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To Fight AIDS, Tuberculosis and Malaria

Pharmaceutical Sector Country Profile Questionnaire

SRI LANKA

Section 0 General Info

0.01 Contact Info

0.01.01	Country (precoded)	Sri Lanka-F
0.01.02	Name coordinator	
0.01.03	Address (Street, City)	
0.01.04	Phone number	
0.01.05	Email address	
0.01.06	Web address	
0.01.07	Institution	

Section 1 Health and Demographic data

1.00 Respondent Information Section 1

1.00.01	Name of person responsible for filling out Survey section 1	
1.00.02	Phone number	
1.00.03	Email address	
1.00.04	Other respondents for filling out this section	

1.01 Demographic and Socioeconomic Indicators

Core questions ([click here for help](#))

			Year	Source
1.01.01	Population , total (,000)	20,217	2008	Socio-Economic data 2009, Central Bank
1.01.02	Population growth rate (Annual %)	1.0	2008	Socio-Economic data 2009, Central Bank
1.01.03	Total Gross Domestic Product (GDP) (millions US\$)	49550		
1.01.04	GDP growth (Annual %)	6.0	2008	Socio-Economic data 2009, Central Bank
1.01.05C	GDP per capita (US\$ current exchange rate)	1,540		
1.01.06	Comments and References			

Supplementary questions ([click here for help](#))



			Year	Source
1.01.07S	Population < 15 years (% of total population)	26.4	2007	MoH
1.01.08S	Population > 60 years (% of total population)	9.3	2007	MoH
1.01.09S	Urban population (% of total population)	21.5	2008	Socio-Economic data 2009, Central Bank
1.01.10S	Fertility rate, total (Births per woman)	2.3	2007	MoH
1.01.11S	Population living with less than \$1.25/day (international PPP) (%)	10.3	2005	WHS 2009
1.01.12S	Population living below nationally defined poverty line (%)	12.6	2007	Department of Census and Statistics
1.01.13S	Income share held by lowest 20% of the population (% of national income)	6.99	2002	World Bank 2008
1.01.14S	Adult literacy rate, 15+ years (% of relevant population)	90.8	2006	Central Bank
1.01.15S	Comments and References			

1.02 Mortality and Causes of Death

Core questions ([click here for help](#))

			Year	Source
1.02.01	Life expectancy at birth for men (Years)	68.2	2006	Central Bank
1.02.02	Life expectancy at birth for women (Years)	75.8	2006	Central Bank
1.02.03	Infant mortality rate , between birth and age 1 (/1,000 live births)	11.22	2006	Ministry of Health

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1.02.04	Under 5 mortality rate (/1,000 live births)	13.39	2003	Ministry of Health
1.02.05	Maternal mortality ratio (/100,000 live births)	44.3	2005	Ministry of Health
1.02.06	Please provide a list of top 10 diseases causing mortality 		2007	Ministry of Health
1.02.06.01	Disease 1	Ischaemic heart disease		
1.02.06.02	Disease 2	Neoplasms		
1.02.06.03	Disease 3	Pulmonary heart disease and diseases of the pulmonary circulation		
1.02.06.04	Disease 4	Cerebrovascular disease		
1.02.06.05	Disease 5	Diseases of the gastrointestinal tract		
1.02.06.06	Disease 6	Diseases of the respiratory system, excluding diseases of the upper respiratory tract		
1.02.06.07	Disease 7	Zoonotic and other bacterial diseases		
1.02.06.08	Disease 8	Symptoms, signs and abnormal clinical and laboratory findings		
1.02.06.09	Disease 9	Diseases of the urinary system		
1.02.06.10	Disease 10	Traumatic Injuries		
1.02.07	Please provide a list of top 10 diseases causing morbidity 		2007	Ministry of Health
1.02.07.01	Disease 1	Traumatic injuries		
1.02.07.02	Disease 2	Diseases of the respiratory system, excluding diseases of upper respiratory tract		
1.02.07.03	Disease 3	Symptoms, signs and abnormal clinical and laboratory findings		
1.02.07.04	Disease 4	Viral diseases		
1.02.07.05	Disease 5	Diseases of the gastrointestinal tract		

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1.02.07.06	Disease 6	Direct and indirect obstetric causes		
1.02.07.07	Disease 7	Diseases of the urinary system		
1.02.07.08	Disease 8	Intestinal infectious diseases		
1.02.07.09	Disease 9	Diseases of the skin and subcutaneous tissue		
1.02.07.10	Disease 10	Diseases of the musculoskeletal system and connective tissue		
1.02.08	Comments and References			
Supplementary questions (click here for help)				
		Year	Source	
1.02.09S	Adult mortality rate for both sexes between 15 and 60 years (/1,000 population)	155	2007	WHS 2009
1.02.10S	Neonatal mortality rate (/1,000 live births)	8.7	2003	MoH
1.02.11S	Age-standardized mortality rate by non-communicable diseases (/100,000 population)	681	2004	WHS 2009
1.02.12S	Age-standardized mortality rate by cardiovascular diseases (/100,000 population)	301	2004	WHS 2009
1.02.13S	Age-standardized mortality rate by cancer (/100,000 population)	114	2004	WHS 2009
1.02.14S	Mortality rate for HIV/AIDS (/100,000 population)	0	2007	WHS 2009
1.02.15S	Mortality rate for tuberculosis (/100,000 population)	1	2007	Ministry of Health
1.02.16S	Mortality rate for Malaria (/100,000 population)	0.01	2006	WHS 2009
1.02.17S	Comments and References			

Section 2 Health Services



2.00 Respondent Information Section 2


2.00.01	Name of person responsible for filling out this section of the instrument	
2.00.02	Phone number	
2.00.03	Email address	
2.00.04	Other respondents for filling out this section	



2.01 Health Expenditures

Core questions ([click here for help](#))

			Year	Source
2.01.01.01	Total annual expenditure on health (millions NCU)	117,850	2006	Institute of Health Policy
2.01.01.02	Total annual expenditure on health (millions US\$ average exchange rate)	1459	2010	NHA
2.01.02C	Total health expenditure as % of Gross Domestic Product	4.2		
2.01.03.01C	Total annual expenditure on health per capita (NCU)	5,926		
2.01.03.02C	Total annual expenditure on health per capita (US\$ average exchange rate)	57		
2.01.04.01	General government annual expenditure on health (millions NCU)	57,750	2006	Institute of Health Policy
2.01.04.02	General government annual expenditure on health (millions US\$ average exchange rate)	656.5	2010	Calculated from the IHP
2.01.05	Government annual expenditure on health as percentage of total government budget (% of total	6	2010	NHA





	government budget)			
2.01.06C	Government annual expenditure on health as % of total expenditure on health (% of total expenditure on health)	45	2010	NHA
2.01.07.01C	Annual per capita government expenditure on health (NCU)	2,151		
2.01.07.02C	Annual per capita government expenditure on health (US\$ average exchange rate)	20.02		
2.01.08C	Private health expenditure as % of total health expenditure (% of total expenditure on health)	50.2	2006	Institute of Health Policy
2.01.09	Population covered by a public health service or public health insurance or social health insurance , or other sickness funds of total population) 			
2.01.10	Population covered by private health insurance (% of total population) 			
2.01.11.01	Total pharmaceutical expenditure (millions NCU)	17,419	2006	Institute of Health Policy
2.01.11.02	Total pharmaceutical expenditure (millions US\$ current exchange rate)	167.55	2006	Calculated from the IHP
2.01.12.01C	Total pharmaceutical expenditure per capita (NCU)	876.2		
2.01.12.02C	Total pharmaceutical expenditure per capita (US\$ current exchange rate)	8.43		
2.01.13C	Pharmaceutical expenditure as a % of GDP (% of GDP)	0.77		

2.01.14C	Pharmaceutical expenditure as a % of Health Expenditure (% of total health expenditure)	14.78		
2.01.15.01	Total public expenditure on pharmaceuticals (millions NCU)	5,014	2006	Institute of Health Policy
2.01.15.02	Total public expenditure on pharmaceuticals (millions US\$ current exchange rate)	48.23	2006	Calculated from the IHP
2.01.16C	Share of public expenditure on pharmaceuticals as percentage of total expenditure on pharmaceuticals (%)	28.8	2006	Calculated from the IHP
2.01.17.01C	Total public expenditure on pharmaceuticals per capita (NCU)	252.21		
2.01.17.02C	Total public expenditure on pharmaceuticals per capita (US\$ current exchange rate)	43		
2.01.18.01	Total private expenditure on pharmaceuticals (millions NCU)	12,405	2006	Institute of Health Policy
2.01.18.02	Total private expenditure on pharmaceuticals (millions US\$ current exchange rate)	119.32	2006	Calculated from the IHP
2.01.19	Comments and References			
Supplementary questions (click for help)				
			Year	Source
2.01.20S	Social security expenditure as % of government expenditure on health (% of government expenditure on health)	0.1	2008	NHA
2.01.21S	Market share of generic pharmaceuticals branded and INN by value (%) 			




2.01.22S	Annual growth rate of total pharmaceuticals market value (%) 			
2.01.23S	Annual growth rate of generic pharmaceuticals market value (%) 			
2.01.24S	Private out-of-pocket expenditure as % of private health expenditure (% of private expenditure on health)	86.7	2008	MHA
2.01.25S	Premiums for private prepaid health plans as % of total private health expenditure (% of private expenditure on health)	9.1	2008	NHA
2.01.26S	Comments and References			

2.02 Health Personnel and Infrastructure

Core questions [\[click for help\]](#)

			Year	Source
2.02.01	Total number of pharmacists licensed/registered to practice in your country 	7,237	2010	Sri Lanka Medical Council
2.02.02C	Pharmacists per 10,000 population			
2.02.03	Total number of pharmacists working in the public sector 	1,026	2008	MoH
2.02.04	Total number of pharmaceutical technicians and assistants 	943	2008	MoH
2.02.05	A strategic plan for pharmaceutical human resource development is in place in your country? 	Yes <input type="checkbox"/> No <input type="checkbox"/>		
2.02.06	Total number of physicians	12,067	2008	MoH
2.02.07C	Physicians per 10,000 pop			

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2.02.08	Total number of nursing and midwifery personnel	33,332	2008	MoH
2.02.09C	Nurses and midwives per 10,000 pop			
2.02.10	Total number of hospitals	763	2009	MoH
2.02.11	Number of hospital beds per 10,000 pop	36	2009	WHS
2.02.12	Total number of primary health care units and centers			
2.02.13	Total number of licensed pharmacies 	2950	2010	MoH
2.02.14	Comments and References			
Supplementary questions (click here for help)				
			Year	Source
2.02.15S	Starting annual salary for a newly registered pharmacist in the public sector (NCU) 	185,280	2010	MoH
2.02.16S	Total number of pharmacists who graduated (first degree) in the past 2 years in your country 	20	2009	University of Colombo
2.02.17S	Are there accreditation requirements for pharmacy schools?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
2.02.18S	Is the Pharmacy Curriculum regularly reviewed?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
2.02.19S	Comments and References			





Section 3 Policy issues


3.00 Respondent Information Section 4




3.00.01	Name of person responsible for filling out this section of the instrument			
3.00.02	Phone number			
3.00.03	Email address			
3.00.04	Other respondents for filling out this section			

3.01 Policy Framework

Core questions ([click here for help](#))

		Year	Source
3.01.01	National Health Policy exists. If yes, please write year of the most recent document in the "year" field. 	Yes <input type="checkbox"/> No <input type="checkbox"/>	
3.01.02	National Health Policy Implementation plan exists. If yes, please write the year of the most recent document in the "year" 	Yes <input type="checkbox"/> No <input type="checkbox"/>	
3.01.03	Please provide comments on the Health policy and its implementation plan		
3.01.04	National Medicines Policy official document exists. If yes, please write the year of the most recent document in the "year" field. 	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2005 MoH
3.01.05	Group of policies addressing pharmaceuticals exist. 	Yes <input type="checkbox"/> No <input type="checkbox"/>	
3.01.06	National Medicines Policy covers the following components: —		

3.01.06.01	Selection of Essential Medicines	<input checked="" type="checkbox"/> Yes		
3.01.06.02	Medicines Financing	<input checked="" type="checkbox"/> Yes		
3.01.06.03	Medicines Pricing	<input checked="" type="checkbox"/> Yes		
3.01.06.04	Medicines Procurement	<input checked="" type="checkbox"/> Yes		
3.01.06.05	Medicines Distribution	<input checked="" type="checkbox"/> Yes		
3.01.06.06	Medicines Regulation	<input checked="" type="checkbox"/> Yes		
3.01.06.07	Pharmacovigilance	<input checked="" type="checkbox"/> Yes		
3.01.06.08	Rational Use of Medicines	<input checked="" type="checkbox"/> Yes		
3.01.06.09	Human Resource Development	<input checked="" type="checkbox"/> Yes		
3.01.06.10	Research	<input checked="" type="checkbox"/> Yes		
3.01.06.11	Monitoring and Evaluation	<input checked="" type="checkbox"/> Yes		
3.01.06.12	Traditional Medicine	<input checked="" type="checkbox"/> Yes		
3.01.07	National medicines policy implementation plan exists. If yes, please write year of the most recent document. 	Yes <input type="checkbox"/> No <input type="checkbox"/>		
3.01.08	Policy or group of policies on clinical laboratories exist. If yes, please write year of the most recent document in the "year" field	Yes <input type="checkbox"/> No <input type="checkbox"/>		
3.01.09	National clinical laboratory policy implementation plan exists. If yes, please write year of the most recent document in the "year" field	Yes <input type="checkbox"/> No <input type="checkbox"/>		
3.01.10	Access to essential medicines/technologies as part of the fulfillment of the right to health, recognized in the constitution or	Yes <input type="checkbox"/> No <input type="checkbox"/>		

	national legislation?			
3.01.11	There are official written guidelines on medicines donations.	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
3.01.12	Is pharmaceutical policy implementation being regularly monitored/assessed? 	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
3.01.12.01	Who is responsible for pharmaceutical policy monitoring?	Ministry of Health		
3.01.13	Is there a national good governance policy ?	Yes <input type="checkbox"/> No <input type="checkbox"/>		
3.01.13.01	Multisectoral 	<input type="checkbox"/> Yes		
3.01.13.02	For the pharmaceutical sector 	<input type="checkbox"/> Yes		
3.01.13.03	Which agencies are responsible?			
3.01.14	A policy is in place to manage and sanction conflict of interest issues in pharmaceutical affairs.	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
3.01.15	There is a formal code of conduct for public officials.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	1985	Ministry of Public Administration
3.01.16	Is there a whistle-blowing mechanism allowing individuals to raise a concern about wrongdoing occurring in the pharmaceutical sector of your country (ombudsperson)?	Yes <input type="checkbox"/> No <input type="checkbox"/>		
3.01.16.01	Please describe:	Code of conduct for public officials is in the Establishments Code issued by the Ministry of Public Administration. This is available as a printed document only		
3.01.17	Comments and References			

Section 4 Medicines Trade and Production


4.00 Respondent Information Section 4



4.00.01	Name of person responsible for filling out this section of the instrument	
4.00.02	Phone number	
4.00.03	Email address	
4.00.04	Other respondents for filling out this section	

4.01 Intellectual Property Laws and Medicines

Core questions ([click here for help](#))

			Year	Source
4.01.01	Country is a member of the World Trade Organization	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2007	WHO level I
4.01.02	Legal provisions provide for granting of Patents on:		2007	WHO Level I
4.01.02.01	Pharmaceuticals	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
4.01.02.02	Laboratory supplies	Yes <input type="checkbox"/> No <input type="checkbox"/>		
4.01.02.03	Medical supplies	Yes <input type="checkbox"/> No <input type="checkbox"/>		
4.01.02.04	Medical equipment	Yes <input type="checkbox"/> No <input type="checkbox"/>		
4.01.03.01	Please provide name and address of the institution responsible for managing and enforcing intellectual property rights			
4.01.03.02	Please provide URL			
4.01.04	National Legislation has been modified to implement the TRIPS Agreement	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2007	WHO Level I
4.01.05	Current laws contain (TRIPS)	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2007	WHO Level

	flexibilities and safeguards			I
4.01.06	Country is eligible for the transitional period to 2016	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
4.01.07	Which of the following (TRIPS) flexibilities and safeguards are present in the national law?		2007	WHO Level I
4.01.07.01	Compulsory licensing provisions that can be applied for reasons of public health	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
4.01.07.02	Bolar exception	Yes <input type="checkbox"/> No <input type="checkbox"/>		
4.01.08	Are parallel importing provisions present in the national law?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2007	WHO Level I
4.01.09	The country is engaged in initiatives to strengthen capacity to manage and apply intellectual property rights to contribute to innovation and promote public health	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
4.01.10	Are there legal provisions for data exclusivity for pharmaceuticals	Yes <input type="checkbox"/> No <input type="checkbox"/>		
4.01.11	Legal provisions exist for patent extension	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
4.01.12	Legal provisions exist for linkage between patent status and Marketing Authorization	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
4.01.13	Comments and References			
4.02 Manufacturing				
Core questions (click here for help)				
			Year	Source
4.02.01	Number of licensed pharmaceutical manufacturers in the country 	8	2010	Ministry of Health

4.02.02	Country has manufacturing capacity	2010	Ministry of Health
4.02.02.01	R&D to discover new active substances	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Unknown <input type="checkbox"/>	
4.02.02.02	Production of pharmaceutical starting materials (APIs)	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Unknown <input type="checkbox"/>	
4.02.02.03	Production of formulations from pharmaceutical starting material	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>	
4.02.02.04	Repackaging of finished dosage forms	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>	
4.02.03	Percentage of market share by value produced by domestic manufacturers (%)	7	
4.02.04	Comments and References		
Supplementary questions (click here for help)			
		Year	Source
4.02.05S	Percentage of market share by volume produced by domestic manufacturers (%) 		
4.02.06S	Number of multinational pharmaceutical companies manufacturing medicines locally	1	2010 Ministry of Health
4.02.07S	Number of manufacturers that are Good Manufacturing Practice (GMP) certified 	4	2010 Ministry of Health
4.02.08S	Comments and References		



Section 5 Medicines Regulation

5.00 Respondent Information Section 4

5.00.01	Name of person responsible for filling out this section of the instrument	
5.00.02	Phone number	
5.00.03	Email address	
5.00.04	Other respondents for filling out this section	

5.01 Regulatory Framework

Core questions ([click here for help](#))

			Year	Source
5.01.01	Are there legal provisions establishing the powers and responsibilities of the Medicines Regulatory Authority (MRA)? 	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Ministry of Health
5.01.02	There is a Medicines Regulatory Authority	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
5.01.03	If yes, please provide name and address of the Medicines regulatory authority			
5.01.04	The Medicines Regulatory Authority is: 			
5.01.04.01	Part of MoH	<input checked="" type="checkbox"/> Yes		
5.01.04.02	Semi autonomous agency	<input type="checkbox"/> Yes		
5.01.04.03	Other (please specify)			
5.01.05	What are the functions of the National Medicines Regulatory Authority?			


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5.01.05.01	Marketing authorization / registration	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.01.05.02	Inspection	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.01.05.03	Import control	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.01.05.04	Licensing	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.01.05.05	Market control	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.01.05.06	Quality control	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.01.05.07	Medicines advertising and promotion	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.01.05.08	Clinical trials control	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.01.05.09	Pharmacovigilance	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.01.05.10	Other: (please explain)			
5.01.06	Number of the MRA permanent staff			
5.01.06.01	Date of response			
5.01.07	The MRA has its own website	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.01.07.01	- If yes, please provide MRA Web site address (URL)			
5.01.08	The MRA receives external technical assistance	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.01.08.01	If yes, please describe:			
5.01.09	The MRA is involved in harmonization/ collaboration initiatives	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	MoH
5.01.09.01	- If yes, please specify			
5.01.10	An assessment of the medicines regulatory system has been conducted in the last five years.	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	MoH
5.01.11	Medicines Regulatory Authority gets funds from regular budget of the	Yes <input type="checkbox"/> No <input type="checkbox"/>		

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	government.			
5.01.12	Medicines Regulatory Authority is funded from fees for services provided.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	MoH
5.01.13	Medicines Regulatory Authority receives funds/support from other sources	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	MoH
5.01.13.01	- If yes, please specify	World Health Organization		
5.01.14	Revenues derived from regulatory activities are kept with the Regulatory Authority 	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	MoH
5.01.15	The Regulatory Authority is using a computerized information management system to store and retrieve information on registration, inspections, etc. 	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	MoH
5.01.16	Comments and References			
5.02 Marketing Authorization (Registration)				
Core questions (click here for help)				
			Year	Source
5.02.01	Legal provisions require a Marketing Authorization (registration) for all pharmaceutical products on the market	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Ministry of Health
5.02.02	Are there any mechanism for exception/waiver of registration?	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.02.03	Are there mechanisms for recognition of registration done by other countries	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.02.03.01	If yes, please explain:			

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5.02.04	Explicit and publicly available criteria exist for assessing applications for Marketing Authorization of pharmaceutical products	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Ministry of Health
5.02.05	Information from the prequalification programme managed by WHO is used for product registration	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.02.06	Number of pharmaceutical products registered in your country	6,149	2010	Ministry of Health
5.02.07	Legal provisions require the MRA to make the list of registered pharmaceuticals with defined periodicity publicly available	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		Ministry of Health
5.02.07.01	If yes, how frequently updated			
5.02.07.02	If yes, please provide updated list or URL *			
5.02.08	Medicines registration always includes the INN (International Non-proprietary Names)	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Ministry of Health
5.02.09	Legal provisions require the payment of a fee for Medicines Marketing Authorization (registration) applications	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Ministry of Health
5.02.10	Comments and References			
Supplementary questions (click here for help)				
			Year	Source
5.02.11S	Legal provisions require Marketing Authorization holders to provide information about variations to the existing Marketing Authorization	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Ministry of Health
5.02.12S	Legal provisions require publication of a Summary of Product Characteristics (SPCs) of the	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	Ministry of Health

	medicines registered			
5.02.13S	Legal provisions require the establishment of an expert committee involved in the marketing authorization process	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Ministry of Health
5.02.14S	Certificate for Pharmaceutical Products in accordance with the WHO Certification scheme is required as part of the Marketing Authorization application	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Ministry of Health
5.02.15S	Legal provisions require declaration of potential conflict of interests for the experts involved in the assessment and decision-making for registration	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	Ministry of Health
5.02.16S	Legal provisions allow applicants to appeal against MRAs decisions	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Ministry of Health
5.02.17S	Registration fee - the amount per application for pharmaceutical product containing New Chemical Entity (NCE) (US\$) 			
5.02.18S	Registration fee - the Amount per application for a generic pharmaceutical product (US\$) 			
5.02.19S	Time limit for the assessment of a Marketing Authorization application (months)			
5.02.20S	Comments & References			
5.03 Regulatory Inspection Core Questions(click here for help)				
			Year	Source
5.03.01	Legal provisions exist allowing for appointment of government	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Ministry of Health

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	pharmaceutical inspectors			
5.03.02	Legal provisions exist permitting inspectors to inspect premises where pharmaceutical activities are performed	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Ministry of Health
5.03.02.01	If yes, legal provisions exist requiring inspections to be performed	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
5.03.03	Inspection is a pre-requisite for licensing of:			
5.03.03.01	Public facilities	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.03.03.02	Private facilities	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.03.04	Inspection requirements are the same for public and private facilities 	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	Ministry of Health
5.03.05.01	Local manufactures are inspected for GMP compliance	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.03.05.02	Private wholesalers are inspected	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.03.05.03	Retail distributors are inspected	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.03.05.04	Public pharmacies and stores are inspected	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.03.05.05	Pharmacies and dispensing points of health facilities are inspected	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.03.05.06	Please provide details on frequency of inspections for the different categories of facilities			
5.03.06	Comments and References			
5.04 Import Control				
Core Questions (click here for help)				
			Year	Source

5.04.01	Legal provisions exist requiring authorization to import medicines	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Ministry of Health
5.04.02	Legal provisions exist allowing the sampling of imported products for testing	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Ministry of Health
5.04.03	Legal provisions exist requiring importation of medicines through authorized ports of entry	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Ministry of Health
5.04.04	Legal provisions exist allowing inspection of imported pharmaceutical products at the authorized ports of entry	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Ministry of Health
5.04.05	Comments and References			
5.05 Licensing				
			Year	Source
5.05.01	Legal provisions exist requiring manufacturers to be licensed	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Ministry of Health
5.05.02	Legal provisions exist requiring both domestic and international manufacturers to comply with Good manufacturing Practices (GMP)	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Ministry of Health
5.05.02.01	If no, please explain			
5.05.03	GMP requirements are published by the government.	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	Ministry of Health
5.05.04	Legal provisions exist requiring importers to be licensed	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Ministry of Health
5.05.05	Legal provisions exist requiring wholesalers and distributors to be licensed	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Ministry of Health
5.05.06	Legal provisions exist requiring wholesalers and distributors to comply with Good Distributing	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Ministry of Health

	Practices When filling in this part, please also fill in the relevant questions in the procurement and distribution section (Section 7)			
5.05.07	National Good Distribution Practice requirements are published by the government	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	Ministry of Health
5.05.08	Legal provisions exist requiring pharmacists to be registered	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Ministry of Health
5.05.09	Legal provisions exists requiring private pharmacies to be licensed	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Ministry of Health
5.05.10	Legal provision exist requiring public pharmacies to be licensed	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	Ministry of Health
5.05.11	National Good Pharmacy Practice Guidelines are published by the government	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	Ministry of Health
5.05.12	Legal provisions require the publication of a list of all licensed pharmaceutical facilities	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.05.13	Comments and References			
5.06 Market Control and Quality Control Core Questions (click here for help)				
			Year	Source
5.06.01	Legal Provisions for regulating the pharmaceutical market exist	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	Ministry of Health
5.06.02	Does a laboratory exist in the country for Quality Control testing?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Ministry of Health
5.06.02.01	If yes, is the laboratory part of the MRA ?	Yes <input type="checkbox"/> No <input type="checkbox"/>		

5.06.02.02	Does the regulatory authority contract services elsewhere? Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>			
5.06.02.03	If yes, please describe			
5.06.03	Is there any national laboratory accepted for collaboration with WHO prequalification Programme ? Please describe.			
5.06.04	Medicines are tested:			
5.06.04.01	For quality monitoring in the public sector (routine sampling in pharmacy stores and health facilities)	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.06.04.02	For quality monitoring in private sector (routine sampling in retail outlets)	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.06.04.03	When there are complaints or problem reports	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.06.04.04	For product registration	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.06.04.05	For public procurement prequalification	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.06.04.06	For public program products prior to acceptance and/or distribution	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.06.05	Samples are collected by government inspectors for undertaking post-marketing surveillance testing	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.06.06	How many Quality Control samples were taken for testing in the last two years?	1432	2010	National Drugs Quality Assurance Laboratory
5.06.07	Total number of samples tested in the last two years that failed to meet	393	2010	National Drugs

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	quality standards			Quality Assurance Laboratory
5.06.08	Results of quality testing in past two years are publicly available	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	Ministry of Health
5.06.09	Comments and References			
5.07 Medicines Advertising and Promotion				
Core Questions (click here for help)				
			Year	Source
5.07.01	Legal provisions exist to control the promotion and/or advertising of prescription medicines	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	
5.07.02	Who is responsible for regulating, promotion and/or advertising of medicines? Please describe:	Drug Regulatory Authority		
5.07.03	Legal provisions prohibit direct advertising of prescription medicines to the public	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Ministry of Health
5.07.04	Legal provisions require a pre-approval for medicines advertisements and promotional materials 	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Ministry of Health
5.07.05	Guidelines/Regulations exist for advertising and promotion of non-prescription medicines	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Ministry of Health
5.07.06	A national code of conduct exists concerning advertising and promotion of medicines by marketing authorization holders and is publicly available	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	Ministry of Health
5.07.06.01	If yes, the code of conduct applies to			

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domestic manufacturers only, multinational manufacturers only, or both		Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Domestic only		<input type="checkbox"/> Yes
Multinational only		<input type="checkbox"/> Yes
Both		<input type="checkbox"/> Yes
5.07.06.02	If yes, adherence to the code is voluntary	Yes <input type="checkbox"/> No <input type="checkbox"/>
5.07.06.03	If yes, the code contains a formal process for complaints and sanctions	Yes <input type="checkbox"/> No <input type="checkbox"/>
5.07.06.04	If yes, list of complaints and sanctions for the last two years is publicly available	Yes <input type="checkbox"/> No <input type="checkbox"/>
5.07.07	Comments and References	

5.08 Clinical trials

Core Questions ([click here for help](#))

			Year	Source
5.08.01	Legal provisions exist requiring authorization for conducting Clinical Trials by the MRA	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	Ministry of Health
5.08.02	Legal provisions exist requiring the agreement by an ethics committee/ institutional review board of the Clinical Trials to be performed	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	Ministry of Health
5.08.03	Legal provisions exist requiring registration of the clinical trials into international/national/regional registry	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Sri Lanka Medical Association
5.08.04	Comments and References	MRA is in the process of drafting legislation with regard to clinical		




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		trials		
Supplementary questions (click here for help)				
			Year	Source
5.08.05S	Legal provisions exist for GMP compliance of investigational products	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.08.06S	Legal provisions require sponsor, investigator to comply with Good Clinical Practices (GCP)	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.08.07S	National GCP regulations are published by the Government.	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.08.08S	Legal provisions permit inspection of facilities where clinical trials are performed	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.08.09S	Comments and References			
5.09 Controlled Medicines				
Core Questions (click here for help)				
			Date	Source
5.09.01	The country has adopted the following conventions:			
5.09.01.01	Single Convention on Narcotic Drugs, 1961	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	National Dangerous Drugs Control Board (NDDCB)
5.09.01.02	The 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	NDDCB
5.09.01.03	Convention on Psychotropic Substances 1971	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	NDDCB

5.09.01.04	United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances , 1988	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	NDDCB
5.09.02	Laws for the control of narcotic and psychotropic substances, and precursors exist	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	NDDCB
5.09.03	Annual consumption of Morphine (mg/capita)	0.490000	2010	NDDCB
5.09.04	Comments and References			
Supplementary questions (click here for help)				
			Year	Source
5.09.05S	The legal provisions and regulations for the control of narcotic and psychotropic substances, and precursors have been reviewed by a WHO International Expert or Partner Organization to assess the balance between the prevention of abuse and access for medical need	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>	2010	NDDCB
5.09.05.01S	If yes, year of review			
5.09.06S	Annual consumption of Fentanyl (mg/capita)	0.0008	2007	INCB
5.09.07S	Annual consumption of Pethidine (mg/capita)	1.1	2007	INCB
5.09.08S	Annual consumption of Oxycodone (mg/capita)			
5.09.09S	Annual consumption of Hydrocodone (mg/capita)			
5.09.10S	Annual consumption of Phenobarbital (mg/capita)			
5.09.11S	Annual consumption of Methadone (mg/capita)	0.013	2007	INCB

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5.09.12S	Comments and References			
5.10 Pharmacovigilance				
Core Questions (click here for help)				
			Year	Source
5.10.01	There are legal provision in the Medicines Act that provides for pharmacovigilance activities as part of the MRA mandate	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.10.02	Legal provisions exist requiring the Marketing Authorization holder to continuously monitor the safety of their products and report to the MRA	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Ministry of Health
5.10.03	Legal provisions about monitoring Adverse Drug Reactions (ADR) exist in your country	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.10.04	A national pharmacovigilance centre linked to the MRA exists in your country	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Ministry of Health
5.10.04.01	If a national pharmacovigilance centre exists in your country, how many staff does it employ full-time	0		
5.10.04.02	If a national pharmacovigilance center exists in your country, an analysis report has been published in the last two years.	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.10.04.03	If a national pharmacovigilance center exists in your country, it publishes an ADR bulletin	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.10.05	An official standardized form for reporting ADRs is used in your country	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	National Pharmacovigilance Centre

5.10.06	A national Adverse Drug Reactions database exists in your country	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	National Pharmacovigilance Centre
5.10.07	How many ADR reports are in the database? 	703	2010	National Pharmacovigilance Centre
5.10.08	How many reports have been submitted in the last two years? 	131	2010	National Pharmacovigilance Centre
5.10.09	Are ADR reports sent to the WHO database in Uppsala?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	National Pharmacovigilance Centre
5.10.09.01	If yes, number of reports sent in the last two years 	95	2010	National Pharmacovigilance Centre
5.10.10	Is there a national ADR or pharmacovigilance advisory committee able to provide technical assistance on causality assessment, risk assessment, risk management, case investigation and, where necessary, crisis management including crisis communication?	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.10.11	Is there a clear communication strategy for routine communication and crises communication?	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.10.12	In the absence of a national pharmacovigilance system, ADRs are monitored in at least one public health program (for example TB, HIV, AIDS)?	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.10.13	Please describe how you intend to enhance the Pharmacovigilance			

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	system			
5.10.14	Comments and References			
Supplementary questions (click here for help)				
			Year	Source
5.10.15S	Feedback is provided to reporters	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	National Pharmacovigilance Centre
5.10.16S	The ADR database is computerized	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.10.17S	Medication errors (MEs) are reported	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	National Pharmacovigilance Centre
5.10.18S	How many MEs are there in the ADRs database?			
5.10.19S	There is a risk management plan presented as part of product dossier submitted for Marketing Authorization?	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.10.20S	In the past two years, who has reported ADRs?		2010	National Pharmacovigilance Centre
5.10.20.01S	Doctors	<input checked="" type="checkbox"/> Yes		
5.10.20.02S	Nurses	<input type="checkbox"/> Yes		
5.10.20.03S	Pharmacists	<input checked="" type="checkbox"/> Yes		
5.10.20.04S	Consumers	<input type="checkbox"/> Yes		
5.10.20.05S	Pharmaceutical Companies	<input checked="" type="checkbox"/> Yes		
5.10.20.06S	Others, please specify whom			

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5.10.21S	Was there any regulatory decision based on local pharmacovigilance data in the last 2 years?	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.10.22S	Are there training courses in pharmacovigilance?	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.10.22.01S	If yes, how many people have been trained in the last two years?			
5.10.23S	Comments and References			

Section 6 Medicines Financing

6.00 Respondent Information Section 5

- 6.00.01 Name of person responsible for filling out this section of the instrument
- 6.00.02 Phone number
- 6.00.03 Email address
- 6.00.04 Other respondents for this sections

6.01 Medicines Coverage and Exemptions

Core Questions ([click here for help](#))

		Year	Source
6.01.01	Do the followings receive medicines free of charge:	2010	Ministry of Health
6.01.01.01	Patients who cannot afford them	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
6.01.01.02	Children under 5	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
6.01.01.03	Pregnant women	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
6.01.01.04	Elderly persons	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
6.01.01.05	Please describe/explain your yes answers for questions above	Ministry of Health provides medicines to the above categories free of charge but there are no special programmes for each category separately	
6.01.02	Is there a public health system or social health insurance scheme or public programme providing medicines free of charge for :	2010	Ministry of Health
6.01.02.01	All medicines included in the EML	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
6.01.02.02	Any non-communicable diseases	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
6.01.02.03	Malaria medicines	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
6.01.02.04	Tuberculosis medicines	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	

6.01.02.05	Sexually transmitted diseases medicines	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
6.01.02.06	HIV/AIDS medicines	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
6.01.02.07	Expanded Program on Immunization (EPI) vaccines	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
6.01.02.08	If others, please specify			
6.01.02.09	Please describe/explain your yes answers for questions above			
6.01.03	Does a national health insurance, social insurance or other sickness fund provide at least partial medicines coverage ?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Ministry of Health
6.01.03.01	Does it provide coverage for medicines that are on the EML for inpatients	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
6.01.03.02	Does it provide coverage for medicines that are on the EML for outpatients	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
6.01.03.03	Please describe the medicines benefit of public/ social insurance schemes	The public health service and a special fund (President's Fund) provide coverage for the above		
6.01.04	Do private health insurance schemes provide any medicines coverage?	Yes <input type="checkbox"/> No <input type="checkbox"/>		
6.01.04.01	If yes, is it required to provide coverage for medicines that are on the EML ?	Yes <input type="checkbox"/> No <input type="checkbox"/>		
6.01.05	Comments and References			
6.02 Patients Fees and Copayments Core Questions (click here for help)				
			Year	Source
6.02.01	In your health system, at the point of delivery, are there any co-	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	Ministry of

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	payment /fee requirements for consultations			Health
6.02.02	In your health system, at the point of delivery, are there any co-payment/fee requirements for medicines	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	Ministry of Health
6.02.03	In practice, (even though this may be contrary to regulations) is revenue from fees or sales of medicines sometimes used to pay the salaries or supplement the income of public health personnel in the same facility?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	Ministry of Health
6.02.03.01	Please describe the patient fees and copayments system			
6.02.04	Comments and References			
6.03 Pricing Regulation for the Private Sector				
Core Questions (click here for help)				
			Year	Source
6.03.01	Are there legal or regulatory provisions affecting pricing of medicines	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
6.03.01.01	If yes, are the provisions aimed at Manufacturers	Yes <input type="checkbox"/> No <input type="checkbox"/>		
6.03.01.02	If yes, are the provisions aimed at Wholesalers	Yes <input type="checkbox"/> No <input type="checkbox"/>		
6.03.01.03	If yes, are the provisions aimed at Retailers	Yes <input type="checkbox"/> No <input type="checkbox"/>		
6.03.01.04	Please explain the positive answers above: (explain scope of provisions i.e generics vs. originator or subsets of medicines, EML etc.)			
6.03.02	Government runs an active national medicines price monitoring system	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	Ministry of Health

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	for retail prices			
6.03.03	Regulations exists mandating that retail medicine price information should be publicly accessible	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Consumer Affairs Authority
6.03.03.01	-if yes, please explain how the information is made publically available	By price marking of the products and with price lists		
6.03.04	Comments and References			

6.04 Prices, Availability and Affordability

Core Questions ([click here for help](#))

		Year	Source
6.04.01-04	<p>Please state if a medicines price survey using the WHO/HAI methodology has been conducted in the past 5 years in your country.</p> <p>If yes, please indicate the year of the survey and use the results to fill in this table</p> <p>If no, but other surveys on medicines prices and availability have been conducted, please do not use them to fill in this section, but rather use the comment box to write some of the results and attach the report to the questionnaire</p>	Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>	

	Basket Of key medicines			Public procurement	Public patient	Private patient		
	Availability (one or both of)	Mean (%)	Orig		6.04.01.01	6.04.01.03		
			LPG		6.04.01.02	6.04.01.04		
		Median	Orig		6.04.02.01	6.04.02.03		

		(%)					
			LPG		6.04.02.02	6.04.02.04	
	Price	Median Price Ratio	Orig	6.04.03.01	6.04.03.03	6.04.03.05	
			LPG	6.04.03.02	6.04.03.04	6.04.03.06	
	Affordability	Number of days' wages	Orig		6.04.04.01	6.04.04.03	
	Days' wages of the lowest paid govt worker for standard treatment with co-trimoxazole for a child respiratory infection		LPG		6.04.04.02	6.04.04.04	
6.04.05	Comments and References						

6.05 Price Components and Affordability

Core Questions ([click here for help](#))

		Year	Source
6.05.01	Please state if a survey of medicines price components has been conducted in the past 5 years in your country	Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>	
6.05.02	Median cumulative percentage mark-up between Manufacturer Selling Price (MSP)/ Cost Insurance and Freight (CIF) price and final medicine price for a basket of key medicines in the public sector (Median % contribution)		
6.05.03	Median cumulative percentage mark-up between MSP/CIF price and final medicine price for a basket of key medicines in the private sector		

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	(Median % contribution)	
6.05.04	Comment and References	
Supplementary questions (click here for help)		
6.05.05S	Median percentage contribution of MSP/CIF to final medicine price for a basket of key medicines in the public sector (Median % contribution)	
6.05.06S	Median percentage contribution of MSP/CIF to final medicine price for a basket of key medicines in the private sector (Median % contribution)	
6.05.07S	Median manufacturer selling price (CIF) as percent of final medicine price for a basket of key medicines (%)	
6.05.08S	Median wholesaler selling price as percent of final medicine price for a basket of key medicines (%)	
6.05.09S	Median pharmacist mark-up or dispensing fee as percent of retail price for a basket of key medicines (%)	
6.05.10S	Median percentage contribution of the wholesale mark-up to final medicine price for a basket of key medicines (in the public and private sectors) (%)	
6.05.11S	Median percentage contribution of the retail mark-up to final medicine price for a basket of key medicines (in the public and private sectors) (%)	
6.05.12S	Comment and References	
6.06 Duties and Taxes on Pharmaceuticals (Market)		

Core Questions ([click here for help](#))

			Year	Source
6.06.01	There are duties on imported active pharmaceutical ingredients (APIs)	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	Ministry of Health
6.06.02	There are duties on imported finished products	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	Ministry of Health
6.06.03	VAT (value-added tax) or any other tax is levied on finished pharmaceuticals products	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Sri Lanka Chamber of Pharmaceutical Industry
6.06.04	There are provisions for tax exceptions or waivers for pharmaceuticals and health products	Yes <input type="checkbox"/> No <input type="checkbox"/>		
6.06.05	Please specify categories of pharmaceuticals on which the taxes are applied and describe the exemptions and waivers that exist	Ports and Airports Development Levy (PAL) 2% Natin Building Tax - 3%		
6.06.06	Comments and References			

Supplementary questions ([click here for help](#))

			Year	Source
6.06.07S	Duty on imported active pharmaceutical ingredients, APIs (%)			
6.06.08S	Duty on imported finished products (%)			
6.06.09S	VAT on pharmaceutical products (%)			
6.06.10S	Comments and References			

Section 7 Pharmaceutical procurement and distribution

7.00 Respondent Information Section 6

- 7.00.01 Name of person responsible for filling out this section of the instrument
- 7.00.02 Phone number
- 7.00.03 Email address
- 7.00.04 Other respondents for filling out this section

7.01 Public Sector Procurement

Core Questions ([click here for help](#))


		Date	Source
7.01.01	Public sector procurement is:	2010	Ministry of Health
7.01.01.01	Decentralized <input type="checkbox"/> Yes		
7.01.01.02	Centralized and decentralized <input checked="" type="checkbox"/> Yes		
7.01.01.03	Please describe	Public sector procurement is done by the State Pharmaceuticals Corporation of Sri Lanka	
7.01.02	If public sector procurement is wholly or partially centralized, it is under the responsibility of a procurement agency which is:	2010	Ministry of Health
7.01.02.01	Part of MoH	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
7.01.02.02	Semi-Autonomous	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	

7.01.02.03	Autonomous	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
7.01.02.04	A government procurement agency which procures all public goods	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.01.03	Public sector requests for tender documents are publicly available	Yes <input type="checkbox"/> No <input type="checkbox"/>		
7.01.04	Public sector tender awards are publicly available	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Ministry of Health
7.01.05	Procurement is based on prequalification of suppliers	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Ministry of Health
7.01.05.01	If yes, please describe how it works	Products and suppliers should be registered with the MRA. Attachments; 60105_Prequalification.pdf; 60105_procurementguide.pdf		
7.01.06	Comments and References			
Supplementary questions (click here for help)				
			Year	Source
7.01.07S	Is there a written public sector procurement policy?. If yes, please write the year of approval in the "year" field	Yes <input type="checkbox"/> No <input type="checkbox"/>		
7.01.08S	Are there legal provisions giving priority in public procurement to goods produced by local manufacturers?	Yes <input type="checkbox"/> No <input type="checkbox"/>		
7.01.09S	The key functions of the procurement unit and those of the tender committee are clearly separated	Yes <input type="checkbox"/> No <input type="checkbox"/>		
7.01.10S	A process exists to ensure the quality of products procured	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Ministry of Health
7.01.10.01S	If yes, the quality assurance process includes pre-qualification of products and suppliers	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		

7.01.10.02S	If yes, explicit criteria and procedures exist for pre-qualification of suppliers	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
7.01.10.03S	If yes, a list of pre-qualified suppliers and products is publicly available	Yes <input type="checkbox"/> No <input type="checkbox"/>		
7.01.11S	List of samples tested during the procurement process and results of quality testing are available	Yes <input type="checkbox"/> No <input type="checkbox"/>		
7.01.12S	Which of the following tender methods are used in public sector procurement:		2010	State Pharmaceuticals Corporation
7.01.12.01S	National competitive tenders	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.01.12.02S	International competitive tenders	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.01.12.03S	Direct purchasing	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.01.13S	Comments and References			

7.02 Public Sector Distribution

Core Questions ([click here for help](#))

			Year	Source
7.02.01	The government supply system department has a Central Medical Store at National Level	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Ministry of Health
7.02.02	Number of public warehouses in the secondary tier of public distribution (State/Regional/Provincial) 	26	2010	Ministry of Health
7.02.03	There are national guidelines on Good Distribution Practices (GDP)	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	Ministry of Health

7.02.04	There is a licensing authority that issues GDP licenses	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	Ministry of Health
7.02.04.01	If a licensing authority exists, does it accredit public distribution facilities? Yes <input type="checkbox"/> No <input type="checkbox"/>			
7.02.05	List of GDP certified warehouses in the public sector exists	Yes <input type="checkbox"/> No <input type="checkbox"/>		
7.02.06	List of GDP certified distributors in the public sector exists	Yes <input type="checkbox"/> No <input type="checkbox"/>		
7.02.07	Comments and References			
Supplementary questions (click here for help)				
			Year	Source
7.02.08S	Which of the following processes is in place at the Central Medical Store:		2010	Ministry of Health
7.02.08.01S	Forecasting of order quantities	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.02.08.02S	Requisition/Stock orders	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.02.08.03S	Preparation of picking/packing slips	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.02.08.04S	Reports of stock on hand	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.02.08.05S	Reports of outstanding order lines	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.02.08.06S	Expiry dates management	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.02.08.07S	Batch tracking	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.02.08.08S	Reports of products out of stock	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.02.09S	Percentage % availability of key medicines at the Central Medical Store			
7.02.10S	Average stock-out duration for a basket of medicines at the Central Medical Store, in days			

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7.02.11S	Routine Procedure exists to track the expiry dates of medicines at the Central Medical Store	Yes <input type="checkbox"/> No <input type="checkbox"/>		
7.02.12S	The Public Central Medical Store is GDP certified by a licensing authority	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	Ministry of Health
7.02.13S	The Public Central Medical Store is ISO certified	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	Ministry of Health
7.02.14S	The second tier public warehouses are GDP certified by a licensing authority	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	Ministry of Health
7.02.15S	The second tier public warehouses are ISO certified	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	Ministry of Health
7.02.16S	Comments and References			

7.03 Private Sector Distribution

Core Questions ([click here for help](#))

			Year	Source
7.03.01	Legal provisions exist for licensing wholesalers in the private sector	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.03.02	Legal provisions exist for licensing distributors in the private sector	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
7.03.03	List of GDP certified wholesalers in the private sector exists	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
7.03.04	List of GDP certified distributors in the private sector exists	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
7.03.05	Comments and References			

Section 8 Selection and rational use

8.00 Respondent Information Section 7

8.00.01	Name of person responsible for filling out this section of the instrument	
8.00.02	Phone number	
8.00.03	Email address	
8.00.04	Other respondents for filling out this section	

8.01 National Structures

Core Questions ([click here for help](#))

			Year	Source
8.01.01	National essential medicines list (EML) exists. If yes, please write year of last update of EML in the "year" field	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2009	WHO (updated)
8.01.01.01	If yes, number of medicines on the EML (no. of INN)	477		
8.01.01.02	If yes, there is a written process for selecting medicines on the EML	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
8.01.01.03	If yes, the EML is publicly available	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
8.01.01.04	If yes, is there any mechanism in place to align the EML with the Standard Treatment Guidelines (STG)	Yes <input type="checkbox"/> No <input type="checkbox"/>		
8.01.02	National Standard Treatment Guidelines (STGs) for most common illnesses are produced/endorsed by the MoH. If yes, please insert year of last update of STGs in the "year" field	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Ministry of Health
8.01.03	STGs specific to Primary care exist. Please use the "year" field to	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Ministry of

	write the year of last update of primary care guidelines			Health
8.01.04	STGs specific to Secondary care (hospitals) exists. Please use the "year" field to write the year of last update of secondary care STGs.	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	Ministry of Health
8.01.05	STGs specific to Paediatric conditions exist. Please use the "year" field to write the year of last update of paediatric condition STGs	Yes <input type="checkbox"/> No <input type="checkbox"/>		
8.01.06	% of public health facilities with copy of EML (mean)- Survey data			
8.01.07	% of public health facilities with copy of STGs (mean)- Survey data			
8.01.08	A public or independently funded national medicines information centre provides information on medicines to prescribers, dispensers and consumers	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Ministry of Health
8.01.09	Public education campaigns on rational medicine use topics have been conducted in the previous two years	Yes <input type="checkbox"/> No <input type="checkbox"/>		
8.01.10	A survey on rational medicine use has been conducted in the previous two years	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	Ministry of Health
8.01.11	A national programme or committee (involving government, civil society, and professional bodies) exists to monitor and promote rational use of medicines	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	Ministry of Health
8.01.12	A written National strategy exists to contain antimicrobial resistance . If yes, please write year of last update of the strategy in the "year"	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	Ministry of Health

	field			
8.01.13	Comments and References	http://www.who.int/selection_medicines/country_lists/lka/en/index.htm		
Supplementary questions (click here for help)				
			Year	Source
8.01.14S	The Essential Medicines List (EML) includes formulations specific for children	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Ministry of Health
8.01.15S	There are explicitly documented criteria for the selection of medicines in the EML	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	Ministry of Health
8.01.16S	There is a formal committee or other equivalent structure for the selection of products on the National EML	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	Ministry of Health
8.01.16.01S	If yes, conflict of interest declarations are required from members of national EML committee	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
8.01.17S	National medicines formulary exists	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	Ministry of Health
8.01.18S	Is there a funded national inter-sectoral task force to coordinate the promotion of appropriate use of antimicrobials and prevention of spread of infection?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	Ministry of Health
8.01.19S	A national reference laboratory/or any other institution has responsibility for coordinating epidemiological surveillance of antimicrobial resistance	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	Ministry of Health
8.01.20S	Comments and References			
8.02 Prescribing				

Core Questions ([click here for help](#))

			Year	Source
8.02.01	Legal provisions exist to govern the licensing and prescribing practices of prescriber	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	Ministry of Health
8.02.02	Legal provisions exist to restrict dispensing by prescribers	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	Ministry of Health
8.02.03	Do prescribers in the private sector dispense medicines?	Yes <input type="checkbox"/> No <input type="checkbox"/>		
8.02.04	Regulations require hospitals to organize/develop Drug and Therapeutics Committees (DTCs)	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	Ministry of Health
8.02.05	Do more than half of referral hospitals have a DTC?	Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>		
8.02.06	Do more than half of general hospitals have a DTC?	Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>		
8.02.07	Do more than half of regions/provinces have a DTC?	Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>		
8.02.08	The core medical training curriculum includes components on:		2010	University of Colombo
8.02.08.01	Concept of EML	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
8.02.08.02	Use of STGs	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
8.02.08.03	Pharmacovigilance	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
8.02.08.04	Problem based pharmacotherapy	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
8.02.09	Mandatory continuing education that includes pharmaceutical issues is required for doctors (see physician)	Yes <input type="checkbox"/> No <input type="checkbox"/>		
8.02.10	Mandatory continuing education that includes pharmaceutical issues is required for nurses	Yes <input type="checkbox"/> No <input type="checkbox"/>		

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8.02.11	Mandatory continuing education that includes pharmaceutical issues is required for paramedical staff	Yes <input type="checkbox"/> No <input type="checkbox"/>		
8.02.12	Prescribing by INN name is obligatory in:			
8.02.12.01	Public sector	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
8.02.12.02	Private sector	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
8.02.13	Average number of medicines prescribed per patient contact in public health facilities (mean)			
8.02.14	% of medicines prescribed in outpatient public health care facilities that are in the national EML (mean)			
8.02.15	% of medicines in outpatient public health care facilities that are prescribed by INN name (mean)			
8.02.16	% of patients in outpatient public health care facilities receiving antibiotics (mean)			
8.02.17	% of patients in outpatient public health care facilities receiving injections (mean)			
8.02.18	% of prescribed drugs dispensed to patients (mean)			
8.02.19	% of medicines adequately labelled in public health facilities (mean)			
8.02.20	Comments and References			
Supplementary questions (click here for help)				
			Year	Source
8.02.21S	A professional association code of conduct exists governing	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		

	professional behaviour of doctors			
8.02.22S	A professional association code of conduct exists governing professional behaviour of nurses	Yes <input type="checkbox"/> No <input type="checkbox"/>		
8.02.23S	Diarrhoea in children treated with Oral Rehydration Solution (ORS) (%)			
8.02.24S	Comments and References			

8.03 Dispensing

Core Questions ([click here for help](#))

		Year	Source
8.03.01	Legal provisions exist to govern dispensing practices of pharmaceutical personnel	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010 Ministry of Health
8.03.02	The basic pharmacist training curriculum includes components on:	2010	Ministry of Health
8.03.02.01	Concept of EML	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
8.03.02.02	Use of STGs	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	
8.03.02.03	Drug Information	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
8.03.02.04	Clinical pharmacology	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
8.03.02.05	Medicines supply management	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
8.03.03	Mandatory continuing education that includes rational use of medicines is required for pharmacists	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010 Pharmaceutical Society of Sri Lanka
8.03.04	Generic substitution at the point of dispensing in public sector facilities is allowed	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010 Ministry of Health

8.03.05	Generic substitution at the point of dispensing in private sector facilities is allowed	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	Ministry of Health
8.03.06	In practice, (even though this may be contrary to regulations) are antibiotics sometimes sold over-the-counter without any prescription?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Unknown <input type="checkbox"/>	2010	Ministry of Health
8.03.07	In practice, (even though this may be contrary to regulations) are injections sometimes sold over-the-counter without any prescription?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Unknown <input type="checkbox"/>	2010	Ministry of Health
8.03.08	Comments and References			
Supplementary questions (click here for help)				
			Year	Source
8.03.09S	A professional association code of conduct exists governing professional behaviour of pharmacists	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Pharmaceutical Society of Sri Lanka
8.03.10S	In practice, (even though this may be contrary to regulations) do the following groups of staff <i>sometimes</i> prescribe prescription-only medicines at the primary care level in the public sector?		2010	Ministry of Health
8.03.10.01S	Nurses 	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Unknown <input type="checkbox"/>		
8.03.10.02S	Pharmacists 	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Unknown <input type="checkbox"/>		
8.03.10.03S	Paramedics 	Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>		
8.03.10.04S	Personnel with less than one month training 	Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>		
8.03.11S	Comments and References			

Section 9 Household data/access

9.00 Respondent Information section 8

9.00.01	Name of person responsible for filling out this section of the instrument	
9.00.02	Phone number	
9.00.03	Email address	
9.00.04	Other respondents for filling out this section	

9.01 Data from Household Surveys

Core Questions ([click here for help](#))

		Year		Source
9.01.01	What household surveys have been undertaken in the past 5 years to assess access to medicines?			
9.01.02	Adults with acute condition in two-week recall period who took all medicines prescribed by an authorized prescriber (%)	92.5	2003	World Health Survey
9.01.03	Adults with acute conditions not taking all medicines because they cannot afford them (%)			
9.01.04	Adults (from poor households) with an acute health condition in two-week recall period who took all medicines prescribed by an authorized prescriber (%)	87.3	2003	World Health Survey
9.01.05	Adults (from poor households) with an acute condition in two-week recall period who did not take all medicines because they cannot afford them (%)	72.4	2003	World Health Survey

9.01.06	Adults with chronic conditions taking all medicines prescribed by an authorized prescriber (%)	90.7	2003	World Health Survey
9.01.07	Adults (from poor households) with chronic conditions not taking all medicines because they cannot afford them (%)	57.8	2003	World Health Survey
9.01.08	Adults (from poor households) with chronic conditions who usually take all medicines prescribed by an authorized prescriber (%)	78.4	2003	World Health Survey
9.01.09	Children (from poor households) with an acute condition in two-week recall period who took all medicines prescribed by an authorized prescriber (%)	93.9	2003	World Health Survey
9.01.10	Percentage of people who obtained the medicines prescribed in the 15 days before the interview (%)		2003	World Health Survey
9.01.11	People who obtained prescribed medicines for free in the 15 days before the interview (%)		2003	World Health Survey
9.01.12	Comments and References			
Supplementary questions (click here for help)				
			Year	Source
9.01.13S	Adults with acute conditions not taking all medicines because the medicines were not available (%)	0.5	2003	World Health Survey
9.01.14S	Adults with chronic conditions not taking all medicines because they cannot afford them (%)	57.9	2003	World Health Survey
9.01.15S	Adults with chronic conditions not taking all medicines because the medicines were not available (%)	0.5	2003	World Health Survey

9.01.16S	Children with acute conditions taking all medicines prescribed by an authorized prescriber (%)	94	2003	World Health Survey
9.01.17S	Children with acute conditions not taking all medicines because they cannot afford them (%)	41	2003	World Health Survey
9.01.18S	Children with acute conditions not taking all medicines because the medicines were not available (%)	13.5	2003	World Health Survey
9.01.19S	Children (from poor households) with acute conditions not taking all medicines because they cannot afford them (%)	58.1	2003	World Health Survey
9.01.20S	Comments and References			

Key Documents to be attached

Document	Exact title	Author	Publisher	Year	File name
National Medicines Policy (NMP)					
NMP implementation plan					
National Medicines Act					
National pharmaceutical human resources report or strategic plan					
Latest report on the national pharmaceutical market (any source)					
National Pharmacovigilance Centre report (including Adverse Drug Reaction, ADR, analysis report in the last two years)					
National pharmaceutical legislation for regulation					
Annual report of quality control laboratories					
Annual report of national regulatory authority					
Legal provisions on medicines price regulations					
Medicines procurement policy					
National Essential Medicines List (EML)					
National Standard Treatment Guidelines (STGs)					
National Strategy for anti-microbial resistance					
Any other medicines					

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pricing/availability surveys, household surveys, and rational use surveys than the ones used to prefill in the instrument.					
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