of Drug Establishments And Outlets, <a href="http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO56s1989.pdf">http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO56s1989.pdf</a> , 1989  Department of Health Administrative Order No. 142 s. 2004, <a href="http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO142s2004.pdf">http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO142s2004.pdf</a> , 2004  Data via e-mail from BFAD c/o Ms. Regina Obligacion, FDRO III, December 2009	
12.9	Republic Act 3720, <a href="http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=691">http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=691</a> , 1963  Department of Health Administrative Order No. 56 s. 1989: Revised Regulations For The Licensing Of Drug Establishments And Outlets, <a href="http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO56s1989.pdf">http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO56s1989.pdf</a> , 1989  Department of Health Administrative Order No. 31 s. 2005, <a href="http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=541">http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=541</a> , 2005  Data via e-mail from BFAD c/o Ms. Regina Obligacion, FDRO III, December 2009	
12.10, 12.11	Philippine Pharmaceutical Industry Factbook 7 <sup>th</sup> Edition, <a href="http://www.phap.org.ph/images/page/main.factbook/factbook_11_2008.pdf">http://www.phap.org.ph/images/page/main.factbook/factbook_11_2008.pdf</a> , 2008  Data via e-mail from BFAD c/o Ms. Regina Obligacion, FDRO III, December 2009	

### 13. Medicines Trade: Quality Assurance

**Actual sources:** BFAD (13.1), DOH (13.1, 13.2, 13.3, 13.4), Ms. Regina Obligacion, FDRO III of BFAD (13.5, 13.6, 13.7)

Item	Value
13.1. Legal provisions exist to inspect premises and collect samples	<i>RA 3720 (Food, Drug and Cosmetic Act)</i> <i>RA 9711 (FDA Act of 2009)</i> <i>RA 8203 (Special Law on Counterfeit Drugs)</i> <i>AO 1999-43</i>
13.2. Legal provisions exist for detecting and combating counterfeit medicines	<i>RA 8203</i>
13.3. Legal provisions exist to ensure quality control of imported medicines	<i>RA 3720 (Food, Drug and Cosmetic Act)</i> <i>RA 6675 (Generics Act of 1988)</i>
13.4. Legal provisions exist to ensure quality control of locally produced medicines	<i>RA 6675 (Generics Act of 1988)</i>
13.5. Total number of samples tested for quality in past year, [including samples tested at importation, for registration, or sampled from market]	<i>Upon request from FDA</i>
13.6. Total number of above samples that failed quality testing in past year	<i>Upon request from FDA</i>
13.7. List is publicly available giving detailed results of quality testing in past year	<i>Upon request from FDA</i>

**Document source of each item and year collected:**

Item Number(s)	Source, Location, & Year	Comments
13.1	<p>Republic Act 3720, <a href="http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=691">http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=691</a>, 1963</p> <p>Republic Act 9711, <a href="http://www.senate.gov.ph/republic_acts/ra%209711.pdf">http://www.senate.gov.ph/republic_acts/ra%209711.pdf</a>, 2008</p> <p>Republic Act No. 8203 - Special Law on Counterfeit Drugs, <a href="http://www.doh.gov.ph/ra/ra8203">http://www.doh.gov.ph/ra/ra8203</a>, 1996</p> <p>Administrative Order 43 series of 1999 as amended <a href="http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO43s1999.pdf">http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO43s1999.pdf</a></p> <p><i>Section 2 – “The premises for manufacturing shall be of suitable size, design, construction and location to facilitate proper operation, cleaning and maintenance. The individual working areas shall be adequate so that any risk of confusion, cross-contamination and other mistakes that will adversely affect the quality of drugs and devices will be avoided.”</i></p>	
13.2	<p>Republic Act No. 8203 - Special Law on Counterfeit Drugs, <a href="http://www.doh.gov.ph/ra/ra8203">http://www.doh.gov.ph/ra/ra8203</a>, 1996</p>	
13.3	<p>Republic Act 3720, <a href="http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=691">http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=691</a>, 1963</p> <p>Republic Act No. 6675 - Generics Act of 1988, <a href="http://www.doh.gov.ph/ra/ra6675">http://www.doh.gov.ph/ra/ra6675</a>, 1988</p>	Section 10 lists the provisions on procurement of drugs through importation
13.4	<p>Republic Act No. 6675 - Generics Act of 1988, <a href="http://www.doh.gov.ph/ra/ra6675">http://www.doh.gov.ph/ra/ra6675</a>, 1988</p>	Section 7 – DOH is responsible for quality control
13.5-7	Data via e-mail from BFAD c/o Ms. Regina Obligacion, FDRO III, December 2009	The list is not publicly available but can be requested from the BFAD.

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

**Actual sources:** DOH (14.1, 14.3, 14.4, 14.5), Dr. Robert So, Head Executive Assistant of DOH (14.2, 14.4, 14.5)

Item	Value
<b>Legal or regulatory provisions for medicines price control</b>	
14.1. Legal or regulatory provisions exist for setting	<i>RA 9502 (Universally Accessible Cheaper and Quality Medicine Act of 2008)</i>
a. Manufacturer selling price	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
b. Maximum wholesale markup	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
c. Maximum retail markup	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
d. Duty on imported raw materials	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
e. Duty on imported finished products	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
f. VAT or other taxes on medicines	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
14.2. Legal or regulatory provisions for controlling medicines prices vary for different types of medicines	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
<b>Medicines price transparency</b>	
14.3. Government runs an active national medicine price monitoring system for retail prices	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <i>LGUs, DTI, DOH</i>

Item	Value
14.4. Regulations exist mandating that retail medicine price information should be publicly accessible	IRR of RA 9502
14.5. Consumer price of medicines on the list of top 20 medicines is publicly available	<input checked="" type="checkbox"/> Yes & <input type="checkbox"/> No

&. If yes, obtain list and append to report

#### Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
14.1a-c	Joint DOH-DTI-IPO-BFAD Administrative Order No. 2008-01: The Implementing Rules and Regulation of RA 9502, <a href="http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=1234">http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=1234</a> , 2008 <i>Chapter VI</i> "Section 1. Power of the President to Impose MRP. The President of the Philippines, upon recommendation of the Secretary of Health, shall have the power to impose MRP over any or all drugs and medicines. (17)" "Section 3. Coverage of MRP. The MRP shall be construed as the imposition of maximum prices at all levels of the supply chains including but not limited to manufacturer's price, trader's price, distributor's price and wholesaler's price, and retailer's price. (19A, 19F, 26a)." (IRR of RA 9502)	The MRP is maximum price a drug will cost to the buying public as mandated by law.
14.1d-e	Executive Order 64, <a href="http://www.tariffcommission.gov.ph/eo_264.htm">http://www.tariffcommission.gov.ph/eo_264.htm</a> , 2003 <a href="http://www.tariffcommission.gov.ph/EO%20264%20annex.pdf">http://www.tariffcommission.gov.ph/EO%20264%20annex.pdf</a> , 2003	Annex A lists raw materials and finished products and the rates of duties.
14.1f	Republic Act 9337, <a href="http://www.lawphil.net/statutes/repacts/ra2005/ra_9337_2005.html">http://www.lawphil.net/statutes/repacts/ra2005/ra_9337_2005.html</a> , 2005	VAT is currently at 12%.
14.2	Joint DOH-DTI-IPO-BFAD Administrative Order No. 2008-01: The Implementing Rules and Regulation of RA 9502, <a href="http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=1234">http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=1234</a> , 2008 <i>Chapter V Section 5</i>  Interview with Dr. Robert So, Head Executive Assistant, Department of Health, November 23, 2009	Section 5 lists the types of drugs that may subject to price regulation. Any drug that does not fulfill the specifications listed by Section 5 will not be subject to price regulation.
14.3	Joint DOH-DTI-IPO-BFAD Administrative Order No. 2008-01: The Implementing Rules and Regulation of RA 9502, <a href="http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=1234">http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=1234</a> , 2008 <i>Chapter XII</i> "Rule 62. Reports from Local Government Units (LGUs) and the Department of Trade and Industry (DTI). All local government units and the DTI shall help ensure the implementation of pricing policies provided under the Act and these Implementing Rules and Regulations by submitting quarterly price monitoring reports to the Secretary of Health of drugs and medicines identified by the latter, and any and all necessary information that the Secretary of Health may require. (27)" (IRR of RA 9502)	A multi-departmental approach for monitoring is implemented.

14.4	<p>Joint DOH-DTI-IPO-BFAD Administrative Order No. 2008-01: The Implementing Rules and Regulation of RA 9502, <a href="http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=1234">http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=1234</a>, 2008</p> <p><i>Rule 44</i></p> <p><i>“e. Drug outlets, including drugstores, hospital and non-hospital pharmacies and non-traditional outlets such as supermarkets, convenience stores and other retail establishments, shall inform any buyer about any and all other drug products having the same generic name, together with their corresponding prices so that the buyer may adequately be informed to exercise his option. (38d, n)”</i></p> <p><i>“The drug outlets referred to herein shall post in conspicuous places as determined by the BFAD in their establishments a list of drug products with the same generic names and their corresponding prices and shall form part of the licensing requirements for such outlets. (38d, n) Posting of information shall be through, but not limited to, the following: hard copies, printed materials, or through programmed computers accessible to the public. (n)” (IRR of RA 9502)</i></p>	Pharmacies have a price catalog beside the dispensing counter. The catalog contains all the drug products the pharmacy dispenses including the generic name, price, manufacturer, and dosage.
14.5	<p>PhilHealth’s Drug Price Reference Index (DPRI), <a href="http://www.doh.gov.ph/files/FINAL_DPRI_0.pdf">http://www.doh.gov.ph/files/FINAL_DPRI_0.pdf</a>, 2006</p> <p>Joint DOH-DTI-IPO-BFAD Administrative Order No. 2008-01: The Implementing Rules and Regulation of RA 9502, <a href="http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=1234">http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=1234</a>, 2008</p> <p><i>Rule 44</i></p> <p><i>“e. Drug outlets, including drugstores, hospital and non-hospital pharmacies and non-traditional outlets such as supermarkets, convenience stores and other retail establishments, shall inform any buyer about any and all other drug products having the same generic name, together with their corresponding prices so that the buyer may adequately be informed to exercise his option. (38d, n)”</i></p> <p><i>“The drug outlets referred to herein shall post in conspicuous places as determined by the BFAD in their establishments a list of drug products with the same generic names and their corresponding prices and shall form part of the licensing requirements for such outlets. (38d, n) Posting of information shall be through, but not limited to, the following: hard copies, printed materials, or through programmed computers accessible to the public. (n)” (IRR of RA 9502)</i></p>	<p>DPRI has not yet been updated because the prices are stable.</p> <p>Drugstores are required to post the list of top 20 medicines (and all other prices).</p>

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

**Actual source:** The Prices People Have to Pay for Medicines in the Philippines by Dennis B. Batangan, M.D., M.Sc. et al. 2005

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:	17.28 (Batangan 2005)
a. Originator brand products (Median MPR)	
b. Lowest price generics (Median MPR)	5.64 (Batangan 2005)

Item	Value
15.2. Median manufacturer selling price (CIF) as percent of retail price for a basket of key medicines (%)	<i>Data not available</i>
15.3. Median wholesaler selling price as percent of retail price for a basket of key medicines (%)	<i>Data not available</i>
15.4. Median pharmacist mark-up or dispensing fee as percent of retail price for a basket of key medicines (%)	<i>Data not available</i>
15.5. Maximum VAT and other taxes and duties as percent of retail price for a basket of key medicines (%)	13.4 ( <i>Batangan 2005</i> )
15.6. Maximum manufacturer selling price (CIF) as percent of retail price for a basket of key medicines (%)	26.8 ( <i>Batangan 2005</i> )
15.7. Maximum wholesaler selling price as percent of retail price for a basket of key medicines (%)	23.5 ( <i>Batangan 2005</i> )
15.8. Maximum pharmacist mark-up or dispensing fee as percent of retail price for a basket of key medicines (%)	29.8 ( <i>Batangan 2005</i> )

**Document source of each item and year collected:**

Item Number(s)	Source, Location, & Year	Comments
15.1	The Prices People Have to Pay for Medicines in the Philippines Dennis B. Batangan, M.D., M.Sc. et al. <a href="http://www.haiweb.org/medicineprices/surveys/200502PH/sdocs/survey_report.pdf">http://www.haiweb.org/medicineprices/surveys/200502PH/sdocs/survey_report.pdf</a> , 2005 <i>“Looking at the MPR range, the originator brands ranged from 3.33 to 184.09 while that of the cheapest generics were 2.32 to 26.10.” (The Prices People Have to Pay...)</i>	Survey done between February and April 2005 in private pharmacies involving core and non-core drugs. Of the 51 private pharmacies surveyed, a total of 29 branded medicines and 23 generics were included.
15.5	The Prices People Have to Pay for Medicines in the Philippines Dennis B. Batangan, M.D., M.Sc. et al. <a href="http://www.haiweb.org/medicineprices/surveys/200502PH/sdocs/survey_report.pdf">http://www.haiweb.org/medicineprices/surveys/200502PH/sdocs/survey_report.pdf</a> , 2005	Includes VAT, import tariff and national corporate taxes
15.6-15.8	The Prices People Have to Pay for Medicines in the Philippines Dennis B. Batangan, M.D., M.Sc. et al. <a href="http://www.haiweb.org/medicineprices/surveys/200502PH/sdocs/survey_report.pdf">http://www.haiweb.org/medicineprices/surveys/200502PH/sdocs/survey_report.pdf</a> , 2005	Maximum potential price component

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

Actual sources: HAI Survey 2005

[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	3.11	--	3.33	2.52
16.2. Glibenclamide 5 mg Cap/tab	27.85	13.59	44.56	22.28
16.3. Atenolol 50 mg Cap/tab	29.17	10.80	47.73	14.83
16.4. Captopril 25 mg Cap/tab	17.30	7.44	17.99	6.92
16.5. Simvastatin 20 mg Cap/tab	--	--	--	--
16.6. Amitriptyline 25 mg Cap/tab	--	--	--	--
16.7. Ciprofloxacin 500 mg Cap/tab	42.22	19.49	44.84	15.51
16.8. Co-trimoxazole 8 + 40 mg/ml Susp.	<i>Data for this particular formulation is not available</i>			
16.8a. Co-trimoxazole 40 + 200 mg/ml Susp.	--	4.65	11.38	3.81
16.9. Amoxicillin 500 mg Cap/tab	--	3.24	6.90	4.78
16.10. Ceftriaxone 1 g/ vial Injection	6.13	1.70	7.62	3.75
16.11. Diazepam 5 mg Cap/tab	--	--	--	--
16.12. Diclofenac 50 mg Cap/tab	--	--	41.55	17.91
16.13. Paracetamol 24 mg/ml Susp.	--	6.90	18.28	8.62
16.14. Omeprazole 20 mg Cap/tab	8.81	--	10.34	3.87

Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
16.1, 16.2, 16.3, 16.4, 16.7, 16.8a, 16.9, 16.10, 16.12, 16.14	HAI Survey February 2005, <a href="http://www.haiweb.org/medicineprices/">http://www.haiweb.org/medicineprices/</a> , 2005	
16.13	HAI Survey 2002, <a href="http://www.haiweb.org/medicineprices/">http://www.haiweb.org/medicineprices/</a> , 2002	
16.5, 16.6, 16.11	No data available	

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

**Actual sources:** BFAD (17.1, 17.2, 17.4), Ms. Regina Obligacion, FDRO III of BFAD (17.5, 17.7, 17.8), Atty. Estanislao Granados, Executive Director of Procurement Service (17.6)

Item	Value
17.1. Legal provisions exist to control the promotion and/or advertising of prescription medicines	DOH AO 1989-065 (Guidelines on Advertisement and Promotions to Implement the Generics Act Of 1988)
17.2. Legal provisions exist to make direct advertising to the public illegal	DOH AO 1989-065
17.3. Legal provisions exist to control gifts from the pharmaceutical industry to prescribers	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No But self-regulation exists
17.4. Regulatory pre-approval is required for medicines advertisements and/or promotional materials	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No RA 3720 AO 1989-065
17.5. Regulatory committee exists for controlling medicines advertising and promotion	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
a. If yes, committee procedures are clearly documented and publicly available	Upon request
b. If yes, list of committee members is publicly available	Upon request
c. If yes, members must declare conflicts of interest	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
17.6. Standard Operating Procedures (SOP) exist governing the behavior of public procurement agencies in their interactions with sales representatives/wholesalers	RA 9184 (Government Procurement Reform Act of 2003)
17.7. Reports of complaints regarding promotional practices are publicly available	Upon request
17.8. Number of violations and sanctions related to legal provisions controlling advertising of medicines	2 in year 2008

&: If yes, obtain list and append to report

### Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
17.1	Department of Health Administrative Order No. 65 s. 1989, <a href="http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO65s1989.pdf">http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO65s1989.pdf</a> , 1989  Section 2.3  "No pharmaceutical product classified by BFAD as a Prescription or Ethical Drug shall be advertised or promoted in any form of mass media except through medical journals, publications and/or literature solely intended for medical and allied professions." (AO 1989-065)	.
17.2	Department of Health Administrative Order No. 65 s. 1989, <a href="http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO65s1989.pdf">http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO65s1989.pdf</a> , 1989  Section 2.3  "No pharmaceutical product classified by BFAD as a Prescription or Ethical Drug shall be advertised or promoted in any form of mass media except through medical journals, publications and/or literature solely intended for medical and allied professions." (AO 1989-065)	Direct advertising is defined as marketing of prescription and ethical medicines directed toward patients. Only advertising of prescription and ethical medicines directed towards dispensers is allowed.

17.3	<p>Press Releases – House of Representatives of the Philippines “Solon seeks ban on medical gift giving”, <a href="http://www.congress.gov.ph/press/details.php?pressid=3246">http://www.congress.gov.ph/press/details.php?pressid=3246</a>, 2009</p>	<p>No law has yet been passed. House Bill 6063 or the Medical Gift Giving Ban Act of 2009 is still in the House of Representatives pending to be passed to the Senate.</p>
17.4	<p>RA 3720 – PTC drugs can be advertised freely, but prescription drugs can only be advertised on scientific journals.</p> <p>Department of Health Administrative Order No. 65 s. 1989, <a href="http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO65s1989.pdf">http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO65s1989.pdf</a>, 1989</p> <p><i>Section 4.3</i></p> <p><i>“No prior clearance from BFAD is required for initial printing and broadcast or dissemination of advertisement and other promotional materials for drug products.” (AO 1989-065)</i></p>	
17.5	<p>Department of Health Administrative Order No. 65 s. 1989, <a href="http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO65s1989.pdf">http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO65s1989.pdf</a>, 1989</p> <p><i>Section 4.4</i></p> <p><i>“BFAD shall monitor advertisement and promotion of drug products as well as receive complaints regarding these. On the basis of its monitored finding or complaints, BFAD shall determine if any advertising or promotional material violates these guidelines” (AO 1989-065)</i></p> <p>Data via e-mail from BFAD c/o Ms. Regina Obligacion, FDRO III, December 2009 :</p> <p><i>“The Ads Standard Council (ADS), formerly ADBOARD, is the office in charge and responsible for issuing permit for any advertisement or commercial through TV, radio and print media. The FDA’s role is post monitoring, i.e., if the product is registered, if claims are approved including label and packaging.”</i></p>	
17.5	<p>Anecdotal experience of the investigators (Dr. Noel Juban et al. 2009)</p>	<p>Upon contacting the Ads Standard Council, the investigators were advised to write to the OIC, Ms. Cris Dasig to request for the procedures and the list of committee members.</p>
17.6	<p>Republic Act 9184, <a href="http://www.philgeps.net/GEPS/ViewAnnex.aspx?FileType=RulesRegulationsPath&amp;NameOfFile=549c53d2-2dee-4bc2-9c87-0a79d6d67d6a.pdf&amp;FileName=RA_9184.pdf">http://www.philgeps.net/GEPS/ViewAnnex.aspx?FileType=RulesRegulationsPath&amp;NameOfFile=549c53d2-2dee-4bc2-9c87-0a79d6d67d6a.pdf&amp;FileName=RA_9184.pdf</a>, 2002</p> <p><i>Article XX Section 63</i></p> <p>Interview with Atty. Estanislao Granados, Executive Director, Procurement Service, Department of Budget and Management, December 7, 2009</p>	<p>The procedures for public procurement are listed. The processes are made transparent. Disclosure of relations and conflict of interest statements are also required from the bidders.</p> <p>The Procurement Service has a policy of no contact and no gift-receiving from bidders during the bidding process.</p>

17.7	Data via e-mail from BFAD c/o Ms. Regina Obligacion, FDRO III, December 2009	The Legal Information and Compliance Division (LICD) in FDA is the office in charge of reports of complaint / violation re promotional sale practices. The public may secure reports of complaint upon presentation of written request and reason/s for requesting the same.
17.8	Data via e-mail from BFAD c/o Ms. Regina Obligacion, FDRO III, December 2009	

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

**Actual sources:** PMA (18.1), PHAP Factbook 7<sup>th</sup> ed. (18.2), Mr. Reiner Gloor, Executive Director of PHAP (18.2, 18.3), BIR (18.3),

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

### Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
18.1	Code of Ethics of Philippine Medical Association, <a href="http://www.thepafp.org/pdfs/FINAL-PMA-CODEOFETHICS2008.pdf">http://www.thepafp.org/pdfs/FINAL-PMA-CODEOFETHICS2008.pdf</a> , 2008	Provisions in Article VI of the Code of Ethics
18.2a-c	PHAP Code of Ethics- Philippine Pharmaceutical Industry Factbook 7 <sup>th</sup> Edition, <a href="http://www.phap.org.ph/images/page/main.factbook/factbook_11_2008.pdf">http://www.phap.org.ph/images/page/main.factbook/factbook_11_2008.pdf</a> , 2008  Department of Health Administrative Order No. 65 s. 1989, <a href="http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO65s1989.pdf">http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO65s1989.pdf</a> , 1989  Department of Health Administrative Order No. 55 s. 1988, <a href="http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO55s1988.pdf">http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO55s1988.pdf</a> , 1988  Republic Act 3720, <a href="http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=691">http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=691</a> , 1963  <i>Chapter II Section 4</i>	Monitoring is by self-regulation.  The PHAP Code covers not only member companies of PHAP but also local subsidiaries of IFPMA member companies.

18.2d	Data via e-mail from BFAD c/o Ms. Regina Obligacion, FDRO III, December 2009  Interview with Mr. Reiner W. Gloor, Executive Director, Pharmaceutical and Health Association of the Philippines, December 14, 2009	The public may secure reports of complaint upon presentation of written request and reason/s for requesting the same.  PHAP also has a list of complaints and may be obtained through a written request.
18.3	Republic Act 8424 TAX REFORM ACT OF 1997, <a href="http://www.bir.gov.ph/taxcode/taxcode.htm#nirc_outline">http://www.bir.gov.ph/taxcode/taxcode.htm#nirc_outline</a> , 1997  <a href="http://www.bir.gov.ph/taxcode/1593.htm">http://www.bir.gov.ph/taxcode/1593.htm</a> , 1997  Interview with Mr. Reiner W. Gloor, Executive Director, Pharmaceutical and Health Association of the Philippines, December 14, 2009	Companies' financial statement is also submitted in filing income tax.  Advertising and promotion budget is included in the financial statements of pharmaceutical companies, although the breakdown is not publicly available.

## 19. Medicines Supply System: Selection

**Actual sources:** PhilHealth (19.1), PNDF (19.2, 19.3, 19.4)

Item	Value
19.1. 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	2006
19.2. National essential medicines list (EML) exists.	PNDF
a. If yes, number of unique medicine formulations on the national EML	1,509
b. If yes, frequency of revisions over the past 20 years	7
c. If yes, year of last update in EML	2008
d. If yes, process for selecting medicines on the EML are clearly documented and publicly available	PNDF Appendices H, J and K
e. If yes, criteria for selecting medicines on the EML are clearly documented and publicly available	PNDF Appendices H, J and K
f. If yes, list of national EML committee members is publicly available	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Appendix of PNDF
g. 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. Explicit criteria for selecting medicines on national EML	PNDF Appendices V and J
19.4. National medicines formulary manual exists.	PNDF
a. If yes, national medicines formulary manual is limited to essential medicines	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
b. If yes, year of last update in national medicines formulary manual	2008

&: If yes, obtain list and append to report

**Document source of each item and year collected:**

Item Number(s)	Source, Location, & Year	Comments
19.1	The HTA Forum volume 4 no. 1, 2006 – Performance Report on Philhealth use of CPGs for Quality Assurance and accreditation, <a href="http://www.philhealth.gov.ph/providers/download/hta_forum_v4n1-2006.pdf">http://www.philhealth.gov.ph/providers/download/hta_forum_v4n1-2006.pdf</a> 2006	Lists CPGs for: Pediatric and Adult CAP, Acute Appendicitis, Hypertension, Acute Bronchitis, Dyspepsia, Acute Bronchitis, Adult Asthma, UTI, Acute Gastroenteritis and Maternity Care
19.2, 19.3, 19.4	Philippine National Drug Formulary/Essential Drug List, 7 <sup>th</sup> Edition, 2008	19.2d and e – Guidelines for classification included in Appendix H, J and K respectively 19.2g – Yes but there is no explicit statement to this effect in the selection of resource persons/committee members. Conflict of interest declaration is included in the application form for members of the Formulary committee. 19.3 – Located in Appendix V and J 19.4 – Essential Drug list is integrated with the national Drug Formulary

**20. Medicines Supply System: Procurement in the Public Sector**

**Actual sources:** Atty. Estanislao Granados, Executive Director of Procurement Service (20.1, 20.3, 20.5, 20.6, 20.7, 20.8), Dr. Robert So, Head Executive Assistant of DOH (20.2, 20.9a), DOH COBAC (20.9b), PhilGEPS (20.4, 20.5, 20.6), Commission on Audit Annual Financial Report 2007 (20.9a)

Item	Value
20.1. There is a tender board/committee overseeing public procurement that is independent from the procurement office	<i>Government Procurement Policy Board</i>
20.2. Public procurement is limited to medicines on the national EML	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
20.3. A functioning process exists to prequalify suppliers for public procurement	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
a. If yes, explicit criteria and procedures exist for prequalification of suppliers	<input type="checkbox"/> Yes <sup>&amp;</sup> <input type="checkbox"/> No
b. If yes, a list of prequalified suppliers is publicly available	<input type="checkbox"/> Yes <sup>&amp;</sup> <input type="checkbox"/> No
c. 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:	<i>No summary report available</i>
a. National competitive tenders (%)	
b. International competitive tenders (%)	<i>No summary report available</i>
c. Negotiation//direct purchasing (%)	<i>No summary report available</i>
20.5. Public sector tenders are publicly available	<a href="http://www.philgeps.net">http://www.philgeps.net</a>
20.6. Winning bids in the public sector are publicly available	<a href="http://www.philgeps.net">http://www.philgeps.net</a>
20.7. Public sector tenders use a transparent electronic bidding process	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
20.8. Results of quality testing during the procurement process are publicly available	<i>Upon request</i> <i>Public viewing of testing, if applicable</i>

Item	Value
20.9. Percent of public sector procurement expenditures in last year on: a. Medicines on the national EML (%)	4.67% (COA 2007) Between 4-5 billion pesos (So 2009)
b. Medicines produced by local manufacturers (%)	No data available

& If yes, obtain list and append to report

#### Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
20.1	<p>Interview with Atty. Estanislao Granados, Executive Director, Procurement Service, Department of Budget and Management, December 7, 2009</p> <p>Republic Act 9184, <a href="http://www.philgeps.net/GEPS/ViewAnnex.aspx?FileType=RulesRegulationsPath&amp;NameOfFile=549c53d2-2dee-4bc2-9c87-0a79d6d67d6a.pdf&amp;FileName=RA_9184.pdf">http://www.philgeps.net/GEPS/ViewAnnex.aspx?FileType=RulesRegulationsPath&amp;NameOfFile=549c53d2-2dee-4bc2-9c87-0a79d6d67d6a.pdf&amp;FileName=RA_9184.pdf</a>, 2002</p> <p>Article XX Section 63</p> <p><i>“Organization and Functions. - A Government Procurement Policy Board (GPPB) is hereby established to: (a) protect national interest in all matters affecting public Procurement, having due regard to the country’s regional and international obligations; (b) formulate and amend, whenever necessary, the IRR and the corresponding standard forms for Procurement; (c) ensure that Procuring Entities regularly conduct Procurement training programs and prepare a Procurement operations manual for all offices and agencies of government; and (d) conduct an annual review of the effectiveness of this Act and recommend any amendments thereto, as may be necessary.” (RA 9184)</i></p> <p>Government Procurement Policy Board Official Website “About Us”, <a href="http://www.gppb.gov.ph/about_us/gppb.htm">http://www.gppb.gov.ph/about_us/gppb.htm</a>, 2009</p> <p><i>“Mission</i></p> <p><i>“To be the principal body responsible for procurement policy formulation and the implementation and monitoring of effective public procurement reform, thereby promoting and achieving good governance, in general, and transparency, accountability, equity, effectiveness, efficiency and economy in Government, in particular.”</i></p>	The GPPB oversees all public procurement.
20.2	<p>Joint DOH-DTI-IPO-BFAD Administrative Order No. 2008-01: The Implementing Rules and Regulation of RA 9502, <a href="http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=1234">http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=1234</a>, 2008</p> <p>Chapter I</p> <p><i>“Section 3. Philippine National Drug Formulary (PNDF). Only drugs and medicines in the latest edition of the PNDP can be procured by government agencies or reimbursed by PhilHealth. (n)” (IRR of RA 9502)</i></p>	The PNDP is the national essential medicine list.
20.3	<p>Revised Implementing Rules and Regulations of Republic Act 9184 Rule VIII, <a href="http://www.philgeps.net/GEPS/ViewAnnex.aspx?FileType=RulesRegulationsPath&amp;NameOfFile=244d5e34-19ff-467f-a3f2-8b65ccaefa6f.pdf&amp;FileName=RevisedIRR_Res03-2009.pdf">http://www.philgeps.net/GEPS/ViewAnnex.aspx?FileType=RulesRegulationsPath&amp;NameOfFile=244d5e34-19ff-467f-a3f2-8b65ccaefa6f.pdf&amp;FileName=RevisedIRR_Res03-2009.pdf</a>, 2009</p> <p>Section 23</p> <p>Interview with Atty. Estanislao Granados, Executive Director, Procurement Service, Department of Budget and Management, December 7, 2009</p>	<p>Prequalification is defined as being registered with a government office for the capability to bid.</p> <p>Currently, anyone can bid as long as one submits the requirements for bidding. Prequalification is no longer being followed.</p>
20.4	<p>Phone Interview with an employee of PhilGEPS, name withheld upon request of source, December 7, 2009</p>	The raw data is available if one would analyze the contracts awarded. However statistics is no longer a responsibility of the PhilGEPS.

20.5	<p>Republic Act 9184, <a href="http://www.philgeps.net/GEPS/ViewAnnex.aspx?FileType=RulesRegulationsPath&amp;NameOfFile=549c53d2-2dee-4bc2-9c87-0a79d6d67d6a.pdf&amp;FileName=RA_9184.pdf">http://www.philgeps.net/GEPS/ViewAnnex.aspx?FileType=RulesRegulationsPath&amp;NameOfFile=549c53d2-2dee-4bc2-9c87-0a79d6d67d6a.pdf&amp;FileName=RA_9184.pdf</a>, 2002</p> <p><i>Article III Section 8</i></p> <p><i>“Procurement By Electronic Means. – To promote transparency and efficiency, information and communications technology shall be utilized in the conduct of procurement procedures. Accordingly, there shall be a single portal that shall serve as the primary source of information on all government procurement. The G-EPS shall serve as the primary and definitive source of information on government procurement.” (RA 9184)</i></p>	Can be found at <a href="http://www.philgeps.net/">http://www.philgeps.net/</a> listed as “Open Opportunities”.
20.6	<p>Republic Act 9184, <a href="http://www.philgeps.net/GEPS/ViewAnnex.aspx?FileType=RulesRegulationsPath&amp;NameOfFile=549c53d2-2dee-4bc2-9c87-0a79d6d67d6a.pdf&amp;FileName=RA_9184.pdf">http://www.philgeps.net/GEPS/ViewAnnex.aspx?FileType=RulesRegulationsPath&amp;NameOfFile=549c53d2-2dee-4bc2-9c87-0a79d6d67d6a.pdf&amp;FileName=RA_9184.pdf</a>, 2002</p> <p><i>Article III Section 8</i></p> <p><i>“Procurement By Electronic Means. – To promote transparency and efficiency, information and communications technology shall be utilized in the conduct of procurement procedures. Accordingly, there shall be a single portal that shall serve as the primary source of information on all government procurement. The G-EPS shall serve as the primary and definitive source of information on government procurement.” (RA 9184)</i></p> <p>Government Procurement Policy Board Circular No. 01-2005, <a href="http://www.philgeps.net/GEPS/ViewAnnex.aspx?FileType=RulesRegulationsPath&amp;NameOfFile=a2105709-5f2e-4157-a192-2ac5302bb157.pdf&amp;FileName=Circular%20No.%2001-2005.pdf">http://www.philgeps.net/GEPS/ViewAnnex.aspx?FileType=RulesRegulationsPath&amp;NameOfFile=a2105709-5f2e-4157-a192-2ac5302bb157.pdf&amp;FileName=Circular%20No.%2001-2005.pdf</a>, 2005</p> <p><i>“To fully comply with the requirement under Section 8.2.1 (a) of the IRR-A, and to promote transparency and efficiency in government procurement, all notices of awards of contract, and other related information must be posted in the bulletin board of the G-EPS website, being the single portal of information on all government procurement activities, in addition to the posting in the website of the procuring entity concerned, if available.”</i></p>	Can be found at <a href="http://www.philgeps.net/">http://www.philgeps.net/</a> listed as “Recent Award Notices”.
20.7	<p>Republic Act 9184, <a href="http://www.philgeps.net/GEPS/ViewAnnex.aspx?FileType=RulesRegulationsPath&amp;NameOfFile=549c53d2-2dee-4bc2-9c87-0a79d6d67d6a.pdf&amp;FileName=RA_9184.pdf">http://www.philgeps.net/GEPS/ViewAnnex.aspx?FileType=RulesRegulationsPath&amp;NameOfFile=549c53d2-2dee-4bc2-9c87-0a79d6d67d6a.pdf&amp;FileName=RA_9184.pdf</a>, 2002</p> <p><i>Article III Section 8</i></p> <p><i>“Procurement By Electronic Means. – To promote transparency and efficiency, information and communications technology shall be utilized in the conduct of procurement procedures. Accordingly, there shall be a single portal that shall serve as the primary source of information on all government procurement. The G-EPS shall serve as the primary and definitive source of information on government procurement.” (RA 9184)</i></p> <p>Interview with Atty. Estanislao Granados, Executive Director, Procurement Service, Department of Budget and Management, December 7, 2009</p>	An electronic bidding website is still being developed and is scheduled to be operational late 2010.
20.8	<p>Interview with Atty. Estanislao Granados, Executive Director, Procurement Service, Department of Budget and Management, December 7, 2009</p>	<p>Products from bidders are tested publicly, especially before the other bidders. However, there are some testing sites (laboratories) that do not allow the public access; the results are forwarded to the procuring office.</p> <p>Results of testing are not published or disseminated but may be requested with a written letter.</p>
20.9a	<p>Interview with Dr. Robert So, Head Executive Assistant, Department of Health, November 23, 2009</p> <p>2007 Annual Financial Report of the National Government, <a href="http://www.coa.gov.ph/Financial_Reports.htm">http://www.coa.gov.ph/Financial_Reports.htm</a>, 2008</p>	<p>The National Government’s Annual Financial Report for 2008 has not yet been made publicly available by the Commission on Audit.</p> <p>2007 percentage computed using Drugs and Medicine Expenses (1.333B) and Supplies and Material Expenses (28.541B).</p>

20.9b	Interview with Ms. Minda Marie Gugol, Officer-in-charge, Department of Health Central Office Bids and Awards Committee, November 23, 2009	No such studies with this data are publicly available.  Bids for public expenditure on medicines are awarded to suppliers who may supply medicines produced by both local and international manufacturers.
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## 21. Medicines Supply System: Procurement Price of Medicines (HAI Global List)

**Actual source:** Public Procurement Prices of Medicines in the Philippines (Main Report) by Douglas Ball and Klara Tisocki (WHO/HAI 2008)

[List all prices in MPR]

Medicine, Strength, Formulation	Public Sector	
	Originator	Low price generic
21.1. Salbutamol 0.1mg/dose Inhaler	3.2	2.8
21.2. Glibenclamide 5 mg Cap/tab	33.3	2.3
21.3. Atenolol 50 mg Cap/tab	5.3	2.5
21.4. Captopril 25 mg Cap/tab	9.3	1.6
21.5. Simvastatin 20 mg Cap/tab	10.1	1.4
21.6. Amitriptyline 25 mg Cap/tab	--	--
21.7. Ciprofloxacin 500 mg Cap/tab	33.1	0.7
21.8. Co-trimoxazole 8 + 40 mg/ml Susp.	7.2	1.2
21.9. Amoxicillin 500 mg Cap/tab	4.8	0.7
21.10. Ceftriaxone 1 g/ vial Injection	19.1	0.6
21.11. Diazepam 5 mg Cap/tab	62.3	9.4
21.12. Diclofenac 50 mg Cap/tab	72.5	4.0
21.13. Paracetamol 24 mg/ml Susp.	5.1	1.0
21.14. Omeprazole 20 mg Cap/tab	16.6	1.6

### Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
21.1-21.14	Public Sector Procurement: Summary Survey Report WHO/HAI. Measuring medicine prices, availability, affordability and price components, 2nd Ed., Geneva, World Health Organization, <a href="http://www.haiweb.org/medicineprices/surveys/200807PHP/sdocs/Philippines-procurement-Final.pdf">http://www.haiweb.org/medicineprices/surveys/200807PHP/sdocs/Philippines-procurement-Final.pdf</a> , July 2008  Public Procurement Prices of Medicines in the Philippines (Main Report) by Douglas Ball and Klara Tisocki  WHO/HAI July 2008  (Complete report emailed to the investigator by Dr. D Ball upon request on November 20, 2009)	Procurement prices from 2008 were recorded for the originator brand product and the lowest cost generic equivalent product which was determined at each facility. Data was collected from a total of 5 DOH-retained, 6 provincial and 5 municipal hospitals, plus one public non-DOH hospital, BLOM and PITC Pharma

## 22. Medicines Supply System: Distribution

**Actual sources:** Ms. Regina Obligacion, FDRO III of BFAD (22.1, 22.2, 22.10, 22.11, 22.12, 22.13), Dr. Robert So, Head Executive Assistant of DOH (22.3, 22.4, 22.5, 22.6, 22.7),

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 checked="" type="checkbox"/> Yes <sup>&amp;</sup> <input 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	DOH AO 1989-056 (Revised regulations for the Licensing of Drug Establishments & Outlets)
22.10. List of wholesalers is publicly available	Upon request
22.11. Number of wholesalers in market	3,759 (FDA 2009)
22.12. National association of wholesalers exists	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No PCPI, DSAP
22.13. Number of domestic manufacturers with integrated wholesale activities	45 (FDA 2009)

&: If yes, obtain list and append to report

### Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
22.1, 22.2	Data via e-mail from BFAD c/o Ms. Regina Obligacion, FDRO III, December 2009	
22.3-22.7	Interview with Dr. Robert So, Head Executive Assistant, Department of Health, November 23, 2009	According to Dr. So, there is an existing central facility for storing of drugs procured by the central government.
22.8	As defined by law - Generics Act of 1988 (R.A. 6675)	
22.9	Administrative Order No. 56 s.1989 – Revised Regulation for the Licensing of Drug Establishments and Outlets, <a href="http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO56s1989.pdf">http://www.bfad.gov.ph/pdf/RegulatoryGuidance/drug/ao/AO56s1989.pdf</a> , 1989	
22.10	Data via e-mail from BFAD c/o Ms. Regina Obligacion, FDRO III, December 2009	The list is not available publicly but may be provided upon presentation of written request and reason/s for requesting the same.
22.11 – 22.13	Data via e-mail from BFAD c/o Ms. Regina Obligacion, FDRO III, December 2009	DSAP – Drug Store Association of the Philippines PCPI – Philippine Chamber of the Pharmaceutical Industry

## 23. Medicines Access

**Actual sources:** WHO Level II Survey-Preliminary by Batangan (23.1, 23.8), IMCI (23.3), JNC 7 (23.4), ATP III (23.5), Dr. Robert So, Head Executive Assistant of DOH (23.7)

Item	Value
<b>Geographic access</b>	
23.1. Percentage of patients who travel more than one hour to reach primary care facility (%)	5% (public facilities)
23.2. Percentage of households obtaining medicines for recent illness at a public health care facility (%)	No data available
<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	0.24 (0.20)
23.4. Number of days' wages of the lowest paid government worker for standard treatments with atenolol for hypertension	1.12 (0.52)
23.5. Number of days' wages of the lowest paid government worker for monthly standard treatment with simvastatin for hypercholesterolemia	2.76 (1.34)
23.6. Percentage of households obtaining free medicines at public health care facilities (%)	No data available
<b>Availability of medicines</b>	
23.7. Availability of basket of key medicines in health care facilities (%)	60% in public pharmacies; 96.7% in private pharmacies (Batangan 2009) ~66% (So 2009)
23.8. Percentage of prescribed medicines actually dispensed (%)	90.5% (Batangan 2009)
<b>Equity in access</b>	
23.9. Percentage of households by socioeconomic (SE) quintile whose monthly medicines expenditures represent 40% or more of discretionary expenditures (%)	No data available
23.10. Percentage of households by SE quintile with a chronically ill member who requires medicines but having no medicines at home (%)	No data available
23.11. Average monthly cost of medicines for the most frequent chronic disease in households by SE quintile (Local cur.) <sup>6</sup>	No data available

### Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
23.2	Interview with Dr. Robert So, Head Executive Assistant, Department of Health, November 23, 2009	The World Health Survey has yet to publish the data.
23.1	Preliminary data of a WHO Level II Survey sent to the investigators via e-mail from Dr. Dennis Batangan, December 2009	
23.3	"Statement of Secretary Eduardo R. Ermita: PGMA thanks Congress for go-signal to increase gov't worker's pay", <a href="http://www.gov.ph/index.php?option=com_content&amp;task=view&amp;id=2000788&amp;Itemid=2">http://www.gov.ph/index.php?option=com_content&amp;task=view&amp;id=2000788&amp;Itemid=2</a> , 2009	Daily minimum wage of government employees at PhP402.

	<p>Integrated Management of Childhood Illnesses Chart Booklet, <a href="http://whqlibdoc.who.int/publications/2008/9789241597289_eng.pdf">http://whqlibdoc.who.int/publications/2008/9789241597289_eng.pdf</a>, 2008</p> <p>PhilHealth's Drug Price Reference Index, <a href="http://www.doh.gov.ph/files/FINAL_DPRI_0.pdf">http://www.doh.gov.ph/files/FINAL_DPRI_0.pdf</a>, 2006 <i>Cotrimoxazole 40/200mg/5ml syrup (60ml) price ranges from PhP 79.00 to 98.00</i></p>	<p>Standard treatment for a child with respiratory tract infection is 7.5 ml of 40/200mg/5ml cotrimoxazole syrup 2x/day for 3 days.</p> <p>Number of days' wages value computed with highest price. Number of days' wages with lowest price value enclosed in parentheses.</p>
23.4	<p>"Statement of Secretary Eduardo R. Ermita: PGMA thanks Congress for go-signal to increase gov't worker's pay", <a href="http://www.gov.ph/index.php?option=com_content&amp;task=view&amp;id=2000788&amp;Itemid=2">http://www.gov.ph/index.php?option=com_content&amp;task=view&amp;id=2000788&amp;Itemid=2</a>, 2009</p> <p>The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure, <a href="http://www.nhlbi.nih.gov/guidelines/hypertension/jnc7full.pdf">http://www.nhlbi.nih.gov/guidelines/hypertension/jnc7full.pdf</a>, 2004</p> <p>PhilHealth's Drug Price Reference Index, <a href="http://www.doh.gov.ph/files/FINAL_DPRI_0.pdf">http://www.doh.gov.ph/files/FINAL_DPRI_0.pdf</a>, 2006 <i>Atenolol 50mg/tab price ranges from PhP 7.00 to 15.00</i></p>	<p>Daily minimum wage of government employees at PhP402</p> <p>Standard treatment with atenolol is 25-100mg/day.</p> <p>Treatment of atenolol 50mg/day for 30 days requires 30 caps/tabs.</p> <p>Number of days' wages value computed with highest price. Number of days' wages with lowest price value enclosed in parentheses.</p>
23.5	<p>"Statement of Secretary Eduardo R. Ermita: PGMA thanks Congress for go-signal to increase gov't worker's pay", <a href="http://www.gov.ph/index.php?option=com_content&amp;task=view&amp;id=2000788&amp;Itemid=2">http://www.gov.ph/index.php?option=com_content&amp;task=view&amp;id=2000788&amp;Itemid=2</a>, 2009</p> <p>Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III), <a href="http://www.nhlbi.nih.gov/guidelines/cholesterol/atp3full.pdf">http://www.nhlbi.nih.gov/guidelines/cholesterol/atp3full.pdf</a>, 2002</p> <p>Mercury Drugstore drug price catalogue on December 7, 2009 <i>Simvastatin 20mg/tab price ranges from PhP 18.00 to 37.00</i></p>	<p>Daily minimum wage of government employees at PhP402.</p> <p>Standard treatment with simvastatin is 20-80mg/day.</p> <p>Treatment of simvastatin 20mg/day for 30 days requires 30 caps/tabs.</p> <p>Number of days' wages value computed with highest price. Number of days' wages with lowest price value enclosed in parentheses.</p>
23.6	<p>Interview with Dr. Robert So, Head Executive Assistant, Department of Health, November 23, 2009</p>	
23.7	<p>Approximate value collected from interview with Dr. Robert So, Head Executive Assistant, Department of Health, November 23, 2009</p>	
23.8	<p>Preliminary data of a WHO Level II Survey sent to the investigators via e-mail from Dr. Dennis Batangan, December 2009</p>	<p>This value is applicable for patients at public health facility dispensaries</p>
23.9 – 23.11	<p>Interview with Dr. Robert So, Head Executive Assistant, Department of Health, November 23, 2009</p>	<p>The World Health Survey has yet to publish the data.</p>

## 24. Medicines Use: National Structures

**Actual sources:** DOH (24.1, 24.4, 24.5), HAIN (24.1), Dr. Robert So, Head Executive Assistant of DOH (24.2), RITM - Antimicrobial Resistance Surveillance Program (24.3), WHO Level II Survey-Preliminary by Batangan (24.6, 24.7)

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	<i>National Drug Policy-Pharmaceutical Management Unit 50</i> <i>HAIN</i>
24.2. Public education campaigns about rational medicines use have been conducted by the DOH in the previous two years	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
24.3. A written national strategy exists to contain antimicrobial resistance	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
24.4. 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. Percentage of facilities with copy of national STGs (%)	<i>34.8% (Batangan 2009)</i>
24.7. Percentage of facilities with copies of national EML (%)	<i>100% (Batangan 2009)</i>

### Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
24.1	National Drug Policy-Pharmaceutical Management Unit 50, <a href="http://www.doh.gov.ph/ndp">http://www.doh.gov.ph/ndp</a>  Health Action Information Network (HAIN), <a href="http://www.hain.org/?page_id=34">http://www.hain.org/?page_id=34</a>	HAIN is an NGO whose advocacies include rational drug use
24.2	Interview with Dr. Robert So, Head Executive Assistant, Department of Health, November 23, 2009	P100 project is piloted in DOH-retained hospitals and LGU hospitals. The project would ensure access to drugs and medicines that are packaged to promote its rational use and will be sold for Php 100 or less.
24.3	Surveillance Standards for Antimicrobial Resistance, <a href="http://www.ritm.gov.ph/arsp/surveillance_standards%20for%20AR.pdf">http://www.ritm.gov.ph/arsp/surveillance_standards%20for%20AR.pdf</a> , World Health Organization 2002  Manual for the Laboratory Identification and Antimicrobial Susceptibility Testing of Bacterial Pathogens of Public Health Importance in the Developing World by Mindy Perilla et al., <a href="http://www.ritm.gov.ph/arsp/Manual%20for%20Lab%20ID,%20AST-cdc,%20who.pdf">http://www.ritm.gov.ph/arsp/Manual%20for%20Lab%20ID,%20AST-cdc,%20who.pdf</a> , World Health Organization 2003  Requirements for Accreditation of Aerobic Bacteriology Laboratories by the Antimicrobial Resistance Surveillance Program, Department of Health, <a href="http://www.ritm.gov.ph/arsp/REQUIREMENTS%20FOR%20ACCREDITATION%20OF%20Bacti%20LABs,%20EDITED%20_4-15-09_.pdf">http://www.ritm.gov.ph/arsp/REQUIREMENTS%20FOR%20ACCREDITATION%20OF%20Bacti%20LABs,%20EDITED%20_4-15-09_.pdf</a> , 2009 <i>“Objectives for Accreditation</i> <i>A. To improve the quality of bacteriology laboratory services and ultimately, the quality of care provided to patients by assessing compliance of these laboratories with international standards</i> <i>B. To encourage hospitals/health care institutions to establish antimicrobial resistance surveillance systems and utilize information from such systems as basis for selecting appropriate antibiotic regimens for treatment of infectious diseases</i> <i>C. To promote cost-effective use of antibiotics while minimizing emergence of antimicrobial resistant microorganisms”</i>	Antimicrobial Resistance Surveillance Program (ARSP) adopted the WHO surveillance standard.  According to Dr. Sonia Sia of ARSP in Research Institute for Tropical Medicine, the group is currently drafting the written national strategy to contain antimicrobial resistance.

24.4	Antimicrobial Resistance Surveillance Program, <a href="http://www.doh.gov.ph/files/ARSP-RITM.pdf">http://www.doh.gov.ph/files/ARSP-RITM.pdf</a> , 2005  Report on Biregional Workshop on Antimicrobial Resistance Surveillance and Containment in Asia and in the Pacific, <a href="http://www.wpro.who.int/internet/resources.ashx/CSR/Publications/FINAL+EDTed+report1.pdf">http://www.wpro.who.int/internet/resources.ashx/CSR/Publications/FINAL+EDTed+report1.pdf</a> , 2005  Department Personnel Order No. 2009-1972, <a href="http://home.doh.gov.ph/dp/dpo2009-1972.pdf">http://home.doh.gov.ph/dp/dpo2009-1972.pdf</a> , 2009	Program is implemented by Department of Health Committee on Antimicrobial Resistance Surveillance.  According to WHO report, multilaboratory networking exists.  The Committee on Antimicrobial Resistance Surveillance is reconstituted under Research Institute for Tropical Medicine
24.5	National Drug Policy-Pharmaceutical Management Unit 50, <a href="http://www.doh.gov.ph/ndp">http://www.doh.gov.ph/ndp</a>  Department Order No. 32, 1994-Creation of the Expanded National Drug Policy Organizational Structure, <a href="http://www.doh.gov.ph/files/pndf_do32_1994.pdf">http://www.doh.gov.ph/files/pndf_do32_1994.pdf</a> , 1994	
24.6, 24.7	Preliminary data of a WHO Level II Survey sent to the investigators via e-mail from Dr. Dennis Batangan, December 2009	

## 25. Medicines Use: Prescribing

**Actual sources:** DOH (25.1, 25.2, 25.4), PMA (25.3), Dr. Robert So, Head Executive Assistant of DOH (25.5), Mr. Reiner Gloor, Executive Director of PHAP (25.6), WHO Level II Survey-Preliminary by Batangan (25.6-25.13)

Item	Value
25.1. Legal provisions exist to govern the licensing and prescribing practice of prescribers and health facilities	<i>RA 6675 (Generics Act of 1988)</i> <i>DOH AO 1989-062 (Rules and Regulations to Implement Prescribing Requirements under the Generics Act of 1988)</i> <i>DOH AO 1990-090 (Amendment to AO 62 s.1989 re: Rules and Regulations to Implement Prescribing Requirements)</i>
25.2. Legal provisions exist to restrict dispensing by prescribers	<i>RA 6675</i> <i>DOH AO 1989-062 DOH AO 1990-090</i>
25.3. A professional association code of conduct exists governing professional behavior of prescribers	<i>PMA Code of Conduct</i>
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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No
25.5. Functioning DTCs are present in what percent of	<i>Data not available</i>
a. Public referral hospitals (%)	<i>Data not available</i>
b. Public regional or district hospitals (%)	<i>Data not available</i>
c. Private hospitals (%)	<i>Data not available</i>
<b>INRUD prescribing indicators</b>	
25.6. Average number of medicines per prescription	<i>2 (Batangan 2009)</i> <i>3-4 (Gloor 2009)</i>
25.7. Percentage of medicines prescribed by INN name (%)	<i>84% (Batangan 2009)</i>
25.8. Percentage of encounters with an antibiotic prescribed (%)	<i>66.2% (Batangan 2009)</i>
25.9. Percentage of encounters with an injection prescribed (%)	<i>18.4% (Batangan 2009)</i>
25.10. Percentage of medicines prescribed from EML or formulary (%)	<i>90.9% (Batangan 2009)</i>
25.11. Average consultation time (minutes)	<i>Data not available</i>
<b>Disease-specific prescribing indicators</b>	
25.12. Percentage of non-pneumonia acute respiratory tract infection (ARI) of any age treated with antibiotics (%)	<i>78.2% (Batangan 2009)</i>
25.13. Percentage of non-bacterial diarrhea in children under age 5 treated with ORT (%)	<i>52.4% (Batangan 2009)</i>

## Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
25.1, 25.2	<p>Republic Act 6675 – Generics Act of 1988, <a href="http://www.doh.gov.ph/ra/ra6675">http://www.doh.gov.ph/ra/ra6675</a>, 1988</p> <p>Medicines use in primary care in developing and transitional countries, <a href="http://www.who.int/entity/medicines/publications/primary_care_8April09.pdf">http://www.who.int/entity/medicines/publications/primary_care_8April09.pdf</a>, 2009</p> <p>Department of Health Administrative Order No. 62 s. 1989, <a href="http://www.bfad.gov.ph/pdf/Regulatory_Guidance/drug/ao/AO62s1989.pdf">http://www.bfad.gov.ph/pdf/Regulatory_Guidance/drug/ao/AO62s1989.pdf</a>, 1989</p> <p>Department of Health Administrative Order No. 90 s.1990, <a href="http://www.bfad.gov.ph/pdf/Regulatory_Guidance/drug/ao/AO90s1990.pdf">http://www.bfad.gov.ph/pdf/Regulatory_Guidance/drug/ao/AO90s1990.pdf</a>, 1990</p>	
25.3	Philippine Medical Association Code of Conduct	Has no specific entry regarding prescribing
25.4a	<p>Republic Act 6675 – Generics Act of 1988, <a href="http://www.doh.gov.ph/ra/ra6675">http://www.doh.gov.ph/ra/ra6675</a>, 1988</p> <p>Anecdotal experiences of the investigators (Dr. Noel Juban et al. 2009)</p>	
25.4b	Anecdotal experiences of the investigators (Dr. Noel Juban et al. 2009)	
25.4c, 25.5	Interview with Dr. Robert So, Head Executive Assistant, Department of Health, November 23, 2009	25.5a and b– ideally, all public referral, district or regional hospitals are mandated to have a functioning DTC, but no data has been collected so far.
25.6	<p>Preliminary data of a WHO Level II Survey sent to the investigators via e-mail from Dr. Dennis Batangan, December 2009</p> <p>Interview with Mr. Reiner W. Gloor, Executive Director, Pharmaceutical and Health Association of the Philippines, December 14, 2009</p>	Mr. Gloor's estimate based on his experience.
25.7-25.10, 25.12, 25.13	Preliminary data of a WHO Level II Survey sent to the investigators via e-mail from Dr. Dennis Batangan, December 2009	Data based on national averages.

## 26. Medicines Use: Dispensing

**Actual sources:** BFAD (26.1, 26.2, 26.4, 26.5, 26.6, 26.7), Philippine Pharmacists Association (26.3), WHO Level II Survey-Preliminary by Batangan (26.9-26.11) Anecdotal experience

Item	Value
26.1. Legal provisions exist to govern licensing and dispensing practice of pharmacists and pharmacy establishments	<i>RA 5921 (Pharmacy Law)</i>
26.2. Legal provisions exist to restrict prescribing by dispensers	<i>DOH AO 1989-062 (Rules and Regulations to Implement Prescribing Requirements under the Generics Act of 1988)</i>
26.3. A professional association code of conduct exists governing professional behavior of pharmacists	<i>PPhA Code of Ethics</i>
26.4. Substitution of generic equivalents is permitted for:	
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. Dispensing of antibiotics is not allowed without a prescription	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
26.6. Dispensing of injections is not allowed without a prescription	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

Item	Value
26.7. Dispensing of narcotics, psychotropic drugs and precursors is not allowed without a prescription	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No RA 9165 (Comprehensive Dangerous Drugs Act)
<b>INRUD dispensing indicators</b>	
26.8. Average dispensing time (minutes)	Data not available
26.9. Percentage of prescribed medicines actually dispensed at facility where they were prescribed (%)	89.4% (Batangan 2009)
26.10. Percentage of dispensed medicines that are adequately labeled (%)	92.9% (Batangan 2009)
26.11. Percentage of patients who know the correct dosing of all dispensed medicines (%)	52.9% (Batangan 2009)

#### Document source of each item and year collected:

Item Number(s)	Source, Location, & Year	Comments
26.1	Republic Act 5921, <a href="http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=697">http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=697</a> , 1969 updated 1987  <i>"Section 1. Objectives - This act provides for and shall govern (a) the standardization and regulation of pharmaceutical education; (b) the examination for registration of graduates of school of pharmacy and (c) the supervision, control and regulation of the practice of pharmacy in the Philippines."</i>  <i>"Section 25. Sales of medicine, pharmaceuticals, drugs, devices. - No medicine, pharmaceutical or drug whatever nature and kind or device shall be compounded, dispensed, sold or resold, or otherwise be made available to the consuming public except through a prescription drug store or hospital pharmacy duly established in accordance with the provisions of this Act." (RA 5921)</i>	
26.2	Department of Health Administrative Order No. 62 s. 1989, <a href="http://www.doh.gov.ph/files/ao62-89.pdf">http://www.doh.gov.ph/files/ao62-89.pdf</a> , 1989  <i>"Prescription or Ethical Drugs. These drugs can only be dispensed upon a written order of a validly-registered physician, dentist or veterinarian." (AO 1989-062)</i>	
26.3	Philippine Pharmacists Association Code of Ethics, <a href="http://www.philpharm.org/vision.html">http://www.philpharm.org/vision.html</a> , 2009	
26.4a, 26.4b	Republic Act 6675, <a href="http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=818">http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=818</a> , 1988  <i>"Who Shall Use Generic Terminology - (a) All government health agencies and their personnel as well as other government agencies shall use generic terminology or generic names in all transactions related to purchasing, prescribing, dispensing and administering of drugs and medicines..."</i>  <i>"...(d) Drug outlets, including drugstores, hospital and non-hospital pharmacies and non-traditional outlets such as supermarkets and stores, shall inform any buyer about any and all other drug products having the same generic name, together with their corresponding prices so that the buyer may adequately exercise, his option. Within one (1) year after approval of this Act, the drug outlets referred to herein, shall post in conspicuous places in their establishments, a list of drug products with the same generic name and their corresponding prices." (RA 6675)</i>  Department of Health Administrative Order No. 62 s. 1989, <a href="http://www.doh.gov.ph/files/ao62-89.pdf">http://www.doh.gov.ph/files/ao62-89.pdf</a> , 1989  <i>Section 3.1</i> <i>"Generic names shall be used in all prescriptions." (AO 1989-062)</i> <i>Section 4.1.3</i> <i>"Where the brand name is indicated and instructions added, such as the phrase 'No Substitution' which tend to obstruct, hinder or prevent proper generic dispensing." (AO 1989-062)</i>	Prescriptions with "no substitutions" are violative prescriptions.

26.5	<p>Department of Health Administrative Order No. 62 s. 1989, <a href="http://www.doh.gov.ph/files/ao62-89.pdf">http://www.doh.gov.ph/files/ao62-89.pdf</a>, 1989</p> <p><i>Section 2.1</i></p> <p><i>"Prescription or Ethical Drugs. These drugs can only be dispensed upon a written order of a validly-registered physician, dentist or veterinarian."</i> (AO 1989-062)</p> <p>Anecdotal experiences of the investigators (Dr. Noel Juban et al. 2009)</p>	Although the law requires prescriptions for antibiotics, some pharmacies allow dispensing of some antibiotics without a prescription.
26.6	<p>Department of Health Administrative Order No. 62 s. 1989, <a href="http://www.doh.gov.ph/files/ao62-89.pdf">http://www.doh.gov.ph/files/ao62-89.pdf</a>, 1989</p> <p><i>Section 2.1</i></p> <p><i>"Prescription or Ethical Drugs. These drugs can only be dispensed upon a written order of a validly-registered physician, dentist or veterinarian."</i> (AO 1989-062)</p>	
26.7	<p>Republic Act 9165, <a href="http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=706">http://www.bfad.gov.ph/cfc/pdf.cfm?pdfid=706</a>, 2002</p> <p><i>Article V Section 40</i></p> <p><i>"b) A physician, dentist, veterinarian or practitioner authorized to prescribe any dangerous drug shall issue the prescription therefor [sic] in one (1) original and two (2) duplicate copies. The original, after the prescription has been filled, shall be retained by the pharmacist for a period of one (1) year from the date of sale or delivery of such drug. One (1) copy shall be retained by the buyer or by the person to whom the drug is delivered until such drug is consumed, while the second copy shall be retained by the person issuing the prescription.</i></p> <p><i>"For purposes of this Act, all prescriptions issued by physicians, dentists, veterinarians or practitioners shall be written on forms exclusively issued by and obtainable from the DOH. Such forms shall be made of a special kind of paper and shall be distributed in such quantities and contain such information and other data as the DOH may, by rules and regulations, require. Such forms shall only be issued by the DOH through its authorized employees to licensed physicians, dentists, veterinarians and practitioners in such quantities as the Board may authorize. In emergency cases, however, as the Board may specify in the public interest, a prescription need not be accomplished on such forms. The prescribing physician, dentist, veterinarian or practitioner shall, within three (3) days after issuing such prescription, inform the DOH of the same in writing. No prescription once served by the drugstore or pharmacy be reused nor any prescription once issued be refilled."</i> (RA 9165)</p>	A special form (S2) is used to prescribe regulated drugs such as narcotics, psychotropic drugs and precursors.
26.9-26.11	Preliminary data of a WHO Level II Survey sent to the investigators via e-mail from Dr. Dennis Batangan, December 2009	Data based on national averages

## 27. Medicines Use: Pharmacovigilance

**Actual sources:** BFAD (27.1, 27.2), Ms. Regina Obligacion, FDRO III of BFAD (27.3)

Item	Value
27.1. Legal provisions exist for monitoring adverse drug reactions (ADRs) on a routine basis	RA 9711 (FDA Act of 2009)
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	1,358 ADR reports in year 2008

**Document source of each item and year collected:**

Item Number(s)	Source, Location, & Year	Comments
27.1	<p>Republic Act 9711: Food and Drug Administration Act of 2009, <a href="http://www.senate.gov.ph/republic_acts/ra%209711.pdf">http://www.senate.gov.ph/republic_acts/ra%209711.pdf</a>, 2008</p> <p><i>“To require all manufacturers, traders, distributors, importers, exporters, wholesalers, retailers, consumers, and non-consumer users of health products to report to the FDA any incident that reasonably indicates that said product has caused or contributed to the death, serious illness or serious injury to a consumer, a patient, or any person” (RA 9711)</i></p>	<p>Bureau of Food and Drugs (BFAD) is hereby renamed the Food and Drug Administration (FDA)</p>
27.2	<p>National Adverse Drug Reaction Advisory Committee (NADRAC) website, <a href="http://www.bfad.gov.ph/oldsite/NADRAC/INDEX.htm">http://www.bfad.gov.ph/oldsite/NADRAC/INDEX.htm</a></p> <p>BFAD Memorandum Circular No. 5 S. 1994 (Submission of Reports on Adverse Drug Reaction)</p> <p>Department Order No. 345 – I s. 1994 Creation of National Adverse Drug Reaction Advisory Committee (NADRAC)</p> <p>Press Release/27 October 2009: “FDA launches hotline for Drug Complaints or Problems”, <a href="http://www.doh.gov.ph/node/2484">http://www.doh.gov.ph/node/2484</a>, 2009</p> <p><i>“FDA came up with the Medicines Surveillance Integrating Consumer Reporting Project in the National Capital Region which aims to educate consumers on the proper use of drugs and increase consumer awareness as to where to report complaints or problems with their medicines.</i></p> <p><i>“Consumers can report drug complaints to FDA at telephone number: (02) 807-8275 or SMS at 0905-4171771 and 0909-2080500, or e-mail <a href="mailto:ireport@bfad.gov.ph">ireport@bfad.gov.ph</a>. Reports can also be made via the Bantay Gamot Report Forms available in most drugstores.”</i></p>	<p>National Adverse Drug Reaction Advisory Committee (NADRAC) was created in 1994 to ensure safety of drug products and other therapeutic agent through nationwide postmarketing monitoring of Adverse Drug Reactions (ADR). It was also established to provide technical assistance to BFAD in the evaluation of these reports.</p> <p>Roles and Responsibilities of NADRAC</p> <ul style="list-style-type: none"> <li>○ Strengthens, expand and systematize the ADR monitoring system.</li> <li>○ Reviews and evaluate drugs with reported adverse drug experience.</li> <li>○ Recommends to BFAD to course of action needed to ensure safety of pharmaceutical products.</li> <li>○ Assists the BFAD in monitoring adverse drug experience. Submits an annual report of action to the Director of the BFAD</li> </ul>
27.3	<p>Data via e-mail from BFAD c/o Ms. Regina Obligacion, FDRO III, December 2009</p>	<p>These denote only reports made to the FDA; the FDA conducts investigations on reports and determines the validity of these reports, as such the actual number of verified reports is different.</p>

**References\***

- (1) Medicine Transparency Alliance. Laying the foundations-Medicine Transparency Alliance Annual Review 2008-2009.
- (2) Philippine Pharmaceutical Industry Factbook 7<sup>th</sup> Edition. Accessed at [http://www.phap.org.ph/images/page/main.factbook/factbook\\_11\\_2008.pdf](http://www.phap.org.ph/images/page/main.factbook/factbook_11_2008.pdf), 2008. Accessed on 18 December 2009.

\*Cited in the introduction