<u>Country Data Profile on the Pharmaceutical Situation</u> in the Southern African Development Community (SADC)



Botswana

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Country	BOTSWANA
	N. LL D.
Name of Coordinator/Principal	Mr. John Botsang
Respondent	
Position	Chief Pharmacist
E-mail address	Jbotsang@gov.bw
Tel number	74188231
Date Submitted	18 September 2009
Name of Endorser	Mr John Botsang
Position of Endorser	Chief Pharmacist

Methodology

The SADC Pharmaceutical Business Plan 2007-2013 aims at ensuring availability of essential medicines, including African traditional medicines, in order to reduce disease burden in countries. Within this context, **Botswana** has collaborated with WHO in the collection and analysis of data on it's pharmaceutical situation. This information will be used as a baseline before embarking on the implementation of the Pharmaceutical Business Plan, and will be used: to take stock of the pharmaceutical situation and identify areas in need of strengthening and support; to compare results with those of other countries fostering a sharing of experiences and enabling identification of strengths and opportunities for cooperation; and to measure over time the impact of the support provided by the SADC Secretariat, WHO and other partners.

A questionnaire on pharmaceutical policies and structures was developed by WHO based on previous tools elaborated by the organization and other leading partners such as the Medicines Transparency Alliance. To facilitate the work at country level, the questionnaire was filled in at central level by WHO with data available from global sources (e.g. WHO Statistical System) as well as with specific information available within the Essential Medicines Department of WHO. This included not only the WHO 2007 Level I Survey, but also country-specific assessments such as the level II facility survey¹, the WHO/HAI pricing surveys² etc.

After being populated, the questionnaire was sent to **Botswana** so that public officials could review and correct the filled data and, where possible, complete the missing data fields. A local consultant was recruited to facilitate the process and collect information from key agencies (Department of Pharmaceuticals, Central Medical Store, etc.). The names of respondents to each section were registered, in case follow-up was needed; the source of each data was also included in the questionnaire as a guarantee of the quality of the information and can be seen in the last column on each table. A senior official in the Ministry of Health has confirmed the accuracy of the information and provided permission for its publication on SADC and WHO web sites.

¹ WHO Operational package for assessing, monitoring and evaluating country pharmaceutical situations. Guide for coordinators and data collectors. Geneva, World Health Organization, 2007.

² WHO, Health Action International, *Measuring medicine prices, availability, affordability and price components 2nd edition*, Geneva, World Health Organization, 2008.

PART 1- HEALTH and DEMOGRAPHIC DATA

1.1 Demographic and Socioeconomic Indicators						
Population, mortality, fertility			YEAR	SOURCE		
Population, total	1,882	,000	2007	Botswana Demographic Survey		
Population < 15 years	35%	% of total population	2007	Botswana Demography Survey (BDS)		
Population > 60 years	7%	% of total population	2007	BDS		
Urban population	59%	% of total population	2007 2006	BDS		
Population growth	1.9%	Annual %	2006	BDS		
Fertility rate, total	2.9	Births per woman	2007	BDS		
Economic status		_	YEAR	SOURCE		
GDP	12.3	US\$ Billions current exchange rates	2007	World Development Indicators database, April 2009		
GDP growth	2.9%	Annual %	2008	CSO Botswana 2008		
GNI per capita	6,120	Current US\$	2007	World Development Indicators database, April 2009		
Population living < PPP int. \$1 a day	23.1%	%	2005	World Health Statistics		
Income share held by lowest 20%	N/A	%	<u> </u>			

Education and literacy			YEAR	SOURCE
Adult literacy rate, 15+ years	81.2%	% of total population	2003	WHOSIS Report on the 2 nd National CSO ON Literacy in Botswana
Primary school enrolment rate, males	83%	% of male population	2005	WHOSIS
Primary school enrolment rate, females	85%	% of female population	2005	WHOSIS

1.2 Mortality and Causes of Death						
Life expectancy and mortalit	у		YEAR	SOURCE		
Life expectancy at birth (both sexes)	54.4	Years	2006	Botswana Demographic survey 2006		
Adult mortality rate (both sexes, 15 to 60 years)	514	/1,000 population	2007	World Health Statistics		
Maternal mortality ratio	193	/100,000 live births	2007	Central Statistics Office Calculations 2007		
Neonatal mortality rate	46	/1,000 live births	2004	World Health Statistics		
Infant mortality rate (between birth and age 1)	33	/1,000 live births	2007	World Health Statistics		
Under 5 mortality rate	40	/1,000 live births	2007	World Health Statistics		

PART 2- HEALTH SERVICES

2.1 Health Expenditures					
Overall health expenditures			YEAR	SOURCE	
Total annual expenditure on health. (Per Capita)	703,971,821	US\$ average exchange rate	2006	NHA	
Total annual per capita expenditure on health	296	US\$ average exchange rate	2006	World Health Statistics	
Health expenditure as % of GDP	7.10%	% of gross domestic product	2006	World Health Statistics	
Government expenditure on health as % of total government budget	18%	% of total government budget	2006	World Health Statistics	
Government annual expenditure on health (MOH + Local Govt)	279,399,711	US\$ average exchange rate 2008	2008	NHA	
	ditures by sourc	e	YEAR	SOURCE	
Annual per capita government expenditure on health	148.2	US\$ average exchange rate 2008	2008	NHA	
Government annual expenditure on health as % of total	76.50%	% of total expenditure on health	2006	World Health Statistics	
Social security expenditure as % of government on health	93%	% of government expenditure on health	2006	World Health Statistics	
Annual per capita private expenditure on health	69.56	US\$ average exchange rate	2006	CALCULATED from World Health Statistics	
Private expenditure as % of total health expenditure	23.50%	% of total expenditure on health	2006	World Health Statistics	
Private out-of-pocket expenditure as % of private health expenditure	100%	% of private expenditure on health	2006	World Health Statistics	

Premiums for private prepaid health plans as % of total private health expenditure	% of private expenditure on health	World Health Statistics
Population covered by national, social, or private health insurance or other sickness funds	% of total population	

2.2 Health Personnel and Infrastructure						
Personnel			YEAR	SOURCE		
Total number of physicians	715	Total number	September 2009	Health Manpower Establishment Register		
Physicians per 1,000 population	0.4	per 1,000 pop	September 2009	Health Manpower Establishment Register		
Total number of nursing and midwifery personnel	6,079	Total number	September 2009	Health Manpower Establishment Register		
Nursing and midwifery personnel per 1,000 population	2.68	per 1,000 pop	September 2009	Health Manpower Establishment Register		
Total number of pharmaceutical personnel ³	401	Total number	2009	Health Manpower Establishment Register		
pharmaceutical personnel per 1,000 pop	0.23	per 1,000 pop	2009	Health Manpower Establishment Register		
Total number of pharmacists ⁴	125	Total number	September 2009	Health Manpower Establishment Register		
Total number of pharmaceutical technicians and assistants ⁵	276	Total number	September 2009	Health Manpower Establishment Register		
Number of newly registered pharmacists in the previous year		Total number		Botswana Health Professional Council Records		

³ Pharmaceutical personnel include pharmacists, pharmaceutical assistants, pharmaceutical technicians and related occupations.

⁴ *Pharmacists* store, preserve, compound, test and dispense medicinal products and counsel on the proper use and adverse effects of drugs and medicines following prescriptions issued by medical doctors and other health professionals. They contribute to researching, preparing, prescribing and monitoring medicinal therapies for optimizing human health. ⁵ *Pharmaceutical technicians and assistants* perform a variety of tasks associated with dispensing medicinal products under the guidance

of a pharmacist or other health professional.

Facilities			YEAR	SOURCE
Hospitals	34	Total number	2005	Health Statistics report 2005
Hospital beds	22	/10,000 population	2007	Health Statistics report 2005
Primary health care units and centres		Total number		Health Statistics report 2005
Licensed pharmacies	95	Total number		DRU Pharmacy Inspection List

PART 3- POLICY and REGULATORY FRAMEWORK

3.1 Policy Framework						
INDICATOR			YEAR	SOURCE		
National Health Policy exists (NHP)	Yes	Yes/No	2009	National Health Policy (NHP) 1995		
-If yes, year of the most recent document	1995	Year	2009	NHP 1995		
National Medicines Policy official document exists	Yes	Yes/No	2009	NMP		
-If yes, year of the most recent document	2002	Year	2009	NMP		
-If no, draft NMP document exists						
-If exists, NMP is integrated into NHP	No ⁶	Yes/No	2009	NMP		
National Medicines Policy Implementation Plan exists	Yes	Yes/No	2009	National Drug Policy Implementation Plan		
-If yes, year of the most recent document	2002	Year	2009	National Drug Policy Implementation Plan		
Traditional Medicine Policy exists	No	Yes/No	2009			
If yes, year of the most updated document						

⁶ The NMP was done after the last issue of the NHP.

3.2 Regulatory Framework				
			YEAR	SOURCE
Legal provision exists establishing the powers and responsibility of a Medicine Regulatory Authority (MRA)	No ⁷	Yes/No	2009	
Formal Medicines Regulatory Authority exists	No ⁸	Yes/No	2009	
-If yes, Medicines Regulatory Authority is an independent agency			_	
-If yes, number of regulatory staff	9 ²	Number	2009	Establishment register MOH
-Medicines Regulatory Authority is funded from regular budget from the government	No	Yes/No	2009	
-Medicines Regulatory Authority is funded from fees from registration of medicines	Νο	Yes/No	2009	
Legal provisions exist for market authorization	Yes	Yes/No	1992	Drugs and Related Substances Act (DRSA)
WHO Certification Scheme may be part of the marketing authorization process	Yes	Yes/No	2009	WHO Level 1
Regulatory agency has website	No	Yes/No	2009	
-If yes, please provide URL address			-	
The Regulatory Authority has a computerized information management system to store and retrieve information on registration, inspections, etc.	Yes	Yes/No	2009	SIAMED WHO Version 6

 ⁷ Existing Law does not provide for this but it is under review to include provision for the establishment of the MRA
 ⁸ A drug regulatory unit was formed to carry out regulatory affairs.

3.3 Medicines Regulatory Authority Involvement in Harmonization initiatives (e.g. countries in SADC have recently established a shared network for posting medicines regulatory information)

regulatory information)					
			YEAR	SOURCE	
Regulatory Authority or MoH is actively involved in regional harmonization initiatives	Yes	Yes/No	2009	SADC Guidelines. www.sadc.int	
-If yes, Regulatory Authority is actively involved in regional initiatives for the harmonization of registration of pharmaceuticals	Yes	Yes/No	2009	SADC guidelines for submitting application for registration of a medicine <u>www.sadc.int</u>	
-If yes, Regulatory Authority is actively involved in regional initiatives for the harmonization of regulation on Clinical Trials	Yes	Yes/No	2009	SADC guidelines on clinical trials www.sadc.int	
-If yes, Regulatory Authority is actively involved in regional initiatives for the harmonization of laws to combat counterfeits	No ⁹	Yes/No	2009		
-If yes, Regulatory Authority is actively involved in regional initiatives for the harmonization of Good Manufacturing Practices	Yes	Yes/No	2009	SADC adopted the WHO cGMP guidelines <u>www.sadc.int</u>	

⁹ Currently the regional harmonisation has worked on technical requirements but the laws are still national.

3	.4 Registrat	ion		
			YEAR	SOURCE
Number of medicines registered	1,451	Number	2009	List of Medicines allowed into Botswana
List of medicines registered is publicly available	Yes ¹⁰	Yes/No	2008	List of Medicines allowed into Botswana
An explicit and transparent process exists for assessing applications for registration of pharmaceutical products	Νο	Yes/No	2009	
Functional formal committee exists responsible for assessing applications for registration of pharmaceutical products	No ¹¹	Yes/No	2009	
List and application status of products submitted for registration are publicly available	No	Yes/No	2009	
INN names are used to register medicines	Yes	Yes/No	1992	Drugs and Related Substances Act (DRSA)
Medicines registration fees exist	Yes	Yes/No	1992	DRSA Regulations
-If yes, amount per application (US\$) for originator product	150	US\$	1992	DRSA
-If yes, amount per application (US\$) for generic product	150	US\$	1992	DRSA
Average length of time from submission of a product application to decision (months)	12-36 with outliers of >60	Months	2009	
A transparent process exists to appeal medicines registration decisions	Yes	Yes/No		
Computerized system exists for retrieval of information on registered products	No	Yes/No	2009	WHO Level I

¹⁰ The plan is to post the list of registered medicines to the MOH website: <u>www.moh.gov.bw</u> ¹¹ In House peer review is used to decide on approval of medicines.

3.5 Manufacturing					
Domestic Manufacturers			YEAR	SOURCE	
Legal provisions exist for licensing domestic manufacturers	Yes	Yes/No	1992	DRSA, Industrial Development Act	
The country has guidelines on Good Manufacturing Practices (GMP)	Yes	Yes/No	2009		
-If yes, these guidelines are used in the licensing process	Yes	Yes/No	2009		
The country has capacity for:					
-R&D to discover new active substances	No	Yes/No	2009	WHO Level I	
Production of pharmaceutical starting materials	No	Yes/No	2009	WHO Level I	
-Formulation from pharmaceutical starting material	No	Yes/No	2009	WHO Level I	
Repackaging of finished dosage forms	No	Yes/No	2009	WHO Level I	
Number of domestic manufacturers	0	Number	2009		
Number of GMP compliant domestic manufacturers	0	Number	2009		
Multinational manufacturers and importers			YEAR	SOURCE	
Legal provisions exist for licensing multinational manufacturers that produce medicines locally	Yes ¹²	Yes/No	2009	DRSA, Industrial Development Act	
Number of multinational pharmaceutical companies with a local subsidiary	0	Number	2009		
Number of multinational pharmaceutical companies producing medicines locally	0	Number	2009		
Legal provisions exist for licensing importers	Yes	Yes/No	1992	DRSA	

¹² These have never been used as there is no manufacturing taking place in the country.

3.6 Quality Control	3.6 Quality Control					
			YEAR	SOURCE		
Legal provisions exist to inspect premises and collect samples	Yes	Yes/No	1992	DRSA		
Legal provisions exist for detecting and combating counterfeit medicines	No	Yes/No	2009			
Samples are tested for post-marketing surveillance	No	Yes/No	2009			
List is publicly available giving detailed results of quality testing in past year	No	Yes/No	2009			
Legal provisions exist to ensure quality control of imported medicines	No	Yes/No	2009			
Legal provisions exist for the recall and disposal of defective products	No ¹³	Yes/No	2009			

3.7 Pharmacovigilance	3.7 Pharmacovigilance					
			YEAR	SOURCE		
Legal provisions exist for monitoring adverse drug reactions (ADRs) on a routine basis	No	Yes/No	2009			
ADRs are monitored	Yes ¹⁴	Yes/No	2008	WHO Collaboration Centre		
-If yes, ADRs are monitored at						
-Central level	Yes	Yes/No	2009	WHO Level I		
-Regional level	No	Yes/No	2009	WHO Level I		
-Local health facilities	Yes	Yes/No	2009	WHO Level I		
-If yes, ADRs are reported to the WHO Collaborating Centre for International Drug Monitoring	Yes ¹⁵	Yes/No	2009	WHO Collaboration Centre		

 ¹³ There are legal provisions for recall of drugs only under the regulations section 9 in the DRSA of 1992. The disposal of defective products is not covered.
 ¹⁴ But not consistently done.
 ¹⁵ Some reporting done

3.8 Medicines	3.8 Medicines Advertising and Promotion					
Legal and regulatory provisions			YEAR	SOURCE		
Legal provisions exist to control the promotion and/or advertising of medicines	Yes	Yes/No	1992	DRSA		
Who is responsible for regulating promotion and/or advertising of medicines	Government	Governme nt/Industry /Co- Regulatio n	1992	DRSA		
Direct advertising of prescription medicines to the public is prohibited	Yes	Yes/No	1992	DRSA		
Regulatory pre-approval is required for medicines advertisements and/or promotional materials	Yes	Yes/No	1992	DRSA		
Guidelines exist for advertising and promotion of non-prescription medicines	No	Yes/No	2009			
Regulatory committee exists for controlling medicines advertising and promotion	No	Yes/No	2009			
-If yes, members must declare conflicts of interest						
Code of conduct			YEAR	SOURCE		
A national code of conduct exists concerning advertising and promotion of medicines by pharmaceutical manufacturers	No	Yes/No				
-If yes, adherence to the code is voluntary	N/A	Yes/No				
A national code of conduct for doctors exists to regulate their relationship with manufacture sales representatives	No	Yes/No				

PART 4 – FINANCING

	4.1 Medicines Expenditure					
			YEAR	SOURCE		
Total medicines expenditure (US\$)	N/A					
Medicines expenditure as a % of GDP	N/A	% of GDP				
Medicines expenditure as a % of Health Expenditure	N/A	% of total health expenditure				
Total public expenditure on medicines (US\$)	51,686,261	US\$ average exchange rate April 2008-March 2009	2008	CMS DATABASE		
MoH annual budget for medicines (US\$)	N/A	US\$ current exchange rates				
Total private expenditure on medicines (US\$)	N/A	US\$ current exchange rates				

4	4.2 Health Insurance and Free Care				
			YEAR	SOURCE	
National Health Insurance (NHI) or Social Health Insurance (SHI) exists	Νο	Yes/No			
-If yes, NHI/SHI provides at least partial medicines coverage	N/A	Yes/No			
Proportion of the population covered by NHI or SHI	N/A	% of total population			
Existence of public programmes providing free medicines	Yes ¹⁶	Yes/No	1995	National Health Policy	
-If yes, medicines are available free-of-charge for:					

¹⁶ Healthcare is free to citizens although some groups have to pay a nominal fee of P5.00 \sim <1 USD for all medical services from consultation to medication until condition is resolved. Note: None citizens have to pay for medical services.

-Patients who cannot afford them	Yes	Yes/No	1995	NHP
-Children under 5	Yes	Yes/No	1995	NHP
-Older children	Yes	Yes/No	1995	NHP
-Pregnant women	Yes	Yes/No	1995	NHP
-Elderly persons	Yes	Yes/No	1995	NHP
-If yes, the following types of medicines are free:				
-All	Yes	Yes/No	1995	NHP
-Malaria medicines	Yes	Yes/No	1995	NHP
-Tuberculosis medicines	Yes	Yes/No	1995	NHP
-Sexually transmitted diseases medicines	Yes	Yes/No	1995	NHP
-HIV/AIDS medicines	Yes	Yes/No	1995	NHP
- At least one vaccine	Yes	Yes/No	1995	NHP

	4.3 Patients Fees and Copayments					
			YEAR	SOURCE		
Inpatients pay a fee for medicines in public hospitals	Νο	Yes/No	2009			
Registration/consultation fees are common in public health facilities	Yes	Yes/No	1995	NHP		
Fixed dispensing fees are common for outpatients in public primary health- care facilities	No	Yes/No	2009			
Outpatients pay varying amounts for medicines in public primary health- care facilities		Yes/No				
Medicines copayments are used to pay salaries of public health-care workers	Νο	Yes/No	2009			

4.4 Pricing Regulation						
Price Control for the private sector			YEAR	SOURCE		
Legal or regulatory provisions exist for setting:						
 Manufacturer's selling price 	No	Yes/No	2009			
- Maximum wholesale mark-up	No	Yes/No	2009			
- Maximum retail mark-up	No	Yes/No	2009			
- Maximum retail price (exit price)	No	Yes/No	2009			
Legal or regulatory provisions for controlling medicines prices vary for different types of medicines	N/A	Yes/No				
Government runs an active national medicines price monitoring system for retail prices	No	Yes/No	2009			
Retail medicines price information is made publicly accessible according to existing regulation	No	Yes/No	2009			

4.5 Results of WHO/HAI Pricing Survey					
			YEAR	SOURCE	
Median Price Ratio of originator brand products to international reference prices for a basket of key medicines PUBLIC SECTOR PROCUREMENT	N/A	Median Price Ratio (Actual Price/Internati onal Reference Price)			
Median Price Ratio of Iowest-priced generics to international reference prices for a basket of key medicines PUBLIC SECTOR PROCUREMENT	N/A	Median Price Ratio			
Median Price Ratio of originator brand products to international reference prices for a basket of key medicines PUBLIC SECTOR PATIENT PRICE	N/A	Median Price Ratio			
Median Price Ratio of lowest-priced generics to international reference prices for a basket of key medicines PUBLIC SECTOR PATIENT PRICE	N/A	Median Price Ratio			

Median Price Ratio of originator brand products to international reference prices for a basket of key medicines PRIVATE SECTOR PATIENT PRICE	N/A	Median Price Ratio	
Median Price Ratio of lowest-priced generics to international reference prices for a basket of key medicines PRIVATE SECTOR PATIENT PRICE	N/A	Median Price Ratio	

4.6 Duties and Taxes on Pharmaceuticals in the Private Sector				
			YEAR	SOURCE
Duty on imported raw materials	Yes	Yes/No	1970	Customs Act cap 50.01, section 41 (2)
Duty on imported finished products	Yes	Yes/No	2004	Botswana Unified Revenue Service ACT Section
VAT or other taxes on medicines	Yes	Yes/No	2002	Value Added Tax cap 50:03
-If yes, amount of VAT on pharmaceutical products (%)	10%	%	2002	Value Added Tax cap 50:03

PART 5 – PATENTS				
5.1 Me	dicines Patent	Laws		
			YEAR	SOURCE
Country is a member of the World Trade Organization	Yes	Yes/No	2008	Industrial Property Bill
Patents are granted on pharmaceutical products by a National Patent Office	Yes	Yes/No	2008	Industrial Property Bill
List of patented medicines is available	No	Yes/No	2009	
National legislation has been modified to implement the TRIPS Agreement	Yes	Yes/No	2008	Industrial Property Bill
-If yes, the transitional period has been extended per Doha Declaration	No	Yes/No	2009	
-If yes, TRIPS flexibilities have been incorporated into legislation	Yes	Yes/No	2009	WHO Level I
-If TRIPS flexibilities have been incorporated, they are:				
-Compulsory licensing provisions	Yes	Yes/No	2008	Industrial Property Bill
-Government use	Yes	Yes/No	2008	Industrial Property Bill
-Parallel importing provisions	Yes	Yes/No	2008	Industrial Property Bill
-Bolar exception	No	Yes/No	2009	

P/	PART 6 – SUPPLY					
	6.1 Procure					
			YEAR	SOURCE		
Is there a written public sector procurement strategy? &	No	Yes/No	2009			
-If yes, in what year was it approved?	No	Year	2009			
Are there provisions giving priority in public procurement to goods produced by domestic manufacturers?	Yes	Yes/No	2005	DIRECTIVE ON THE USE OF LOCALLY MANUFACTURED GOODS AND SERVICES		
Are there provisions giving priority in public procurement to goods produced by manufacturers from SADC countries?	Νο	Yes/No	2009			
Do the public sector procurement regulations apply to pharmaceutical procurement?	Yes	Yes/No	2006	PUBLIC PROCUREMENT AND ASSET DISPOSAL REGULATIONS		
How many people are working full-time only on procurement of pharmaceuticals for the public sector?	15	Number	2009	CMS Establishment Register		
There is a tender board/committee overseeing public procurement of medicines	Yes	Yes/No	2001	PUBLIC PROCUREMENT AND ASSET DISPOSAL ACT		
-If yes, the key functions of the procurement office and those of the tender committee are clearly separated	Yes	Yes/No	2006	PUBLIC PROCUREMENT AND ASSET DISPOSAL ACT REGULATIONS		
Public procurement is limited to medicines on the national EML	No	Yes/No	2009			
WHO-prequalification system is used to identify suppliers for ARVs, TB, ATM and RHR	No	Yes/No	2009			
WHO certification system is used to identify suppliers	Νο	Yes/No	2009			
A functioning process exists to ensure the quality of other products procured	Νο	Yes/No	2009			
-If yes, this process includes prequalification of products and suppliers	No	Yes/No	2009			
-If yes, explicit criteria and procedures exist for prequalification of suppliers	Νο	Yes/No	2009			

suppliers and products is publicly available				
How many people are working full-time on quality assurance for procurement?	6	Number	2009	Central Medical Stores Establishment Register
Percentage of public sector procurement expenditures in last year awarded by:				
-National competitive tenders	No	% of total value		
-International competitive tenders	No	% of total value		
-Negotiation	No	% of total value		
-Direct purchasing	No	% of total value		
Public sector tenders are publicly available	Yes	Yes/No	2009	Government gazette
Public sector awards are publicly available	Yes	Yes/No	2009	Government Gazette, Free Daily news paper
Public sector tenders use an e- procurement system	No ¹⁷	Yes/No	2009	Integrated procurement management System
A written code of conduct exists governing the behaviour of public procurement agencies in their interactions with sales representatives and wholesalers	Yes	Yes/No	2006	CODE OF CONDUCT
List of samples tested during the procurement process and results of quality testing is available	Yes	Yes/No	2009	Test Report Register
Public sector procurement is centralized at the national level	Yes	Yes/No	2008	WHO Level I
Is there a capacity building strategy for procurement and supply management?	Yes	Yes/No	2008	National Procurement training Master Plan
-If yes, when was it finalized?	2008	Year	2009	PPADB strategic plan 2008-2013
-If yes, what period does it cover?	2008-2013	Year-Year	2009	PPADB strategic plan 2008-2013

¹⁷ Comprehensive e-procurement Under development.

6.2 Procurement Budget					
		CURRENCY	YEAR	SOURCE	
Total value of medicines procured in the public sector in the previous year	51,686,262	US\$ Average exchange rate Apr08- Mar09	2008-2009	CMS SYSTEM	
Public procurement expenditure on products from national manufacturers in the previous year (if available)	N/A				
Public procurement expenditure on products from SADC manufacturers in the previous year (if available)	N/A				
Public procurement expenditure on products on the EML in the previous year (if available)					

6.3 Distribution					
Distributors ¹⁸			YEAR	SOURCE	
There are national guidelines on Good Distribution Practices (GDP)	Νο	Yes/No	2009		
There a list of all GDP compliant distributors	Νο	Yes/No	2009		
CMS			YEAR	SOURCE	
Software tools are available for planning medicines supply	Yes	Yes/No	2009	CMS Database	
Software tools are available for management of medicines supply (procurement tracking, expenditure tracking, stock levels)	Yes ¹⁹	Yes/No	2009	CMS Database	
Data on months of stock on hand is routinely reported to managers	Yes	Yes/No	2009	CMS Database	

 ¹⁸ For the purpose of this profile, distributors deliver medicines on behalf of others and do not carry any risk for stock lost or expired.
 ¹⁹ Excluding procurement tracking.

6.4 Wholesale Market Characteristics ²⁰						
			YEAR	SOURCE		
Legal provisions exist for licensing wholesalers	Yes	Yes/No	1992	DRSA		
Number of wholesalers in market		Number				
Number of GDP compliant wholesalers in market		Number				
List of GDP compliant wholesalers is publicly available	No	Yes/No	2009			

²⁰ Wholesalers own the products that they sell/distribute and carry the risk for stock lost or expired.

PART 7- SELECTION and RATIONAL USE of MEDICINES

7.1 National Structures				
			YEAR	SOURCE
National standard treatment guidelines (STGs) for major conditions are produced by the MoH	Yes	Yes/No	2007	Botswana Treatment Guidelines
-If yes, year of last update of national STGs	2007	Year		Botswana Treatment Guidelines
National essential medicines list (EML) exists	Yes	Yes/No	2005	Botswana Essential Drug List (BEDL)
-If yes, number of medicine formulations on the national EML	500	Number	2005	BEDL
-If yes, year of last update of EML	2005	Year	2005	BEDL
-If yes, process for selecting medicines on the EML is publicly available	No	Yes/No	2009	
There is a committee for the selection of products on the national EML	Yes	Yes/No	1995	DRSA
-If yes, conflict of interest declarations are required from members on national EML committee	N/A	Yes/No	2009	
There are explicit criteria for selecting medicines for national EML		Yes/No		
National medicines formulary manual exists	Νο	Yes/No	2009	
-If yes, national medicines formulary manual is limited to essential medicines				
-If yes, year of last update of national medicines formulary manual				
National STGs for paediatric conditions exist	Νο	Yes/No	2009	
-If yes, year of last update of national paediatric STGs				
EML used in public insurance reimbursement	Νο	Yes/No	2009	
Rational use national audit done in the last two years	Νο	Yes/No	2009	
% of public health facilities with EML (mean)- Survey data	N/A	%		
% of public health facilities with STGs (mean)- Survey data	N/A	%		

Public education campaigns about rational medicines use have been conducted by MoH, NGOs or academia in the previous two years	No	Yes/No	2009	
A national programme or committee involving government, civil society, and professional bodies exists to monitor and promote rational use of medicines	Yes	Yes/No	2002	National Drug Policy
A national strategy exists to contain antimicrobial resistance	No	Yes/No	2009	
-If yes, date of last update of the strategy				
A national reference laboratory has responsibility for coordinating epidemiological surveillance of antimicrobial resistance	No	Yes/No	2009	
A public or independently funded national medicines information centre provides information on medicines to consumers	No	Yes/No	2009	
Legal provisions exist for the control of narcotics, psychotropic substances, and precursors	Yes	Yes/No	1992	DRSA
The country is a signatory to the International Conventions on the Control of Narcotics, Psychotropic Substances and Precursors	Yes	Yes/No	1984	www.agc.gov.b w

7.2 Prescribing					
			YEAR	SOURCE	
Legal provisions exist to govern the licensing and prescribing practices of prescribers	Yes	Yes/No	2001	Botswana Health Profession's Act	
-The following types of health workers are legally allowed to prescribe	· · · · · · · · · · · · · · · · · · ·				
-Nurses	Yes	Yes/No	2001	Botswana Health Professional Act	
-Midwives	No	Yes/No	2009		
-Community health workers	No	Yes/No	2009		
-Pharmacists	Νο	Yes/No	2009		

Prescribers are legally allowed to dispense	Yes	Yes/No	1992	DRSA
Prescribers in the public sector dispense medicines	Yes	Yes/No	1992	DRSA
Prescribers in the private sector dispense medicines	Yes	Yes/No	1992	DRSA
The basic <u>medical</u> training curriculum includes components on:				
- Use of the national EML	N/A	Yes/No		
- Use of national STGs	N/A	Yes/No		
- Problem-based pharmacotherapy	N/A	Yes/No		
- Good practices in prescribing	N/A	Yes/No		
The basic <u>nursing</u> training curriculum includes components on:				
- Use of the national EML	Yes	Yes/No	2009	WHO Level I
- Use of national STGs	Yes	Yes/No	2009	WHO Level I
- Problem-based pharmacotherapy	Yes	Yes/No	2009	WHO Level I
- Good practices in prescribing	Yes	Yes/No	2009	WHO Level I
The basic training curriculum for paramedical staff includes components on:				
- Use of the national EML	Νο	Yes/No	2009	WHO Level I
- Use of national STGs	No	Yes/No	2009	WHO Level I
- Problem-based pharmacotherapy	Νο	Yes/No	2009	WHO Level I
- Good practices in prescribing	No	Yes/No	2009	WHO Level I
Regulations exist requiring hospitals to organize/develop Drug and Therapeutics Committees (DTCs)	Yes	Yes/No	2002	NDP
Mandatory, non-commercially funded continuing education that includes use of medicines is required for doctors	No	Yes/No	2009	WHO Level I
A public or independently funded national medicines information centre exists that provides information on demand to prescribers	No	Yes/No	2009	

Prescribing by generic name is obligatory in:				
-Public sector	Yes	Yes/No	1992	DRSA
-Private sector	Yes	Yes/No	1992	DRSA
Incentives exist to encourage prescribing of generic medicines in public health facilities	No	Yes/No	2009	
Incentives exist to encourage prescribing of generic medicines in private health facilities	No	Yes/No	2009	
INRUD prescribing indicators			YEAR	SOURCE
Number of medicines prescribed per patient contact in public health facilities (mean)	2.1	Number	1997	Report on Botswana Drug Use indicator
% of patients receiving antibiotics (mean)	41.2%	%	1997	Report on Botswana Drug Use indicator
% of patients receiving injections (mean)	9%	%	1997	Report on Botswana Drug Use indicator
% of drugs prescribed that are in the EML (mean)	7.2%	%	1997	Report on Botswana Drug Use indicator
Diarrhoea in children treated with ORS (%)	N/A	%	1997	Report on Botswana Drug Use indicator
Non-pneumonia ARIs treated with antibiotics (%)	50%	%	1997	Report on Botswana Drug Use indicator

7.3 Dispensing							
			YEAR	SOURCE			
Legal provisions exist to govern licensing and practice of pharmacy	Yes	Yes/No	2001	Botswana Health Profession's Act			
A professional association code of conduct exists governing professional behaviour of pharmacists	No	Yes/No	2009				
The basic <u>pharmacist</u> training curriculum includes components on							
-Use of the national EML	N/A	Yes/No					
-Use of national STGs	N/A	Yes/No					
-Problem-based pharmacotherapy	N/A	Yes/No					
-Good practices in prescribing	N/A	Yes/No					
Mandatory, non-commercially funded continuing education that includes use of medicines is required for pharmacists	No	Yes/No	2009				
A public or independently funded national medicines information centre exists that provides information on demand to dispensers	Νο	Yes/No	2009				
Substitution of generic equivalents is permitted for:							
-Public sector dispensers	Yes	Yes/No	1992	DRSA			
-Private sector dispensers	Yes	Yes/No	1992	DRSA			
Incentives exist to encourage dispensing of generic medicines in:							
-Public pharmacies	No	Yes/No	2009				
-Private pharmacies	No	Yes/No	2009				
Antibiotics are sold over-the-counter without a prescription	No	Yes/No	2009				
Injections are sold over-the-counter without a prescription	No	Yes/No	2009				
Narcotics are sold over-the-counter without a prescription	No	Yes/No	2009				
Tranquillisers are sold over-the-counter without a prescription	No	Yes/No	2009				

INRUD dispensing indicators			YEAR	SOURCE
% of prescribed drugs dispensed to patients (mean)	88.3%	%	1997	Report on Botswana Drug Use Indicator
Percentage of medicines adequately labelled in public health facilities (mean)	45.9%	%	1997	Report on Botswana Drug Use Indicator
Percentage of patients knowing correct dosage in public health facilities (mean)	62.6%	%	1997	Report on Botswana Drug Use Indicator

PART 8 - HOUSEHOLD DATA

8.1 Data from Household surveys						
			YEAR	SOURCE		
Adults with acute conditions taking all medicines prescribed	N/A	%				
Adults with acute conditions not taking all medicines because they cannot afford them	N/A	%				
Adults with acute conditions not taking all medicines because they cannot find them	N/A	%				
Adults (from poor households) with acute conditions taking all medicines prescribed	N/A	%				
Adults (from poor households) with acute conditions not taking all medicines because they cannot afford them	N/A	%				
Adults with chronic conditions taking all medicines prescribed	N/A	%				
Adults with chronic conditions not taking all medicines because they cannot afford them	N/A	%				
Adults with chronic conditions not taking all medicines because they cannot find them	N/A	%				
Adults (from poor households) with chronic conditions taking all medicines prescribed	N/A	%				
Adults (from poor households) with chronic conditions not taking all medicines because they cannot afford them	N/A	%				
Children with acute conditions taking all medicines prescribed	N/A	%				
Children with acute conditions not taking all medicines because they cannot afford them	N/A	%				
Children with acute conditions not taking all medicines because they cannot find them	N/A	%				
Children (from poor households) with acute conditions taking all medicines prescribed	N/A	%				
Children (from poor households) with acute conditions not taking all medicines because they cannot afford them	N/A					
		%				