

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



# **Lesotho**

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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, **Lesotho** 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 survey<sup>1</sup>, the WHO/HAI pricing surveys<sup>2</sup> etc.

After being populated, the questionnaire was sent to **Lesotho** 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.

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

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

## PART 1- HEALTH and DEMOGRAPHIC DATA

<b>1.1 Demographic and Socioeconomic Indicators</b>				
<b>Population, mortality, fertility</b>			<b>YEAR</b>	<b>SOURCE</b>
Population, total	<b>2, 506</b>	,000	2007	Ministry of Finance and Development Planning
Population < 15 years	<b>40%</b>	% of total population	2007	World Health Statistics
Population > 60 years	<b>7%</b>	% of total population	2007	World Health Statistics
Urban population	<b>25%</b>	% of total population	2007	World Health Statistics
Population growth	<b>0.5%</b>	Annual %	2007	World Bank Nutrition, Health and Population
Fertility rate, total	<b>3.4</b>	Births per woman	2007	World Health Statistics
<b>Economic status</b>			<b>YEAR</b>	<b>SOURCE</b>
GDP	<b>1.6</b>	Current US\$ Billions	2007	World Development Indicators database, April 2009
GDP growth	<b>4.9</b>	Annual %	2007	World Development Indicators database, April 2009
GNI per capita	<b>1,030</b>	Current US\$	2007	World Development Indicators database, April 2009
Population living < PPP int. \$1 a day	<b>38.7%</b>	%	2005	World Health Statistics
Income share held by lowest 20%	–	%		

<b>Education and literacy</b>			<b>YEAR</b>	<b>SOURCE</b>
Adult literacy rate, 15+ years	<b>82.2%</b>	% of total population	2001	WHOSIS
Primary school enrolment rate, males	<b>71%</b>	% of male population	2006	WHOSIS
Primary school enrolment rate, females	<b>74%</b>	% of female population	2006	WHOSIS

### ***1.2 Mortality and Causes of Death***

<b>Life expectancy and mortality</b>			<b>YEAR</b>	<b>SOURCE</b>
Life expectancy at birth (both sexes)	<b>45</b>	Years	2007	World Health Statistics
Adult mortality rate (both sexes, 15 to 60 years)	<b>725</b>	/1,000 population	2007	World Health Statistics
Maternal mortality ratio	<b>762</b>	/100,000 live births	2007	Medicines Access Survey 2007
Neonatal mortality rate	<b>52</b>	/1,000 live births	2004	World Health Statistics
Infant mortality rate (between birth and age 1)	<b>91</b>	/1,000 live births	2007	Medicines Access Survey 2007
Under 5 mortality rate	<b>84</b>	/1,000 live births	2007	World Health Statistics

## PART 2- HEALTH SERVICES

<b>2.1 Health Expenditures</b>				
<b>Overall health expenditures</b>			<b>YEAR</b>	<b>SOURCE</b>
Total annual expenditure on health	<b>125,300,000</b>	US\$ average exchange rate	2009	2009 Budget Speech
Total annual per capita expenditure on health	<b>50.1</b>	US\$ average exchange rate	2009	CALCULATED from 2009 Budget Speech
Health expenditure as % of GDP	<b>6.86%</b>	% of gross domestic product	2006	World Health Statistics
Government expenditure on health as % of total government budget	<b>12.5%</b>	% of total government budget	2009	Posadas Study 2009
Government annual expenditure on health	<b>80,372,176</b>	US\$ average exchange rate	2009	Ministry of Health Annual Joint Review Report
<b>Health expenditures by source</b>			<b>YEAR</b>	<b>SOURCE</b>
Annual per capita government expenditure on health	<b>32.2</b>	US\$ average exchange rate	2009	CALCULATED from Ministry of Health Annual Joint Review Report
Government annual expenditure on health as % of total	<b>64.2%</b>	% of total expenditure on health	2009	CALCULATED from Ministry of Health Annual Joint Review Report
Social security expenditure as % of government on health	<b>0%</b>	% of government expenditure on health	2006	World Health Statistics
Annual per capita private expenditure on health	<b>17.9</b>	US\$ average exchange rate	2009	CALCULATED from Ministry of Health Annual Joint Review Report
Private expenditure as % of total health expenditure	<b>35.8%</b>	% of total expenditure on health	2009	CALCULATED from Ministry of Health Annual Joint Review Report
Private out-of-pocket expenditure as % of private health expenditure	<b>69%</b>	% 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		

<b>2.2 Health Personnel and Infrastructure</b>				
<b>Personnel</b>			<b>YEAR</b>	<b>SOURCE</b>
Total number of physician	<b>89</b>	Total number	2003	WHO Global Atlas of health workforce
Physicians per 1,000 population	<b>0.05</b>	per 1,000 pop	2003	WHO Global Atlas of health workforce
Total number of nursing and midwifery personnel	<b>1,123</b>	Total number	2003	WHO Global Atlas of health workforce
Nursing and midwifery personnel per 1,000 population	<b>0.62</b>	per 1,000 pop	2003	WHO Global Atlas of health workforce
Total number of pharmaceutical personnel <sup>3</sup>	<b>62</b>	Total number	2003	WHO Global Atlas of health workforce
pharmaceutical personnel per 1,000 pop	<b>0.03</b>	per 1,000 pop	2003	WHO Global Atlas of health workforce
Total number of pharmacists <sup>4</sup>	-	Total number		
Total number of pharmaceutical technicians and assistants <sup>5</sup>	-	Total number		
Number of newly registered pharmacists in the previous year		Total number		

<sup>3</sup> Pharmaceutical personnel include pharmacists, pharmaceutical assistants, pharmaceutical technicians and related occupations.

<sup>4</sup> **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.

<sup>5</sup> **Pharmaceutical technicians and assistants** perform a variety of tasks associated with dispensing medicinal products under the guidance of a pharmacist or other health professional.

<b>Facilities</b>			<b>YEAR</b>	<b>SOURCE</b>
Hospitals	<b>21</b>	Total number	2007	Ministry of Health Facilities List 2007
Hospital beds	<b>13</b>	/10,000 population	2007	World Bank Nutrition, Health and Population
Primary health care units and centres	<b>195</b>	Total number	2007	Ministry of Health Facilities List 2007
Licensed pharmacies	<b>N/A</b>	Total number		



## PART 3- POLICY and REGULATORY FRAMEWORK

<b>3.1 Policy Framework</b>				
INDICATOR		Yes/No	YEAR	SOURCE
National Health Policy exists (NHP)	<b>Yes</b>	Yes/No		Ministry of Health
-If yes, year of the most recent document	<b>2004</b>	Year		Ministry of Health
National Medicines Policy official document exists	<b>Yes</b>	Yes/No		Ministry of Health
-If yes, year of the most recent document	<b>2005</b>	Year		Ministry of Health,
-If no, draft NMP document exists	<b>N/A</b>	Yes/No		
-If exists, NMP is integrated into NHP	<b>Yes</b>	Yes/No		Ministry of Health
National Medicines Policy Implementation Plan exists	<b>Yes</b>	Yes/No		Ministry of Health
-If yes, year of the most recent document	<b>2005</b>	Year	2003	Ministry of Health
Traditional Medicine Policy exists	<b>No</b>	Yes/No		
If yes, year of the most updated document	<b>N/A</b>	Year		

<b>3.2 Regulatory Framework</b>				
		Yes/No	YEAR	SOURCE
Legal provision exists establishing the powers and responsibility of a Medicine Regulatory Authority (MRA)	<b>No</b>	Yes/No		Ministry of Health
Formal Medicines Regulatory Authority exists	<b>No</b>	Yes/No		Ministry of Health
-If yes, Medicines Regulatory Authority is an independent agency	<b>N/A</b>	Yes/No		
-If yes, number of regulatory staff	<b>N/A</b>	Number		
-Medicines Regulatory Authority is funded from regular budget from the government	<b>N/A</b>	Yes/No		
-Medicines Regulatory Authority is funded from fees from registration of medicines	<b>N/A</b>	Yes/No		

Legal provisions exist for market authorization	<b>No</b>	Yes/No		
WHO Certification Scheme may be part of the marketing authorization process	<b>No</b>	Yes/No	2003	WHO Level I
Regulatory agency has website	<b>No</b>	Yes/No	2003	WHO Level I
-If yes, please provide URL address	<b>N/A</b>	URL		
The Regulatory Authority has a computerized information management system to store and retrieve information on registration, inspections, etc.	<b>N/A</b>	Yes/No		

**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)**

			<b>YEAR</b>	<b>SOURCE</b>
Regulatory Authority or MoH is actively involved in regional harmonization initiatives	<b>Yes</b>	Yes/No		
-If yes, Regulatory Authority is actively involved in regional initiatives for the harmonization of registration of pharmaceuticals	<b>No</b>	Yes/No		
-If yes, Regulatory Authority is actively involved in regional initiatives for the harmonization of regulation on Clinical Trials	<b>No</b>	Yes/No		
-If yes, Regulatory Authority is actively involved in regional initiatives for the harmonization of laws to combat counterfeits	<b>No</b>	Yes/No		
-If yes, Regulatory Authority is actively involved in regional initiatives for the harmonization of Good Manufacturing Practices	<b>No</b>	Yes/No		

<b>3.4 Registration</b>				
			<b>YEAR</b>	<b>SOURCE</b>
Number of medicines registered	<b>N/A</b>	Number		
List of medicines registered is publicly available	<b>No</b>	Yes/No	2003	WHO Level I
An explicit and transparent process exists for assessing applications for registration of pharmaceutical products	<b>N/A</b>	Yes/No		
Functional formal committee exists responsible for assessing applications for registration of pharmaceutical products	<b>N/A</b>	Yes/No		
List and application status of products submitted for registration are publicly available	<b>N/A</b>	Yes/No		
INN names are used to register medicines	<b>N/A</b>	Yes/No		
Medicines registration fees exist	<b>N/A</b>	Yes/No		
-If yes, amount per application (US\$) for originator product	<b>N/A</b>	US\$		
-If yes, amount per application (US\$) for generic product	<b>N/A</b>	US\$		
Average length of time from submission of a product application to decision (months)	<b>N/A</b>	Months		
A transparent process exists to appeal medicines registration decisions	<b>N/A</b>	Yes/No		
Computerized system exists for retrieval of information on registered products	<b>N/A</b>	Yes/No	2003	WHO Level I

<b>3.5 Manufacturing</b>				
<b>Domestic Manufacturers</b>			<b>YEAR</b>	<b>SOURCE</b>
Legal provisions exist for licensing domestic manufacturers	<b>No</b>	Yes/No		
The country has guidelines on Good Manufacturing Practices (GMP)	<b>No</b>	Yes/No		
-If yes, these guidelines are used in the licensing process	<b>N/A</b>	Yes/No		

The country has capacity for:				
-R&D to discover new active substances	<b>No</b>	Yes/No	2003	WHO Level I
-Production of pharmaceutical starting materials	<b>No</b>	Yes/No	2003	WHO Level I
-Formulation from pharmaceutical starting material	<b>No</b>	Yes/No	2003	WHO Level I
-Repackaging of finished dosage forms	<b>No</b>	Yes/No		
Number of domestic manufacturers	<b>0</b>	Number		
Number of GMP compliant domestic manufacturers	<b>0</b>	Number		
<b>Multinational manufacturers and importers</b>			<b>YEAR</b>	<b>SOURCE</b>
Legal provisions exist for licensing multinational manufacturers that produce medicines locally	<b>No</b>	Yes/No		
Number of multinational pharmaceutical companies with a local subsidiary	<b>0</b>	Number		
Number of multinational pharmaceutical companies producing medicines locally	<b>0</b>	Number		
Legal provisions exist for licensing importers	<b>No</b>	Yes/No	2003	WHO Level I

<b>3.6 Quality Control</b>				
			<b>YEAR</b>	<b>SOURCE</b>
Legal provisions exist to inspect premises and collect samples	<b>Yes</b>	Yes/No	2003	WHO Level I
Legal provisions exist for detecting and combating counterfeit medicines	<b>No</b>	Yes/No		
Samples are tested for post-marketing surveillance	<b>No</b>	Yes/No		
List is publicly available giving detailed results of quality testing in past year	<b>No</b>	Yes/No		
Legal provisions exist to ensure quality control of imported medicines	<b>No</b>	Yes/No		
Legal provisions exist for the recall and disposal of defective products	<b>No</b>	Yes/No		

<b>3.7 Pharmacovigilance</b>				
			<b>YEAR</b>	<b>SOURCE</b>
Legal provisions exist for monitoring adverse drug reactions (ADRs) on a routine basis	<b>No</b>	Yes/No		
ADRs are monitored	<b>Yes</b>	Yes/No	2003	WHO Level I
-If yes, ADRs are monitored at				
-Central level	<b>No</b>	Yes/No		
-Regional level	<b>No</b>	Yes/No		
-Local health facilities	<b>Yes</b>	Yes/No		
-If yes, ADRs are reported to the WHO Collaborating Centre for International Drug Monitoring	<b>No</b>	Yes/No		

<b>3.8 Medicines Advertising and Promotion</b>				
<b>Legal and regulatory provisions</b>			<b>YEAR</b>	<b>SOURCE</b>
Legal provisions exist to control the promotion and/or advertising of medicines	<b>No</b>	Yes/No	2003	WHO Level I
Who is responsible for regulating promotion and/or advertising of medicines	<b>N/A</b>	Government/ Industry or Co-Regulation		
Direct advertising of prescription medicines to the public is prohibited	<b>No</b>	Yes/No		
Regulatory pre-approval is required for medicines advertisements and/or promotional materials	<b>N/A</b>	Yes/No		
Guidelines exist for advertising and promotion of non-prescription medicines	<b>No</b>	Yes/No		
Regulatory committee exists for controlling medicines advertising and promotion	<b>No</b>	Yes/No		
-If yes, members must declare conflicts of interest	<b>N/A</b>	Yes/No		

<b>Code of conduct</b>			<b>YEAR</b>	<b>SOURCE</b>
A national code of conduct exists concerning advertising and promotion of medicines by pharmaceutical manufacturers	<b>No</b>	Yes/No		
-If yes, adherence to the code is voluntary	<b>N/A</b>	Yes/No		
A national code of conduct for doctors exists to regulate their relationship with manufacture sales representatives	<b>No</b>	Yes/No		

## PART 4 - FINANCING

<b>4.1 Medicines Expenditure</b>				
			<b>YEAR</b>	<b>SOURCE</b>
Total medicines expenditure (US\$)	<b>N/A</b>	US\$ current exchange rates		
Medicines expenditure as a % of GDP	–	% of GDP		
Medicines expenditure as a % of Health Expenditure	<b>12%</b>	% of total health expenditure	2006	Ministry of Health Recurrent Budget
Total public expenditure on medicines (US\$)	<b>8,681,543</b>	US\$ current exchange rates	2009	Ministry of Health Annual Joint Report 2009
MoH annual budget for medicines (US\$)	<b>23,639,585</b>	US\$ current exchange rates	2009	Ministry of Health Budget 2009
Total private expenditure on medicines (US\$)	<b>N/A</b>	US\$ current exchange rates		

<b>4.2 Health Insurance and Free Care</b>				
			<b>YEAR</b>	<b>SOURCE</b>
National Health Insurance (NHI) or Social Health Insurance (SHI) exists	<b>No</b>	Yes/No	2003	WHO Level I
-If yes, NHI/SHI provides at least partial medicines coverage	<b>N/A</b>	Yes/No		
Proportion of the population covered by NHI or SHI	<b>N/A</b>	Yes/No		
Existence of public programmes providing free medicines	<b>Yes</b>	Yes/No	2003	WHO Level I
-If yes, medicines are available free-of-charge for:				
-Patients who cannot afford them	<b>Yes</b>	Yes/No	2003	WHO Level I

-Children under 5	<b>No</b>	Yes/No	2003	WHO Level I
-Older children	<b>Yes</b>	Yes/No		
-Pregnant women	<b>Yes</b>	Yes/No	2003	WHO Level I
-Elderly persons	<b>Yes</b>	Yes/No		
-If yes, the following types of medicines are free:				
-All	<b>Yes</b>	Yes/No		
-Malaria medicines	<b>N/A</b>	Yes/No		
-Tuberculosis medicines	<b>Yes</b>	Yes/No		
-Sexually transmitted diseases medicines	<b>Yes</b>	Yes/No		
-HIV/AIDS medicines	<b>Yes</b>	Yes/No		
At least one vaccine	<b>Yes</b>	Yes/No		

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



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

<b>4.5 Results of WHO/HAI Pricing Survey</b>				
			<b>YEAR</b>	<b>SOURCE</b>
Median Price Ratio of <b>originator brand</b> products to international reference prices for a basket of key medicines <b>PUBLIC SECTOR PROCUREMENT</b>	<b>N/A</b>	Median Price Ratio		
Median Price Ratio of <b>lowest-priced generics</b> to international reference prices for a basket of key medicines <b>PUBLIC SECTOR PROCUREMENT</b>	<b>N/A</b>	Median Price Ratio		
Median Price Ratio of <b>originator brand</b> products to international reference prices for a basket of key medicines <b>PUBLIC SECTOR PATIENT PRICE</b>	<b>N/A</b>	Median Price Ratio		
Median Price Ratio of <b>lowest-priced generics</b> to international reference prices for a basket of key medicines <b>PUBLIC SECTOR PATIENT PRICE</b>	<b>N/A</b>	Median Price Ratio		

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

<b>4.6 Duties and Taxes on Pharmaceuticals in the Private Sector</b>				
			<b>YEAR</b>	<b>SOURCE</b>
Duty on imported raw materials	<b>N/A</b>	Yes/No		
Duty on imported finished products	<b>Yes</b>	Yes/No		
VAT or other taxes on medicines	<b>Yes</b>	Yes/No		
-If yes, amount of VAT on pharmaceutical products (%)	<b>14%</b>	%		

## PART 5 - PATENTS

<b>5.1 Medicines Patent Laws</b>				
			<b>YEAR</b>	<b>SOURCE</b>
Country is a member of the World Trade Organization	<b>Yes</b>	Yes/No	2003	WHO Level I
Patents are granted on pharmaceutical products by a National Patent Office	<b>Yes</b>	Yes/No		
List of patented medicines is available	<b>No</b>	Yes/No		
National legislation has been modified to implement the TRIPS Agreement	<b>Yes</b>	Yes/No	2003	WHO Level I
-If yes, the transitional period has been extended per Doha Declaration	<b>No</b>	Yes/No		
-If yes, TRIPS flexibilities have been incorporated into legislation	<b>Yes</b>	Yes/No	2003	WHO Level I
-If TRIPS flexibilities have been incorporated, they are:				
-Compulsory licensing provisions	<b>Yes</b>	Yes/No	2003	WHO Level I
-Government use	<b>No</b>	Yes/No		
-Parallel importing provisions	<b>Yes</b>	Yes/No		
-Bolar exception	<b>No</b>	Yes/No		

## PART 6 - SUPPLY

<b>6.1 Procurement</b>				
			<b>YEAR</b>	<b>SOURCE</b>
Is there a written public sector procurement strategy?	<b>Yes</b>	Yes/No	2009	Central Procurement Agency
-If yes, in what year was it approved?	<b>2009</b>	Year		
Are there provisions giving priority in public procurement to goods produced by domestic manufacturers?	<b>N/A</b>	Yes/No		
Are there provisions giving priority in public procurement to goods produced by manufacturers from SADC countries?	<b>No</b>	Yes/No		
Do the public sector procurement regulations apply to pharmaceutical procurement?	<b>Yes</b>	Yes/No		
How many people are working full-time only on procurement of pharmaceuticals for the public sector?	<b>60</b>	Number		
There is a tender board/committee overseeing public procurement of medicines	<b>Yes</b>	Yes/No		
-If yes, the key functions of the procurement office and those of the tender committee are clearly separated	<b>Yes</b>	Yes/No		
Public procurement is limited to medicines on the national EML	<b>No</b>	Yes/No	2003	WHO Level I
WHO-prequalification system is used to identify suppliers for ARVs, TB, ATM and RHR	<b>Yes</b>	Yes/No		
WHO certification system is used to identify suppliers	<b>Yes</b>	Yes/No		
A functioning process exists to ensure the quality of other products procured	<b>Yes</b>	Yes/No		
-If yes, this process includes prequalification of products and suppliers	<b>Yes</b>	Yes/No		
-If yes, explicit criteria and procedures exist for prequalification of suppliers	<b>Yes</b>	Yes/No		

-If yes, a list of prequalified suppliers and products is publicly available	<b>No</b>	Yes/No		
How many people are working full-time on quality assurance for procurement?	<b>1</b>	Number		
Percentage of public sector procurement expenditures in last year awarded by:				
-National competitive tenders		% of total value		
-International competitive tenders		% of total value		
-Negotiation		% of total value		
-Direct purchasing		% of total value		
Public sector tenders are publicly available	<b>Yes</b>	Yes/No		
Public sector awards are publicly available	<b>No</b>	Yes/No		
Public sector tenders use an e-procurement system	<b>No</b>	Yes/No		
A written code of conduct exists governing the behaviour of public procurement agencies in their interactions with sales representatives and wholesalers	<b>No</b>	Yes/No		
List of samples tested during the procurement process and results of quality testing is available	<b>No</b>	Yes/No		
Public sector procurement is centralized at the national level	<b>Yes</b>	Yes/No		
Is there a capacity building strategy for procurement and supply management?	<b>Yes</b>	Yes/No		
-If yes, when was it finalized?	<b>March 2009</b>	Year		
-If yes, what period does it cover?	<b>Mar 2009 – Mar 2010</b>	Year-Year		

<b>6.2 Procurement Budget. (Please insert currency in the 3rd column).</b>				
		<b>CURRENCY</b>	<b>YEAR</b>	<b>SOURCE</b>
Total value of medicines procured in the public sector in the previous year	<b>13,032,784</b>	US\$ Average exchange rate 2008	2008	NDSO Board Report
Public procurement expenditure on products from national manufacturers in the previous year (if available)	<b>N/A</b>			
Public procurement expenditure on products from SADC manufacturers in the previous year (if available)	<b>N/A</b>			
Public procurement expenditure on products on the EML in the previous year (if available)	<b>N/A</b>			

<b>6.3 Procurement Price of Medicines on the WHO/HAI Global List</b>			
<i>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 amoxicillim 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.</i>			
<b>For Year: 2009</b>	<b>Currency in Maloti</b>		
<b>Medicine, Strength, Formulation</b>		<b>UNIT price for Originator</b>	<b>UNIT price for lowest priced generic</b>
Amitriptyline 25 mg Cap/tab			<b>M 0.03</b>
Amoxicillin 500 mg Cap/tab			<b>M 0.17</b>
Atenolol 50 mg Cap/tab			<b>M 0.04</b>
Captopril 25 mg Cap/tab			<b>M 0.08</b>
Ceftriaxone 500mg/ vial Injection			<b>M 12.95</b>
Ciprofloxacin 500 mg Cap/tab			<b>M 0.49</b>
Co-trimoxazole 8 + 40 mg/ml Susp.(100ml)			<b>M 4.06</b>
Diazepam 5 mg Cap/tab			<b>M 0.04</b>
Diclofenac 50 mg Cap/tab			<b>M 0.03</b>
Glibenclamide 5 mg Cap/tab			<b>M 0.01</b>
Omeprazole 20 mg Cap/tab			<b>M 0.35</b>
Paracetamol 24 mg/ml Susp.(100ml)			<b>M 2.85</b>
Salbutamol 0.1mg/dose Inhaler			<b>M 9.48</b>
Simvastatin 20 mg Cap/tab			<b>N/A</b>

<b>6.4 Distribution</b>				
<b>Distributors<sup>6</sup></b>			<b>YEAR</b>	<b>SOURCE</b>
There are national guidelines on Good Distribution Practices (GDP)	<b>No</b>	Yes/No		
There a list of all GDP compliant distributors	<b>No</b>	Yes/No		
<b>CMS</b>			<b>YEAR</b>	<b>SOURCE</b>
Software tools are available for planning medicines supply	<b>Yes</b>	Yes/No		
Software tools are available for management of medicines supply (procurement tracking, expenditure tracking, stock levels)	<b>Yes</b>	Yes/No		
Data on months of stock on hand is routinely reported to managers	<b>Yes</b>	Yes/No		

**TOP 5 distributors by market value**

<b>Name of distributor</b>	<b>Sales by Value</b>		<b>YEAR</b>	<b>SOURCE</b>
<b>National Drugs Service Organisation</b>	N/A	% of Total		
		% of Total		
		% of Total		
		% of Total		
		% of Total		

<sup>6</sup> 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 Characteristics<sup>7</sup>

			YEAR	SOURCE
Legal provisions exist for licensing wholesalers	<b>Yes</b>	Yes/No	2003	WHO Level I
Number of wholesalers in market	<b>3</b>	Number	<b>2009</b>	Ministry of Health
Number of GDP compliant wholesalers in market	<b>N/A</b>	Number		
List of GDP compliant wholesalers is publicly available	<b>N/A</b>	Yes/No		

#### TOP 5 wholesalers by market value

Name of wholesaler	Sales by Value		YEAR	SOURCE
<b>National Drugs Service Organisation</b>	<b>N/A</b>	% of Total		
<b>Tripharm</b>	<b>N/A</b>	% of Total		
<b>Medicare</b>	<b>N/A</b>	% of Total		
		% of Total		
		% of Total		

<sup>7</sup> 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

<b>7.1 National Structures</b>				
			<b>YEAR</b>	<b>SOURCE</b>
National standard treatment guidelines (STGs) for major conditions are produced by the MoH	<b>Yes</b>	Yes/No	2009	Expert Opinion
-If yes, year of last update of national STGs	<b>2006</b>	Year	2009	Expert Opinion
National essential medicines list (EML) exists	<b>Yes</b>	Yes/No	2009	Expert Opinion
-If yes, number of <b>medicine formulations</b> on the national EML	<b>216</b>	Number	2006	Lesotho Essential Medicines List 2006
-If yes, year of last update of EML	<b>2006</b>	Year		
-If yes, process for selecting medicines on the EML is publicly available	<b>No</b>	Yes/No		
There is a committee for the selection of products on the national EML	<b>Yes</b>	Yes/No		
-If yes, conflict of interest declarations are required from members on national EML committee	<b>N/A</b>	Yes/No		
There are explicit criteria for selecting medicines for national EML	<b>N/A</b>	Yes/No		
National medicines formulary manual exists	<b>Yes</b>	Yes/No		
-If yes, national medicines formulary manual is limited to essential medicines	<b>Yes</b>	Yes/No		
-If yes, year of last update of national medicines formulary manual	<b>1980</b>	Year		
National STGs for paediatric conditions exist	<b>Yes</b>	Yes/No		
-If yes, year of last update of national paediatric STGs	<b>2006</b>	Year		
EML used in public insurance reimbursement	<b>N/A</b>	Yes/No	2003	
Rational use national audit done in the last two years	<b>Yes</b>	Yes/No	2007	Medicines Access Survey
% of public health facilities with EML (mean)- Survey data	<b>89%</b>	%	2007	Medicines Access Survey
% of public health facilities with STGs (mean)- Survey data	<b>89%</b>	%	2007	Medicines Access Survey

Public education campaigns about rational medicines use have been conducted by MoH, NGOs or academia in the previous two years	<b>No</b>	Yes/No		
A national programme or committee involving government, civil society, and professional bodies exists to monitor and promote rational use of medicines	<b>No</b>	Yes/No		
A national strategy exists to contain antimicrobial resistance	<b>No</b>	Yes/No	2003	WHO Level I
-If yes, date of last update of the strategy				
A national reference laboratory has responsibility for coordinating epidemiological surveillance of antimicrobial resistance	<b>No</b>	Yes/No	2003	WHO Level I
A public or independently funded national medicines information centre provides information on medicines to consumers	<b>Yes</b>	Yes/No		
Legal provisions exist for the control of narcotics, psychotropic substances, and precursors	<b>Yes</b>	Yes/No	2008	Drugs of Abuse Act 2008
The country is a signatory to the International Conventions on the Control of Narcotics, Psychotropic Substances and Precursors	<b>Yes</b>	Yes/No		

7.2 Prescribing				
			YEAR	SOURCE
Legal provisions exist to govern the licensing and prescribing practices of prescribers	<b>Yes</b>	Yes/No	2003	WHO Level I
-The following types of health workers are legally allowed to prescribe				
-Nurses	<b>Yes</b>	Yes/No		
-Midwives	<b>Yes</b>	Yes/No		
-Community health workers	<b>Yes</b>	Yes/No		
-Pharmacists	<b>No</b>	Yes/No		
Prescribers are legally allowed to dispense	<b>Yes</b>	Yes/No		
Prescribers in the public sector dispense medicines	<b>No</b>	Yes/No		
Prescribers in the private sector dispense medicines	<b>Yes</b>	Yes/No		
The basic <u>medical</u> training curriculum includes components on:				
- Use of the national EML	<b>No</b>	Yes/No	2003	WHO Level I
- Use of national STGs	<b>No</b>	Yes/No	2003	WHO Level I
- Problem-based pharmacotherapy	<b>No</b>	Yes/No	2003	WHO Level I
- Good practices in prescribing	<b>No</b>	Yes/No	2003	WHO Level I
The basic <u>nursing</u> training curriculum includes components on:				
- Use of the national EML	<b>Yes</b>	Yes/No	2003	WHO Level I
- Use of national STGs	<b>No</b>	Yes/No	2003	WHO Level I
- Problem-based pharmacotherapy	<b>No</b>	Yes/No	2003	WHO Level I
- Good practices in prescribing	<b>Yes</b>	Yes/No	2003	WHO Level I
The basic training curriculum for <u>paramedical staff</u> includes components on:				
- Use of the national EML	<b>No</b>	Yes/No	2003	WHO Level I
- Use of national STGs	<b>No</b>	Yes/No	2003	WHO Level I
- Problem-based pharmacotherapy	<b>No</b>	Yes/No	2003	WHO Level I
- Good practices in prescribing	<b>No</b>	Yes/No	2003	WHO Level I

Regulations exist requiring hospitals to organize/develop Drug and Therapeutics Committees (DTCs)	<b>No</b>	Yes/No	2009	Ministry of Health
Mandatory, non-commercially funded continuing education that includes use of medicines is required for doctors	<b>No</b>	Yes/No	2003	WHO Level I
A public or independently funded national medicines information centre exists that provides information on demand to prescribers	<b>No</b>	Yes/No	2003	WHO Level I
Prescribing by generic name is obligatory in:				
-Public sector	<b>Yes</b>	Yes/No	2003	WHO Level I
-Private sector	<b>No</b>	Yes/No	2003	WHO Level I
Incentives exist to encourage prescribing of generic medicines in public health facilities	<b>No</b>	Yes/No		
Incentives exist to encourage prescribing of generic medicines in private health facilities	<b>No</b>	Yes/No		
<b>INRUD prescribing indicators</b>			<b>YEAR</b>	<b>SOURCE</b>
Number of medicines prescribed per patient contact in public health facilities (mean)	<b>3.5</b>	Number	2007	Medicines Access Survey
% of patients receiving antibiotics (mean)	<b>53%</b>	%	2007	Medicines Access Survey
% of patients receiving injections (mean)	<b>8%</b>	%	2007	Medicines Access Survey
% of drugs prescribed that are in the EML (mean)	<b>86%</b>	%	2007	Medicines Access Survey
Diarrhoea in children treated with ORS (%)	<b>72%</b>	%	2007	Medicines Access Survey
Non-pneumonia ARIs treated with antibiotics (%)	-	%		

<b>7.3 Dispensing</b>				
			<b>YEAR</b>	<b>SOURCE</b>
Legal provisions exist to govern licensing and practice of pharmacy	<b>Yes</b>	Yes/No	2003	WHO Level I
A professional association code of conduct exists governing professional behaviour of pharmacists	<b>Yes</b>	Yes/No		
The basic <u>pharmacist</u> training curriculum includes components on				
-Use of the national EML	<b>Yes</b>	Yes/No	2003	WHO Level I
-Use of national STGs	<b>Yes</b>	Yes/No	2003	WHO Level I
-Problem-based pharmacotherapy	<b>Yes</b>	Yes/No	2003	WHO Level I
-Good practices in prescribing	<b>Yes</b>	Yes/No	2003	WHO Level I
Mandatory, non-commercially funded continuing education that includes use of medicines is required for pharmacists	<b>No</b>	Yes/No	2003	WHO Level I
A public or independently funded national medicines information centre exists that provides information on demand to dispensers	<b>No</b>	Yes/No	2003	WHO Level I
Substitution of generic equivalents is permitted for:				
-Public sector dispensers	<b>Yes</b>	Yes/No	2003	WHO Level I
-Private sector dispensers	<b>Yes</b>	Yes/No	2003	WHO Level I
Incentives exist to encourage dispensing of generic medicines in:				
-Public pharmacies	<b>No</b>	Yes/No		
-Private pharmacies	<b>No</b>	Yes/No		
Antibiotics are sold over-the-counter without a prescription	<b>No</b>	Yes/No	2009	Ministry of Health
Injections are sold over-the-counter without a prescription	<b>No</b>	Yes/No	2009	Ministry of Health
Narcotics are sold over-the-counter without a prescription	<b>No</b>	Yes/No		
Tranquillisers are sold over-the-counter without a prescription	<b>No</b>	Yes/No		
<b>INRUD dispensing indicators</b>			<b>YEAR</b>	<b>SOURCE</b>
% of prescribed drugs dispensed to patients (mean)		%		
Percentage of medicines adequately labelled in public health facilities (mean)	<b>20%</b>	%	2007	Medicines Access Survey
Percentage of patients knowing correct dosage in public health facilities (mean)	<b>69%</b>	%	2007	Medicines Access Survey

## PART 8 - HOUSEHOLD DATA

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