

**Country Data Profile on the Pharmaceutical
Situation
in the Southern African Development Community
(SADC)**



SWAZILAND

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INTRODUCTION

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, **Swaziland** has collaborated with WHO in the collection and analysis of data on its 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 **Swaziland** 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	1,018,449	,000	2007	Population and Housing Census
Population < 15 years	39%	% of total population	2007	Population and Housing Census
Population > 60 years	5%	% of total population	2007	Population and Housing Census
Urban population	22%	% of total population	2007	Population and Housing Census
Population growth	0.9%	Annual %	2007	Population and Housing Census
Fertility rate, total	3.5	Births per woman	2007	Demographic and Health Survey (DHS)
Economic status			YEAR	SOURCE
GDP	2.89	Current US\$ Billions	2007	World Development Indicators database, April 2009
GDP growth	3.50%	Annual %	2007	World Development Indicators database, April 2009
GNI per capita	2,560	Current US\$	2007	World Development Indicators database, April 2009
Population living < PPP int. \$1 a day	62.4%	%	2005	World Health Statistics
Income share held by lowest 20%		%		

Education and literacy			YEAR	SOURCE
Adult literacy rate, 15+ years	79.6%	% of total population	2000	WHOSIS
Primary school enrolment rate, males	78.0%	% of male population	2005	WHOSIS
Primary school enrolment rate, females	79.0%	% of female population	2005	WHOSIS

1.2 Mortality and Causes of Death

Life expectancy and mortality			YEAR	SOURCE
Life expectancy at birth (both sexes)	33	Years	2007	Demographic and Health Survey (DHS)
Adult mortality rate (both sexes, 15 to 60 years)	618	/1,000 population	2007	World Health Statistics
Maternal mortality ratio	589	/100,000 live births	2007	Demographic and Health Survey (DHS) 2007
Neonatal mortality rate	22	/1,000 live births	2007	Demographic and Health Survey (DHS) 2007
Infant mortality rate (between birth and age 1)	85	/1,000 live births	2007	Demographic and Health Survey (DHS) 2007
Under 5 mortality rate	120	/1,000 live births	2007	Demographic and Health Survey (DHS) 2007

PART 2- HEALTH SERVICES

2.1 Health Expenditures				
Overall health expenditures			YEAR	SOURCE
Total annual expenditure on health	175,336,719	US\$ average exchange rate	2006	NHA
Total annual per capita expenditure on health	155	US\$ average exchange rate	2006	World Health Statistics
Health expenditure as % of GDP	6.3%	% of gross domestic product	2006	World Health Statistics
Government annual expenditure on health	115,356,454	US\$ average exchange rate	2006	NHA
Government expenditure on health as % of total government budget	11.2%	% of total government budget	2006	World Health Statistics
Health expenditures by source			YEAR	SOURCE
Annual per capita government expenditure on health	102	US\$ average exchange rate	2006	World Health Statistics
Government annual expenditure on health as % of total	65.8%	% of total expenditure on health	2006	World Health Statistics
Social security expenditure as % of government on health	0.0%	% of government expenditure on health	2006	World Health Statistics
Annual per capita private expenditure on health	53.0	US\$ average exchange rate	2006	CALCULATED from World Health Statistics
Private expenditure as % of total health expenditure	34.2%	% of total expenditure on health	2006	World Health Statistics
Private out-of-pocket expenditure as % of private health expenditure	41.4%	% of private expenditure on health	2006	World Health Statistics

Premiums for private prepaid health plans as % of total private health expenditure	18.5%	% of private expenditure on health	2006	World Health Statistics
Population covered by national, social, or private health insurance or other sickness funds	0.9%	% of total population	2007	Demographic and Health Survey (DHS)

2.2 Health Personnel and Infrastructure				
Personnel			YEAR	SOURCE
Total number of physicians	184	Total number	2007	Swaziland Medical and Dental Council Report 2007
Physicians per 1,000 population	0.4	per 1,000 pop	2004	WHO GLOBAL ATLAS of HEALTH WORKFORCE
Total number of nursing and midwifery personnel	3,070	Total number	2007	National Health Policy 2007
Nursing and midwifery personnel per 1,000 population	3	per 1,000 pop	2007	National Health Policy 2007
Total number of pharmaceutical personnel ³	81	Total number	2007	Expert Opinion
pharmaceutical personnel per 1,000 pop	0.07	per 1,000 pop	2007	Expert Opinion
Total number of pharmacists ⁴	44	Total number	2009	Expert Opinion
Total number of pharmaceutical technicians and assistants ⁵	37	Total number	2009	Expert Opinion
Number of newly registered pharmacists in the previous year	2	Total number	2009	Swaziland Medical and Dental 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	8	Total number	2009	Ministry of Health Statistics Unit
Hospital beds	20	/10,000 population	2009	Ministry of Health Statistics Unit
Primary health care units and centres	168	Total number	2009	Ministry of Health Statistics Unit
Licensed pharmacies	69	Total number	2009	Ministry of Commerce and Trade

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PART 3- POLICY and REGULATORY FRAMEWORK

3.1 Policy Framework				
INDICATOR			YEAR	SOURCE
National Health Policy exists (NHP)	Yes	Yes	2007	National Health Policy Document
-If yes, year of the most recent document	2007	year	2007	National Health Policy Document
National Medicines Policy official document exists	Yes	Yes	2000	National Pharmaceutical Policy
-If yes, year of the most recent document	2008	year	2008	National Pharmaceutical Policy
-If no, draft NMP document exists	N/A	N/A		
-If exists, NMP is integrated into NHP	Yes	Yes	2008	National Health Policy Document
National Medicines Policy Implementation Plan exists	No	No	2009	National Pharmaceutical Policy
-If yes, year of the most recent document	N/A		2009	Ministry of Health Pharmaceutical Services Department (PSD)
Traditional Medicine Policy exists	No	No	2009	Ministry of Health PSD
If yes, year of the most updated document	N/A	N/A	2009	Ministry of Health PSD

3.2 Regulatory Framework				
			YEAR	SOURCE
Legal provision exists establishing the powers and responsibility of a Medicine Regulatory Authority (MRA)	No	No (a bill exists but it has not been enacted)	2009	Ministry of Health PSD
Formal Medicines Regulatory Authority exists	No	No	2009	Ministry of Health PSD
-If yes, Medicines Regulatory Authority is an independent agency	N/A	N/A	2009	Ministry of Health PSD
-If yes, number of regulatory staff	N/A	N/A	2009	Ministry of Health PSD
-Medicines Regulatory Authority is funded from regular budget from the government	N/A	N/A	2009	Ministry of Health PSD

-Medicines Regulatory Authority is funded from fees from registration of medicines	N/A	N/A	2009	Ministry of Health PSD
Legal provisions exist for market authorization	N/A	N/A	2009	Ministry of Health PSD
WHO Certification Scheme may be part of the marketing authorization process	Yes	Yes (Certification Scheme used during procurement)	2009	Ministry of Health PSD
Regulatory agency has website	No	N/A	2009	Ministry of Health PSD
-If yes, please provide URL address	N/A	N/A	2009	
The Regulatory Authority has a computerized information management system to store and retrieve information on registration, inspections, etc.	N/A	N/A	2009	Ministry of Health PSD

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)

			YEAR	SOURCE
Regulatory Authority or MoH is actively involved in regional harmonization initiatives	Yes (MoH)	Yes	2009	Ministry of Health PSD
-If yes, Regulatory Authority is actively involved in regional initiatives for the harmonization of registration of pharmaceuticals	Yes (MoH)	Yes (Ministry of Health Pharmaceutical Services in involved in regional initiatives for harmonization)	2009	Ministry of Health PSD
-If yes, Regulatory Authority is actively involved in regional initiatives for the harmonization of regulation on Clinical Trials	Yes (MoH)	Yes (Ministry of Health Pharmaceutical Services in involved in regional initiatives for harmonization)	2009	Ministry of Health PSD

-If yes, Regulatory Authority is actively involved in regional initiatives for the harmonization of laws to combat counterfeits	Yes (MoH)	Yes (Ministry of Health Pharmaceutical Services in involved in regional initiatives for harmonization)	2009	Ministry of Health PSD
-If yes, Regulatory Authority is actively involved in regional initiatives for the harmonization of Good Manufacturing Practices	Yes (MoH)	Yes	2009	Ministry of Health PSD

3.4 Registration				
			YEAR	SOURCE
Number of medicines registered	0	N/A	2009	Ministry of Health PSD
List of medicines registered is publicly available	N/A	N/A	2009	Ministry of Health PSD
An explicit and transparent process exists for assessing applications for registration of pharmaceutical products	N/A	N/A	2009	Ministry of Health PSD
Functional formal committee exists responsible for assessing applications for registration of pharmaceutical products	N/A	N/A	2009	Ministry of Health PSD
List and application status of products submitted for registration are publicly available	N/A	N/A	2009	Ministry of Health PSD
INN names are used to register medicines	N/A	N/A	2009	Ministry of Health PSD
Medicines registration fees exist	N/A	N/A	2009	Ministry of Health PSD
-If yes, amount per application (US\$) for originator product	N/A	N/A	2009	Ministry of Health PSD
-If yes, amount per application (US\$) for generic product	N/A	N/A	2009	Ministry of Health PSD
Average length of time from submission of a product application to decision (months)	N/A	N/A	2009	Ministry of Health PSD
A transparent process exists to appeal medicines registration decisions	N/A	N/A	2009	Ministry of Health PSD
Computerized system exists for retrieval of information on registered products	N/A	N/A	2009	Ministry of Health PSD

3.5 Manufacturing				
Domestic Manufacturers			YEAR	SOURCE
Legal provisions exist for licensing domestic manufacturers	No	No	2009	Ministry of Health PSD
The country has guidelines on Good Manufacturing Practices (GMP)	No	No	2009	Ministry of Health PSD
-If yes, these guidelines are used in the licensing process	No	N/A	2009	Ministry of Health PSD
The country has capacity for:				
.R&D to discover new active substances	No	No	2009	Ministry of Health PSD
.Production of pharmaceutical starting materials	No	No	2009	Ministry of Health PSD
.Formulation from pharmaceutical starting material	No	No	2009	Ministry of Health PSD
.Repackaging of finished dosage forms	No	No	2009	Ministry of Health PSD
Number of domestic manufacturers	1	1	2009	Ministry of Health PSD
Number of GMP compliant domestic manufacturers	0	0	2009	Ministry of Health PSD
Multinational manufacturers and importers			YEAR	SOURCE
Legal provisions exist for licensing multinational manufacturers that produce medicines locally	No	No	2009	Ministry of Health PSD
Number of multinational pharmaceutical companies with a local subsidiary	0	0	2009	Ministry of Health PSD
Number of multinational pharmaceutical companies producing medicines locally	0	0	2009	Ministry of Health PSD
Legal provisions exist for licensing importers	Yes (through collaboration of Ministry of Commerce and Trade & Ministry of Health)	Yes	2009	Ministry of Health PSD

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

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

3.8 Medicines Advertising and Promotion				
Legal and regulatory provisions			YEAR	SOURCE
Legal provisions exist to control the promotion and/or advertising of medicines	No	No (They are contained in the Medicines Bill)	2009	Ministry of Health PSD
Who is responsible for regulating promotion and/or advertising of medicines	None	Government/Industry/Co-Regulation (These are not regulated in country)	2009	Ministry of Health PSD
Direct advertising of prescription medicines to the public is prohibited	No	No	2009	Ministry of Health PSD
Regulatory pre-approval is required for medicines advertisements and/or promotional materials	No	No	2009	Ministry of Health PSD
Guidelines exist for advertising and promotion of non-prescription medicines	No	No	2009	Ministry of Health PSD
Regulatory committee exists for controlling medicines advertising and promotion	No	No	2009	Ministry of Health PSD
-If yes, members must declare conflicts of interest	No	No	2009	Ministry of Health PSD
Code of conduct			YEAR	SOURCE
A national code of conduct exists concerning advertising and promotion of medicines by pharmaceutical manufacturers	No	No	2009	Ministry of Health PSD
-If yes, adherence to the code is voluntary	No	No	2009	Ministry of Health PSD
A national code of conduct for doctors exists to regulate their relationship with manufacture sales representatives	No	No	2009	Ministry of Health PSD

PART 4 - FINANCING

4.1 Medicines Expenditure				
			YEAR	SOURCE
Total medicines expenditure (US\$)		US\$ current exchange rates		
Medicines expenditure as a % of GDP		% of GDP		
Medicines expenditure as a % of Health Expenditure		% of total health expenditure		
Total public expenditure on medicines (US\$)	11,309,200	US\$ current exchange rates	2009	Ministry of Health Budget 2008/2009
MoH annual budget for medicines (US\$)	14,546,176	US\$ current exchange rates	2009	Ministry of Health Budget 2008/2009
Total private expenditure on medicines (US\$)		US\$ current exchange rates		

4.2 Health Insurance and Free Care				
			YEAR	SOURCE
National Health Insurance (NHI) or Social Health Insurance (SHI) exists	No	No	2009	WHO Level I
-If yes, NHI/SHI provides at least partial medicines coverage	No	No	2009	WHO Level I
Proportion of the population covered by NHI or SHI	N/A	% of the population	2009	
Existence of public programmes providing free medicines	Yes	Yes	2009	WHO Level I
-If yes, medicines are available free-of-charge for:				
-Patients who cannot afford them	Yes	Yes	2007	National Health Policy 2007

-Children under 5	Yes	Yes	2007	National Health Policy 2007
-Older children	Yes	Yes	2007	National Health Policy 2007
-Pregnant women	Yes	Yes	2007	National Health Policy 2007
-Elderly persons	Yes	Yes	2007	National Health Policy 2007
-If yes, the following types of medicines are free:				
-All	No	No	2007	National Health Policy 2007
-Malaria medicines	Yes	Yes	2007	National Health Policy 2007
-Tuberculosis medicines	Yes	Yes	2007	National Health Policy 2007
-Sexually transmitted diseases medicines	No	No	2007	National Health Policy 2007
-HIV/AIDS medicines	Yes	Yes	2007	National Health Policy 2007
At least one vaccine	Yes	Yes	2007	National Health Policy 2007

4.3 Patients Fees and Copayments

			YEAR	SOURCE
Inpatients pay a fee for medicines in public hospitals	Yes	Yes	2007	National Health Policy 2007
Registration/consultation fees are common in public health facilities	Yes	Yes	2007	National Health Policy 2007
Fixed dispensing fees are common for outpatients in public primary health-care facilities	No	No	2007	National Health Policy 2007
Outpatients pay varying amounts for medicines in public primary health-care facilities	No	No	2007	National Health Policy 2007
Medicines copayments are used to pay salaries of public health-care workers	No	No	2007	National Health Policy 2007

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

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 (from WHO-HAI Pricing Survey) PUBLIC SECTOR PROCUREMENT		Median Price Ratio		
Median Price Ratio of lowest-priced generics to international reference prices for a basket of key medicines (from WHO-HAI Pricing Survey) PUBLIC SECTOR PROCUREMENT		Median Price Ratio		
Median Price Ratio of originator brand products to international reference prices for a basket of key medicines PUBLIC SECTOR PATIENT PRICE		Median Price Ratio		
Median Price Ratio of lowest-priced generics to international reference prices for a basket of key medicines (from WHO-HAI Pricing Survey) PUBLIC SECTOR PATIENT PRICE		Median Price Ratio		

Median Price Ratio of originator brand products to international reference prices for a basket of key medicines PRIVATE SECTOR PATIENT PRICE		Median Price Ratio		
Median Price Ratio of lowest-priced generics to international reference prices for a basket of key medicines (from WHO-HAI Pricing Survey) PRIVATE SECTOR PATIENT PRICE		Median Price Ratio		

4.6 Duties and Taxes on Pharmaceuticals in the Private Sector				
			YEAR	SOURCE
Duty on imported raw materials	Yes	Yes	2009	Ministry of Health PSD
Duty on imported finished products	No	No	2009	Ministry of Health PSD
VAT or other taxes on medicines	No	No	2009	Ministry of Health PSD
-If yes, amount of VAT on pharmaceutical products (%)	N/A	%	2009	Ministry of Health PSD

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PART 5 - PATENTS

5.1 Medicines Patent Laws				
			YEAR	SOURCE
Country is a member of the World Trade Organization	Yes	Yes	2009	Ministry of Health PSD
Patents are granted on pharmaceutical products by a National Patent Office	Yes	Yes	2009	Ministry of Health PSD
List of patented medicines is available	No	Yes/No	2009	Ministry of Health PSD
National legislation has been modified to implement the TRIPS Agreement	Yes	Yes	2009	Medicines and Related Substance Control Bill
-If yes, the transitional period has been extended per Doha Declaration	Yes	Yes	2009	Medicines and Related Substance Control Bill
-If yes, TRIPS flexibilities have been incorporated into legislation	Yes	Yes	2009	Medicines and Related Substance Control Bill
-If TRIPS flexibilities have been incorporated, they are:				
-Compulsory licensing provisions	Yes	Yes	2009	Medicines and Related Substance Control Bill
-Government use	Yes	Yes	2009	Medicines and Related Substance Control Bill
-Parallel importing provisions	Yes	Yes	2009	Medicines and Related Substance Control Bill
-Bolar exception	No	No	2009	Medicines and Related Substance Control Bill

PART 6 - SUPPLY

6.1 Procurement				
			YEAR	SOURCE
Is there a written public sector procurement strategy?	No	No	2009	Ministry of Health PSD
-If yes, in what year was it approved?	N/A	Year	2009	Ministry of Health PSD
Are there provisions giving priority in public procurement to goods produced by domestic manufacturers?	Yes	Yes	2008	Regulations of Procurement Bill
Are there provisions giving priority in public procurement to goods produced by manufacturers from SADC countries?	No	Yes/No	2008	Regulations of Procurement Bill
Do the public sector procurement regulations apply to pharmaceutical procurement?	Yes	Yes	2008	Regulations of Procurement Bill
How many people are working full-time only on procurement of pharmaceuticals for the public sector?	8	number	2009	Central Medical Stores
There is a tender board/committee overseeing public procurement of medicines	Yes	Yes	2008	Procurement Bill
-If yes, the key functions of the procurement office and those of the tender committee are clearly separated	Yes	Yes	2008	Procurement Bill
Public procurement is limited to medicines on the national EML	Yes	Yes	2008	National Pharmaceutical Policy
WHO-prequalification system is used to identify suppliers for ARVs, TB, ATM and RHR	Yes	Yes	2009	Central Medical Store
WHO certification system is used to identify suppliers	Yes	Yes	2009	Central Medical Store
A functioning process exists to ensure the quality of other products procured	Yes	Yes	2009	Central Medical Store
-If yes, this process includes prequalification of products and suppliers	Yes	Yes	2009	Central Medical Store
-If yes, explicit criteria and procedures exist for prequalification of suppliers	Yes	Yes	2009	Central Medical Store

-If yes, a list of prequalified suppliers and products is publicly available	No	No	2009	Central Medical Store
How many people are working full-time on quality assurance for procurement?	1	Number	2009	Central Medical Store
Percentage of public sector procurement expenditures in last year awarded by:				
-National competitive tenders	100%	% of total value	2009	Central Medical Store
-International competitive tenders	0%	% of total value	2009	Central Medical Store
-Negotiation	0%	% of total value	2009	Central Medical Store
-Direct purchasing	0%	% of total value	2009	Central Medical Store
Public sector tenders are publicly available	Yes	Yes	2009	Central Medical Store
Public sector awards are publicly available	No	No	2009	Central Medical Store
Public sector tenders use an e-procurement system	No	No	2009	Central Medical Store
A written code of conduct exists governing the behaviour of public procurement agencies in their interactions with sales representatives and wholesalers	Yes	Yes	2008	Regulations of Procurement Bill
List of samples tested during the procurement process and results of quality testing is available	No	No	2009	Central Medical Store
Public sector procurement is centralized at the national level	Yes	Yes	2009	Central Medical Store
Is there a capacity building strategy for procurement and supply management?	No	Yes/No	2009	Central Medical Store
-If yes, when was it finalized?	N/A	Year	2009	Central Medical Store
-If yes, what period does it cover?	N/A	Year-Year	2009	Central Medical Store

6.2 Procurement Budget. (Please insert currency in the 3rd column).

		CURRENCY	YEAR	SOURCE
Total value of medicines procured in the public sector in the previous year	3,578,842	USD average exchange rate	2008/2009	CMS Drug trading account statement
Public procurement expenditure on products from national manufacturers in the previous year (if available)	254,364	USD average exchange rate	2008/2009	Central Medical Stores (CMS) Database
Public procurement expenditure on products from SADC manufacturers in the previous year (if available)	Not Available		2008/2009	CMS Database
Public procurement expenditure on products on the EML in the previous year (if available)	3,578,842	USD average exchange rate	2008/2009	CMS

6.3 Procurement Price of Medicines on the WHO/HAI Global List

To calculate the UNIT PRICE please divide the price of the pack by the pack size (e.g. 28, 500, and 100). For example, a pack of 500 amoxicillin 500 mg/caps costing US\$ 23.8 would have a unit price of 23.8 /500, that is a per unit price of US\$ 0.048.

For Year:	2008	US\$
Medicine, Strength, Formulation	UNIT price for Originator	UNIT price for lowest priced generic
Amitriptyline 25 mg Cap/tab	0.0138	0.0040
Amoxicillin 500 mg Cap/tab	0.0636	0.0329
Atenolol 50 mg Cap/tab	0.0307	0.0034
Captopril 25 mg Cap/tab	0.0507	0.0102
Ceftriaxone 1 g/ vial Injection	2.7536	0.5000
Ciprofloxacin 500 mg Cap/tab	0.0505	0.0243
Co-trimoxazole 8 + 40 mg/ml Susp.	0.0109	0.0020
Diazepam 5 mg Cap/tab	0.0099	0.0023
Diclofenac 50 mg Cap/tab	0.0239	0.0035
Glibenclamide 5 mg Cap/tab	0.0116	0.0025
Omeprazole 20 mg Cap/tab	0.1420	0.0105
Paracetamol 24 mg/ml Susp.	0.0114	0.0008
Salbutamol 0.1mg/dose Inhaler	0.0172	0.0056
Simvastatin 20 mg Cap/tab	0.0629	0.0198

6.4 Distribution				
Distributors⁶			YEAR	SOURCE
There are national guidelines on Good Distribution Practices (GDP)	No	Yes/No	2009	
There a list of all GDP compliant distributors	No	Yes/No	2009	
CMS			YEAR	SOURCE
Software tools are available for planning medicines supply	No	Yes/No	2009	CMS
Software tools are available for management of medicines supply (procurement tracking, expenditure tracking, stock levels)	Yes	Yes/No	2009	CMS Database
Data on months of stock on hand is routinely reported to managers	Yes	Yes/No	2009	CMS Database

TOP 5 distributors by market value

Name of distributor	Sales by Value		YEAR	SOURCE
International Health Care Distributors (IHD) (only distributor)	2,721,897 USD	% of Total	2009	CMS
		% of Total		
		% of Total		
		% of Total		
		% of Total		

⁶ For the purpose of this profile, distributors deliver medicines on behalf of others and do not carry any risk for stock lost or expired.

6.5 Wholesale Market Characteristics⁷

			YEAR	SOURCE
Legal provisions exist for licensing wholesalers	Yes	Yes/No	2007	Ministry of Commerce and Trade
Number of wholesalers in market	7	Number	2009	Ministry of Health PSD
Number of GDP compliant wholesalers in market	Unknown	Number	2009	Ministry of Health PSD
List of GDP compliant wholesalers is publicly available	No	Yes/No	2009	Ministry of Health PSD

TOP 5 wholesalers by market value

Name of wholesaler	Sales by Value		YEAR	SOURCE
Swazipharm	41.4%	% of Total	2009	CMS
Starross	30.7%	% of Total	2009	CMS
Medquip	20.6%	% of Total	2009	CMS
V & H Surgical & Patient Care	3.9%	% of Total	2009	CMS
Swazimed Centre	3.5%	% of Total	2009	CMS

⁷ 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 (National Programmes)	Yes/No	2007	WHO Level I
-If yes, year of last update of national STGs	2008	Year	2007	WHO Level I
National essential medicines list (EML) exists	Yes (Draft)	Yes/No	2009	MOH
-If yes, number of medicine formulations on the national EML	450	number	2009	WHO Level I
-If yes, year of last update of EML	2009	Year	2009	MOH
-If yes, process for selecting medicines on the EML is publicly available	No	Yes/No	2009	MOH
There is a committee for the selection of products on the national EML	Yes	Yes/No	2007	WHO Level I
-If yes, conflict of interest declarations are required from members on national EML committee	Yes	Yes/No	2009	MOH
There are explicit criteria for selecting medicines for national EML	Yes	Yes/No	2009	MOH
National medicines formulary manual exists	No	Yes/No	2009	Ministry of Health PSD
-If yes, national medicines formulary manual is limited to essential medicines	N/A	Yes/No	2009	Ministry of Health PSD
-If yes, year of last update of national medicines formulary manual	N/A	Year	2009	Ministry of Health PSD
National STGs for paediatric conditions exist	Yes	Yes/No		IMCI guidelines
-If yes, year of last update of national paediatric STGs	Yes	Year	2009	IMCI guidelines
EML used in public insurance reimbursement	No	Yes/No	2009	Ministry of Health PSD
Rational use national audit done in the last two years	Yes	Yes/No	2007	WHO Level I
% of public health facilities with EML (mean)- Survey data		%		
% of public health facilities with STGs (mean)- Survey data		%		

Public education campaigns about rational medicines use have been conducted by MoH, NGOs or academia in the previous two years	Yes	Yes/No	2007	WHO Level I
A national programme or committee involving government, civil society, and professional bodies exists to monitor and promote rational use of medicines	No	Yes/No	2007	Ministry of Health PSD
A national strategy exists to contain antimicrobial resistance	No	Yes/No	2007	Ministry of Health PSD
-If yes, date of last update of the strategy	N/A	year		Ministry of Health PSD
A national reference laboratory has responsibility for coordinating epidemiological surveillance of antimicrobial resistance	No	Yes/No	2007	Ministry of Health PSD
A public or independently funded national medicines information centre provides information on medicines to consumers	No	Yes/No	2007	Ministry of Health PSD
Legal provisions exist for the control of narcotics, psychotropic substances, and precursors	Yes	Yes/No	2007	Ministry of Health PSD
The country is a signatory to the International Conventions on the Control of Narcotics, Psychotropic Substances and Precursors	Yes	Yes/No	2007	Ministry of Health PSD

7.2 Prescribing				
			YEAR	SOURCE
Legal provisions exist to govern the licensing and prescribing practices of prescribers	No	Yes/No	2009	Ministry of Health PSD
-The following types of health workers are legally allowed to prescribe				
-Nurses	Yes (Primary Health Care (PHC))	Yes/No	2007	National Health Policy
-Midwives	Yes (PHC)	Yes/No	2007	National Health Policy
-Community health workers	No	Yes/No	2007	National Health Policy
-Pharmacists	Yes (Over the counter medicines)	Yes/No	2007	National Health Policy

Prescribers are legally allowed to dispense	Yes (Medicine Bill will discontinue his practice)	Yes/No	2009	Ministry of Health PSD
Prescribers in the public sector dispense medicines	No	Yes/No	2007	National Health Policy
Prescribers in the private sector dispense medicines	Yes	Yes/No	2007	WHO Level I
The basic <u>medical</u> training curriculum includes components on:				
- Use of the national EML	No school of medicine in the country	Yes/No		Ministry of Health PSD
- Use of national STGs	N/A	Yes/No		Ministry of Health PSD
- Problem-based pharmacotherapy	N/A	Yes/No		Ministry of Health PSD
- Good practices in prescribing	N/A	Yes/No		Ministry of Health PSD
The basic <u>nursing</u> training curriculum includes components on:				
- Use of the national EML	No	Yes/No	2007	WHO Level I
- Use of national STGs	Yes	Yes/No	2007	WHO Level I
- Problem-based pharmacotherapy	Yes	Yes/No	2007	WHO Level I
- Good practices in prescribing	No	Yes/No		
The basic training curriculum for <u>paramedical staff</u> includes components on:				
- Use of the national EML	No	Yes/No	2007	WHO Level I
- Use of national STGs	No	Yes/No	2007	WHO Level I
- Problem-based pharmacotherapy	No	Yes/No	2007	WHO Level I
- Good practices in prescribing	No	Yes/No	2007	WHO Level I
Regulations exist requiring hospitals to organize/develop Drug and Therapeutics Committees (DTCs)	Yes	Yes/No	2007	WHO Level I

Mandatory, non-commercially funded continuing education that includes use of medicines is required for doctors	No	Yes/No	2007	WHO Level I
A public or independently funded national medicines information centre exists that provides information on demand to prescribers	No	Yes/No	2007	WHO Level I
Prescribing by generic name is obligatory in:				
-Public sector	Yes	Yes/No	2007	WHO Level I
-Private sector	No	Yes/No	2007	WHO Level I
Incentives exist to encourage prescribing of generic medicines in public health facilities	No	Yes/No	2009	Ministry of Health PSD
Incentives exist to encourage prescribing of generic medicines in private health facilities	No	Yes/No	2009	Ministry of Health PSD
INRUD prescribing indicators			YEAR	SOURCE
Number of medicines prescribed per patient contact in public health facilities (mean)		Number		
% of patients receiving antibiotics (mean)		%		
% of patients receiving injections (mean)		%		
% of drugs prescribed that are in the EML (mean)		%		
Diarrhoea in children treated with ORS (%)		%		
Non-pneumonia ARIs treated with antibiotics (%)		%		

7.3 Dispensing				
			YEAR	SOURCE
Legal provisions exist to govern licensing and practice of pharmacy	Yes	Yes/No	1929	Pharmacy Act(1929)
A professional association code of conduct exists governing professional behaviour of pharmacists	No (New Pharmacy Bill will address this aspect)	Yes/No	2009	
The basic <u>pharmacist</u> training curriculum includes components on				
-Use of the national EML	No school of pharmacy in country	Yes/No	2009	Ministry of Health PSD

-Use of national STGs	N/A	Yes/No	2009	Ministry of Health PSD
-Problem-based pharmacotherapy	N/A	Yes/No	2009	Ministry of Health PSD
-Good practices in prescribing	N/A	Yes/No	2009	Ministry of Health PSD
Mandatory, non-commercially funded continuing education that includes use of medicines is required for pharmacists	No	Yes/No	2007	WHO Level I
A public or independently funded national medicines information centre exists that provides information on demand to dispensers	No	Yes/No	2007	WHO Level I
Substitution of generic equivalents is permitted for:				
-Public sector dispensers	Yes	Yes/No	2007	WHO Level I
-Private sector dispensers	Yes	Yes/No	2007	WHO Level I
Incentives exist to encourage dispensing of generic medicines in:				
-Public pharmacies	No	Yes/No	2007	WHO Level I
-Private pharmacies	Yes	Yes/No	2007	WHO Level I
Antibiotics are sold over-the-counter without a prescription	Yes	Yes/No	2007	WHO Level I
Injections are sold over-the-counter without a prescription	Yes	Yes/No	2007	WHO Level I
Narcotics are sold over-the-counter without a prescription	No	Yes/No	1922	Opium and Habit-Forming Drugs act (1922)
Tranquillisers are sold over-the-counter without a prescription	Yes	Yes/No	2009	Ministry of Health PSD
INRUD dispensing indicators			YEAR	SOURCE
% of prescribed drugs dispensed to patients (mean)		%		
Percentage of medicines adequately labelled in public health facilities (mean)		%		
Percentage of patients knowing correct dosage in public health facilities (mean)		%		

PART 8 - HOUSEHOLD DATA

8.1 Data from Household surveys				
			YEAR	SOURCE
Adults with acute conditions taking all medicines prescribed	100.0%	%	2002-3	WHS (World Health Survey)
Adults with acute conditions not taking all medicines because they cannot afford them	0.0%	%	2002-3	WHS
Adults with acute conditions not taking all medicines because they cannot find them	0.0%	%	2002-3	WHS
Adults (from poor households) with acute conditions taking all medicines prescribed	100.0%	%	2002-3	WHS
Adults (from poor households) with acute conditions not taking all medicines because they cannot afford them	0.0%	%	2002-3	WHS
Adults with chronic conditions taking all medicines prescribed	92.2%	%	2002-3	WHS
Adults with chronic conditions not taking all medicines because they cannot afford them	0.0%	%	2002-3	WHS
Adults with chronic conditions not taking all medicines because they cannot find them	0.0%	%	2002-3	WHS
Adults (from poor households) with chronic conditions taking all medicines prescribed	82.6%	%	2002-3	WHS
Adults (from poor households) with chronic conditions not taking all medicines because they cannot afford them	0.0%	%	2002-3	WHS
Children with acute conditions taking all medicines prescribed	88.1%	%	2002-3	WHS
Children with acute conditions not taking all medicines because they cannot afford them	0.0%	%	2002-3	WHS
Children with acute conditions not taking all medicines because they cannot find them	9.1%	%	2002-3	WHS
Children (from poor households) with acute conditions taking all medicines prescribed	86.5%	%	2002-3	WHS
Children (from poor households) with acute conditions not taking all medicines because they cannot afford them	0.0%	%	2002-3	WHS