

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



United Republic of Tanzania

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Country	UNITED REPUBLIC OF TANZANIA
Name of Coordinator/Principal Respondent	Rose Shija
Position	EDM/NPO
E-mail address	shijar@tz.afro.who.int
Tel number	255 22 2113005
Date Submitted	5 October 2009
Name of Endorser	Dr Margaret Evelyn Mhando
Position of Endorser	Director of Hospital Services

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, the **United Republic of Tanzania** 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 the **United Republic of Tanzania** 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	40,454	,000	2007	World Health Statistics
Population < 15 years	44%	% of total population	2007	World Health Statistics
Population > 60 years	5%	% of total population	2007	World Health Statistics
Urban population	25%	% of total population	2007	World Health Statistics
Population growth	2.4%	Annual %	2007	World Bank Nutrition, Health and Population
Fertility rate, total	5.2	Births per woman	2007	World Health Statistics
Economic status			YEAR	SOURCE
GDP	16.18	Current US\$ Billions	2007	World Development Indicators database, April 2009
GDP growth	7.1%	Annual %	2007	World Development Indicators database, April 2009
GNI per capita	410	Current US\$	2007	World Development Indicators database, April 2009
Population living < PPP int. \$1 a day	82.4%	%	2005	World Health Statistics
Income share held by lowest 20%	7.3%	%	2007	World Development Indicators database, April 2009

Education and literacy			YEAR	SOURCE
Adult literacy rate, 15+ years	72.3%	% of total population	2000-2007	World Health Statistics
Primary school enrolment rate, males	98.0%	% of male population	2006	WHOSIS
Primary school enrolment rate, females	97.0%	% of female population	2006	WHOSIS

1.2 Mortality and Causes of Death

Life expectancy and mortality			YEAR	SOURCE
Life expectancy at birth (both sexes)	52	Years	2007	World Health Statistics
Adult mortality rate (both sexes, 15 to 60 years)	472	/1,000 population	2007	World Health Statistics
Maternal mortality ratio	578	/100,000 live births	2004/5	Demographic and Health survey
Neonatal mortality rate	29	/1,000 live births	2007	United Republic of Tanzania HIV Malaria Indicator Survey, 2007/2008
Infant mortality rate (between birth and age 1)	58	/1,000 live births	2007	United Republic of Tanzania HIV Malaria Indicator Survey, 2007/2008
Under 5 mortality rate	91	/1,000 live births	2007	United Republic of Tanzania HIV Malaria Indicator Survey, 2007/2008

PART 2- HEALTH SERVICES

<i>2.1 Health Expenditures</i>				
Overall health expenditures			YEAR	SOURCE
Total annual expenditure on health	910,584,707	US\$ average exchange rate	2006	NHA
Total annual per capita expenditure on health	23	US\$ average exchange rate	2006	World Health Statistics
Health expenditures as percent of GDP	6.4%	% of gross domestic product	2006	World Health Statistics
Government expenditure on health as % of total government budget	13.7%	% of total government budget	2006	World Health Statistics
Government annual expenditure on health	525,900,905	US\$ average exchange rate	2006	NHA
Health expenditures by source			YEAR	SOURCE
Annual per capita government expenditure on health	13	US\$ average exchange rate	2006	World Health Statistics
Government annual expenditure on health as % of total	57.8%	% of total expenditure on health	2006	World Health Statistics
Social security expenditure as % of government on health	0.9%	% of government expenditure on health	2006	World Health Statistics
Annual per capita private expenditure on health	9.7	US\$ average exchange rate	2006	CALCULATED from World Health Statistics
Private expenditure as % of total health expenditure	42.2%	% of total expenditure on health	2006	World Health Statistics
Private out-of-pocket expenditure as % of private health expenditure	54.3%	% of private expenditure on health	2006	World Health Statistics
Premiums for private prepaid health plans as % of total private health expenditure	7.7%	% of private expenditure on health	2006	World Health Statistics
Population covered by national, social, or private health insurance or other sickness funds	Less than 10%	% of total population	2009	National Health Insurance Fund

2.2 Health Personnel and Infrastructure				
Personnel			YEAR	SOURCE
Total number of physicians	4,143	Total number	2009	Registrar, Medical Council of Tanganyika
Physicians per 1,000 population	0.10	per 1,000 pop	2002	Registrar, Medical Council of Tanganyika
Total number of nursing and midwifery personnel	23,168	Total number	2009	Tanzania National Nurses and midwives council
Nursing and midwifery personnel per 1,000 population	0.57	per 1,000 pop	2002	Tanzania National Nurses and midwives council
Total number of pharmaceutical personnel ³	1,423	Total number	2009	Assessment of the HR for the pharmaceutical sector in Tanzania, 2009
pharmaceutical personnel per 1,000 pop	0.04	per 1,000 pop	2009	Assessment of the HR for the pharmaceutical sector in Tanzania, 2009
Total number of pharmacists ⁴	639	Total number	2009	Assessment of the HR for the pharmaceutical sector in Tanzania, 2009
Total number of pharmaceutical technicians and assistants ⁵	784	Total number	2008	Assessment of the HR for the pharmaceutical sector in Tanzania, 2009
Number of newly registered pharmacists in the previous year	46	Total number		
Facilities			YEAR	SOURCE
Hospitals	212	Total number	2009	MOHSW, 2009
Hospital beds	11	/10,000 population	2007	World Bank Nutrition, Health and Population
Primary health care units and centres	5,406	Total number	2009	MOHSW, 2009
Licensed pharmacies	1,036	Total number	2009	Assessment of the HR for the pharmaceutical sector in Tanzania, 2009

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.

PART 3- POLICY and REGULATORY FRAMEWORK

3.1 Policy Framework				
INDICATOR			YEAR	SOURCE
National Health Policy exists (NHP)	Yes	Yes/No		WHO level I
-If yes, year of the most recent document	2006	Year		WHO level I
National Medicines Policy official document exists	Yes	Yes/No	1991.	WHO level I
-If yes, year of the most recent document	1991/2008	Year	(2008 for Zanzibar)	EDMNPO
-If no, draft NMP document exists	Yes	Yes/No	2009 Mainland	EDMNPO
-If exists, NMP is integrated into NHP	Yes	Yes/No		WHO level I
National Medicines Policy Implementation Plan exists	Yes	Yes/No		WHO level I
-If yes, year of the most recent document	1992/2008⁶	Year	2009	WHO level I
Traditional Medicine Policy exists	Yes	Yes/No		EDMNPO
If yes, year of the most updated document	2000/2008	Year		EDMNPO

3.2 Regulatory Framework				
			YEAR	SOURCE
Legal provision exists establishing the powers and responsibility of a Medicine Regulatory Authority (MRA)	Yes	Yes/No	2003	WHO level I
Formal Medicines Regulatory Authority exists	Yes	Yes/No	2007	WHO level I
-If yes, Medicines Regulatory Authority is an independent agency	Yes	Yes/No	2003	TFDA
-If yes, number of regulatory staff	143	Number		TFDA
-Medicines Regulatory Authority is funded from regular budget from the government	Yes	Yes/No	2007	WHO level I
-Medicines Regulatory Authority is funded from fees from registration of medicines	Yes	Yes/No	2007	WHO level I

⁶ Draft is available for mainland (2009). National Medicines Policy for Zanzibar is dated 2008.

Legal provisions exist for market authorization	Yes	Yes/No	2007	WHO level I
WHO Certification Scheme may be part of the marketing authorization process	Yes	Yes/No	2007	WHO level I
Regulatory agency has website	Yes	Yes/No	2007	WHO level I
-If yes, please provide URL address	www.tfda.or.tz	Address	2003	TFDA
The Regulatory Authority has a computerized information management system to store and retrieve information on registration, inspections, etc.	Yes	Yes/No	2008	TFDA

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)

	Yes	Yes/No	YEAR	SOURCE
Regulatory Authority or MoH is actively involved in regional harmonization initiatives	Yes	Yes/No	2007	WHO level I
-If yes, Regulatory Authority is actively involved in regional initiatives for the harmonization of registration of pharmaceuticals	Yes	Yes/No	2009	TFDA
-If yes, Regulatory Authority is actively involved in regional initiatives for the harmonization of regulation on Clinical Trials	Yes	Yes/No	2009	TFDA
-If yes, Regulatory Authority is actively involved in regional initiatives for the harmonization of laws to combat counterfeits	Yes	Yes/No	2009	TFDA
-If yes, Regulatory Authority is actively involved in regional initiatives for the harmonization of Good Manufacturing Practices	Yes	Yes/No	2009	TFDA

3.4 Registration				
			YEAR	SOURCE
Number of medicines registered	4,713	Number	2009	WHO level I
List of medicines registered is publicly available	Yes	Yes/No	2007	WHO level I
An explicit and transparent process exists for assessing applications for registration of pharmaceutical products	Yes	Yes/No		TFDA
Functional formal committee exists responsible for assessing applications for registration of pharmaceutical products	Yes	Yes/No	2007	WHO level I
List and application status of products submitted for registration are publicly available	Yes	Yes/No		Government Gazette
INN names are used to register medicines	Yes	Yes/No	2007	WHO level I
Medicines registration fees exist	Yes	Yes/No		TFDA - Fees and Charges Regulations
-If yes, amount per application (US\$) for originator product	1,000	US\$		TFDA - Fees and Charges Regulations
-If yes, amount per application (US\$) for generic product	750	US\$		TFDA - Fees and Charges Regulations
Average length of time from submission of a product application to decision (months)	12	Months		Registration guidelines
A transparent process exists to appeal medicines registration decisions	Yes	Yes/No		Registration guidelines
Computerized system exists for retrieval of information on registered products	Yes	Yes/No	2007	WHO level I

3.5 Manufacturing				
Domestic Manufacturers			YEAR	SOURCE
Legal provisions exist for licensing domestic manufacturers	Yes	Yes/No	2003	TFDA Act, 2003
The country has guidelines on Good Manufacturing Practices (GMP)	Yes	Yes/No	2008	TFDA
-If yes, these guidelines are used in the licensing process	Yes	Yes/No	2008	TFDA
The country has capacity for:				
.R&D to discover new active substances	No	Yes/No	2007	WHO level I
.Production of pharmaceutical starting materials	No	Yes/No	2007	WHO level I

.Formulation from pharmaceutical starting material	Yes	Yes/No	2007	WHO level I
.Repackaging of finished dosage forms	No	Yes/No	2007	WHO level I
Number of domestic manufacturers	7	Number	2009	TFDA
Number of GMP compliant domestic manufacturers	2	Number	2009	TFDA
Multinational manufacturers and importers			YEAR	SOURCE
Legal provisions exist for licensing multinational manufacturers that produce medicines locally	Yes	Yes/No	2003	The Tanzania Food, Drugs and Cosmetics Act No 1, 2003
Number of multinational pharmaceutical companies with a local subsidiary	-	Number		
Number of multinational pharmaceutical companies producing medicines locally	None	Number		TFDA
Legal provisions exist for licensing importers	Yes	Yes/No	2007	WHO level I

3.6 Quality Control				
			YEAR	SOURCE
Legal provisions exist to inspect premises and collect samples	Yes	Yes/No	2007	WHO level I
Legal provisions exist for detecting and combating counterfeit medicines	Yes	Yes/No	2007	WHO level I
Samples are tested for post-marketing surveillance	Yes	Yes/No	2007	WHO level I
List is publicly available giving detailed results of quality testing in past year	No	Yes/No		EDMNPO
Legal provisions exist to ensure quality control of imported medicines	Yes	Yes/No	2007	WHO level I
Legal provisions exist for the recall and disposal of defective products	Yes	Yes/No	2007	WHO level I

3.7 Pharmacovigilance				
			YEAR	SOURCE
Legal provisions exist for monitoring adverse drug reactions (ADRs) on a routine basis	Yes	Yes/No	2003	TFDC Act, 2003
ADRs are monitored	Yes	Yes/No	2007	WHO level I
-If yes, ADRs are monitored at				
-Central level	Yes	Yes/No	2007	WHO level I
-Regional level	Yes	Yes/No	2007	WHO level I
-Local health facilities	Yes	Yes/No	2007	WHO level I
-If yes, ADRs are reported to the WHO Collaborating Centre for International Drug Monitoring	Yes	Yes/No	2003	TFDA

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	2003	TFDA
Who is responsible for regulating promotion and/or advertising of medicines	Government	Government /Industry/Co-Regulation	2007	TFDA
Direct advertising of prescription medicines to the public is prohibited	Yes	Yes/No	2003	TFDA
Regulatory pre-approval is required for medicines advertisements and/or promotional materials	Yes	Yes/No	2007	WHO level I
Guidelines exist for advertising and promotion of non-prescription medicines	Yes	Yes/No		TFDA
Regulatory committee exists for controlling medicines advertising and promotion	No	Yes/No		TFDA
-If yes, members must declare conflicts of interest		Yes/No		
Code of conduct			YEAR	SOURCE
A national code of conduct exists concerning advertising and promotion of medicines by pharmaceutical manufacturers	Yes	Yes/No		TFDA
-If yes, adherence to the code is voluntary	Yes	Yes/No		TFDA
A national code of conduct for doctors exists to regulate their relationship with manufacture sales representatives	No	Yes/No		TFDA

PART 4 - FINANCING

4.1 Medicines Expenditure				
			YEAR	SOURCE
Total medicines expenditure (US\$)	57,000,000	US\$ current exchange rates	2008/09	MOHSW
Medicines expenditure as a % of GDP		% of GDP		MOHSW
Medicines expenditure as a % of Health Expenditure	32%	% of total health expenditure	2009/10	MOHSW
Total public expenditure on medicines (US\$)	37,900,000	US\$ current exchange rates	2008/09	MOHSW
MoH annual budget for medicines (US\$)		US\$ current exchange rates		
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	Yes	Yes/No	2007	WHO level I
-If yes, NHI/SHI provides at least partial medicines coverage	Yes	Yes/No	2007	WHO level I
Proportion of the population covered by NHI or SHI	Less than 10%	% of the population	2009	NHIF
Existence of public programmes providing free medicines	Yes	Yes/No	2007	WHO level I
-If yes, medicines are available free-of-charge for:				
-Patients who cannot afford them	Yes	Yes/No	2007	WHO level I
-Children under 5	Yes	Yes/No	2007	WHO level I

-Older children	No	Yes/No	2007	WHO level I
-Pregnant women	Yes	Yes/No	2007	WHO level I
-Elderly persons	Yes	Yes/No	2007	WHO level I
-If yes, the following types of medicines are free:				
-All	No	Yes/No	2007	WHO level I
-Malaria medicines	No	Yes/No	2007	WHO level I
-Tuberculosis medicines	Yes	Yes/No	2007	WHO level I
-Sexually transmitted diseases medicines	Yes	Yes/No	2007	WHO level I
-HIV/AIDS medicines	Yes	Yes/No	2007	WHO level I
At least one vaccine	Yes	Yes/No	2007	WHO level I

4.3 Patients Fees and Copayments				
			YEAR	SOURCE
Inpatients pay a fee for medicines in public hospitals	Yes	Yes/No	2009	MOHSW
Registration/consultation fees are common in public health facilities	Yes	Yes/No	2007	WHO level I
Fixed dispensing fees are common for outpatients in public primary health-care facilities	No	Yes/No	2009	MOHSW
Outpatients pay varying amounts for medicines in public primary health-care facilities	Yes	Yes/No	2009	MOHSW
Medicines copayments are used to pay salaries of public health-care workers	No	Yes/No	2007	WHO level I

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	2007	WHO level I
- Maximum retail mark-up	No	Yes/No	2007	WHO level I
- Maximum retail price (exit price)	No	Yes/No	2009	EDMNPO
Legal or regulatory provisions for controlling medicines prices vary for different types of medicines	No	Yes/No	2009	EDMNPO
Government runs an active national medicines price monitoring system for retail prices	No	Yes/No	2007	WHO level I
Retail medicines price information is made publicly accessible according to existing regulation	No	Yes/No	2007	WHO level I

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	2005	WHO/HAI Pricing Survey
Median Price Ratio of lowest-priced generics to international reference prices for a basket of key medicines PUBLIC SECTOR PROCUREMENT	0.7	Median Price Ratio	2005	WHO/HAI Pricing Survey
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	2005	WHO/HAI Pricing Survey
Median Price Ratio of lowest-priced generics to international reference prices for a basket of key medicines PUBLIC SECTOR PATIENT PRICE	1.3	Median Price Ratio	2005	WHO/HAI Pricing Survey
Median Price Ratio of originator brand products to international reference prices for a basket of key medicines PRIVATE SECTOR PATIENT PRICE	18.8	Median Price Ratio	2005	WHO/HAI Pricing Survey
Median Price Ratio of lowest-priced generics to international reference prices for a basket of key medicines PRIVATE SECTOR PATIENT PRICE	2.7	Median Price Ratio	2005	WHO/HAI Pricing Survey

4.6 Duties and Taxes on Pharmaceuticals in the Private Sector

			YEAR	SOURCE
Duty on imported raw materials	No	Yes/No	2007	WHO level I
Duty on imported finished products	No	Yes/No	2009	Ministry of finance
VAT or other taxes on medicines	Yes on imported raw materials	Yes/No		Association of pharmaceutical manufacturers
-If yes, amount of VAT on pharmaceutical products (%)	18%	%		Association of pharmaceutical manufacturers

PART 5 - PATENTS

5.1 Medicines Patent Laws				
			YEAR	SOURCE
Country is a member of the World Trade Organization	Yes	Yes/No		
Patents are granted on pharmaceutical products by a National Patent Office	Yes	Yes/No	2007	WHO level I
List of patented medicines is available	No	Yes/No		TFDA
National legislation has been modified to implement the TRIPS Agreement	No	Yes/No	2007	WHO level I
-If yes, the transitional period has been extended per Doha Declaration	No	Yes/No	2007	WHO level I
-If yes, TRIPS flexibilities have been incorporated into legislation	No	Yes/No	2007	WHO level I
-If TRIPS flexibilities have been incorporated, they are:				
-Compulsory licensing provisions	No	Yes/No	2007	WHO level I
-Government use	No	Yes/No	2007	WHO level I
-Parallel importing provisions	No	Yes/No	2007	WHO level I
-Bolar exception	No	Yes/No	2007	WHO level I

PART 6 - SUPPLY

6.1 Procurement

	Yes	Yes/No	YEAR	SOURCE
Is there a written public sector procurement strategy?	Yes	Yes/No	2004	Public procurement ACT 2004
-If yes, in what year was it approved?	Yes	2004		Public procurement ACT 2004
Are there provisions giving priority in public procurement to goods produced by domestic manufacturers?	Yes	Yes/No	2004	Public procurement ACT 2004
Are there provisions giving priority in public procurement to goods produced by manufacturers from SADC countries?	No	Yes/No		
Do the public sector procurement regulations apply to pharmaceutical procurement?	Yes	Yes/No	2004	Public procurement ACT 2004
How many people are working full-time only on procurement of pharmaceuticals for the public sector?	Yes	5	2009	Directorate of Finance and Administration, MSD
There is a tender board/committee overseeing public procurement of medicines	Yes	Yes/No	2007	WHO level I
-If yes, the key functions of the procurement office and those of the tender committee are clearly separated	Yes	Yes/No	2007	WHO level I
Public procurement is limited to medicines on the national EML	Yes	Yes/No	2007	WHO level I
WHO-prequalification system is used to identify suppliers for ARVs, TB, ATM and RHR	Yes	Yes/No	2007	WHO Level I
WHO certification system is used to identify suppliers	Yes	Yes/No	2007	MSD TENDER DOCUMENTS
A functioning process exists to ensure the quality of other products procured	Yes	Yes/No		QUALITY CONTROL SECTION, MSD
-If yes, this process includes prequalification of products and suppliers	Yes	Yes/No	1993	QUALITY CONTROL SECTION, MSD

-If yes, explicit criteria and procedures exist for prequalification of suppliers	Yes	Yes/No		TFDA GUIDELINES & PPRA REQUIREMENTS
-If yes, a list of prequalified suppliers and products is publicly available	Yes	Yes/No		TFDC ACT 2003
How many people are working full-time on quality assurance for procurement?	4		2009	Directorate of Finance and Administration, MSD
Percentage of public sector procurement expenditures in last year awarded by:				
-National competitive tenders	10%	% of total value	2007	WHO level I
-International competitive tenders	80%	% of total value	2007	WHO level I
-Negotiation		% of total value		
-Direct purchasing		% of total value		
Public sector tenders are publicly available	Yes	Yes/No		MSD WEBSITE, NEWSPAPERS and PPRA WEBSITE
Public sector awards are publicly available	Yes	Yes/No		MSD WEBSITE, NEWSPAPERS and PPRA WEBSITE
Public sector tenders use an e-procurement system	No	Yes/No		
A written code of conduct exists governing the behaviour of public procurement agencies in their interactions with sales representatives(not applicable) and wholesalers	Yes	Yes/No	2007	PPRA BIDDING DOCUMENT
List of samples tested during the procurement process and results of quality testing is available	Yes	Yes/No		QUALITY CONTROL SECTION,MSD
Public sector procurement is centralized at the national level	Yes	Yes/No	2007	WHO level I
Is there a capacity building strategy for procurement and supply management?	Yes	Yes/No	2007	MSD STARERGIC MEDIUM TERM PLAN 2007-2013
-If yes, when was it finalized?	Yes	2008		MSD STARERGIC MEDIUM TERM PLAN 2007-20013
-If yes, what period does it cover?	2007-2013	2007-2013		MSD STARERGIC MEDIUM TERM PLAN 2007-20013

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	80,471,640.70	USD	2008/2009	MSD
Public procurement expenditure on products from national manufacturers in the previous year (if available)	4,989,892.40	USD	2008/2009	MSD
Public procurement expenditure on products from SADC manufacturers in the previous year (if available)	NOT APPLICABLE			
Public procurement expenditure on products on the EML in the previous year (if available)	13,370,871.50	USD	2008/2009	MSD

6.3 Data on Top 50 Products by Value Procured in the Public Sector					YEAR of DATA	
Product	Unit	Volume	Price	Total value (please specify currency)	Country of supplier	
Amoxicillin Caps 250mg	1000T	120000	15.550	1,866,000.00	Tanzania	
Erythromycin 250 mg Tabs	1000T	35620	17.37	618,719.40	Tanzania	
Cloxacillin 250 mg Caps	1000T	33000	14.900	491,700.00	Tanzania	
Quinine Tabs 300mg	1000T	13000	37.750	490,750.00	Tanzania	
Paracetamol 500 mg Tabs	1000T	160000	2.540	406,400.00	Tanzania	
Chloramphenicol 250 mg Caps	1000T	26000	13.680	355,680.00	Tanzania	
Rabies vaccine USP (potency of rabies antigen < 2.5 IU/dose)	1 vial	48000	6.300	302,400.00 (EURO)	France	
Acetylsalicylic acid 300 mg Tabs	1000T	134,000	1.980	265,320.00	Tanzania	
Amoxycyline granules 125mg/5ml , 100ml	24P	32500	7.160	232,700.00	Tanzania	
Hyoscine N-Butyl Bromide 10 MG Tabs	500T	28000	7.992	223,776.00	India	

				(EURO)	
Cresol saponated liquid 50%	5Lts	12000	14.840	178,080.00	Tanzania
Amoxicillin Trihydrate + Clavulanic Potassium 500mg +125mg Tabs	15P	44000	1.720	75,680.00	India
Ciprofloxacin 500mg Tabs	100T	40000	1.760	70,400.00	Tanzania
Methylated spirit liquid 70%	5Lts	9600	7.200	69,120.00	Tanzania
Mebendazole Tabs 100mg	1000T	20000	2.751	55,020.00	Tanzania
Glipizide 5 mg Tabs	100T	2400	20.000	48,000.00	India
Ketoconazole 200 mg Tabs	100T	16000	2.800	44,800.00	Tanzania
Vitamin B Complex Tabs	1000T	25000	1.750	43,750.00	Tanzania
Phenobarbital 100 mg Tabs	1000T	8000	5.220	41,760.00	Tanzania
Metronidazole injection 5mg/ml,100ml	10 vials	23000	1.800	41,400.00	India
Prednisolone 5mg Tabs	1000T	7700	5.200	40,040.00	Tanzania
Aminophylline 100mg	1000T	13,200	2.680	35,376.00	India
Diclofenac 50mg Tabs	100T	82000	0.400	32,800.00	Tanzania
Hydrocortisone pdr f injection 100mg	10 vials	15605	2.100	32,770.50	India
Phenobarbital 30 mg Tabs	1000T	15000	1.990	29,850.00	Tanzania
Bendrofluazide Tabs 5mg	1000T	9600	2.890	27,744.00	Tanzania
Fluconazole 150 mg Tabs	100T	9600	2.880	27,648.00	Tanzania
Potassium chloride injection 7.45%	10 vials	500	50.00	25,000.00	Greece
Salbutamol aerosol inhalation 0.1mg/Inhaler	20gm	17600	1.230	21,648.00	India
Ascorbic Acid Tabs 100mg	1000T	4800	4.500	21,600.00	Tanzania
Diclofenac sodium injection 25mg/ml	10 amps	39000	0.54	21,060.00	India
Captopril 25 mg Tabs	100T	12000	1.690	20,280.00	Cyprus
Folic acid 5 mg Tabs	1000T	18200	0.990	18,018.00	Tanzania
Salbutamol Tabs 4mg	1000T	7800	2.000	15,600.00	Tanzania
Tramadol 50 mg Cap	100T	3400	4.532	15,408.80	India
Betamethasone cream 0.1% ,15gm	12P	4400	3.240	14,256.00	India
Nystatin susp 100,000 IU/ML	30ML	36000	0.370	13,320.00	Kenya
Phenytoin 100 mg Tabs	1000T	4600	2.850	13,110.00	India
Chlorpheniramine 4mg Tabs	1000T	18000	0.671	12,078.00	Tanzania
Chlopromazine 25 mg Tabs	500T	8200	1.386	11,365.20 (EURO)	India
Metformin 500 mg Tabs	100T	8700	1.220	10,614.00	India
Clotrimazole Pessary with applicator 100mg	6P	57000	0.180	10,260.00	Kenya

Magnesium Trisilicate Compd	1000T	23500	0.42	9,870.00	Tanzania
Carbamazepine Tabs 200mg	500T	3000	3.150	9,450.00 (EURO)	India
Tinidazole 500mg Tabs	100T	4500	1.990	8,955.00	Tanzania
Carbimazole 5 mg Tabs	100T	3400	2.530	8,602.00 (EURO)	Cyprus
Nifedipine Retard 20 mg Tabs	100T	14200	0.600	8,520.00	India
Bisacodyl Tablets 5mg	200T	2800	2.920	8,176.00	Cyprus
Ranitidine 150mg Tabs	500T	7900	0.900	7,110.00	India
Simvastatin 20 mg Tabs	100	2800	2.100	5,880.00	India
Benzhexol 5 mg Tabs	100T	3400	1.640	5,576.00 (EURO)	Cyprus

6.4 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:

Medicine, Strength, Formulation	UNIT price for Originator	UNIT price for lowest priced generic
Amitriptyline 25 mg Cap/tab		0.0108
Amoxicillin 500 mg Cap/tab		0.01555
Atenolol 50 mg Cap/tab		0.006
Captopril 25 mg Cap/tab		0.0169
Ceftriaxone 1 g/ vial Injection		0.3
Ciprofloxacin 500 mg Cap/tab		0.0176
Co-trimoxazole 80 + 40 mg/ml Susp.		0.00275/ML
Diazepam 5 mg Cap/tab		0.00079
Diclofenac 50 mg Cap/tab		0.004
Glibenclamide 5 mg Cap/tab		0.0045
Omeprazole 20 mg Cap/tab		0.0061
Paracetamol 24 mg/ml Susp.		0.0022/ML
Salbutamol 0.1mg/dose Inhaler		0.0615
Simvastatin 20 mg Cap/tab		0.023

6.5 Distribution				
Distributors⁷			YEAR	SOURCE
There are national guidelines on Good Distribution Practices (GDP)	No, but draft available 2009	Yes/No	2009	TFDA
There a list of all GDP compliant distributors	No	Yes/No		TFDA
CMS			YEAR	SOURCE
Software tools are available for planning medicines supply	Yes	Yes/No		MSD
Software tools are available for management of medicines supply (procurement tracking, expenditure tracking, stock levels)	Yes	Yes/No		MSD
Data on months of stock on hand is routinely reported to managers	Yes	Yes/No		MSD

TOP 5 distributors by market value (Top 5 Manufacturers)

Name of distributor	Sales by Value		YEAR	SOURCE
Shelys PharmaceuticalsTz		24% of Total	2008/2009	MSD
Keko Pharmaceuticals-Tz		11.87% of Total	2008/2009	
Medopharm-India		1.83 % of Total	2008/2009	MSD
Zenufa Laboratories-Tz		1.15% of Total	2008/2009	MSD
Elys Chemicals-Kenya		0.4% of Total	2008/2009	MSD

⁷ For the purpose of this profile, distributors deliver medicines on behalf of others and do not carry any risk for stock lost or expired.

6.6 Wholesale Market Characteristics⁸				
			YEAR	SOURCE
Legal provisions exist for licensing wholesalers	Yes	Yes/No	2003	TFDA
Number of wholesalers in market	243	Number	2009	TFDA
Number of GDP compliant wholesalers in market	-	Number		
List of GDP compliant wholesalers is publicly available	No	Yes/No		

TOP 5 wholesalers by market value

Name of wholesaler	Sales by Value		YEAR	SOURCE
Nufaika Distributors	290,096,754,518.44	% of Total	2007	TFDA
Phillips Distributors	188,112,705,926.47	% of Total	2007	TFDA
Salama Pharmaceuticals	101,855,764,195.78	% of Total	2007	TFDA
K&C Trading Company	8,497,030,522.60	% of Total	2007	TFDA
J. D Pharmacy LTD	7,529,444,285.14	% of Total	2007	TFDA

⁸ 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	2009	WHO NPO
-If yes, year of last update of national STGs	2007/2009	Year	2009	WHO NPO
National essential medicines list (EML) exists	Yes	Yes/No	2009	WHO NPO
-If yes, number of medicine formulations on the national EML		number		
-If yes, year of last update of EML	2007	Year	2009	WHO NPO
-If yes, process for selecting medicines on the EML is publicly available	Yes	Yes/No		
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	No	Yes/No		WHO NPO
There are explicit criteria for selecting medicines for national EML	No	Yes/No		WHO NPO
National medicines formulary manual exists	Yes	Yes/No	2007	WHO level I
-If yes, national medicines formulary manual is limited to essential medicines	No	Yes/No	2007	WHO level I
-If yes, year of last update of national medicines formulary manual	2006	Year	2007	WHO level I
National STGs for paediatric conditions exist	No, but IMCI guidelines available	Yes/No	2009	WHO NPO
-If yes, year of last update of national paediatric STGs		Year		
EML used in public insurance reimbursement	Yes	Yes/No	2007	WHO level I
Rational use national audit done in the last two years	No	Yes/No	2007	WHO level I
% of public health facilities with EML (mean)- Survey data		%		
% of public health facilities with STGs (mean)- Survey data	20%	%	2002	WHO Level II

Public education campaigns about rational medicines use have been conducted by MoH, NGOs or academia in the previous two years	No	Yes/No	2002	WHO Level II
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	WHO level I
A national strategy exists to contain antimicrobial resistance	No	Yes/No	2007	WHO level I
-If yes, date of last update of the strategy		Year		
A national reference laboratory has responsibility for coordinating epidemiological surveillance of antimicrobial resistance	No	Yes/No	2007	WHO level I
A public or independently funded national medicines information centre provides information on medicines to consumers	No	Yes/No	2007	WHO level I
Legal provisions exist for the control of narcotics, psychotropic substances, and precursors	Yes	Yes/No	2007	WHO level I
The country is a signatory to the International Conventions on the Control of Narcotics, Psychotropic Substances and Precursors	Yes	Yes/No	2007	WHO level I

7.2 Prescribing				
			YEAR	SOURCE
Legal provisions exist to govern the licensing and prescribing practices of prescribers	Yes	Yes/No	2007	WHO level I
-The following types of health workers are legally allowed to prescribe				
-Nurses	No	Yes/No		MOHSW
-Midwives	No	Yes/No		MOHSW
-Community health workers	No	Yes/No		MOHSW
-Pharmacists	No	Yes/No		MOHSW
Prescribers are legally allowed to dispense	No	Yes/No		MOHSW
Prescribers in the public sector dispense medicines	Yes	Yes/No	2007	WHO level I
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	Yes	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	Yes	Yes/No	2007	WHO level I
The basic <u>nursing</u> training curriculum includes components on:				
- Use of the national EML	Yes	Yes/No	2007	WHO level I
- Use of national STGs	Yes	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
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)	No	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		WHO NPO
Incentives exist to encourage prescribing of generic medicines in private health facilities	No	Yes/No		WHO NPO

INRUD prescribing indicators			YEAR	SOURCE
Number of medicines prescribed per patient contact in public health facilities (mean)	1.8	number	2002	WHO Level II
% of patients receiving antibiotics (mean)	42%	%	2002	WHO Level II
% of patients receiving injections (mean)	14%	%	2002	WHO Level II
% of drugs prescribed that are in the EML (mean)	98.5%	%	2002	WHO Level II
Diarrhoea in children treated with ORS (%)	82%	%	2002	WHO Level II
Non-pneumonia ARIs treated with antibiotics (%)	90%	%	2002	WHO Level II

7.3 Dispensing				
			YEAR	SOURCE
Legal provisions exist to govern licensing and practice of pharmacy	Yes	Yes/No	2007	WHO level I
A professional association code of conduct exists governing professional behaviour of pharmacists	Yes	Yes/No	2008	Pharmacy Council
The basic <u>pharmacist</u> training curriculum includes components on				
-Use of the national EML	Yes	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
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	No	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	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)		%		
Percentage of medicines adequately labelled in public health facilities (mean)	76%	%	2002	WHO Level II
Percentage of patients knowing correct dosage in public health facilities (mean)	80%	%	2002	WHO Level II

PART 8 - HOUSEHOLD DATA

8.1 Data from Household surveys				
			YEAR	SOURCE
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		%		