World Health Organization

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Pharmaceutical Sector Country Profile Questionnaire

Maldives

Section 0 General Info

0.01 Contact Info

0.01.01	Country (precoded)	Maldives-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)	306	2006	World Health Statistics
1.01.02	Population growth rate (Annual %)	1.7	2008	World Bank, Population
1.01.03	Total Gross Domestic Product (GDP) (millions US$)	1790	2008	NHA
1.01.04	GDP growth (Annual %)	2.1	2010	Maldives Mionetary Authority
1.01.05C	GDP per capita (US$ current exchange rate)			
1.01.06	Comments and References			

Supplementary questions (click here for help)

			Year	Source
1.01.07S	Population < 15 years (% of total population)	32	2007	World Health Statistics

1.01.08S	Population > 60 years (% of total population)	6	2007	World Health Statistics
1.01.09S	Urban population (% of total population)	37	2007	World Health Statistics
1.01.10S	Fertility rate, total (Births per woman)	2.6	2007	World Health Statistics
1.01.11S	Population living with less than $1.25/day (international PPP) (%)	0	2005	Vulnerability and pverty assessment, 2004. Department of Planning, Government of Maldives
1.01.12S	Population living below nationally defined poverty line (%)			
1.01.13S	Income share held by lowest 20% of the population (% of national income)			
1.01.14S	Adult literacy rate, 15+ years (% of relevant population)	97.0	2007	World Helth Statistics
1.01.15S	Comments and References	Between 1997 and 2004 the proportion of people living below $1 (ppp) per day declined from 3 to 1 %. According to the National Social Protection Agency, the absolute poverty line is defined by Rf 21. 600 (six hundred) people were registered under the Absolute Poverty Scheme in April 2010.		

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)	72.5	2008	Maldives Health Statistics, 2009
1.02.02	Life expectancy at birth for women (Years)	74.1	2008	Maldives Health Statistics, 2009
1.02.03	Infant mortality rate, between birth and age 1 (/1,000 live births)	11	2008	Maldives Health Statistics, 2009
1.02.04	Under 5 mortality rate (/1,000 live births)	14	2008	Maldives Health Statistics, 2009
1.02.05	Maternal mortality ratio (/100,000 live births)	57	2008	Maldives Health Statistics, 2009
1.02.06	Please provide a list of top 10 diseases causing mortality		2008	Table 25 B Maldives Health Statistics, 2009. MoH and Family, Maldives
1.02.06.01	Disease 1	Diseases of the circulatory system (100-I99)		
1.02.06.02	Disease 2	Diseases of the respiratory systems (J00-J99)		
1.02.06.03	Disease 3	Symptoms, Signs Abnormal findings not elsewhere classified (R00-R99)		
1.02.06.04	Disease 4	Neoplasms (C00-D48)		
1.02.06.05	Disease 5	Certain Infectious and Parasitic Diseases (A00-B99)		
1.02.06.06	Disease 6	Certain conditions originating in Perinatal period (P00-P96)		

1.02.06.07	Disease 7	External causes of the morbidity & Mortality (V01-Y99)		
1.02.06.08	Disease 8	Diseases of the Digestive System (K00-K93)		
1.02.06.09	Disease 9	Diseases of Nervous System (G00-G99)		
1.02.06.10	Disease 10	Diseases of the Genitourinary system (N00-N99)		
1.02.07	Please provide a list of top 10 diseases causing morbidity		2010	7th Epidemiological Report, Disease Surveillance Unit, Centre for Community Health and Disease Control, Ministry of Health and Family, Maldives.
1.02.07.01	Disease 1	ARI		
1.02.07.02	Disease 2	Viral Fever		
1.02.07.03	Disease 3	Diarrhoea		
1.02.07.04	Disease 4	Conjuctivitis		
1.02.07.05	Disease 5	HFMD		
1.02.07.06	Disease 6	Chicken Pox		
1.02.07.07	Disease 7	Chickunggunya		
1.02.07.08	Disease 8	Dengue Fever		
1.02.07.09	Disease 9	Scrub Typhus		
1.02.07.10	Disease 10	Mumps		

1.02.08	Comments and References	Chronic non-communicable diseases (NCDs) have emerged as the main cause of morbidity and mortality in the country. Cardiovascular diseases, cancers, chronic respiratory diseases, accidents and injuries are currently the leading causes of death in the country. WHO estimates that 36% of all years of life lost in Maldives in 2002 were due to NCDs. Other chronic diseases that are of public health concern are thalassaemia (prevalence of 20%) and renal diseases. Source: "Aneh Dhivehiraajje" - The Strategic Action Plan 2009 – 2013, Government of Maldives.

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)	94	2007	World Health Statistics
1.02.10S	Neonatal mortality rate (/1,000 live births)	8.04	2008	Maldives Health Statistics, 2009
1.02.11S	Age-standardized mortality rate by non-communicable diseases (/100,000 population)	953	2004	World Health Statistics
1.02.12S	Age-standardized mortality rate by cardiovascular diseases (/100,000 population)	334	2004	World Health Statistics
1.02.13S	Age-standardized mortality rate by cancer (/100,000 population)	306	2004	World Health Statistics
1.02.14S	Mortality rate for HIV/AIDS (/100,000 population)		2008	
1.02.15S	Mortality rate for tuberculosis (/100,000 population)	2.9	2008	Global TB control: a short update to the 2009 report.

				WHO
1.02.16S	Mortality rate for Malaria (/100,000 population)			
1.02.17S	Comments and References	HIV The first case of HIV in the Maldives was reported in 1991. The latest data show 14 Maldivians have been diagnosed with HIV/AIDS, and of these 10 have died. Malaria Malaria is not a public health problem in Maldives. Since 1984, no indigenous transmission has been reported. The country is maintaining a malaria free status. Imported cases reported each year range from 10 to 30.		

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)	1,804	2008	National Health Accounts
2.01.01.02	Total annual expenditure on health (millions US$ average exchange rate)	141	2008	Calculated from the NHA
2.01.02C	Total health expenditure as % of Gross Domestic Product	11.2		
2.01.03.01C	Total annual expenditure on health per capita (NCU)	5,895		
2.01.03.02C	Total annual expenditure on health per capita (US$ average exchange rate)	462		
2.01.04.01	General government annual expenditure on health (millions NCU)	1,255	2008	National Health Accounts
2.01.04.02	General government annual expenditure on health (millions US$ average exchange rate)	98.5	2008	National Health Accounts
2.01.05	Government annual expenditure on health as percentage of total	12.8	2008	National Health

	government budget (% of total government budget)			Accounts
2.01.06C	Government annual expenditure on health as % of total expenditure on health (% of total expenditure on health)	69.6	2008	National Health Accounts
2.01.07.01C	Annual per capita government expenditure on health (NCU)	4,101		
2.01.07.02C	Annual per capita government expenditure on health (US$ average exchange rate)	322		
2.01.08C	Private health expenditure as % of total health expenditure (% of total expenditure on health)	30.4	2008	National Health Accounts
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)	149.9	2006	National Health Accounts
2.01.11.02	Total pharmaceutical expenditure (millions US$ current exchange rate)	11.7	2006	Calculated from the NHA
2.01.12.01C	Total pharmaceutical expenditure per capita (NCU)	499		
2.01.12.02C	Total pharmaceutical expenditure per capita (US$ current exchange rate)	39		
2.01.13C	Pharmaceutical expenditure as a % of GDP (% of GDP)	1.28		

2.01.14C	Pharmaceutical expenditure as a % of Health Expenditure (% of total health expenditure)	12.33		
2.01.15.01	Total public expenditure on pharmaceuticals (millions NCU)	115.4	2006	National Health Accounts
2.01.15.02	Total public expenditure on pharmaceuticals (millions US$ current exchange rate)	9.01	2006	Calculated from the NHA
2.01.16C	Share of public expenditure on pharmaceuticals as percentage of total expenditure on pharmaceuticals (%)	76.9	2006	Caluclated from NHA
2.01.17.01C	Total public expenditure on pharmaceuticals per capita (NCU)	384		
2.01.17.02C	Total public expenditure on pharmaceuticals per capita (US$ current exchange rate)	30		
2.01.18.01	Total private expenditure on pharmaceuticals (millions NCU)	23.3	2006	National Health Accounts
2.01.18.02	Total private expenditure on pharmaceuticals (millions US$ current exchange rate)	1.82	2006	Calculated from the NHA
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)	3.9	2008	National Health Accounts
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)	71.6	2008	National Health Accounts
2.01.25S	Premiums for private prepaid health plans as % of total private health expenditure (% of private expenditure on health)	4.6	2008	National Health Accounts
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	158	2009	Maldives Food and Drug Authority
2.02.02C	Pharmacists per 10,000 population			
2.02.03	Total number of pharmacists working in the public sector			
2.02.04	Total number of pharmaceutical technicians and assistants	48	2009	Maldives Food and Drug Authority
2.02.05	A strategic plan for pharmaceutical human resource development is in place in your country?	Yes ☐ No ☒	2009	Maldives Food and Drug Authority

2.02.06	Total number of physicians	552	2007	Maldives Health Statistics, 2009
2.02.07C	Physicians per 10,000 pop			
2.02.08	Total number of nursing and midwifery personnel	1,539	2007	Maldives Health Statistics, 2009
2.02.09C	Nurses and midwives per 10,000 pop			
2.02.10	Total number of hospitals	22	2008	Statistical Year Book of Maldives, 2009. Department of Planning, Government of Maldives
2.02.11	Number of hospital beds per 10,000 pop	785	2008	Statistical Year Book of Maldives, 2009. Department of Planning, Government of Maldives
2.02.12	Total number of primary health care units and centers	185	2010	Health Service Division, Ministry of Health and Family

2.02.13	Total number of licensed pharmacies	243	2009	Maldives Food and Drug Authority
2.02.14	Comments and References	2.02.11 Answer is the toal number of hospital beds, not per 10,000 pop Pharmacists and Pharmaceutical Assistants Pharmacists and pharmaceutical assistants are licensed by the Maldives Board of Health Sciences and registered by the Medicine and Therapeutic Goods Division of Maldives Food and Drug Authority. Majority of the pharmacies in Maldives employ expatriate pharmacists. To practise as a pharmacist, expatriates should have a minimum of diploma in pharmacy. The expatriate pharmacists have to clear a written test at Maldives Food and Drug Authority. The pharmaceutical assistants can only dispense under supervision of a pharmacist, a doctor or a community health worker (CHW). Majority of the pharmaceutical assistants are nationals. They should have an Advanced Certificate in Pharmacy from Faculty of Health Sciences. The certificate is accredited by the Maldives Accreditation Board. After accreditation the certificate is registered at Maldives Health Sciences Board. On registration the person is qualified to work as a pharmaceutical assistant. It is the responsibility of the pharmacy offering the job to apply for an identification card to the Medicine and Therapeutics Goods Division, Maldives Food and Drug Authority. In absence of a pharmacist or pharmaceutical assistant, people with a minimum qualification of 'O' level can dispense the medicines prescribed by a doctor or a community health worker. To ensure that wrong medicines are not dispensed, on dispensing they need to		

Supplementary questions (click here for help)

			Year	Source
2.02.15S	Starting annual salary for a newly registered pharmacist in the public sector (NCU)			

2.02.16S	Total number of pharmacists who graduated (first degree) in the past 2 years in your country			
2.02.17S	Are there accreditation requirements for pharmacy schools?	Yes ☒ No☐		
2.02.18S	Is the Pharmacy Curriculum regularly reviewed?	Yes ☐ No ☐		
2.02.19S	Comments and References	2.02.17s Starting annual salary for a newly registered pharmacist in the public sector The salaries and scales are being finalized by the Civil Service Commission. Number of pharmacists who graduated (first degree) in the past 2 years Five nationals have received a two year diploma in Pharmacy from the Faculty of Health Sciences. Pharmacy Curriculum The Faculty of Health Sciences offers a two year diploma in Pharmacy and an Advanced Certificate in Pharmacy called “Certificate III in Pharmacy”. Accreditation is provided by the Maldives Accreditation Board		

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 ☒ No ☐	2009	Ministry of Health and Familiy. Aneh Dhivehiraajje" - The Strategic Action Plan 2009 – 2013, Government of Maldives.
3.01.02	National Health Policy Implementation plan exists. If yes, please write the year of the most recent document in the "year"	Yes ☐ No ☐		
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	Yes ☒ No ☐		Maldives Food and Drug Authority

	document in the "year" field.			
3.01.05	Group of policies addressing pharmaceuticals exist.	Yes ☐ No ☐		
3.01.06	National Medicines Policy covers the following components:	—		
3.01.06.01	Selection of Essential Medicines	☒Yes		
3.01.06.02	Medicines Financing	☐Yes		
3.01.06.03	Medicines Pricing	☒Yes		
3.01.06.04	Medicines Procurement	☒Yes		
3.01.06.05	Medicines Distribution	☒Yes		
3.01.06.06	Medicines Regulation	☒Yes		
3.01.06.07	Pharmacovigilance	☒Yes		
3.01.06.08	Rational Use of Medicines	☒Yes		
3.01.06.09	Human Resource Development	☐Yes		
3.01.06.10	Research	☒Yes		
3.01.06.11	Monitoring and Evaluation	☒Yes		
3.01.06.12	Traditional Medicine	☒Yes		
3.01.07	National medicines policy implementation plan exists. If yes, please write year of the most recent document.	Yes ☐ No ☒	2010	Maldives Food and Drug Authority
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 ☐ No ☐		

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 ☐ No ☐		
3.01.10	Access to essential medicines/technologies as part of the fulfillment of the right to health, recognized in the constitution or national legislation?	Yes ☐ No ☒		See comments
3.01.11	There are official written guidelines on medicines donations.	Yes ☐ No ☒	2010	Maldives Food and Drug Authority
3.01.12	Is pharmaceutical policy implementation being regularly monitored/assessed?	Yes ☒ No ☐		See comments
3.01.12.01	Who is responsible for pharmaceutical policy monitoring?	Medicine and Therapuetic Goods Division of the Maldives Food and Drug Authority		
3.01.13	Is there a national good governance policy?	Yes ☒ No ☐		
3.01.13.01	Multisectoral	☒Yes	2010	Ministry of Health and Family
3.01.13.02	For the pharmaceutical sector	☐Yes		
3.01.13.03	Which agencies are responsible?	Anti-Corruption COmmision, 2010 (MoH and Fam)		
3.01.14	A policy is in place to manage and sanction conflict of interest issues in pharmaceutical affairs.	Yes ☐ No ☐		
3.01.15	There is a formal code of conduct for public officials.	Yes ☒ No ☐	2010	Civil Service Commission
3.01.16	Is there a whistle-blowing mechanism allowing individuals to raise a	Yes ☐ No ☒	2010	Maldives Food and

	concern about wrongdoing occurring in the pharmaceutical sector of your country (ombudsperson)?	Drug Authority
3.01.16.01	Please describe:	
3.01.17	Comments and References	3.01.10 and 3.01.12 Regular Monitoring of pharmaceutical policy implementation Examples:Post market surveillance is done twice a week in Male,' the capital, where majority of the pharmacies are concentrated. Two pharmacies are covered per day, i.e. 4 pharmacies per week. It involves looking at packaging, labelling and the maintenance of the cold chain. Regulation at Port of Entry: It is mandatory to submit the invoice of each shipment 24 hrs before customs clearance. The invoice is checked against the approved drug list. Drugs on invoice not found on the list are put on 'hold' for discarding or re-exporting. The list is also compared with packaging list to exclude import of unapproved brands. Disposal of Expired Drugs: MFDA sends out a circular once in three months to importers, pharmacies, customs, hospitals for disposal of expired drugs. Each concerned party sends the expired drugs with a drug disposal form to a pre-assigned place. The disposal of drugs is conducted by MFDA. Traditional Medicine. 'Dhivehi Beys' is the system of traditional medicine followed in the Maldives. The registration of imported traditional medicines became mandatory in mid-2007. The list of approved medicines is available on health ministry website. Access to essential medicines/technologies as part of the fulfillment of the right to health. The Government of the Maldives recognizes the importance of health. The 7th National Development Plan identified health as a basic human right for all Maldivian

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 ☒ No☐	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 ☐ No☒		
4.01.02.02	Laboratory supplies	Yes ☐ No ☐		
4.01.02.03	Medical supplies	Yes ☐ No ☐		
4.01.02.04	Medical equipment	Yes ☐ No ☐		
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 ☐ No ☐		
4.01.05	Current laws contain (TRIPS)	Yes ☐ No☐		

	flexibilities and safeguards			
4.01.06	Country is eligible for the transitional period to 2016	Yes ☐ No☐		
4.01.07	Which of the following (TRIPS) flexibilities and safeguards are present in the national law?			
4.01.07.01	Compulsory licensing provisions that can be applied for reasons of public health	Yes ☐ No ☐		
4.01.07.02	Bolar exception	Yes ☐ No ☐		
4.01.08	Are parallel importing provisions present in the national law?	Yes ☐ No ☐		
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 ☐ No ☒	2010	Ministry of Health and Family
4.01.10	Are there legal provisions for data exclusivity for pharmaceuticals	Yes ☐ No ☒		Ministry of Health and Family
4.01.11	Legal provisions exist for patent extension	Yes ☐ No ☐		
4.01.12	Legal provisions exist for linkage between patent status and Marketing Authorization	Yes ☐ No ☐		
4.01.13	Comments and References	Maldives does not have a patent law. It is in the process of drafting a patent law. The Ministry of Health and Family is actively engaged with the other concerned Ministries to ensure that public health safeguards are incorporated.		

4.02 Manufacturing

Core questions (click here for help)

	Year	Source

4.02.01	Number of licensed pharmaceutical manufacturers in the country	1	2010	MFDA. Manufacturer for Divehi Beys Trad. Medicines
4.02.02	Country has manufacturing capacity		2007	WHO Level I
4.02.02.01	R&D to discover new active substances	Yes ☐ No ☒ Unknown ☐		
4.02.02.02	Production of pharmaceutical starting materials (APIs)	Yes ☐ No ☒ Unknown ☐		
4.02.02.03	Production of formulations from pharmaceutical starting material	Yes ☐ No ☒ Unknown ☐		
4.02.02.04	Repackaging of finished dosage forms	Yes ☐ No ☒ Unknown ☐		
4.02.03	Percentage of market share by value produced by domestic manufacturers (%)			
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 (%)	0	2010	Maldives Food and Drug Authority
4.02.06S	Number of multinational pharmaceutical companies manufacturing medicines locally	0	2010	Maldives Food and Drug Authority
4.02.07S	Number of manufacturers that are Good Manufacturing Practice (GMP) certified	0	2010	Maldives Food and Drug Authority

4.02.08S	Comments and References	Maldives imports all its requirements for pharmaceutical products (allopathic).

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 ☒ No ☐	2010	Maldives Food and Drug Authority
5.01.02	There is a Medicines Regulatory Authority	Yes ☐ No ☐		
5.01.03	If yes, please provide name and address of the Medicines regulatory authority			
5.01.04	The Medicines Regulatory Authority is:		2010	Maldives Food and Drug Authority
5.01.04.01	Part of MoH	☒ Yes		
5.01.04.02	Semi autonomous agency	☐ Yes		
5.01.04.03	Other (please specify)			
5.01.05	What are the functions of the National Medicines Regulatory			

	Authority?			
5.01.05.01	Marketing authorization / registration	Yes ☐ No ☐		
5.01.05.02	Inspection	Yes ☐ No ☐		
5.01.05.03	Import control	Yes ☐ No ☐		
5.01.05.04	Licensing	Yes ☐ No ☐		
5.01.05.05	Market control	Yes ☐ No ☐		
5.01.05.06	Quality control	Yes ☐ No ☐		
5.01.05.07	Medicines advertising and promotion	Yes ☐ No ☐		
5.01.05.08	Clinical trials control	Yes ☐ No ☐		
5.01.05.09	Pharmacovigilance	Yes ☐ No ☐		
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 ☐ No ☒	2010	Maldives Food and Drug Authority
5.01.07.01	- If yes, please provide MRA Web site address (URL)	http://www.health.gov.mv/. Look under Standards for information on: Approved Drug List; Control drug guideline; Control drug list; Criteria for grading of health facilities; Herbal Drug List; Raajjeygai faruvaadhey clinic hingumuge gavaidhu. Look under Forms for forms for registration of medicines.		
5.01.08	The MRA receives external technical assistance	Yes ☐ No ☐		
5.01.08.01	If yes, please describe:			
5.01.09	The MRA is involved in harmonization/ collaboration initiatives	Yes ☐ No ☒	2010	Maldives Food and Drug

				Authority
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 ☒ No ☐		See comments
5.01.11	Medicines Regulatory Authority gets funds from regular budget of the government.	Yes ☒ No ☐	2010	Maldives Food and Drug Authority
5.01.12	Medicines Regulatory Authority is funded from fees for services provided.	Yes ☐ No ☒	2010	Maldives Food and Drug Authority
5.01.13	Medicines Regulatory Authority receives funds/support from other sources	Yes ☒ No ☐	2010	Maldives Food and Drug Authority
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 ☐ No ☒	2010	Maldives Food and Drug Authority
5.01.15	The Regulatory Authority is using a computerized information management system to store and retrieve information on registration, inspections, etc.	Yes ☒ No ☐	2010	Maldives Food and Drug Authority
5.01.16	Comments and References	5.01.10 Assessment of the medicines regulatory system Draft Medicines Act: Currently, the medicines are regulated under Medicine Act of 1978. It contains three short paragraphs. An exhaustive Medicines Act has been drafted. It is awaiting parliamentary approval.		

		It is expected to cover the following aspects of pharmaceutical regulation: Registration of warehouses and pharmacies; Registration of homeopathy, allopathic and herbal medicines; permission for selling; pharmacists; importing of medicine; sale of medicines; controlled drugs, prescribing of medicines; disposal of drugs; penalties; registration fee; product registration; pharmacist identification card.		
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 ☒ No ☐	2007	WHO Level I
5.02.02	Are there any mechanism for exception/waiver of registration?	Yes ☐ No ☐		
5.02.03	Are there mechanisms for recognition of registration done by other countries	Yes ☐ No ☐		
5.02.03.01	If yes, please explain:			
5.02.04	Explicit and publicly available criteria exist for assessing applications for Marketing Authorization of pharmaceutical products	Yes ☒ No ☐	2010	MFDA (see comments)
5.02.05	Information from the prequalification programme managed by WHO is used for product registration	Yes ☐ No ☐		
5.02.06	Number of pharmaceutical products registered in your country	852	2010	Maldives Food and Drug Authority

5.02.07	Legal provisions require the MRA to make the list of registered pharmaceuticals with defined periodicity publicly available	Yes ☐ No ☐		
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 ☒ No ☐	2010	Maldives Food and Drug Authority
5.02.09	Legal provisions require the payment of a fee for Medicines Marketing Authorization (registration) applications	Yes ☒ No ☐	2010	Maldives Food and Drug Authority
5.02.10	Comments and References	5.02.04 The product information file needs to be submitted with: Certificate of pharmaceutical Product(CPP); Good manufacturing practice (GMP); Stability test reports; Raw material details; criteria exist for assessing applications for marketing authorization of pharmaceutical products; Registration certificate in one of the authorities in attached list (other than the manufacturing certificates). A submission fees of Rf 200/- has to be paid. 5.02.06 852 drugs registered and 2,785 authorized. Prior to 2000, all drugs approved to be marketed in the country were listed in authorized drugs list which currently contains 2,785 drugs. However since early 2000 registration process involves submission of the dossier through the importer. The dossier is evaluated by the Medicine and Therapeutic Goods Division of Maldives Food and Drug Authority. The Product Evaluation Report is sent to the Pharmaceutical Board, which takes the final decision. If approved, the drug makes it to an “Approved Drug List”. Registration fee of Rf 300 is payable on approval. The approved drug list is updated on a monthly basis.		

Supplementary questions (click here for help)

			Year	Source
5.02.11S	Legal provisions require Marketing Authorization holders to provide	Yes ☒ No ☐	2010	Maldives Food and

	information about variations to the existing Marketing Authorization			Drug Authority
5.02.12S	Legal provisions require publication of a Summary of Product Characteristics (SPCs) of the medicines registered	Yes ☐ No ☒	2010	Maldives Food and Drug Authority
5.02.13S	Legal provisions require the establishment of an expert committee involved in the marketing authorization process	Yes ☒ No ☐	2007	WHO Level I
5.02.14S	Certificate for Pharmaceutical Products in accordance with the WHO Certification scheme is required as part of the Marketing Authorization application	Yes ☒ No ☐	2010	Maldives Food and Drug Authority
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 ☐ No ☒	2010	Maldives Food and Drug Authority
5.02.16S	Legal provisions allow applicants to appeal against MRAs decisions	Yes ☐ No ☒	2010	Maldives Food and Drug Authority39
5.02.17S	Registration fee - the amount per application for pharmaceutical product containing New Chemical Entity (NCE) (US$)	39	2010	Maldives Food and Drug Authority
5.02.18S	Registration fee - the Amount per application for a generic pharmaceutical product (US$)			
5.02.19S	Time limit for the assessment of a Marketing Authorization application (months)			
5.02.20S	Comments & References	Variations to the existing marketing authorization. The marketing authorization holder has to notify MFDA in writing. Only then the information about the drug is amended. If there is a change in		

		ingredient then a new dossier has to be submitted. Expert committee involved in the marketing authorization process. Pharmaceutical Board: Gynaecologist, Paediatrician, Physician, Representation from Center for Community Health & Disease Control (CCHDC), Customs, Trade Ministry, Maldives Food and Drug Authority and Maldives National Defence Force.

5.03 Regulatory Inspection

Core Questions(click here for help)

			Year	Source
5.03.01	Legal provisions exist allowing for appointment of government pharmaceutical inspectors	Yes ☒ No ☐	2010	Maldives Food and Drug Authority
5.03.02	Legal provisions exist permitting inspectors to inspect premises where pharmaceutical activities are performed	Yes ☒ No ☐	2010	Maldives Food and Drug Authority
5.03.02.01	If yes, legal provisions exist requiring inspections to be performed	Yes ☒ No ☐		
5.03.03	Inspection is a pre-requisite for licensing of:		2010	Maldives Food and Drug Authority
5.03.03.01	Public facilities	Yes ☒ No ☐		
5.03.03.02	Private facilities	Yes ☒ No ☐		
5.03.04	Inspection requirements are the same for public and private facilities	Yes ☒ No ☐	2010	Maldives Food and Drug Authority
5.03.05.01	Local manufactures are inspected for GMP compliance	Yes ☐ No ☐		
5.03.05.02	Private wholesalers are inspected	Yes ☐ No ☐		

5.03.05.03	Retail distributors are inspected	Yes ☐ No ☐
5.03.05.04	Public pharmacies and stores are inspected	Yes ☐ No ☐
5.03.05.05	Pharmacies and dispensing points of health facilities are inspected	Yes ☐ No ☐
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 ☒ No ☐		Maldives Food and Drug Authority
5.04.02	Legal provisions exist allowing the sampling of imported products for testing	Yes ☒ No ☐	2010	Maldives Food and Drug Authority
5.04.03	Legal provisions exist requiring importation of medicines through authorized ports of entry	Yes ☒ No ☐	2010	Maldives Food and Drug Authority
5.04.04	Legal provisions exist allowing inspection of imported pharmaceutical products at the authorized ports of entry	Yes ☒ No ☐	2010	Maldives Food and Drug Authority
5.04.05	Comments and References			

5.05 Licensing

		Year	Source

5.05.01	Legal provisions exist requiring manufacturers to be licensed	Yes ☒ No ☐	2010	Maldives Food and Drug Authority
5.05.02	Legal provisions exist requiring both domestic and international manufacturers to comply with Good manufacturing Practices (GMP)	Yes ☒ No ☐	2010	Maldives Food and Drug Authority
5.05.02.01	If no, please explain			
5.05.03	GMP requirements are published by the government.	Yes ☐ No ☒	2010	Maldives Food and Drug Authority
5.05.04	Legal provisions exist requiring importers to be licensed	Yes ☒ No ☐	2007	WHO Level I
5.05.05	Legal provisions exist requiring wholesalers and distributors to be licensed	Yes ☒ No ☐	2007	WHO Level I
5.05.06	Legal provisions exist requiring wholesalers and distributors to comply with Good Distributing Practices **When filling in this part, please also fill in the relevant questions in the procurement and distribution section (Section 7)**	Yes ☐ No ☒	2010	Maldives Food and Drug Authority
5.05.07	National Good Distribution Practice requirements are published by the government	Yes ☐ No ☒	2010	Maldives Food and Drug Authority
5.05.08	Legal provisions exist requiring pharmacists to be registered	Yes ☒ No ☐	2010	Maldives Food and Drug Authority
5.05.09	Legal provisions exists requiring	Yes ☒ No ☐	2010	Maldives Food and

	private pharmacies to be licensed			Drug Authority
5.05.10	Legal provision exist requiring public pharmacies to be licensed	Yes ☒ No ☐	2010	Maldives Food and Drug Authority
5.05.11	National Good Pharmacy Practice Guidelines are published by the government	Yes ☐ No ☒	2010	Maldives Food and Drug Authority
5.05.12	Legal provisions require the publication of a list of all licensed pharmaceutical facilities	Yes ☒ No ☐	2010	Maldives Food and Drug Authority
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 ☐ No ☐		
5.06.02	Does a laboratory exist in the country for Quality Control testing?	Yes ☒ No ☐	2010	Maldives Food and Drug Authority
5.06.02.01	If yes, is the laboratory part of the MRA?	Yes ☐ No ☐		
5.06.02.02	Does the regulatory authority contract services elsewhere?	Yes ☐ No ☐		
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 ☐ No ☐		
5.06.04.02	For quality monitoring in private sector (routine sampling in retail outlets)	Yes ☐ No ☐		
5.06.04.03	When there are complaints or problem reports	Yes ☐ No ☐		
5.06.04.04	For product registration	Yes ☐ No ☐		
5.06.04.05	For public procurement prequalification	Yes ☐ No ☐		
5.06.04.06	For public program products prior to acceptance and/or distribution	Yes ☐ No ☐		
5.06.05	Samples are collected by government inspectors for undertaking post-marketing surveillance testing	Yes ☒ No ☐	2007	WHO Level I
5.06.06	How many Quality Control samples were taken for testing in the last two years?			
5.06.07	Total number of samples tested in the last two years that failed to meet quality standards			
5.06.08	Results of quality testing in past two years are publicly available	Yes ☐ No ☒	2010	Maldives Food and Drug Authority
5.06.09	Comments and References	Laboratory for Quality Control Testing: National Health Laboratory		

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 ☒ No ☐	2010	WHO Level I
5.07.02	Who is responsible for regulating, promotion and/or advertising of medicines? Please describe:	Approved over-the-counter medicines, food supplements, vitamins etc can be advertised with permission from the Maldives Food and Drug Authority. The applicant needs to submit samples of the products, the advertisement with specification of the medium.		
5.07.03	Legal provisions prohibit direct advertising of prescription medicines to the public	Yes ☒ No ☐	2007	WHO Level I
5.07.04	Legal provisions require a pre-approval for medicines advertisements and promotional materials	Yes ☒ No ☐	2007	WHO Level I
5.07.05	Guidelines/Regulations exist for advertising and promotion of non-prescription medicines	Yes ☒ No ☐	2007	WHO Level I
5.07.06	A national code of conduct exists concerning advertising and promotion of medicines by marketing authorization holders and is publicly available	Yes ☒ No ☐	2010	Maldives Food and Drug Authority
5.07.06.01	If yes, the code of conduct applies to domestic manufacturers only, multinational manufacturers only, or both			
	Domestic only	☐Yes		
	Multinational only	☐Yes		
	Both	☐Yes		

5.07.06.02	If yes, adherence to the code is voluntary	Yes ☐ No ☒		
5.07.06.03	If yes, the code contains a formal process for complaints and sanctions	Yes ☐ No ☒		
5.07.06.04	If yes, list of complaints and sanctions for the last two years is publicly available	Yes ☐ No ☒		
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 ☐ No ☐		
5.08.02	Legal provisions exist requiring the agreement by an ethics committee/ institutional review board of the Clinical Trials to be performed	Yes ☐ No ☐		
5.08.03	Legal provisions exist requiring registration of the clinical trials into international/national/regional registry	Yes ☐ No ☐		
5.08.04	Comments and References	NOT applicable. Clinical trials are not allowed in Maldives.		

Supplementary questions (click here for help)

			Year	Source
5.08.05S	Legal provisions exist for GMP compliance of investigational products	Yes ☐ No ☐		
5.08.06S	Legal provisions require sponsor, investigator to comply with Good Clinical Practices (GCP)	Yes ☐ No ☐		

5.08.07S	National GCP regulations are published by the Government.	Yes ☐ No ☐		
5.08.08S	Legal provisions permit inspection of facilities where clinical trials are performed	Yes ☐ No ☐		
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 ☒ No ☐	2009	International Narcotics Control Board
5.09.01.02	The 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961	Yes ☒ No ☐	2009	International Narcotics Control Board
5.09.01.03	Convention on Psychotropic Substances 1971	Yes ☒ No ☐	2009	International Narcotics Control Board
5.09.01.04	United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988	Yes ☒ No ☐	2009	International Narcotics Control Board
5.09.02	Laws for the control of narcotic and psychotropic substances, and precursors exist	Yes ☒ No ☐	2009	International Narcotics Control Board
5.09.03	Annual consumption of Morphine (mg/capita)	295.980000	2009	Maldies Food and Drug

				Authority
5.09.04	Comments and References	5.09.03 This is the annual consumption in grams, not in mg/captia		
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 ☐ No ☐ Unknown ☐		
5.09.05.01S	If yes, year of review			
5.09.06S	Annual consumption of Fentanyl (mg/capita)	0.5218	2009	Maldives Food and Drug Authority
5.09.07S	Annual consumption of Pethidine (mg/capita)	1038,9	2009	Maldives Food and Drug Authority
5.09.08S	Annual consumption of Oxycodone (mg/capita)	0	2010	Maldives Food and Drug Authority
5.09.09S	Annual consumption of Hydrocodone (mg/capita)	0	2010	Maldives Food and Drug Authority
5.09.10S	Annual consumption of Phenobarbital (mg/capita)	7,845.6	2009	Maldives Food and Drug Authority
5.09.11S	Annual consumption of Methadone (mg/capita)	2,000	2009	Maldives Food and Drug

				Authority
5.09.12S	Comments and References	5.09.6s - 5.09.11s values in grams not in mg/capita 5.09.08s, 5.09.09s: both are not imported Data on consumption of controlled medicines was provided ny the Maldives Food and Drug Authority in grams, the annual consumption per capita has been calculated starting from the provided figures. These were: morphine 295.98 grams, fentanyl 0.5218 grams, Pethidine 1038.9 grams, Phenobarbital 7845.6 grams, methadone 2,000 grams. The consumption of other controlled drugs in 2009 was: Pentazocine (160.1gms); Alprazolam (30.15 gms); Chlordiazepoxide (132.50 gms); Clobazam (131.20 gms); Clonazepam (47.70 gms); and Diazepam (620.70 gms).		

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 ☐ No ☐		
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 ☐ No ☐		
5.10.03	Legal provisions about monitoring Adverse Drug Reactions (ADR) exist in your country	Yes ☐ No ☐		
5.10.04	A national pharmacovigilance centre linked to the MRA exists in your country	Yes ☐ No ☐		
5.10.04.01	If a national pharmacovigilance centre exists in your country, how many staff does it employ full-time			

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 ☐ No ☐		
5.10.04.03	If a national pharmacovigilance center exists in your country, it publishes an ADR bulletin	Yes ☐ No ☐		
5.10.05	An official standardized form for reporting ADRs is used in your country	Yes ☐ No ☐		
5.10.06	A national Adverse Drug Reactions database exists in your country	Yes ☐ No ☐		
5.10.07	How many ADR reports are in the database?			
5.10.08	How many reports have been submitted in the last two years?			
5.10.09	Are ADR reports sent to the WHO database in Uppsala?	Yes ☐ No ☐		
5.10.09.01	If yes, number of reports sent in the last two years			
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 ☐ No ☐		
5.10.11	Is there a clear communication strategy for routine communication and crises communication?	Yes ☐ No ☐		
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,	Yes ☐ No ☐		

	AIDS)?			
5.10.13	Please describe how you intend to enhance the Pharmacovigilance system			
5.10.14	Comments and References	The Maldives Food and Drug Authority is in the process of establishing a pharmacovigilance unit. Two focal points have been nominated. A form to report ADR has been developed using the British National Formulary format. This was distributed to all health facilities including private. There were 4 respondents. Further strengthening of this initiative has been planned by sensitising the doctors about the importance of pharmacovigilance and also orienting them on how they can report. The Maldives Food and Drug Authority follows WHO alerts and USFDA alerts on a weekly basis. For example, following WHO Alert No 123 import, sale and use of all Dextropropoxyphene containing medicines was banned in October 2009. Stocks were physically removed from the pharmacies. In the islands assistance was taken of health centers to remove and destroy the drugs from the pharmacies.		
Supplementary questions (click here for help)				
			Year	Source
5.10.15S	Feedback is provided to reporters	Yes ☐ No ☐		
5.10.16S	The ADR database is computerized	Yes ☐ No ☐		
5.10.17S	Medication errors (MEs) are reported	Yes ☐ No ☐		
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 ☐ No ☐		
5.10.20S	In the past two years, who has reported ADRs?			

5.10.20.01S	Doctors	☐Yes		
5.10.20.02S	Nurses	☐Yes		
5.10.20.03S	Pharmacists	☐Yes		
5.10.20.04S	Consumers	☐Yes		
5.10.20.05S	Pharmaceutical Companies	☐Yes		
5.10.20.06S	Others, please specify whom			
5.10.21S	Was there any regulatory decision based on local pharmacovigilance data in the last 2 years?	Yes ☐ No☐		
5.10.22S	Are there training courses in pharmacovigilance?	Yes ☐ No☐		
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	The National Social Protection Agency
6.01.01.01	Patients who cannot afford them	Yes ☒ No☐		
6.01.01.02	Children under 5	Yes ☐ No☒		
6.01.01.03	Pregnant women	Yes ☐ No☒		
6.01.01.04	Elderly persons	Yes ☒ No☐		
6.01.01.05	Please describe/explain your yes answers for questions above	The National Social Protection Agency		
6.01.02	Is there a public health system or social health insurance scheme or public programme providing medicines free of charge for :		2010	Centre for Community Health & Disease Control (CCHDC)
6.01.02.01	All medicines included in the EML	Yes ☐ No ☒		
6.01.02.02	Any non-communicable diseases	Yes ☒ No ☐		
6.01.02.03	Malaria medicines	Yes ☒ No ☐		

6.01.02.04	Tuberculosis medicines	Yes ☒ No ☐		
6.01.02.05	Sexually transmitted diseases medicines	Yes ☐ No ☒		
6.01.02.06	HIV/AIDS medicines	Yes ☒ No ☐		
6.01.02.07	Expanded Program on Immunization (EPI) vaccines	Yes ☒ No ☐		
6.01.02.08	If others, please specify	Mental Health and Epilepsy		
6.01.02.09	Please describe/explain your yes answers for questions above	Mental Health: Registered patients are provided psychiatric medications free. Medicines are procured through State Trading Corporation. Tuberculosis Drugs: The Government procures through Global Drug Facility. Extended Programme of Immunization: Vaccines are provided free for children under 5. These are procured through Unicef or Unicef approved suppliers. For vaccines like MMR local tenders are invited. HIV/AIDS: ARVs are procured through Global Fund. Three nationals are on ARV treatment. Malaria: Stocks for prophylaxis are procured through the state trading corporation.		
6.01.03	Does a national health insurance, social insurance or other sickness fund provide at least partial medicines coverage?	Yes ☒ No ☐	2010	The National Social Protection Agency
6.01.03.01	Does it provide coverage for medicines that are on the EML for inpatients	Yes ☒ No ☐		
6.01.03.02	Does it provide coverage for medicines that are on the EML for outpatients	Yes ☒ No ☐		
6.01.03.03	Please describe the medicines benefit of public/social insurance schemes	In order to ensure Universal Health Coverage, the Government has scaled up Social Health Insurance Scheme (Madhana). Under the scheme an annual premium of RF 2000/- provides an yearly		

		coverage of Rf 100,000. A co-payment of Rf 40 for each outpatient prescription that exceeds Rf 40 and 15% service fee for the services obtained from private providers. There is no co-payment for inpatients. There is an annual limit of Rf 30,000 for reimbursement of medicines. Only the medicines listed in the approved drug list are eligible for reimbursement.		
6.01.04	Do private health insurance schemes provide any medicines coverage?	Yes ☒ No ☐	2010	Allied Insurance
6.01.04.01	If yes, is it required to provide coverage for medicines that are on the EML?	Yes ☐ No ☐		
6.01.05	Comments and References	According to Allied Insurance an annual premium of Rf 2800 provides a coverage of 150,000. Costs incurred on medicines are reimbursed on production of bills. There is no list of reimbursable medicines.		

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-payment/fee requirements for consultations	Yes ☒ No ☐	2007	WHOLevel I
6.02.02	In your health system, at the point of delivery, are there any co-payment/fee requirements for medicines	Yes ☒ No ☐	2010	National Social Protection Agency
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 ☐ No ☒	2007	WHO Level I
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 ☒ No ☐	2010	Maldives Food and Drug Authority
6.03.01.01	If yes, are the provisions aimed at Manufacturers	Yes ☒ No ☐		
6.03.01.02	If yes, are the provisions aimed at Wholesalers	Yes ☒ No ☐		
6.03.01.03	If yes, are the provisions aimed at Retailers	Yes ☒ No ☐		
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.)	'Cost Plus' pricing devised by the Ministry of Economic Development is followed: Imported Medicines: 50% on c.i.f. (price quoted in the invoice to the customs). Importer Margin: 30% maximum (Importer to Wholesaler) Wholesaler to Retail: 15% maximum		
6.03.02	Government runs an active national medicines price monitoring system for retail prices	Yes ☐ No ☐		
6.03.03	Regulations exists mandating that retail medicine price information should be publicly accessible	Yes ☐ No ☒	2010	Maldives Food and Drug Authority
6.03.03.01	-if yes, please explain how the information is made publically available			

6.03.04	Comments and References	During inspections MFDA randomly checks prices with respect to allowed margins and prices quoted in the invoice.

6.04 Prices, Availability and Affordability

Core Questions (click here for help)

			Year	Source
6.04.01-04	Please state if a medicines price survey using the WHO/HAI methodology has been conducted in the past 5 years in your country. **If yes**, please indicate the year of the survey and use the results to fill in this table ***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	Yes ☐ No ☐ Unknown ☐		

	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**	**Orig**	6.04.03.01	6.04.03.03	6.04.03.05		

		Ratio	**LPG**	6.04.03.02	6.04.03.04	6.04.03.06	
	Affordability Days' wages of the lowest paid govt worker for standard treatment with co-trimoxazole for a child respiratory infection	**Number of days' wages**	**Orig**		6.04.04.01	6.04.04.03	
			LPG		6.04.04.02	6.04.04.04	
6.04.05	Comments and References			Whole section 6.04 is not applicable			

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 ☐ No ☐ Unknown ☐		
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 (Median % contribution)			
6.05.04	Comment and References	Whole section 6.05 is not applicable		
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 ☒ No ☐	2010	Maldives Food and Drug Authority
6.06.02	There are duties on imported finished	Yes ☒ No ☐	2010	Maldives Food and

	products			Drug Authority
6.06.03	VAT (value-added tax) or any other tax is levied on finished pharmaceuticals products	Yes ☐ No ☒	2010	Maldives Food and Drug Authority
6.06.04	There are provisions for tax exceptions or waivers for pharmaceuticals and health products	Yes ☐ No ☐		
6.06.05	Please specify categories of pharmaceuticals on which the taxes are applied and describe the exemptions and waivers that exist			
6.06.06	Comments and References	A 25% duty applied on medicines classified as cosmetics. In March 2010, MFDA collaborated with customs in identification and reclassification of medicines classified as cosmetics.		

Supplementary questions (click here for help)

			Year	Source
6.06.07S	Duty on imported active pharmaceutical ingredients, APIs (%)	5	2010	Maldives Food and Drug Authority
6.06.08S	Duty on imported finished products (%)	5	2010	Maldives Food and Drug Authority
6.06.09S	VAT on pharmaceutical products (%)			
6.06.10S	Comments and References	6.05.10s Not applicable		

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	Centre for Community Health & Disease Control (CCHDC)
7.01.01.01	Decentralized 	☒Yes		
7.01.01.02	Centralized and decentralized 	☐Yes		
7.01.01.03	Please describe	Medicines are procured under programmes according to the relevant arrangements.		
7.01.02	If public sector procurement is wholly or partially centralized, it is under the responsibility of a procurement agency which is: 			

7.01.02.01	Part of MoH	Yes ☐ No ☐		
7.01.02.02	Semi-Autonomous	Yes ☐ No ☐		
7.01.02.03	Autonomous	Yes ☐ No ☐		
7.01.02.04	A government procurement agency which procures all public goods	Yes ☐ No ☐		
7.01.03	Public sector requests for tender documents are publicly available	Yes ☒ No ☐	2010	Maldives Food and Drug Authority
7.01.04	Public sector tender awards are publicly available	Yes ☐ No ☒	2010	Maldives Food and Drug Authority
7.01.05	Procurement is based on prequalification of suppliers	Yes ☐ No ☒	2010	maldives Food and Drug Authority
7.01.05.01	If yes, please describe how it works			
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 ☐ No ☐		
7.01.08S	Are there legal provisions giving priority in public procurement to goods produced by local manufacturers?	Yes ☐ No ☐		
7.01.09S	The key functions of the procurement unit and those of the tender committee are clearly separated	Yes ☐ No ☐		

7.01.10S	A process exists to ensure the quality of products procured	Yes ☐ No ☐		
7.01.10.01S	If yes, the quality assurance process includes pre-qualification of products and suppliers	Yes ☐ No ☐		
7.01.10.02S	If yes, explicit criteria and procedures exist for pre-qualification of suppliers	Yes ☐ No ☐		
7.01.10.03S	If yes, a list of pre-qualified suppliers and products is publicly available	Yes ☐ No ☐		
7.01.11S	List of samples tested during the procurement process and results of quality testing are available	Yes ☐ No ☐		
7.01.12S	Which of the following tender methods are used in public sector procurement:		2007	WHO Level I
7.01.12.01S	National competitive tenders	Yes ☐ No ☒		
7.01.12.02S	International competitive tenders	Yes ☐ No ☒		
7.01.12.03S	Direct purchasing	Yes ☒ No ☐		
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 ☐ No ☒	2010	Maldives Food and Drug Authority
7.02.02	Number of public warehouses in the secondary tier of public distribution			

	(State/Regional/Provincial)			
7.02.03	There are national guidelines on Good Distribution Practices (GDP)	Yes ☐ No ☒	2010	Maldives Food and Drug Authority
7.02.04	There is a licensing authority that issues GDP licenses	Yes ☐ No ☐		
7.02.04.01	If a licensing authority exists, does it accredit public distribution facilities?	Yes ☐ No ☐		
7.02.05	List of GDP certified warehouses in the public sector exists	Yes ☐ No ☐		
7.02.06	List of GDP certified distributors in the public sector exists	Yes ☐ No ☐		
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:			
7.02.08.01S	Forecasting of order quantities	Yes ☐ No ☐		
7.02.08.02S	Requisition/Stock orders	Yes ☐ No ☐		
7.02.08.03S	Preparation of picking/packing slips	Yes ☐ No ☐		
7.02.08.04S	Reports of stock on hand	Yes ☐ No ☐		
7.02.08.05S	Reports of outstanding order lines	Yes ☐ No ☐		
7.02.08.06S	Expiry dates management	Yes ☐ No ☐		
7.02.08.07S	Batch tracking	Yes ☐ No ☐		

7.02.08.08S	Reports of products out of stock	Yes ☐ No ☐		
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			
7.02.11S	Routine Procedure exists to track the expiry dates of medicines at the Central Medical Store	Yes ☐ No ☐		
7.02.12S	The Public Central Medical Store is GDP certified by a licensing authority	Yes ☐ No ☐		
7.02.13S	The Public Central Medical Store is ISO certified	Yes ☐ No ☐		
7.02.14S	The second tier public warehouses are GDP certified by a licensing authority	Yes ☐ No ☐		
7.02.15S	The second tier public warehouses are ISO certified	Yes ☐ No ☐		
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 ☒ No ☐	2010	Maldives Food and Drug Authority
7.03.02	Legal provisions exist for licensing distributors in the private sector	Yes ☒ No ☐	2010	Maldives Food and Drug Authority

7.03.03	List of GDP certified wholesalers in the private sector exists	Yes ☐ No ☒	2010	Maldives Food and Drug Authority
7.03.04	List of GDP certified distributors in the private sector exists	Yes ☐ No ☒	2010	Maldives Food and Drug Authority
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 ☒ No ☐	2009	Maldives Food and Drug Authority
8.01.01.01	If yes, number of medicines on the EML (no. of INN)	393		
8.01.01.02	If yes, there is a written process for selecting medicines on the EML	Yes ☐ No ☐		
8.01.01.03	If yes, the EML is publicly available	Yes ☐ No ☐		
8.01.01.04	If yes, is there any mechanism in place to align the EML with the Standard Treatment Guidelines (STG)	Yes ☐ No ☐		
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 ☐ No ☒	2007	WHO Level I
8.01.03	STGs specific to Primary care exist. Please use the "year" field to	Yes ☐ No ☒	2007	WHO Level

	write the year of last update of primary care guidelines			I
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 ☐ No ☐		
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 ☐ No ☐		
8.01.06	% of public health facilities with copy of EML (mean)- Survey data	100	2010	Maldives Food and Drug Authority
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 ☐ No ☒	2007	WHO Level I
8.01.09	Public education campaigns on rational medicine use topics have been conducted in the previous two years	Yes ☐ No ☒	2010	Maldives Food and Drug Authority
8.01.10	A survey on rational medicine use has been conducted in the previous two years	Yes ☐ No ☒	2010	Maldives Food and Drug Authority
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 ☐ No ☒	2007	WHO Level I
8.01.12	A written National strategy exists to contain antimicrobial resistance. If	Yes ☐ No ☒	2007	WHO Level

	yes, please write year of last update of the strategy in the "year" field			I
8.01.13	Comments and References	Essential Medicines List: The essential medicines has been distributed to all health facilities including private. A written process for selecting medicines on the EML: EML was formulated by an expert group that included a WHO consultant using the earlier EML and WHO Model EML. National Medicines List: Initially developed as a reference list for the drugs eligible for reimbursement under 'Madhana'. This comprised of EML and other medicines. This has been superseded by an 'approved drug list'.		
Supplementary questions (click here for help)				
			Year	Source
8.01.14S	The Essential Medicines List (EML) includes formulations specific for children	Yes ☒ No ☐	2010	Maldives Food and Drug Authority
8.01.15S	There are explicitly documented criteria for the selection of medicines in the EML	Yes ☒ No ☐	2010	Maldives Food and Drug Authority
8.01.16S	There is a formal committee or other equivalent structure for the selection of products on the National EML	Yes ☐ No ☒	2010	Maldives Food and Drug Authority
8.01.16.01S	If yes, conflict of interest declarations are required from members of national EML committee	Yes ☐ No ☐		
8.01.17S	National medicines formulary exists	Yes ☐ No ☒	2010	Maldives Food and Drug Authority
8.01.18S	Is there a funded national inter-sectoral task force to coordinate the promotion of appropriate use of	Yes ☐ No ☒	2010	Ministry of Health and

	antimicrobials and prevention of spread of infection?			Family
8.01.19S	A national reference laboratory/or any other institution has responsibility for coordinating epidemiological surveillance of antimicrobial resistance	Yes ☐ No ☒	2007	WHO Level I
8.01.20S	Comments and References	National medicines formulary: MFDA is planning to reprint WHO model formulary and developing a drug index.		

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 ☐ No ☒	2010	Maldives Food and Drug Authority
8.02.02	Legal provisions exist to restrict dispensing by prescribers	Yes ☐ No ☐		
8.02.03	Do prescribers in the private sector dispense medicines?	Yes ☐ No ☐		
8.02.04	Regulations require hospitals to organize/develop Drug and Therapeutics Committees (DTCs)	Yes ☐ No ☒	2007	WHO Level I2007
8.02.05	Do more than half of referral hospitals have a DTC?	Yes ☐ No ☐ Unknown ☐		
8.02.06	Do more than half of general hospitals have a DTC?	Yes ☐ No ☐ Unknown ☐		
8.02.07	Do more than half of regions/provinces have a DTC?	Yes ☐ No ☐ Unknown ☐		
8.02.08	The core medical training curriculum includes components on:		2007	WHO Level I

8.02.08.01	Concept of EML	Yes ☒ No ☐		
8.02.08.02	Use of STGs	Yes ☐ No ☒		
8.02.08.03	Pharmacovigilance	Yes ☐ No ☐		
8.02.08.04	Problem based pharmacotherapy	Yes ☒ No ☐		
8.02.09	Mandatory continuing education that includes pharmaceutical issues is required for doctors (see physician)	Yes ☐ No ☒	2007	WHO Level I
8.02.10	Mandatory continuing education that includes pharmaceutical issues is required for nurses	Yes ☐ No ☒	2010	Faculty of Health Sciences
8.02.11	Mandatory continuing education that includes pharmaceutical issues is required for paramedical staff	Yes ☐ No ☒	2007	WHO Level I
8.02.12	Prescribing by INN name is obligatory in:			
8.02.12.01	Public sector	Yes ☐ No ☒		
8.02.12.02	Private sector	Yes ☐ No ☒		
8.02.13	Average number of medicines prescribed per patient contact in public health facilities (mean)	2.5	1995	Rational Use Survey
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 professional behaviour of doctors	Yes ☐ No ☐		
8.02.22S	A professional association code of conduct exists governing professional behaviour of nurses	Yes ☐ No ☐		
8.02.23S	Diarrhoea in children treated with Oral Rehydration Solution (ORS) (%)			
8.02.24S	Comments and References	Suplpementary section unknown and not available Core medical training curriculum Maldives does not have a medical school. At the time of joining the public health system doctors are provided an orientation by MFDA on EML, National Medicine List, Approved Drugs List, Controlled Drugs and other rules and regulations.		

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 ☒ No ☐	2010	Maldives Food and Drug

				Authority
8.03.02	The basic pharmacist training curriculum includes components on:		2010	Faculty of Health Sciences
8.03.02.01	Concept of EML	Yes ☒ No ☐		
8.03.02.02	Use of STGs	Yes ☒ No ☐		
8.03.02.03	Drug Information	Yes ☒ No ☐		
8.03.02.04	Clinical pharmacology	Yes ☒ No ☐		
8.03.02.05	Medicines supply management	Yes ☒ No ☐		
8.03.03	Mandatory continuing education that includes rational use of medicines is required for pharmacists	Yes ☐ No ☒	2007	WHO Level I
8.03.04	Generic substitution at the point of dispensing in public sector facilities is allowed	Yes ☐ No ☒	2010	Maldives Food and Drug Authority
8.03.05	Generic substitution at the point of dispensing in private sector facilities is allowed	Yes ☐ No ☒	2010	Maldives Food and Drug Authority
8.03.06	In practice, (even though this may be contrary to regulations) are antibiotics sometimes sold over-the-counter without any prescription?	Yes ☐ No ☒ Unknown ☐	2010	Maldives Food and Drug Authority
8.03.07	In practice, (even though this may be contrary to regulations) are injections sometimes sold over-the-counter without any prescription?	Yes ☐ No ☒ Unknown ☐	2007	WHO Level I
8.03.08	Comments and References	Antibiotics are sold over-the-counter without a prescription The regulation does not allow over-the-counter sale of antibiotics		

		without prescription. Despite this antibiotics are sold over-the-counter.		
Supplementary questions (click here for help)				
			Year	Source
8.03.09S	A professional association code of conduct exists governing professional behaviour of pharmacists	Yes ☐ No ☒	2010	Maldives Food and Drug Authority
8.03.10S	In practice, (even though this may be contrary to regulations) do the following groups of staff *sometimes* prescribe prescription-only medicines at the primary care level in the public sector?		2007	WHO Level I
8.03.10.01S	Nurses	Yes ☒ No ☐ Unknown ☐		
8.03.10.02S	Pharmacists	Yes ☐ No ☒ Unknown ☐		
8.03.10.03S	Paramedics	Yes ☐ No ☐ Unknown ☒		
8.03.10.04S	Personnel with less than one month training	Yes ☐ No ☐ Unknown ☒		
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 (%)			
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 (%)			
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 (%)			

9.01.06	Adults with chronic conditions taking all medicines prescribed by an authorized prescriber (%)			
9.01.07	Adults (from poor households) with chronic conditions not taking all medicines because they cannot afford them (%)			
9.01.08	Adults (from poor households) with chronic conditions who usually take all medicines prescribed by an authorized prescriber (%)			
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 (%)			
9.01.10	Percentage of people who obtained the medicines prescribed in the 15 days before the interview (%)			
9.01.11	People who obtained prescribed medicines for free in the 15 days before the interview (%)			
9.01.12	Comments and References	No household survey with focus on access to medicines has been conducted in Maldives.		
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 (%)			
9.01.14S	Adults with chronic conditions not taking all medicines because they cannot afford them (%)			
9.01.15S	Adults with chronic conditions not taking all medicines because the medicines were not available (%)			

9.01.16S	Children with acute conditions taking all medicines prescribed by an authorized prescriber (%)			
9.01.17S	Children with acute conditions not taking all medicines because they cannot afford them (%)			
9.01.18S	Children with acute conditions not taking all medicines because the medicines were not available (%)			
9.01.19S	Children (from poor households) with acute conditions not taking all medicines because they cannot afford them (%)			
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					

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