

# JORDAN



## PHARMACEUTICAL COUNTRY PROFILE





# Jordan Pharmaceutical Country Profile

Published by the Ministry of Health of Jordan in collaboration with the World Health Organization

2011

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## Foreword

The 2011 Pharmaceutical Country Profile for Jordan has been produced by the Ministry of Health, in collaboration with the World Health Organization.

This document contains information on existing socio-economic and health-related conditions, resources; as well as on regulatory structures, processes and outcomes relating to the pharmaceutical sector in Jordan. The compiled data comes from international sources (e.g. the World Health Statistics<sup>12</sup>), surveys conducted in the previous years and country level information collected in 2011. The sources of data for each piece of information are presented in the tables that can be found at the end of this document.

On the behalf of the Ministry of Jordan, I wish to express my appreciation to Dr. Adi Nuseirat from the JFDA for his contribution to the process of data collection and the development of this profile.

It is my hope that partners, researchers, policy-makers and all those who are interested in the Jordan pharmaceutical sector will find this profile a useful tool to aid their activities.

Dr. "Mohammed Said" Rawabdeh  
JFDA Director General  
Date: 27/2/2012



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## Introduction

This Pharmaceutical Country Profile provides data on existing socio-economic and health-related conditions, resources, regulatory structures, processes and outcomes relating to the pharmaceutical sector of Jordan. The aim of this document is to compile all relevant, existing information on the pharmaceutical sector and make it available to the public in a user-friendly format. In 2010, the country profiles project was piloted in 13 countries ([www.who.int/medicines/areas/coordination/coordination\\_assessment/en/index.html](http://www.who.int/medicines/areas/coordination/coordination_assessment/en/index.html)). During 2011, the World Health Organization has supported all WHO Member States to develop similar comprehensive pharmaceutical country profiles.

The information is categorized in 9 sections, namely: (1) Health and Demographic data, (2) Health Services, (3) Policy Issues, (4) Medicines Trade and Production (5) Medicines Regulation, (6) Medicines Financing, (7) Pharmaceutical procurement and distribution, (8) Selection and rational use, and (9) Household data/access. The indicators have been divided into two categories, namely "core" (most important) and "supplementary" (useful if available). This narrative profile is based on data derived from both the core and supplementary indicators. The tables in the annexes also present all data collected for each of the indicators in the original survey form. For each piece of information, the year and source of the data are indicated; these have been used to build the references in the profile and are also indicated in the tables. If key national documents are available on-line, links have been provided to the source documents so that users can easily access these documents.

The selection of indicators for the profiles has involved all technical units working in the Essential Medicines Department of the World Health Organization (WHO), as well as experts from WHO Regional and Country Offices, Harvard Medical



School, Oswaldo Cruz Foundation (known as Fiocruz), University of Utrecht, the Austrian Federal Institute for Health Care and representatives from 13 pilot countries.

Data collection in all 193 member states has been conducted using a user-friendly electronic questionnaire that included a comprehensive instruction manual and glossary. Countries were requested not to conduct any additional surveys, but only to enter the results from previous surveys and to provide centrally available information. To facilitate the work of national counterparts, the questionnaires were pre-filled at WHO HQ using all publicly-available data and before being sent out to each country by the WHO Regional Office. A coordinator was nominated for each of the member states. The coordinator for Jordan was Salah Gammouh.

The completed questionnaires were then used to generate individual country profiles. In order to do this in a structured and efficient manner, a text template was developed. Experts from member states took part in the development of the profile and, once the final document was ready, an officer from the Ministry of Health certified the quality of the information and gave formal permission to publish the profile on the WHO web site.

This profile will be regularly updated by the JFDA. Comments, suggestions or corrections may be sent to:

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[naffas@jor.emro.who.int](mailto:naffas@jor.emro.who.int)



## Section 1 - Health and Demographic Data

This section gives an overview of the demographics and health status of Jordan.

### 1.1 Demographics and Socioeconomic Indicators

The total population of Jordan in 2009 was 5,980,000 with an annual population growth rate of 2.2%. The annual GDP growth rate is 2.3%. The GDP per capita was US\$ 4,207 in 2009.<sup>3</sup>

### 1.2 Mortality and Causes of Death

The life expectancy at birth is 71.6 and 74.4 years for men and women respectively. The infant mortality rate (i.e. children under 1 year) is 23/1,000 live births. For children under the age of 5, the mortality rate is 28/1,000 live births. The maternal mortality rate is 19.1/100,000 live births.<sup>3</sup>

The top 10 diseases causing mortality in Jordan are:

(Jordan: Mortality Country Fact Sheet 2006, WHO

[www.who.int/whosis/mort/profiles/mort\\_emro\\_jor\\_jordan.pdf](http://www.who.int/whosis/mort/profiles/mort_emro_jor_jordan.pdf))

	Disease
1	Ischaemic heart disease
2	Road traffic accidents
3	Congenital Anomalies
4	Cerebrovascular Disease
5	Lower Respiratory Infections
6	Self-inflicted Injuries
7	Diarrhoeal Diseases
8	Perinatal Conditions
9	Breast Cancer
10	Nephritis and nephrosis



**Key reference documents:**

Department of Statistics (DOS), [www.dos.gov.jo](http://www.dos.gov.jo)

Jordan: Mortality Country Fact Sheet 2006, WHO

[www.who.int/whosis/mort/profiles/mort\\_emro\\_jor\\_jordan.pdf](http://www.who.int/whosis/mort/profiles/mort_emro_jor_jordan.pdf)





## Section 2 - Health Services

This section provides information regarding health expenditures and human resources for health in Jordan. The contribution of the public and private sector to overall health expenditure is shown and the specific information on pharmaceutical expenditure is also presented. Data on human resources for health and for the pharmaceutical sector is provided as well.

### 2.1 Health Expenditures

In Jordan, the total annual expenditure on health (THE) in 2008 was 1,381,460,034 JOD (US\$ 1,951 million). The total annual health expenditure was 8.58 % of the GDP. The total annual expenditure on health per capita was 236 JOD (US\$ 333).<sup>4</sup>

The general government<sup>i</sup> health expenditure (GGHE) in 2008, as reflected in the national health accounts (NHA) was JOD 787 million (US\$ 1,112 millions). That is, 57 % of the total expenditure on health, with a total annual per capita public expenditure on health of JOD 134 (US\$ 190). The government annual expenditure on health represents 10.16 % of the total government budget. Private health expenditure covers the remaining 37.5 % of the total health expenditure. Donor's health expenditure covers 5.5 % of the remaining total health expenditure.<sup>4</sup>

Of the total population, 75 % is covered by a public health service (MOH 34%, RMS 23%, UNRWA 9%, and Private Health Insurance 8%). the remaining 25% of population are without any form of health insurance. (Population covered by public insurance service is calculated from numbers reported in Jordan NHA 2008 using the total population for that year).<sup>4</sup>

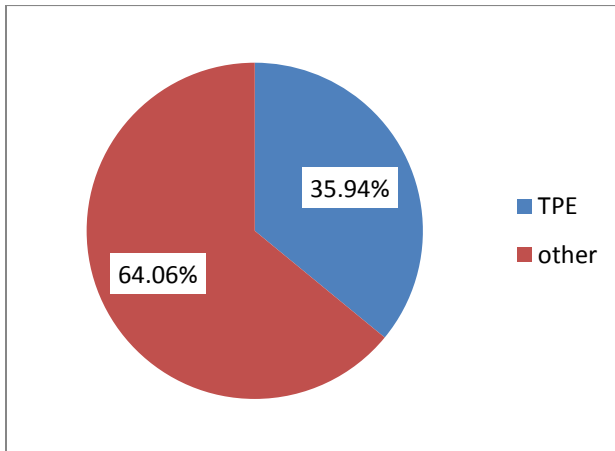
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<sup>i</sup> According to the NHA definition, by "government expenditure" it is meant all expenditure from public sources, like central government, local government, public insurance funds and parastatal companies.



Total pharmaceutical expenditure (TPE) in Jordan in 2008 was 496.4 million JOD (US\$ 701 million), which is a per capita pharmaceutical expenditure of 84.86 JOD (US\$ 120). The total pharmaceutical expenditure accounts for 3.08 % of the GDP and makes up 35.94 % of the total health expenditure. (Figure1) Public expenditure on pharmaceuticals represents 38.44 % of the total expenditure on pharmaceuticals (Figure 2), this converts into a per capita public expenditure on pharmaceuticals of 32.6 JOD (US\$ 46).<sup>4</sup>

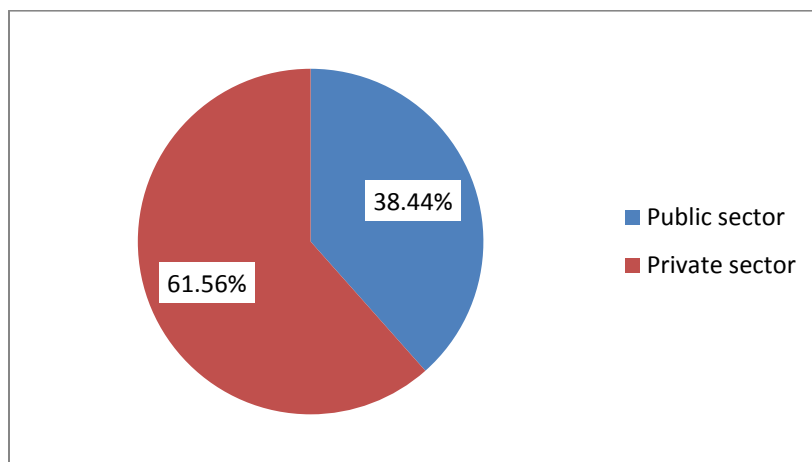
**FIGURE 1: Share of Total Pharmaceutical Expenditure as percentage of the Total Health Expenditure (2008). The THE in 2008 was 1,381 million JOD (US\$ 1,951 million)**



Jordan NHA 2008



**FIGURE 2: Share of Total Pharmaceutical Expenditure by sector (2008)**



Jordan NHA 2008

Total private expenditure on pharmaceuticals is 305.6 million JOD (US\$ 431.5).

## 2.2 Health Personnel and Infrastructure

The health workforce is described in the table below and in Figure 3 and 4.

There are 9,160 (15 per 10,000 population) licensed pharmacists, of which only 439 work in the Ministry of Health. There are 16,200 physicians (26.5 per 10,000 population) and 25,600 nursing and midwifery personnel (41.9 per 10,000 populations) in.

There are 6,540 (12.6 /10,000) pharmaceutical technicians and assistants (in all sectors). There are approximately 0.71 fewer pharmacy technicians as pharmacists.

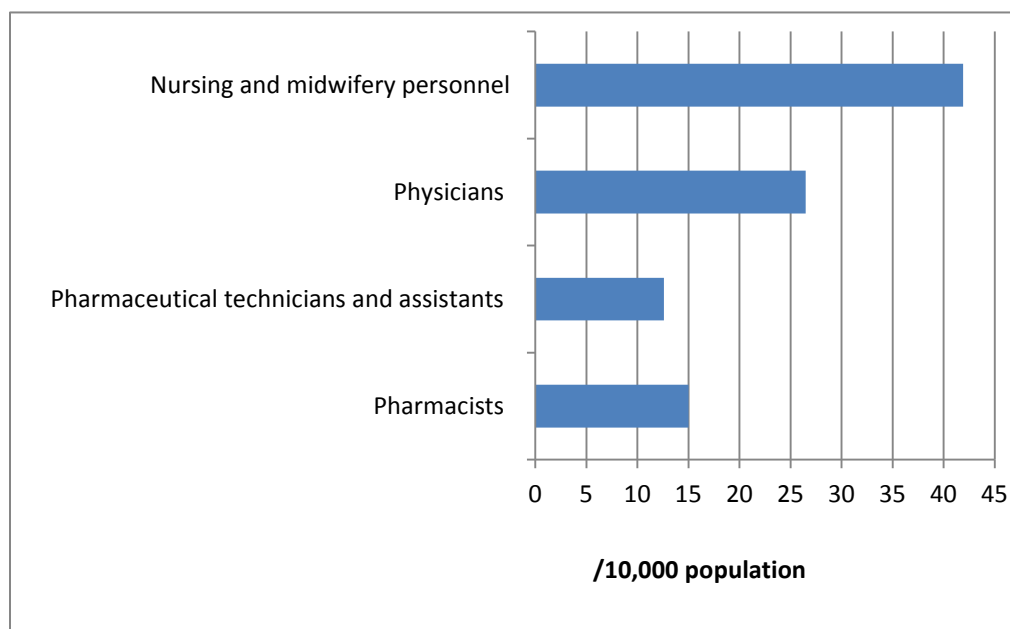
**Table 1: Human resources for health in Jordan (Ministry of Health Report 2010)<sup>3</sup>**

Human Resource	
Licensed pharmacists (all sectors)	9,160 (15/10,000)
Pharmacists in the public sector	439
Pharmaceutical technicians and assistants (all sectors)	6,540 (12.6 /10,000)
Physicians (all sectors)	16,200 (26.5/10,000)



Nursing and midwifery personnel (all sectors)	25,600 (41.9 /10,000)
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**Figure 3: The density of the Health Workforce in Jordan (all sectors)**



Ministry of Health Report 2010

In Jordan, there is not a strategic plan for pharmaceutical human resource development in place.

The health facilities described in the table below and in Table 2. There are 106 hospitals and 11,779 hospital beds in Jordan. There are 1,492 primary health care units and centres (comprehensive health center: 84, primary health center: 368, peripheral health center: 227, MCH center: 432, chest disease center: 12, dental clinic: 369) and 1,919 licensed pharmacies. <sup>3</sup>

**Table 2: Health centre and hospital statistics (Ministry of Health Report 2010)<sup>3</sup>**

Infrastructure	
Hospitals	106
Hospital beds	11,779
Primary health care units and centres	1,492



Licensed pharmacies	1,919
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- In the National Health Strategy 2008-12, strategic objectives for the number of health care workers are stated. However, technical development is not addressed and the strategy does not include an actual working plan. Similarly, the MoH Strategic Plan 2008-2012 also lacks specific plans, and does not address pharmacy. The Human Resource Project (2004-2006) for MoH also includes only projections on numbers of HCW required.

**Key reference documents:**

Jordan National Health Accounts 2008

[www.who.int/nha/country/jor/en/](http://www.who.int/nha/country/jor/en/)

Human Resources for Health 2010, WHO 2009,

[apps.who.int/medicinedocs/documents/s17239e/s17239e.pdf](http://apps.who.int/medicinedocs/documents/s17239e/s17239e.pdf)

Insurance Commission:

[www.irc.gov.jo/doc/RSPP/EnAnnualReport-Optimized.pdf](http://www.irc.gov.jo/doc/RSPP/EnAnnualReport-Optimized.pdf)



## Section 3 - Policy Issues

This section addresses the main characteristics of the pharmaceutical policy in Jordan. The many components of a national pharmaceutical policy are taken from the WHO publication “How to develop and implement national drug policy” ([apps.who.int/medicinedocs/en/d/Js2283e/](https://apps.who.int/medicinedocs/en/d/Js2283e/)). Information about the capacity for manufacturing medicines and the legal provisions governing patents is also provided.

### 3.1 Policy Framework

In Jordan, a National Health Policy (NHP) exists.<sup>5</sup> It was updated in 2009. An associated National Health Policy implementation plan does not exist.

An official National Medicines Policy document exists in Jordan.<sup>6</sup>

It was updated in 2002. A NMP implementation plan does not exist. Policies addressing pharmaceuticals do not exist at present. Pharmaceutical policy implementation is not regularly monitored /assessed.

**Table 3: The National Medicines Policy document covers** <sup>6</sup>

Aspect of policy	Covered
Selection of essential medicines	<u>Yes</u>
Medicines financing	<u>Yes</u>
Medicines pricing	<u>Yes</u>
Medicines Procurement	<u>Yes</u>
Medicines Distribution	<u>Yes</u>
Medicines Regulation	<u>Yes</u>
Pharmacovigilance	<u>Yes</u>
Rational use of medicines	<u>Yes</u>
Human Resource Development	<u>Yes</u>
Research	<u>Yes</u>
Monitoring and evaluation	<u>Yes</u>
Traditional Medicine	<u>No</u>



Access to essential medicines/technologies as part of the fulfillment of the right to health, is not recognized in the constitution<sup>7</sup>, but it is included in national legislation<sup>15</sup> (see further information below). There are official written guidelines on medicines donations. Medicines donations need approval from the Minister of Health (an official letter for accepting donation from the Minister of Health to the Procurement and Supply Department).

Currently there is no national good governance policy. However the government has taken steps toward such a policy by creating a code of conduct for public employees, establishing the Anti-Corruption Committee, and is currently working with WHO to create the document "A Framework for Good Governance in the Pharmaceutical Sector. The Hashemite Kingdom of Jordan".<sup>8</sup>

A policy is not in place to manage and sanction conflict of interest issues in pharmaceutical affairs. There is an associated formal code of conduct for public officials. There is a whistle-blowing mechanism that allows individuals to raise concerns about wrongdoing occurring in the pharmaceutical sector of Jordan (see Key reference documents below).

#### Further information and key findings:

Provisional Law No. (80) for the year 2001, Drugs & Pharmacy Law  
Available at: [www.jfda.jo/custom/law/24.doc](http://www.jfda.jo/custom/law/24.doc)

##### Article (50):

A - The Minister, in coordination with the Association, may issue any instructions by which he defines the types of any registered drugs, which must be made available at all times in any drugstore, and are produced by the companies which he acts as an agent for. In case of failure to secure those drugs, he has to inform the Ministry of such incident and shall be subject to penalty of giving the right to import those drugs by any other pharmaceutical institution on condition that they are sold to public against the determined price.

B - The Minister, under any terms he may determine, may give the permission to any pharmaceutical institution for medicinal security reasons to import any of the registered Drugs.



**Key reference documents:**

High Health Council National Health Strategy (Arabic)

[www.hhc.gov.jo/HHC/.pdf](http://www.hhc.gov.jo/HHC/.pdf) (Right click and save as it does not download otherwise)

A Framework for Good Governance in the Pharmaceutical Sector. The Hashemite Kingdom of Jordan, 2010

[apps.who.int/medicinedocs/documents/s17057e/s17057e.pdf](http://apps.who.int/medicinedocs/documents/s17057e/s17057e.pdf)

Prime Ministry Code of conduct:

[www.pm.gov.jo/uploads/Code\\_of\\_Conduct\\_english.pdf](http://www.pm.gov.jo/uploads/Code_of_Conduct_english.pdf)

Anti-Corruption Commission: [www.jacc.gov.jo](http://www.jacc.gov.jo)

Complaint form (Arabic only): [www.jacc.gov.jo/form2.aspx](http://www.jacc.gov.jo/form2.aspx)





## Section 4 – Medicines Trade and Production

### 4.1 Intellectual Property Laws and Medicines

Jordan is a member of the World Trade Organization.<sup>9</sup> Legal provisions granting patents to manufacturers exist.<sup>10</sup>

National Legislation has been modified to implement the TRIPS Agreement and contains TRIPS-specific flexibilities and safeguards<sup>10</sup>, presented in Table 4.

Jordan is not eligible for the transitional period to 2016.

**Table 4: TRIPS flexibilities and safeguards are present in the national law**

Flexibility and safeguards	Included
Compulsory licensing provisions that can be applied for reasons of public health	<u>Yes</u>
Bolar exceptions <sup>ii</sup>	<u>Yes</u>
Parallel importing provisions	<u>Yes</u>

There are legal provisions for data exclusivity for pharmaceuticals, patent term extension and linkage between patent status and marketing authorization.<sup>11</sup>

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<sup>ii</sup> Many countries use this provision of the TRIPS Agreement to advance science and technology. They allow researchers to use a patented invention for research, in order to understand the invention more fully.

In addition, some countries allow manufacturers of generic drugs to use the patented invention to obtain marketing approval (for example from public health authorities) without the patent owner's permission and before the patent protection expires. The generic producers can then market their versions as soon as the patent expires. This provision is sometimes called the "regulatory exception" or "Bolar" provision. *Article 30*

This has been upheld as conforming with the TRIPS Agreement in a WTO dispute ruling. In its report adopted on 7 April 2000, a WTO dispute settlement panel said Canadian law conforms with the TRIPS Agreement in allowing manufacturers to do this. (The case was titled "Canada - Patent Protection for Pharmaceutical Products")

[In: [WTO OMC Fact sheet: TRIPS and pharmaceutical patents](http://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf), can be found on line at: [www.wto.org/english/tratop\\_e/trips\\_e/tripsfactsheet\\_pharma\\_2006\\_e.pdf](http://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf)]



The country is engaged in capacity-strengthening initiatives to manage and apply Intellectual Property Rights in order to contribute to innovation and promote public health.<sup>11</sup>

**Key reference documents:**

Ministry of Industry and Trade, The Hashemite Kingdom of Jordan,  
[www.mit.gov.jo](http://www.mit.gov.jo)

Trade Policy Review, Report by the Secretariat, Jordan, World Trade Organization, WT/TPR/G/206, 6. Oct 2008  
[www.mit.gov.jo/portals/0/g206.pdf](http://www.mit.gov.jo/portals/0/g206.pdf)

Trade Policy Review report by Jordan, World Trade Organization, WT/TPR/S/206,  
[www.mit.gov.jo/portals/0/s206-00.pdf](http://www.mit.gov.jo/portals/0/s206-00.pdf)

Patent Regulations official Gazette No. 4522 dated 13.12.2001,  
[www.jfda.jo/custom/law/53.doc](http://www.jfda.jo/custom/law/53.doc)

## 4.2 Manufacturing

There are 16 licensed pharmaceutical manufacturers in Jordan.<sup>12</sup> Manufacturing capabilities are presented in Table 5 below.

**Table 5: Jordan manufacturing capabilities<sup>10</sup>**

Manufacturing capabilities	
Research and Development for discovering new active substances	<u>Yes</u>
Production of pharmaceutical starting materials (APIs)	<u>Yes</u>
The production of formulations from pharmaceutical starting material	<u>Yes</u>
The repackaging of finished dosage forms	<u>Yes</u>

In 2008, domestic manufacturers held 33 % of the market share by value produced.<sup>13</sup>

**Key reference documents:**

Prime Ministry Millennium Challenge Account:  
[www.mca-jordan.gov.jo/index.php?page\\_type=pages&page\\_id=259](http://www.mca-jordan.gov.jo/index.php?page_type=pages&page_id=259)



## Section 5 – Medicines Regulation

This section details the pharmaceutical regulatory framework, resources, governing institutions and practices in Jordan.

### 5.1 Regulatory Framework

In Jordan, there are legal provisions establishing the powers and responsibilities of the Medicines Regulatory Authority (MRA).

The MRA is a semi-autonomous agency. The Board of Directors of JFDA is headed by the Minister of Health. The MRA has its own website

[www.jfda.jo/EN/default/](http://www.jfda.jo/EN/default/) .

The MRA is involved in harmonization/collaboration initiatives (such as “A Framework for good governance in the pharmaceutical sector”<sup>8</sup>). No assessment of the medicines regulatory system has been conducted in the last five year. Funding for the MRA is provided through the regular government budget. The Regulatory Authority does not retain revenues derived from regulatory activities. This body does not utilize a computerized information management system to store and retrieve information on processes that include registrations, inspection etc.<sup>14</sup>

#### **Key reference documents:**

MRA Website: [www.jfda.jo](http://www.jfda.jo)

JFDA Law: [www.jfda.jo/custom/law/22.doc](http://www.jfda.jo/custom/law/22.doc)

Drug and Pharmacy Law 2001: [www.jfda.jo/EN/Laws/LawInfo.aspx?id=507](http://www.jfda.jo/EN/Laws/LawInfo.aspx?id=507)

Prime Ministry Code of conduct:

[www.pm.gov.jo/uploads/Code\\_of\\_Conduct\\_english.pdf](http://www.pm.gov.jo/uploads/Code_of_Conduct_english.pdf)



## **5.2 Marketing Authorization (Registration)**

In Jordan, legal provisions require marketing authorization (registration) for all pharmaceutical products on the market.<sup>15</sup> Explicit and publicly available criteria exist for assessing applications for marketing authorization of pharmaceutical products.<sup>14 16</sup> In 2010, there were 7,700 pharmaceutical products registered in Jordan. There are not legal provisions requiring the MRA to make the list of registered pharmaceutical products publicly available and update it regularly. Medicines are always registered by their INN (International Non-proprietary Names) or Brand name + INN. Legal provisions require a fee to be paid for Medicines Market Authorization (registration) based on applications.<sup>16</sup> Marketing Authorization holders are required by law to provide information about variations to the existing Marketing Authorization. Legally, a Summary of Product Characteristics (SPC) of the medicines that are registered is not required to be published. However, legal provisions requiring the establishment of an expert committee involved in the Marketing Authorization process are in place. Possession of a Certificate for Pharmaceutical Products (that accords with the WHO Certification scheme) is required as part of the Marketing Authorization application. By law, potential conflict of interests for experts involved in the assessment and decision-making for registration need not be declared. Applicants may legally appeal MRA decisions.

The registration fee (per application) for a pharmaceutical product containing a New Chemical Entity (NCE) is US\$ 2,119, while this fee for generic pharmaceutical products is US\$ 847. The time limit imposed for the assessment of all Marketing Authorization applications is 6 months.<sup>16</sup>

## **5.3 Regulatory Inspection**

In Jordan, legal provisions exist allowing for appointment of government pharmaceutical inspectors.<sup>15</sup> Legal provisions exist permitting inspectors to inspect premises where pharmaceutical activities are performed. Such



inspections are required by law and are a pre-requisite for the licensing of facilities.<sup>15 17</sup> Inspections are carried out on a number of entities: There are 10 inspectors for pharmacies and 7 inspectors for manufacturers at JFDA. It is completed with district pharmacists from the Ministry of Health who are in charge of inspection for pharmacies in their respective districts.<sup>18</sup>

#### 5.4 Import Control

Legal provisions exist requiring authorization to import medicines. Laws exist that allow the sampling of imported products for testing.

Legal provisions do not requiring importation of medicines through authorized ports of entry. Regulations or laws exist to allow for inspection of imported pharmaceutical products at authorized ports of entry.<sup>15 16</sup>

#### 5.5 Licensing

In Jordan, legal provisions exist requiring manufacturers to be licensed [Accreditation of Manufacturing Sites Regulations, Re-evaluation and Cancellation for the Year 2008].<sup>19</sup> Legal provisions exist requiring manufacturers (both domestic and international) to comply with Good Manufacturing Practices (GMP). Good Manufacturing Practices are published by the government.<sup>20</sup>

Legal provisions exist requiring importers/wholesalers/distributors to be licensed.<sup>15</sup> Legal provisions exist requiring wholesalers and distributors to comply with Good Distributing Practices.

**Table 8: Legal provisions pertaining to licensing**

Entity requiring licensing	
Importers	<u>Yes</u>
Wholesalers	<u>Yes</u>
Distributors	<u>Yes</u>

Good Distribution Practices are published by the government.



Legal provisions exist requiring pharmacists to be registered. Legal provisions exist requiring private/public pharmacies to be licensed.<sup>15</sup> National Good Pharmacy Practice Guidelines are not published by the government. By law, a list of all licensed pharmaceutical facilities is not required to be published.

### **5.6 Market Control and Quality Control**

In Jordan, legal provisions exist for controlling the pharmaceutical market.<sup>15 21</sup>

A laboratory exists in Jordan for Quality Control testing.<sup>22</sup>

Samples are collected by government inspectors for undertaking post-marketing surveillance testing.<sup>10</sup>

In the past year (2009), 16,049 samples were taken for quality control testing. Of the samples tested, 176 (or 0.91 %) failed to meet the quality standards. The results are not publicly available.

### **5.7 Medicines Advertising and Promotion**

In Jordan, legal provisions exist to control the promotion and advertising of prescription medicines. The government and the pharmaceutical industry are responsible for regulating promotion and advertising of medicines. Multinational companies also have their own rules and regulations. Legal provisions do not prohibit direct advertising of prescription medicines to the public and pre-approval of medicines advertisements and promotional materials is required. Guidelines and Regulations exist for advertising and promotion of non-prescription medicines. There is a national code of conduct concerning advertising and promotion of medicines by marketing authorization holders.

The code of conduct applies to domestic manufacturers and multinational manufacturers, for which adherence is not voluntary.<sup>23</sup>

### **5.8 Clinical Trials**

In Jordan, legal provisions exist requiring authorization for conducting Clinical Trials by the MRA. There are additional laws requiring the agreement by an ethics committee or institutional review board of the Clinical Trials to be



performed. Clinical trials are required to be entered into an international/national/regional registry, by law.<sup>24</sup>

Legal provisions do not exist for GMP compliance of investigational products. Sponsor investigators are legally required to comply with Good Clinical Practices (GCP). National GCP regulations are not published by the Government. Legal provisions permit the inspection of facilities where clinical trials are performed.<sup>24</sup>

## 5.9 Controlled Medicines

Jordan is a signatory to a number of international conventions, detailed in Table 10.

**Table 10: International Conventions to which Jordan is a signatory<sup>25</sup>**

Convention	Signatory
Single Convention on Narcotic Drugs, 1961	<u>Yes</u>
1972 Protocol amending the Single Convention on Narcotic Drugs, 1961	<u>Yes</u>
Convention on Psychotropic Substances 1971	<u>Yes</u>
United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988	<u>Yes</u>

Laws exist for the control of narcotic and psychotropic substances, and precursors (WHO Level I, MoH Rules and Regulations, JFDA Schedules and Lists).<sup>10 26 27</sup> The annual consumption of Morphine is 1.922 mg per capita.<sup>25</sup>

Figures regarding the annual consumption of certain controlled substances in the country are outlined in Table 10S below.

**Table 10S: Annual consumption of selected controlled substances in Jordan<sup>28</sup>**

Controlled substance	Annual consumption (mg/capita)
Morphine	1.922000
Fentanyl	0.023



Pethidine	4.247
Oxycodone	-
Hydrocodone	-
Phenobarbital	-
Methadone	0.068

### 5.10 Pharmacovigilance

In Jordan, there are legal provisions in the Medicines Act that provide for pharmacovigilance activities as part of the MRA mandate. Legal provisions exist requiring the Marketing Authorization holder to continuously monitor the safety of their products and report to the MRA. Laws regarding the monitoring of Adverse Drug Reactions (ADR) exist in Jordan.<sup>15 29</sup> A national pharmacovigilance centre linked to the MRA exists.

The Pharmacovigilance centre has 1 full-time staff member. The center has not published an analysis report in the previous two years and it regularly publishes an ADR bulletin. An official standardized form for reporting ADRs is used in Jordan. Information pertaining to ADRs is stored in a national ADR database. The ADR database currently comprises 400 ADR reports, of which 36 have been submitted in the past 2 years. These reports are sent to the WHO collaborating centre in Uppsala.<sup>30</sup> 40 ADR reports from the database have been forwarded to the WHO collaborating centre in the past 2 years.

#### Key reference documents:

Drug and Pharmacy Law 2001, [www.jfda.jo/EN/Laws/LawInfo.aspx?id=507](http://www.jfda.jo/EN/Laws/LawInfo.aspx?id=507)

Pharmacovigilance Directives, [www.jfda.jo/custom/law/55.doc](http://www.jfda.jo/custom/law/55.doc)

Registration Criteria, [www.jfda.jo/EN/Laws/details.aspx?id=72](http://www.jfda.jo/EN/Laws/details.aspx?id=72)





## Section 6 - Medicines Financing

In this section, information is provided on the medicines financing mechanism in Jordan, including the medicines coverage through public and private health insurance, use of user charges for medicines and the existence of public programmes providing free medicines. Policies and regulations affecting the pricing and availability of medicines (e.g. price control and taxes) are also discussed.

### 6.1 Medicines Coverage and Exemptions

In Jordan, concessions are made for certain groups to receive medicines free of charge (see Table 12). Furthermore, the public health system or social health insurance schemes provide medicines free of charge for particular conditions (see Table 13).

**Table 12: Population groups provided with medicines free of charge**<sup>31 32</sup>

Patient group	Covered
Patients who cannot afford them	<u>Yes</u>
Children under 5	<u>Yes</u> <sup>31</sup>
Pregnant women	<u>Yes</u>
Elderly persons	<u>Yes</u>

**Table 13: Medications provided publicly, at no cost**<sup>10</sup>

Conditions	Covered
All diseases in the EML	<u>No</u>
Malaria	<u>Yes</u>
Tuberculosis	<u>Yes</u>
Sexually transmitted diseases	<u>Yes</u>
HIV/AIDS	<u>Yes</u>
Expanded Program on Immunization (EPI) vaccines for children	<u>Yes</u>



A public health service, public health insurance, social insurance or other sickness fund provides at least partial medicines coverage. It provides coverage for medicines that are on the Essential Medicines List (EML) for inpatients and outpatients.

Private health insurance schemes provide medicines coverage. They are not required to provide at least partial coverage for medicines that are on the EML. It is widely known that private insurance companies provide medical coverage depending on the policy purchased.

## **6.2 Patients Fees and Co-payments**

Co-payments or fee requirements for consultations are levied at the point of delivery. Furthermore, there are copayments or fee requirements imposed for medicines. Revenue from fees or from the sale of medicines is not used to pay the salaries or supplement the income of public health personnel in the same facility.<sup>10</sup>

## **6.3 Pricing Regulation for the Private Sector<sup>iii</sup>**

In Jordan, there are legal or regulatory provisions affecting pricing of medicines.<sup>33</sup> These provisions are aimed at the level of manufacturers, wholesalers and retailers. There are differing pricing provisions for generic and originator medicines.

The government runs an active national medicines price monitoring system for retail prices. Regulations do not exist mandating that retail medicine price information should be publicly accessible.

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<sup>iii</sup> This section does not include information pertaining to the non-profit voluntary sector



## **6.4 Prices, Availability and Affordability of Key Medicines**

In 2004, a WHO/HAI pricing survey was conducted in Jordan.<sup>34</sup> Table 13 provides specific details regarding availability, pricing and affordability in the country.

### **Availability**

Public sector availability of originator medicines was 0 %, while availability of the lowest priced generic (LPG) medicines was 27.8 %. Availability in the private sector was higher (60 % for originator and 80 % for generics).

### **Pricing**

The Median Price Ratio is used to indicate how prices of medicines in Jordan relate to those on the international market. That is, prices of medicines have been compared to international reference prices<sup>iv</sup> and expressed as a ratio of the national price to the international price. For example, a price ratio of 2 would mean that the price is twice that of the international reference price. Since prices have been collected for a predefined basket of medicines, the Median Price Ratio has been selected to reflect the situation in the country.

Public procurement prices were above international reference prices: the Median Price Ratio for originators was 1.38 and for generics 0.57. As for patient prices, the Median Price Ratio in the public sector was 5.95 for originators and 0.85 for generics, while the private sector had higher prices (17.05 for originators and 10.50 for generics).

### **Affordability**

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<sup>iv</sup> The International reference price is the median of prices offered by international suppliers (both for profit and not profit) as report by MHS International Price Indicator Guide ([erc.msh.org/mainpage.cfm?file=1.0.htm&module=DMP&language=English](http://erc.msh.org/mainpage.cfm?file=1.0.htm&module=DMP&language=English)). For more information on the methodology WHO/HAI pricing survey, you can download a free copy of the manual at [apps.who.int/medicinedocs/documents/s14868e/s14868e.pdf](http://apps.who.int/medicinedocs/documents/s14868e/s14868e.pdf).



Affordability of medicines is measured in terms of the number of days' of wages necessary to purchase a particular treatment for a specific condition. The wage considered is that paid to the lowest paid government worker in Jordan. Specific data collected for the survey underlying this profile examined the number of days' wages required to purchase treatment with co-trimoxazole for a child respiratory infection; this was calculated to be 0.9 days' wages for the purchase of originator medicines by private patients. In comparison, the purchase of generic medication necessitated 0.1 days' wages for public patients and 0.3 for private patients. It is evident, therefore, that generic medicines are less affordable in the private sector than in the public sector.

**Table 14: Availability, Pricing and Affordability of medicines in Jordan**

		Public procurement	Public patient	Private patient
Availability				
Mean (%)	Originator			
	Lowest priced generic (LPG)			
Median (%)	Originator		0.0	60.0
	Lowest priced generic (LPG)		27.8	80.0
Price				
Mean Price	Originator	1.38	5.95	17.05
Ratio	Lowest priced generic (LPG)	0.57	0.85	10.50
Affordability				
Number of days' wages	Originator		--	0.9
	Lowest priced generic (LPG)		0.1	0.3

## 6.5 Duties and Taxes on Pharmaceuticals (Market)

Jordan imposes duties on imported active pharmaceutical ingredients (APIs) and duties on imported finished products are also imposed.<sup>10</sup>

Value-added tax or other taxes are imposed on finished pharmaceutical products. Provisions for tax exceptions or waivers for pharmaceuticals and health products are in place.



There is no duty tax for medicines, but there is a VAT of 4% for medicines. For pharmaceutical products which are not classified as medicines VAT is 16%.<sup>41</sup>

**Table 14S2: Duties and taxes applied to pharmaceuticals**

	%
Duty <sup>v</sup> on imported active pharmaceutical ingredients, APIs (%)	<u>0</u>
Duty on imported finished products (%)	<u>0</u>
VAT on pharmaceutical products (%)	<u>4</u>

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<sup>v</sup> Import tariff may apply to all imported medicines or there may be a system to exempt certain products and purchases. The import tax or duty may or may not apply to raw materials for local production. It may be different for different products. [In: [HAI/WHO Measuring medicine prices, availability, affordability and price components \(2<sup>nd</sup> Edition\)](http://www.haiweb.org/medicineprices/manual/documents.html) and at: <http://www.haiweb.org/medicineprices/manual/documents.html>]



## **Section 7 - Pharmaceutical procurement and distribution in the public sector**

This section provides a short overview on the procurement and distribution of pharmaceuticals in the public sector of Jordan.

### **7.1 Public Sector Procurement**

Public sector procurement in Jordan is both centralized and decentralized.<sup>35</sup>

The Board of Directors of the Joint Procurement Department (JPD) is headed by the Prime Minister.

Public sector request for tender documents are publicly available and public sector tender awards are publicly available. Procurement is based on the prequalification of suppliers.<sup>36 37</sup> As outlined in Governing Procedures<sup>37</sup> and the tender invitation form<sup>38</sup>, the JPD requires that any bidder for medicine tender be registered and would subsequently need to abide by JFDA rules and regulations and therefore WHO prequalification.

There is a written public sector procurement policy.

This policy was approved in 2002. Legal provisions exist that give priority to locally produces goods in public procurement.

The key functions of the procurement unit and those of the tender committee are clearly separated. A process exists to ensure the quality of products that are publicly procured.

The quality assurance process includes the pre-qualification of products and suppliers. A list of pre-qualified suppliers and products is available.

A list of samples tested during the procurement process and the results of quality testing are not available. The tender methods employed in public sector procurement include national competitive tenders.



## 7.2 Public Sector Distribution

The government supply system department in Jordan has a Central Medical Store at National Level (also known as Department of Procurement and Distribution). There are no national guidelines on Good Distribution Practices (GDP). A licensing authority that issues GDP licenses does not exist.

The percentage availability of key medicines at the Central Medical Store (CMS) is 83 %. The average stock-out duration at the CMS is 41 days.

Routine procedure to track the expiry dates of medicines at the CMS exist. The Public CMS is not ISO certified; the second tier public warehouses are not. The second tier public warehouses are not GDP certified by a licensing authority.

## 7.3 Private Sector Distribution

Legal provisions exist for licensing wholesalers and distributors in the private sector.<sup>15</sup> A list of GDP certified wholesalers or of distributors does not exist in the private sector.

### Key reference documents:

Joint Procurement Department: [www.jpd.gov.jo](http://www.jpd.gov.jo)

JP Law 2002: [www.jpd.gov.jo/ReadPaner.php?id=110&sub\\_id=5](http://www.jpd.gov.jo/ReadPaner.php?id=110&sub_id=5)

Current Tenders: [www.jpd.gov.jo/ReadPaner.php?id=115&sub\\_id=6](http://www.jpd.gov.jo/ReadPaner.php?id=115&sub_id=6)

Tender Invitation Form, Criteria:  
[www.jpd.gov.jo/images/pic/ZZ060402092259.pdf](http://www.jpd.gov.jo/images/pic/ZZ060402092259.pdf)

Governing Procedures/General Terms:  
[www.jpd.gov.jo/ReadPaner.php?id=184&sub\\_id=181](http://www.jpd.gov.jo/ReadPaner.php?id=184&sub_id=181)

Drug and Pharmacy Law 2001: [www.jfda.jo/EN/Laws/details.aspx?id=71](http://www.jfda.jo/EN/Laws/details.aspx?id=71)

Registration Criteria:  
[www.jfda.jo/EN/Laws/details.aspx?id=72](http://www.jfda.jo/EN/Laws/details.aspx?id=72)



## **Section 8 - Selection and rational use of medicines**

This section outlines the structures and policies governing the selection of essential medicines and promotion of rational drug in Jordan.

### **8.1 National Structures**

A National Essential Medicines List (EML) exists.<sup>10</sup>

The EML from 2006 is publicly available. The last update of the EML is publicly available.

There are currently 680 medicines on the EML. Selection of medicines for the EML is undertaken through a written process.

National Standard Treatment Guidelines (STGs) for the most common illnesses are produced / endorsed by the MoH in Jordan.

There is a public or independently funded national medicines information centre providing information on medicines to prescribers, dispensers and consumers.<sup>10</sup>

Public education campaigns on rational medicine use topics have been conducted in the last two years. A survey on rational use of medicines is currently being conducted. There is a national programme or committee, involving government, civil society, and professional bodies, to monitor and promote rational use of medicines.

A written National Strategy for containing antimicrobial resistance does not exist. Jordan's Essential Medicines List (EML) includes formulations specifically for children. Criteria for the selection of medicines to the EML are explicitly documented. A national medicines formulary does exist.

A funded national intersectoral task force to coordinate the promotion of the appropriate use of antimicrobials and prevention of the spread of infection does not exist.





A national reference laboratory or other institution does not have responsibility for coordinating epidemiological surveillance of antimicrobial resistance.

Legal or legislative documentation is not available. However, there exists a National Formulary Advisory Board, a National Pharmacy and Therapeutics Committee, and a Rational Drug List Technical Committee according to the JFDA document "JRDL 2006" in addition to a Rational Drug Unit in the JFDA. The Drug and Pharmacy Law 2001 stipulates that Higher Committee (prior to JFDA) must rationalize the use of medicines.

## 8.2 Prescribing

Legal provisions exist to govern the licensing and prescribing practices of prescribers. Furthermore, legal provisions restricting dispensing by prescribers exist.<sup>39</sup>

There are regulations requiring hospitals to organize/develop Drug and Therapeutics Committees (DTCs).<sup>10</sup>

The training curriculum for doctors and nurses is made up of a number of core components detailed in Table 16.

**Table 16: Core aspects of the medical training curriculum<sup>10</sup>**

Curriculum	Covered
The concept of EML	<u>Yes</u>
Use of STGS	<u>No</u>
Pharmacovigilance	<u>No</u>
Problem based pharmacotherapy	<u>Yes</u>

Mandatory continuing education that includes pharmaceutical issues is required for doctors and paramedical staff, but not for nurses.<sup>10</sup>

Prescribing by INN name is obligatory in the public sector. The average number of medicines prescribed per patient contact in public health facilities is 2.2. Of



the medicines prescribed in the outpatient public health care facilities, 97.8 % are on the national EML and 8.3 % are prescribed by INN name. Of the patients treated in the outpatient public health care facilities, 56.8 % receives antibiotics and 15.6 % receive injections. Of prescribed drugs, 95 % are dispensed to patients. Of medicines in public health facilities, 61% are adequately labelled. → Information will be available in the Level-II Study.

**Table 17: Characteristics of medicines prescribing**

Curriculum	%
% of medicines prescribed in outpatient public health care facilities that are in the national EML (mean)	97.8
% of medicines in outpatient public health care facilities that are prescribed by INN name (mean)	8.3
% of patients in outpatient public health care facilities receiving antibiotics (mean)	56.8
% of patients in outpatient public health care facilities receiving injections (mean)	15.6
% of prescribed drugs dispensed to patients (mean)	95
% of medicines adequately labeled in public health facilities (mean)	61

A professional association code of conduct which governs the professional behaviour of doctors exists. Similarly a professional association code of conduct governing the professional behaviour of nurses exists.<sup>40</sup>

### **8.3 Dispensing**

Legal provisions in Jordan exist to govern dispensing practices of pharmaceutical personnel.<sup>15</sup> The basic pharmacist training curriculum includes a spectrum of components as outlined in Table 18.



**Table 18: Core aspects of the pharmacist training curriculum**

Curriculum	Covered
The concept of EML	<u>No</u>
Use of STGS	<u>No</u>
Drug information	<u>unknown</u>
Clinical pharmacology	<u>Yes</u>
Medicines supply management	<u>unknown</u>

Mandatory continuing education is required for pharmacists for the public sector, but not for the private sector. The inclusion of rational use of medicines in continuing education is not required.<sup>41</sup>

Substitution of generic equivalents at the point of dispensing is allowed in public and private sector facilities. (Comment: There are no regulations that prohibit substitution.) Sometimes antibiotics are sold over-the-counter without a prescription. Sometimes injectable medicines are sold over-the-counter without a prescription.

A professional association code of conduct which governs the professional behaviour of pharmacists exists. In practice, nurses with less than one month of training do sometimes prescribe prescription-only medicines at the primary care level in the public sector (even though this may be contrary to regulations).

**Key reference documents:**

Drug and Pharmacy Law 2001: [www.jfda.jo/EN/Laws/details.aspx?id=71](http://www.jfda.jo/EN/Laws/details.aspx?id=71)

MoH 1972 Laws and Regulations of the Jordanian Pharmacists' Union (Arabic):  
[www.moh.gov.jo/MOH/En/rules\\_regulationsdetails.php?ruleid=93](http://www.moh.gov.jo/MOH/En/rules_regulationsdetails.php?ruleid=93)

JU Faculty of Pharmacy,

[www.ju.edu.jo/faculties/facultyofPharmacy/Pages/QuickLinks/OutcomesandAchievements.aspx](http://www.ju.edu.jo/faculties/facultyofPharmacy/Pages/QuickLinks/OutcomesandAchievements.aspx)



## Section 9 - Household data/access

This section provides information derived from past household surveys in Jordan regarding actual access to medicines by normal and poor households.

In the past 5 years, 1 household survey has been undertaken to assess the access to medicines: WHO Level II Assessment, Household Medicines Survey (2011 DRAFT)<sup>42</sup>

In Jordan, of the adult patients with an acute condition, 76.9 % took all medicines prescribed by an authorized prescriber. 0.11 % of adult patients with an acute condition did not take all medicines prescribed to them because they could not afford them.

Of the adult patients from poor households with an acute condition 0.04 % did not take all medicines because they could not afford them.

0 % of adults from poor households with chronic conditions did not take all medicines prescribed to them because they could not afford them.

The percentage of people with recent acute illness who obtained the medicines prescribed for free was 43.<sup>42</sup>

### Further information and key findings:

Data was calculated from the survey. The "poorest income level" (<50 JOD 4-week spending/person) was used as the "poor household.

Percentage of adult patients with an acute condition who took all medicines prescribed by an authorized prescriber was calculated from the data in the survey (table 3-17) because it was disaggregated into sick persons with an acute illness perceived as very serious, moderately serious and not serious. The survey does not say whether this is for within the two-week recall period.<sup>42</sup>



## **List of key reference documents:**

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- <sup>2</sup> World Health Statistics 2009, Geneva, World Health Organization, 2009; Available from: [www.who.int/whosis/whostat/2009/en/index.html](http://www.who.int/whosis/whostat/2009/en/index.html), 10-05-2011.
- <sup>3</sup> Ministry of Health Report 2010, Department of Statistics, available at: [www.moh.gov.jo/MOH/En/publications.php](http://www.moh.gov.jo/MOH/En/publications.php)
- <sup>4</sup> Jordan National Health accounts 2008 (Jordan NHA 2008), 2011; Available from: [www.who.int/nha/country/jor/en/](http://www.who.int/nha/country/jor/en/), 15-05-2011.
- <sup>5</sup> High Health Council National Strategy (Arabic), High Health Council Jordan. Available from: [www.hhc.gov.jo/HHC/%D8%A7%D9%84%D8%A7%D8%B3%D8%AA%D8%B1%D8%A7%D8%AA%D9%8A...pdf](http://www.hhc.gov.jo/HHC/%D8%A7%D9%84%D8%A7%D8%B3%D8%AA%D8%B1%D8%A7%D8%AA%D9%8A...pdf), 15-05-2011.
- <sup>6</sup> Jordan National Drug Policy (NDP), MoH Jordan, 2002;
- <sup>7</sup> The Constitution of The Hashemite Kingdom of Jordan; Available from: [www.kinghussein.gov.jo/constitution\\_jo.html](http://www.kinghussein.gov.jo/constitution_jo.html), 15-05-2011.
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Patent Regulations official Gazette No. 4522 dated 13.12.2001. Available at: [www.jfda.jo/custom/law/53.doc](http://www.jfda.jo/custom/law/53.doc).
- <sup>12</sup> JFDA Registration Department, unpublished, 2010; [www.jfda.jo/](http://www.jfda.jo/);
- <sup>13</sup> Prime Ministry Millennium Challenge Account - 3.3 Pharmaceutical Industry, 2008; Available from: [www.mca-jordan.gov.jo/index.php?page\\_type=pages&page\\_id=259](http://www.mca-jordan.gov.jo/index.php?page_type=pages&page_id=259), 15-05-2011.
- <sup>14</sup> JFDA; Available from: [www.jfda.jo/Default.aspx](http://www.jfda.jo/Default.aspx), 15-05-2011.
- <sup>15</sup> JFDA Drug and Pharmacy Law 2001, JFDA, 2001. Available from: [www.jfda.jo/EN/Laws/details.aspx?id=71](http://www.jfda.jo/EN/Laws/details.aspx?id=71), 15-05-2011.
- <sup>16</sup> JFDA Registration Criteria, JFDA. Available from: [www.jfda.jo/EN/Laws/details.aspx?id=72](http://www.jfda.jo/EN/Laws/details.aspx?id=72), 15-05-2011.



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- <sup>17</sup> JFDA Law, JFDA, 2003. Available from: [www.jfda.jo/custom/law/22.doc](http://www.jfda.jo/custom/law/22.doc), 15-05-2011.
- <sup>18</sup> JFDA Inspection Department. unpublished. 2010;
- <sup>19</sup> Accreditation of Manufacturing Sites Regulations, Re-evaluation and Cancellation for the Year 2008, JFDA. Available from: [www.jfda.jo/custom/law/52.doc](http://www.jfda.jo/custom/law/52.doc), 15-05-2011.
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[www.jpd.gov.jo/ReadPaner.php?id=115&sub\\_id=6](http://www.jpd.gov.jo/ReadPaner.php?id=115&sub_id=6), 17-05-2011.

<sup>37</sup> Governing Joint Procurements Procedures Of Drugs/General Terms, Joint Procurement Department. Available from: [www.jpd.gov.jo/ReadPaner.php?id=184&sub\\_id=181](http://www.jpd.gov.jo/ReadPaner.php?id=184&sub_id=181), 17-05-2011.

<sup>38</sup> Tender Invitation Form, Criteria, Joint Procurement Department. Available from: [www.jpd.gov.jo/images/pic/ZZ060402092259.pdf](http://www.jpd.gov.jo/images/pic/ZZ060402092259.pdf), 17-05-2011.

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<sup>40</sup> MoH / Jordanian Union for Doctors / Nurses (1972)

<sup>41</sup> Ph. Adi Nuseirat, JFDA, 07-07-2011.

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# Pharmaceutical Sector Country Profile Questionnaire

## Jordan



# The Pharmaceutical Sector Country Profile Survey

## 1. Background and Rationale:

Pharmaceutical Sector Country Profiles aim to increase the availability of quality information on structures, processes and outcomes of health and pharmaceutical sectors of countries. This information will be collected through a questionnaire and is meant to be used by country decision-makers, health and pharmaceutical experts, international partners and the public through databases and published country, regional and global reports.

The information is categorized in nine sections, namely: (1) Health and Demographic data, (2) Health Services, (3) Medicines Policies, (4) Medicines Trade and Production, (5) Medicines Regulation, (6) Medicines Financing, (7) Pharmaceutical Procurement and distribution, (8) Selection and Rational Use and (9) Household data/access.

Every four years since 1999, health officials from the 193 WHO Member States have been invited to complete a standardized questionnaire (named Level I) reporting on the status of the national pharmaceutical situation. Level I indicators assessed structures and processes related to the pharmaceutical situation of a country. They were used to carry out a rapid assessment that would highlight strengths and weaknesses of countries pharmaceutical situations. 156 countries responded to the 2007 level I survey and the results were stored and available in a global WHO database and used to develop a global report as well as a number of regional and sub-regional reports. The Pharmaceutical Sector Country Profile questionnaire described here will replace the Level I tool for the 2011 Member States' survey. The aim of this new approach is to build on the achievements and lessons learnt from the Level I tools and surveys and to improve the quality and scope of information (e.g, outcomes and results indicators) and enhance the involvement and ownership of countries in the development of profiles. The new tool has been piloted in the 15 countries of the Southern African Development Community in 2009 and in 13 countries across the world in 2010. The results of these pilots are available on-line at:

[http://www.who.int/medicines/areas/coordination/coordination\\_assessment/en/index.html](http://www.who.int/medicines/areas/coordination/coordination_assessment/en/index.html)

Another innovation of the 2011 survey is the collaboration between WHO and The Global Fund. In 2009, the Global Fund developed and introduced the Pharmaceutical and Health Product Management ("PHPM") Country Profile to gradually replace the Procurement and Supply Management ("PSM") Plan. In the course of 2010 both agencies have developed a joint Pharmaceutical Sector Country Profile questionnaire that includes key indicators of the

pharmaceutical sector and that will be used by both agencies as the sole tool for pharmaceutical sector data collection in countries. The information captured in the Pharmaceutical Sector Country Profile questionnaire will be used by the Global Fund during grant negotiations and signing, and will also support grant implementation. In addition to the Country Profile that provides an overview of countries' pharmaceutical sectors, the Global Fund will also use a second questionnaire that will focus in more detail on medicines procurement and supply.

## **2. What can Pharmaceutical Sector Country Profiles offer:**

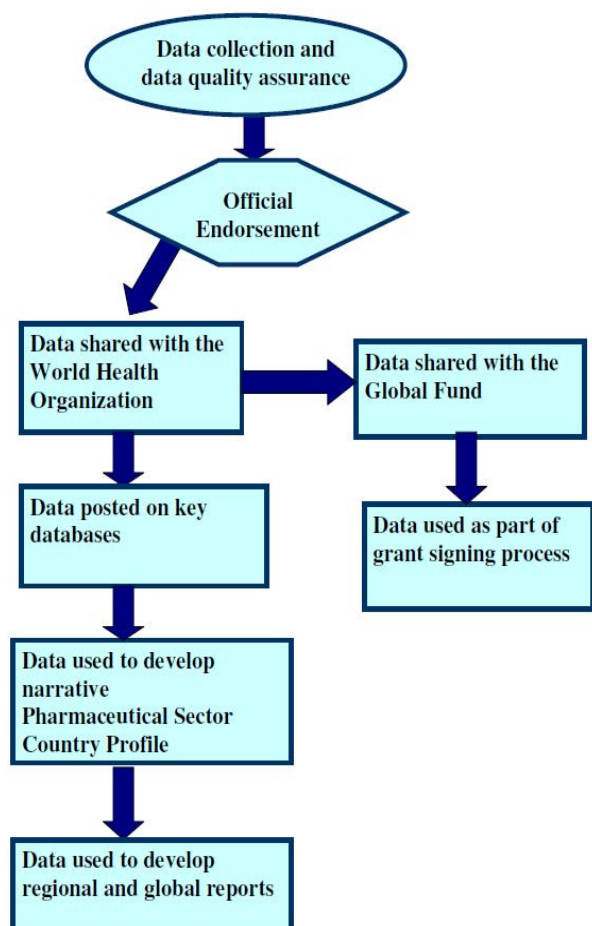
Completing this questionnaire will require the time of national experts and responsible officers but it is worthwhile as your country and your partners will benefit from it in a number of ways:

- I) The questionnaire offers a unique opportunity to consolidate, in one place, information that is available in different locations and institutions e.g. the National Medicines Regulatory Authority, Central Medical Stores, National Health Accounts, etc.
- II) The methodology proposed for filling in the questionnaire will ensure that good quality data are collected and that the source and date of information are known and reported.
- III) Data on structure, process and outcomes are collected, and the questionnaire has been pre-filled with data available in the public domain; indicators are divided into core and supplementary in order to make it easier to identify what is more important.
- IV) The data collected will highlight the strengths and weaknesses of the pharmaceutical sector and will be made available in a national database as official country information, for use by decision-makers, health and pharmaceutical experts, researchers and international partners and the public..
- V) The data collected could be transformed into a narrative report with robust data analysis and bibliographic references, that will summarize the medicines situation in the country.
- VI) Based on experiences from previous surveys, a detailed glossary of key definitions and a manual for use of the questionnaire have been developed and can be found at the end of the questionnaire.

### 3. The process of data collection and analysis:

**3.1 Data collection.** The Pharmaceutical Sector Country Profile questionnaire has already been filled in by WHO with reliable data available from global and country sources. We kindly ask you to review, to correct (if necessary) and to validate the information already included in the questionnaire, and also to fill in the gaps, based on reliable information available in your country.

In order to do this, we recommend that you involve the most appropriate respondents and responsible institutions to fill in the various components of the tool so that the questionnaire is completed within the given deadline, with good quality information. If during the data collection process, clarifications are needed, WHO Regional and Headquarters Offices will provide the necessary assistance and support, including for data quality issues.



**3.2 Official endorsement.** Once the questionnaire has been completed, the information contained in it should be officially endorsed and its disclosure authorized by a senior official in the Ministry of Health. This should be done by signing the formal endorsement form attached to the questionnaire. This will ensure that the quality of the information contained in the Pharmaceutical Sector Country Profile questionnaire is certified by the country.

**3.3 Data shared with the Global Fund.** Data collected from Global Fund priority countries will be shared with the Global Fund and it will be used as part of the Global Fund's own grant signing and implementation procedures.

**3.4 Data posted on key databases.** Data endorsed by the country will be posted on health databases (such as the WHO Global Health Observatory, <http://www.who.int/gho/en/>), making it available to decision-makers, health and medicines experts and researchers, international partners and the public.

**3.5 Development of narrative Pharmaceutical Sector Country Profiles.** Data provided within the country questionnaire can be used by the country to develop a narrative profile that will illustrate the national pharmaceutical sector. In order to do this, WHO has prepared a template profile (included in the CD-Rom shared with you) that can be easily used by countries and that will help presenting data in the form of tables, graphs and charts. Countries could seek support from WHO for the development of their narrative profile, which will be finalized and validated by the country that will own the copyright for it and will publish it as a national official document.

**3.6 Development of Regional and Global Reports.** The information provided by countries in the Pharmaceutical Sector Country Profile questionnaire will be analysed by WHO and used to produce regional and global reports on the pharmaceutical sector of countries in 2011. These reports will provide an overview of the progress made between 2007 and 2011, of the challenges that remain to be addressed and will include data analysis by technical areas, countries' income level and geographical location.

# Guidelines for countries on how to fill in the Pharmaceutical Sector Country Profile Questionnaire

## Please read these instructions carefully before starting data collection

1. Macros: the questionnaire has macros installed. A macro is a series of MS Word commands and instructions that are grouped together as a single command to accomplish a task automatically. For these macros to work properly, the macro security levels for MS Word on your computer should be set as 'low'. This can be easily adjusted by taking the following steps:

1. Open the Word document containing the instrument.
2. Go to 'Tools' > 'Macro' > 'Security'.
3. Click on the tab 'Security Level'.
4. Set the Security on 'Low' and click 'OK'.

After filling in the questionnaire, the setting should be restored to a higher level of security in order to protect your computer.

2. Core and supplementary indicators: the instrument consists of core and supplementary questions. Core questions cover the most important information, while supplementary questions deal with more specific information applicable to particular sections. Please note that core questions have been shaded with different coloured backgrounds for different sections of the instrument, while supplementary questions are all white. This should help you to distinguish between the different categories of indicators. Please try to fill in all the core questions for each section before moving to the supplementary ones. Remember that we are only asking you to collect information that is already available and you are not expected to conduct any additional survey(s).

3. Prefilled data: the answers to some of the questions have been prefilled by WHO HQ. Where this is the case, please verify this information as it may not be up-to-date. If you find that any of the prefilled responses are not correct, please change the value and document the source and year.

4. Calculated fields: for a few items, you will not be required to enter any value as these will be generated at WHO HQ using data entered into related fields. These fields have been clearly marked in red – please do not input any data into them or change data that are already in this field. For example, the per capita expenditure on health will be automatically calculated once the total health expenditure and population are entered into the questionnaire. This system is intended to improve the quality of answers and avoid you having to perform additional calculations. Calculated fields are protected and cannot be changed.

5. Possible answers:

*Checkbox 'Yes/No/Unknown':* tick one of the three options (only one answer is possible).

*Multiple choice checkbox:* tick any of the options that apply (multiple answers are sometimes possible).

*Percentage fields:* 0-100. Please use decimal points ('dots') for decimals (example: 98.11). Please do not use ranges (e.g. "3-5"). If you only have ranges, then use the median and otherwise the mean. In this instance, please detail what data you have used and what the range is in the comment boxes.

*Number fields:* unlimited number. Please use decimal points ('dots') for decimals (example: 29387.93). Please do not use ranges. If you only have ranges, then use the median and otherwise the mean. In this instance, please detail what data you have used and what the range is in the comment boxes.

6. Comments: comments fields allow the entry of free text to clarify or follow up on answers given. Please reference each comment by using the number of the question you are referring to (example: 2.01.02).

7. Year of data : year fields should be used to specify the year of the **data** used to answer the question. Only values between 1930 and 2011 will be accepted. Please use this column as follows:

- When the source refers directly to a specific document (for example: 'Medicines Act' or 'EML'), please put in the publication year of the document (note: only the year and not a specific date can be entered).
- When the source refers to a document that contains older data than the document itself, please put in the original year of the data. For example, when the total population for 2008 is extracted from the World Health Statistics 2010, please put 2008 in the 'year' column and 'World Health Statistics 2010' in the 'source' column.
- When the source of the information is not a document, but the informant himself/herself, please put in the current year.

**8. Source of data:** sources used for the answers given will be referenced in the narrative country profile and in the databases in which the information will be stored. Please specify your sources as clearly as possible by providing the name, year, and writer/publisher of the documents used. Also provide a web (URL) link to the documents, if available. If there is only a non-English version of the reference available, then please include it regardless of the language. Use the 'source' column to enter the name and year of the **source**, and use the "Comments and References" fields at the end of every section to list the sources. In case the source is not documented, then provide the name and title of the person and/or the entity they work for as a source of information. Examples are given below.

7.01.12S	Which of the following <a href="#">tender</a> methods are used in public sector procurement		1996	DoH, 1996
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 type="checkbox"/> No <input type="checkbox"/>		
7.01.13S	Comments and References	National Drug Policy for South Africa , published in 1996. Document availablilt at: <a href="http://www.doh.gov.za/docs/policy/drugsjan1996.pdf">http://www.doh.gov.za/docs/policy/drugsjan1996.pdf</a>		

**9. Documents:** you will see in the questionnaire that we would like you to collect and share a number of key country documents that we believe would greatly enrich the country's profile content and these documents could be made available through countries and WHO web pages. Please attach the following documents, if available:

- 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);
- Pharmacovigilance national centre report (including an Adverse Drug Reaction (ADR), analysis report produced in the last two years);
- National pharmaceutical legislation or 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 antimicrobial resistance;
- Any other medicines pricing/availability surveys, household surveys and rational use surveys, in addition to the ones used to prefill the instrument.

The last page of the questionnaire contains a table with the list of key documents to be attached. Please fill it in by indicating the exact title, publisher and year for each attachment as shown in the example below.

Document	Exact title	Author	Publisher	Year	File name
<b>Essential Medicines List</b>	National Medicines List	Ministry of Health	Ministry of Health	2009	EML.doc
<b>National Medicines Policy</b>	National Drug Policy	Federal Ministry of Health	Federal Ministry of Health	2005	NDP.pdf

These documents will be published on the WHO web site's medicines library (<http://apps.who.int/medicinedocs/en/>) and will therefore have to be endorsed by the Ministry of Health prior to being made publicly available. You can send us these documents by e-mail as attachments or you can upload them into a protected web site. Please use the table at the end of the instrument to report the title, year and author of the documents attached.

10. Attaching files to the questionnaire: please place all files to be attached in a single folder on your computer. Name the documents as follows: <short name of the document>.doc (example: EML.doc). Then compress (ZIP) the files and attach the compressed file with the completed instrument to the email. If the total file size of the compressed file exceeds 7 MB, you can upload the documents in a protected file server called MedNet, which is managed by WHO. The procedure for doing this is very simple and please contact Mr Enrico Cinnella in WHO HQ, Geneva, ([cinnellae@who.int](mailto:cinnellae@who.int)) to be granted access to MedNet and to receive instructions on how to upload files. You can also upload documents to the WHO Medicines Documentation server at <http://hinfo.humaninfo.ro/medicinedocs/>, though the documents will only appear on the Medicines Documentation site at the beginning of the following month.



**11. Manual for use of the questionnaire:** the manual contains detailed instructions on the questionnaire, on where to find information and how to answer questions.

Questions that may be particularly problematic are marked with the following icon:



**12. Glossary:** the glossary contains definitions for all key and/or problematic items in the instrument. It is highly recommended that you use the glossary, since exact definitions might differ between countries and institutions. The glossary is at the end of the file. When a question contains an item that is defined in the glossary, the terms will be marked in bold, underlined and written in blue font.

2.02 Health Personnel and Infrastructure				
Core questions <a href="#">(click for help)</a>				
			Year	Source
2.02.01	Total number of pharmacists licensed/registered to practice in your country			
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 <u>pharmaceutical technicians and assistants</u>			
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"/>		

definition of "pharmaceutical technicians and assistants" is in the glossary

Instructions are available for this specific question

**13. Respondents and acknowledgements:** at the beginning of every section there are fields available to fill in details about the respondent for that particular section. It is also possible to enter the details of multiple respondents. At the end of the instrument please add a list of contributors who should be acknowledged. Provide their names and the main organization(s) they work for.

**14. Endorsement of data:** A formal endorsement needs to be signed by a senior official in the Ministry of Health before the completed questionnaire is sent back to WHO. The endorsement form is included in the pack of CD-ROM documents you have received from WHO. Please present the endorsement form to a senior official in the Ministry of Health for signature, and for obtaining permission to use and publish the data.

15. Process of creating a country profile document: The data you will collect using this questionnaire can be used to develop a pharmaceutical sector country profile for the country. Examples of profiles are available on-line at [http://www.who.int/medicines/areas/coordination/coordination\\_assessment/en/index1.html](http://www.who.int/medicines/areas/coordination/coordination_assessment/en/index1.html)

WHO has prepared a template profile (included in the CD) that can be easily used by countries and that will help presenting data in the form of tables, graphs and charts. Countries can use the generic template provided by WHO and add the information in the questionnaire. Below you can find an example of the template that shows how fields can be changed according to the specific responses provided by each country.

### 3.2 Intellectual Property Laws and Medicines

Country X is/is not a member of the World Trade Organization. The country has/has no patent law. National Legislation has/has not been modified to implement the TRIPS Agreement. Country X is/is not eligible for the transitional period to 2016.

The following (TRIPS) flexibilities and safeguards are present in the national law:

Compulsory licensing provisions that can be applied for reasons of public health	Yes/No
--	--------

In each section of the questionnaire you will find some comment boxes that you can use to expand on the answer to one or more questions. The text of these comments can also be included in the profile in order to present the country situation in more detail.

In the questionnaire you are also asked to indicate the source and date of each piece of information you provide; these should be used to develop bibliographic references for the profile.

If you prefer, WHO can develop the narrative profile and the Organization will then share the document with the country, which will own/maintain the copyright for it and will be able to publish it as a national document.

## Section 0 General Info

### 0.01 Contact Info

0.01.01	Country (precoded)	Jordan-RV
0.01.02	Name coordinator	Salah Gammouh
0.01.03	Address (Street, City)	PO Box 811547
0.01.04	Phone number	+962 79 743 4560
0.01.05	Email address	salahgammouh@gmail.com
0.01.06	Web address	
0.01.07	Institution	WHO Jordan

## 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	<a href="#">Population</a> , total (,000)	6,113	2010	Department of Statistics, Ministry of Health Report 2010
1.01.02	Population growth rate (Annual %)	2.2	2010	Department of Statistics, Ministry of Health Report 2010
1.01.03	Total <a href="#">Gross Domestic Product</a> (GDP) (millions US\$)	27,573.536	2010	World bank data
1.01.04	GDP growth (Annual %)	3.1	2010	Department of Statistics, Ministry of Health Report 2010

1.01.05C	<a href="#">GDP</a> per capita (US\$ current <a href="#">exchange rate</a> )	4,512	2010	Department of Statistics, Ministry of Health Report 2010
1.01.06	Comments and References	Department of Statistics, Ministry of Health Report, 2010		
Supplementary questions ( <a href="#">click here for help</a> )				
			Year	Source
1.01.07S	Population < 15 years (% of total population)	36	2007	World Health Statistics
1.01.08S	Population > 60 years (% of total population)	5	2007	World Health Statistics
1.01.09S	Urban population (% of total population)	78	2007	World Health Statistics
1.01.10S	Fertility rate, total (Births per woman)	3.1	2007	World Health Statistics
1.01.11S	Population living with less than \$1.25/day (international PPP) (%)	1	2005	World Health Statistics
1.01.12S	Population living below nationally defined poverty line (%)	13.3	2008	Jordan Dept. of Statistics
1.01.13S	Income share held by lowest 20% of the population (% of national income)	6.7	2005	World Bank 2007 Global Monitoring Report
1.01.14S	Adult literacy rate, 15+ years (% of relevant population)	93.1	2007	World Health

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				Statistics
1.01.15S	Comments and References			
1.02 Mortality and Causes of Death				
Core questions ( <a href="#">click here for help</a> )				
			Year	Source
1.02.01	<a href="#">Life expectancy at birth</a> for men (Years)	71.6	2010	MOH Report
1.02.02	Life expectancy at birth for women (Years)	74.4	2010	MOH Report
1.02.03	<a href="#">Infant mortality rate</a> , between birth and age 1 (/1,000 live births)	23	2010	MOH Report
1.02.04	<a href="#">Under 5 mortality rate</a> (/1,000 live births)	28	2010	MOH Report
1.02.05	<a href="#">Maternal mortality ratio</a> (/100,000 live births)	19.1	2010	MOH Report
1.02.06	Please provide a list of top 10 diseases causing mortality 		2006	World Health Statistics
1.02.06.01	Disease 1	Ishaemic Hearth Disease		
1.02.06.02	Disease 2	Congenital anomalies		
1.02.06.03	Disease 3	Cerebrovascular Disease		
1.02.06.04	Disease 4	Lower Respiratory Infections		
1.02.06.05	Disease 5	Self inflicted		
1.02.06.06	Disease 6	Diarrhoeal Diseases		
1.02.06.07	Disease 7	Perinatal Conditions		
1.02.06.08	Disease 8	Breast Cancer		

1.02.06.09	Disease 9	Nephritic																		
1.02.06.10	Disease 10																			
1.02.07	Please provide a list of top 10 diseases causing morbidity																			
1.02.07.01	Disease 1																			
1.02.07.02	Disease 2																			
1.02.07.03	Disease 3																			
1.02.07.04	Disease 4																			
1.02.07.05	Disease 5																			
1.02.07.06	Disease 6																			
1.02.07.07	Disease 7																			
1.02.07.08	Disease 8																			
1.02.07.09	Disease 9																			
1.02.07.10	Disease 10																			
1.02.08	Comments and References																			
<b>Supplementary questions</b> <a href="#">(click here for help)</a>																				
		<table border="1"> <thead> <tr> <th></th> <th>Year</th> <th>Source</th> </tr> </thead> <tbody> <tr> <td>1.02.09S</td> <td>Adult mortality rate for both sexes between 15 and 60 years (/1,000 population)</td> <td>150</td> <td>2007</td> <td>World Health Statistics</td> </tr> <tr> <td>1.02.10S</td> <td>Neonatal mortality rate (/1,000 live births)</td> <td>16</td> <td>2004</td> <td>World Health Statistics</td> </tr> <tr> <td>1.02.11S</td> <td>Age-standardized mortality rate by non-communicable diseases (/100,000 population)</td> <td>711</td> <td>2004</td> <td>World Health Statistics</td> </tr> </tbody> </table>		Year	Source	1.02.09S	Adult mortality rate for both sexes between 15 and 60 years (/1,000 population)	150	2007	World Health Statistics	1.02.10S	Neonatal mortality rate (/1,000 live births)	16	2004	World Health Statistics	1.02.11S	Age-standardized mortality rate by non-communicable diseases (/100,000 population)	711	2004	World Health Statistics
	Year	Source																		
1.02.09S	Adult mortality rate for both sexes between 15 and 60 years (/1,000 population)	150	2007	World Health Statistics																
1.02.10S	Neonatal mortality rate (/1,000 live births)	16	2004	World Health Statistics																
1.02.11S	Age-standardized mortality rate by non-communicable diseases (/100,000 population)	711	2004	World Health Statistics																

1.02.12S	Age-standardized mortality rate by cardiovascular diseases (/100,000 population)	433	2004	World Health Statistics
1.02.13S	Age-standardized mortality rate by cancer ( /100,000 population)	126	2004	World Health Statistics
1.02.14S	<a href="#">Mortality rate</a> for HIV/AIDS (/100,000 population)			
1.02.15S	Mortality rate for tuberculosis (/100,000 population)	1	2007	World Health Statistics
1.02.16S	Mortality rate for Malaria (/100,000 population)			
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)	1,381	2008	NHA 2008
2.01.01.02	Total annual expenditure on health (millions US\$ average exchange rate)	1,951	2008	NHA 2008
2.01.02C	Total health expenditure as % of <a href="#">Gross Domestic Product</a>	8.58		
2.01.03.01C	Total annual <a href="#">expenditure on health</a> per capita (NCU)	236		
2.01.03.02C	Total annual expenditure on health per capita (US\$ average exchange rate)	333		
2.01.04.01	<a href="#">General government annual expenditure</a> on health (millions NCU)	787	2008	NHA
2.01.04.02	General government annual expenditure on health (millions US\$ average exchange rate)	1,112	2008	NHA
2.01.05	Government annual expenditure on health as percentage of total government budget (% of total government budget)	57	2008	NHA


2.01.06C	Government annual expenditure on health as % of total expenditure on health (% of total expenditure on health)	10.16	2008	NHA
2.01.07.01C	Annual per capita government expenditure on health (NCU)	126		
2.01.07.02C	Annual per capita government expenditure on health (US\$ average exchange rate)	172		
2.01.08C	<a href="#">Private health expenditure</a> as % of total health expenditure (% of total expenditure on health)	37.5	2008	NHA
2.01.09	Population covered by a public health service or public health insurance or <a href="#">social health insurance</a> , or other <a href="#">sickness funds</a> of total population) 	75	2008	NHA
2.01.10	Population covered by private health insurance (% of total population) 	8	2008	NHA
2.01.11.01	Total pharmaceutical expenditure (millions NCU)	496.4	2008	NHA
2.01.11.02	Total pharmaceutical expenditure (millions US\$ current exchange rate)	701	2008	NHA
2.01.12.01C	Total pharmaceutical expenditure per capita (NCU)	84.86		
2.01.12.02C	Total pharmaceutical expenditure per capita (US\$ current exchange rate)	120		
2.01.13C	Pharmaceutical expenditure as a % of GDP (% of GDP)	3.08		
2.01.14C	Pharmaceutical expenditure as a % of <a href="#">Health Expenditure</a> (% of total health expenditure)	35.94		

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2.01.15.01	Total public expenditure on pharmaceuticals (millions NCU)			
2.01.15.02	Total public expenditure on pharmaceuticals (millions US\$ current exchange rate)			
2.01.16C	Share of public expenditure on pharmaceuticals as percentage of total expenditure on pharmaceuticals (%)	38.44	2008	NHA
2.01.17.01C	Total public expenditure on pharmaceuticals per capita (NCU)	32.6		
2.01.17.02C	Total public expenditure on pharmaceuticals per capita (US\$ current exchange rate)	46		
2.01.18.01	Total private expenditure on pharmaceuticals (millions NCU)	196.4	2007	WHO NHA
2.01.18.02	Total private expenditure on pharmaceuticals (millions US\$ current exchange rate)	276.6	2007	WHO NHA
2.01.19	Comments and References	2.01.09 75% is covered by a public health service (MOH 34%, RMS 23%, UNRWA 9%, Private Health Insurance 8%), 25% without health insurance. Population covered by public insurance is calculated from the numbers reported in Jordan NHA 2008 using the total population for that year.		





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

			Year	Source
2.01.20S	<a href="#">Social security</a> expenditure as % of government expenditure on health (% of government expenditure on health)	0.3	2008	WHO NHA
2.01.21S	Market share of generic pharmaceuticals <a href="#">branded</a> and <a href="#">INN</a> 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 <a href="#">out-of-pocket</a> expenditure as % of private health expenditure (% of private expenditure on health)	88.4	2008	WHO NHA
2.01.25S	Premiums for private prepaid health plans as % of total private health expenditure (% of private expenditure on health)	6.9	2008	WHO NHA
2.01.26S	Comments and References	Population covered by public insurance service is calculated from numbers reported in Jordan NHA 2007 using the total population for that year. For each sector (except University), the % of population covered is calculated directly from the number of people covered as reported, divided by the total population during that year according to the NHA: 33.8% MoH, 27.2% RMS, and 1% University		

## 2.02 Health Personnel and Infrastructure



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

			Year	Source
2.02.01	<b>Total number</b> of pharmacists licensed/registered to practice in your country 	9,160	2010	MOH Report
2.02.02C	Pharmacists per 10,000 population	15		
2.02.03	Total number of pharmacists working in the public sector 	439	2010	MOH Report
2.02.04	Total number of <a href="#">pharmaceutical technicians and assistants</a> 	6,540	2010	MOH Report
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"/>		

Pharmaceutical Sector Country Profile Questionnaire.

2.02.06	Total number of physicians	16,200	2010	MOH report
2.02.07C	Physicians per 10,000 pop	26.5		
2.02.08	Total number of <a href="#">nursing and midwifery personnel</a>	25,600	2010	MOH report
2.02.09C	Nurses and midwives per 10,000 pop	41.9		
2.02.10	Total number of hospitals	106	2010	MOH Report
2.02.11	Number of hospital beds per 10,000 pop	19	2010	MOH Report
2.02.12	Total number of primary health care units and centers	1,492	2010	MOH Report
2.02.13	Total number of licensed pharmacies 	1,919	2010	MOH Report
2.02.14	Comments and References	<p>In the National Health Strategy 2008-12, strategic objectives for the number of health care workers are stated. However, technical development is not addressed and the strategy does not include an actual working plan. Similarly, the MoH Strategic Plan 2008-2012 also lacks specific plans, and does not address pharmacy. The Human Resource Project 92004-2006) for MoH also includes only projections on numbers of HCW required.</p> <p>2.02.12: 1,492 PHC units include comprehensive health center: 84, primary health centres 368, peripheral health centers: 227, MCH centers 432, chest disease centers:12, dental clinic: 369).</p>		

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

			Year	Source
2.02.15S	Starting annual salary for a newly registered <a href="#">pharmacist</a> in the public sector (NCU) 			
2.02.16S	Total number of pharmacists who graduated (first degree) in the past 2 years in your country 	2,370	2007	Human Resources for Health 2010

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2.02.17S	Are there <a href="#">accreditation</a> requirements for pharmacy schools?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2009	Minister for Higher Education Law No. 23
2.02.18S	Is the Pharmacy Curriculum regularly reviewed?	Yes <input type="checkbox"/> No <input 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	<a href="#">National Health Policy</a> exists. If yes, please write year of the most recent document in the "year" field. 	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2009	High Health Council
3.01.02	<a href="#">National Health Policy Implementation plan</a> 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	<a href="#">National Medicines Policy</a> 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"/>	2002	JFDA
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 <a href="#">Essential Medicines</a>	<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 <a href="#">Procurement</a>	<input checked="" type="checkbox"/> Yes		
3.01.06.05	Medicines <a href="#">Distribution</a>	<input checked="" type="checkbox"/> Yes		
3.01.06.06	Medicines <a href="#">Regulation</a>	<input checked="" type="checkbox"/> Yes		
3.01.06.07	<a href="#">Pharmacovigilance</a>	<input checked="" type="checkbox"/> Yes		
3.01.06.08	<a href="#">Rational Use of Medicines</a>	<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	<a href="#">Traditional Medicine</a>	<input 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 checked="" type="checkbox"/>	2010	MOH
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 checked="" type="checkbox"/> No <input type="checkbox"/>	2010	MOH



	national legislation?			
3.01.11	There are official written guidelines on medicines donations.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2007	WHO Level I
3.01.12	Is pharmaceutical policy implementation being regularly monitored/assessed? 	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	MOH
3.01.12.01	Who is responsible for pharmaceutical policy monitoring?			
3.01.13	Is there a national <a href="#">good governance policy</a> ?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
3.01.13.01	Multisectoral 	<input type="checkbox"/> Yes	2010	MOH
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 <a href="#">conflict of interest</a> issues in pharmaceutical affairs.	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	MOH
3.01.15	There is a formal code of conduct for public officials.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Prime Ministry
3.01.16	Is there a <a href="#">whistle-blowing</a> mechanism allowing individuals to raise a concern about wrongdoing occurring in the pharmaceutical sector of your country (ombudsperson)?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2005	Anti-corruption Commission
3.01.16.01	Please describe:			
3.01.17	Comments and References	<p>Currently there is not a national good governance policy, however the government has taken steps toward such a policy by creating code of conduct for public employees, the Anti-Corruption Committee, and currently the work with WHO in creating the document "A framework for good governance in the Pharmaceutical Sector"</p> <p>While not specific to pharmaceutical sector, the Anti-Corruption Commission includes a mechanism of reporting</p>		

		wrongdoing/corruption.
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## 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	<a href="#">Pharmaceuticals</a>	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 <a href="#">URL</a>			
4.01.04	National Legislation has been modified to implement the <a href="#">TRIPS Agreement</a>	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"/>	2007	WHO Level I
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	<a href="#">Compulsory licensing</a> provisions that can be applied for reasons of public health	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
4.01.07.02	<a href="#">Bolar exception</a>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
4.01.08	Are <a href="#">parallel importing</a> 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"/>	2008	Ministry of Industry and Trade (MIT)
4.01.10	Are there legal provisions for <a href="#">data exclusivity</a> for pharmaceuticals	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	1998	MIT
4.01.11	Legal provisions exist for <a href="#">patent</a> extension	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2001	MIT
4.01.12	Legal provisions exist for linkage between patent status and <a href="#">Marketing Authorization</a>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2000	MIT
4.01.13	Comments and References			
<b>4.02 Manufacturing</b>				
<b>Core questions (<a href="#">click here for help</a>)</b>				
			Year	Source
4.02.01	Number of licensed pharmaceutical <a href="#">manufacturers</a> in the country 	16	2010	JFDA Registration Department

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4.02.02	Country has manufacturing capacity	<input type="checkbox"/>	2007	WHO Level I
4.02.02.01	R&D to discover new active substances	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>		
4.02.02.02	Production of pharmaceutical starting materials ( <a href="#">APIs</a> )	Yes <input checked="" type="checkbox"/> No <input 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 (%)	33	2008	Jordan Prime Ministry
4.02.04	Comments and References			
<b>Supplementary questions (<a href="#">click here for help</a>)</b>				
			Year	Source
4.02.05S	Percentage of market share by volume produced by domestic manufacturers (%) 	50	2008	Jordan Prime Ministry
4.02.06S	Number of multinational pharmaceutical companies manufacturing medicines locally	9	2010	JFDA Registration Department
4.02.07S	Number of manufacturers that are <a href="#">Good Manufacturing Practice</a> (GMP) certified 	16	2010	JFDA Inspection Department
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 <a href="#">Medicines Regulatory Authority</a> (MRA)? 	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2007	WHO Level I
5.01.02	There is a Medicines Regulatory Authority	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2003	JFDA
5.01.03	If yes, please provide name and address of the Medicines regulatory authority			
5.01.04	The Medicines Regulatory Authority is: 		2003	JFDA
5.01.04.01	Part of MoH	<input type="checkbox"/> Yes		
5.01.04.02	Semi autonomous agency	<input checked="" 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	<a href="#">Marketing authorization</a> / 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	<a href="#">Licensing</a>	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	<a href="#">Quality control</a>	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	<a href="#">Clinical trials</a> control	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.01.05.09	<a href="#">Pharmacovigilance</a>	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 checked="" type="checkbox"/> No <input type="checkbox"/>	2006	JFDA
5.01.07.01	- If yes, please provide MRA site address (URL)	Web <a href="http://www.jfda.jo/EN/default/">http://www.jfda.jo/EN/default/</a>		
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 checked="" type="checkbox"/> No <input type="checkbox"/>	2007	WHO Level I
5.01.09.01	- If yes, please specify	An example is the "Framework for good governance in the pharmaceutical sector" document: <a href="http://www.emro.who.int/edb/media/pdf/JOD_MIS_E_10.PDF">www.emro.who.int/edb/media/pdf/JOD_MIS_E_10.PDF</a>		
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	JFDA



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5.01.11	Medicines Regulatory Authority gets funds from regular budget of the government.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2003	JFDA Law Article 12
5.01.12	Medicines Regulatory Authority is funded from fees for services provided.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2003	JFDA Law Article 12
5.01.13	Medicines Regulatory Authority receives funds/support from other sources	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2007	WHO Level I
5.01.13.01	- If yes, please specify			
5.01.14	Revenues derived from <a href="#">regulatory activities</a> are kept with the Regulatory Authority 	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2003	JFDA Law Article 12
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	JFDA Departments
5.01.16	Comments and References	<p>5.01.10 While the JFDA Law does allocate appropriations to the JFDA from the treasury, the JFDA has been functioning self sufficiently since inception and excess sums of money are translated to the treasury by year end</p> <p>5.01.15 Some departments do use simple programs to keep track of their work activities based on individual initiative; however, there is not a standard computerized management system for registration, inspection, etc.</p>		
5.02 Marketing Authorization (Registration)				
Core questions ( <a href="#">click here for help</a> )				
			Year	Source
5.02.01	Legal provisions require a <a href="#">Marketing Authorization</a> (registration) for all pharmaceutical products on the	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2001	JFDA: Drug & Pharmacy

	market			Law
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:			
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"/>	2001	JFDA: Registratio n Criteria
5.02.05	Information from the <a href="#">prequalification</a> 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	7,700	2010	JFDA Registratio n Department
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"/>	2010	JFDA
5.02.07.01	If yes, how frequently updated 			
5.02.07.02	If yes, please provide updated list or <a href="#">URL</a> *			
5.02.08	Medicines registration always includes the <a href="#">INN (International Non-proprietary Names)</a>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2001	JFDA: Registratio n Criteria
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	JFDA: Registratio n Criteria

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5.02.10	Comments and References			
Supplementary questions ( <a href="#">click here for help</a> )				
			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"/>	2001	JFDA: Drug & Pharmacy Law and Registration Criteria
5.02.12S	Legal provisions require publication of a <a href="#">Summary of Product Characteristics (SPCs)</a> of the medicines registered	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	JFDA
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"/>	2001	JFDA: Drug and Pharmacy Law
5.02.14S	<a href="#">Certificate for Pharmaceutical Products</a> 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"/>	2007	WHO Level I
5.02.15S	Legal provisions require declaration of potential <a href="#">conflict of interests</a> for the experts involved in the assessment and decision-making for registration	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	JFDA
5.02.16S	Legal provisions allow applicants to appeal against MRAs decisions	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2001	JFDA Registration Criteria
5.02.17S	Registration fee - the amount per application for pharmaceutical product containing <a href="#">New Chemical Entity (NCE)</a> (US\$) 	2119	2010	JFDA Registration Criteria
5.02.18S	Registration fee - the Amount per application for a <a href="#">generic</a> pharmaceutical product 	847	2010	JFDA Registration Criteria

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	(US\$)			
5.02.19S	Time limit for the assessment of a Marketing Authorization application (months)	6	2010	JFDA Registration Criteria
5.02.20S	Comments & References			
<b>5.03 Regulatory Inspection</b>				
<b>Core Questions</b> ( <a href="#">click here for help</a> )				
			Year	Source
5.03.01	Legal provisions exist allowing for appointment of government pharmaceutical inspectors	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2001	JFDA Law Drug & Pharmacy Law
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"/>	2001	JFDA Law Drug & Pharmacy Law
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 checked="" 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 type="checkbox"/>		
5.03.05.01	Local manufactures are inspected for GMP compliance	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.03.05.02	Private <a href="#">wholesalers</a> are inspected	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.03.05.03	<a href="#">Retail distributors</a> 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	There are 10 inspectors for pharmacies and 7 for manufacturers, It is completed with district pharmacists from the Ministry of Health who are in charge of inspection for pharmacies in their respective districts.
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"/>	2001	Drug and Pharmacy Law
5.04.02	Legal provisions exist allowing the sampling of imported products for testing	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2001	Drug and Pharmacy Law
5.04.03	Legal provisions exist requiring importation of medicines through authorized ports of entry	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
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"/>	2001	Drug and Pharmacy Law
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"/>	2008	JFDA Laws and Regulation

Pharmaceutical Sector Country Profile Questionnaire.

5.05.02	Legal provisions exist requiring both domestic and international manufacturers to comply with <a href="#">Good manufacturing Practices (GMP)</a>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2008	JFDA Laws and Regulation
5.05.02.01	If no, please explain			
5.05.03	GMP requirements are published by the government.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	JFDA Laws and Regulation
5.05.04	Legal provisions exist requiring importers to be licensed	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2001	JFDA Laws and Regulation
5.05.05	Legal provisions exist requiring wholesalers and distributors to be licensed	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2001	JFDA Laws and Regulation
5.05.06	Legal provisions exist requiring wholesalers and distributors to comply with <a href="#">Good Distributing Practices</a>  <b>When filling in this part, please also fill in the relevant questions in the procurement and distribution section (Section 7)</b>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	JFDA
5.05.07	National Good Distribution Practice requirements are published by the government	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	JFDA
5.05.08	Legal provisions exist requiring pharmacists to be registered	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2001	JFDA Laws and Regulation
5.05.09	Legal provisions exists requiring private pharmacies to be licensed	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2001	JFDA Laws and Regulation
5.05.10	Legal provision exist requiring public pharmacies to be licensed	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2001	JFDA Laws and Regulation

5.05.11	National Good Pharmacy Practice Guidelines are published by the government	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	JFDA
5.05.12	Legal provisions require the publication of a list of all licensed pharmaceutical facilities	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	JFDA
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 checked="" type="checkbox"/> No <input type="checkbox"/>	2001	Drug and Pharmacy Law & JFDA Laws and Regulations
5.06.02	Does a laboratory exist in the country for Quality Control testing?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	JFDA Organizational Structure and Registration Criteria
5.06.02.01	If yes, is the laboratory part of the <a href="#">MRA</a> ?	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 type="checkbox"/>		
5.06.02.03	If yes, please describe			
5.06.03	Is there any national laboratory accepted for collaboration with <a href="#">WHO prequalification Programme</a> ? Please describe.			
5.06.04	Medicines are tested:			


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s <input checked="" type="checkbox"/>				
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 <a href="#">post-marketing surveillance</a> 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?	10049	2009	JFDA Registratio n Department
5.06.07	Total number of samples tested in the last two years that failed to meet quality standards	176	2009	JFDA Registratio n Department
5.06.08	Results of quality testing in past two years are publicly available	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	JFDA
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"/>	2001	Drug and Pharmacy Law Article 35
5.07.02	Who is responsible for regulating, promotion and/or advertising of medicines? Please describe:	Both government and industry. Multinational companies also have their own rules and regulations.		
5.07.03	Legal provisions prohibit direct advertising of prescription medicines to the public	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2010	JFDA
5.07.04	Legal provisions require a pre-approval for medicines advertisements and promotional materials 	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2001	Drug and Pharmacy Law
5.07.05	Guidelines/Regulations exist for advertising and promotion of non-prescription medicines	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2001	Drug and Pharmacy Law
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 checked="" type="checkbox"/> No <input type="checkbox"/>	2009	JFDA Drug Promotion Regulation
5.07.06.01	If yes, the <a href="#">code of conduct</a> applies to domestic manufacturers only, multinational manufacturers only, or both			
	Domestic only	<input type="checkbox"/> Yes		
	Multinational only	<input type="checkbox"/> Yes		
	Both	<input checked="" type="checkbox"/> Yes		
5.07.06.02	If yes, adherence to the code is voluntary	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		

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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 <a href="#">Clinical Trials</a> by the MRA	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2001	Law of Clinical Studies
5.08.02	Legal provisions exist requiring the agreement by an <a href="#">ethics committee/ institutional review board</a> of the Clinical Trials to be performed	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2001	Law of Clinical Studies
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"/>	2001	Law of Clinical Studies
5.08.04	Comments and References			

### 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 checked="" type="checkbox"/>	2010	
5.08.06S	Legal provisions require sponsor, investigator to comply with <a href="#">Good Clinical Practices (GCP)</a>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2001	Law of clinical studies
5.08.07S	National GCP regulations are published by the Government.	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		

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5.08.08S	Legal provisions permit inspection of facilities where clinical trials are performed	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2001	Law of clinical studies
5.08.09S	Comments and References			
<b>5.09 Controlled Medicines</b>				
<b>Core Questions (<a href="#">click here for help</a>)</b>				
			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"/>	2009	Int. Nacotics Control Board
5.09.01.02	The 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2009	INCB
5.09.01.03	<a href="#">Convention on Psychotropic Substances</a> 1971	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2009	INCB
5.09.01.04	United Nations <a href="#">Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances</a> , 1988	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2009	INCB
5.09.02	Laws for the control of narcotic and psychotropic substances, and precursors exist	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	1988	WHO Level I MoH Rules and Regulations (1988)/JFDA Schedules and Lists (2006)
5.09.03	Annual consumption of Morphine (mg/capita)	1.922000	2007	INCB




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5.09.04	Comments and References			
<b>Supplementary questions (<a href="#">click here for help</a>)</b>				
			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 type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>		
5.09.05.01S	If yes, year of review			
5.09.06S	Annual consumption of Fentanyl (mg/capita)	0.023	2007	INCB
5.09.07S	Annual consumption of Pethidine (mg/capita)	4.247	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)	0.0068	2007	INCB
5.09.12S	Comments and References			
<b>5.10 Pharmacovigilance</b>				
<b>Core Questions (<a href="#">click here for help</a>)</b>				
			Year	Source
5.10.01	There are legal provision in the Medicines Act that provides for <a href="#">pharmacovigilance</a> activities as part	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2001	Drug&Pharmacy Law (2001);JFDA

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	of the MRA mandate			Directives (2006)
5.10.02	Legal provisions exist requiring the <a href="#">Marketing Authorization</a> holder to continuously monitor the safety of their products and report to the MRA	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2001	Drug&Pharmacy Law (2001);JFDA Directives (2006)
5.10.03	Legal provisions about monitoring <a href="#">Adverse Drug Reactions (ADR)</a> exist in your country	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2001	Drug&Pharmacy Law (2001);JFDA Directives (2006)
5.10.04	A national pharmacovigilance centre linked to the MRA exists in your country	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2001	Drug&Pharmacy Law (2001);JFDA Directives (2006)
5.10.04.01	If a national pharmacovigilance centre exists in your country, how many staff does it employ full-time	1		
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 checked="" type="checkbox"/> No <input 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	JFDA; RDU
5.10.06	A national Adverse Drug Reactions database exists in your country	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	JFDA; RDU

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5.10.07	How many ADR reports are in the database? 	400	2010	JFDA; RDU
5.10.08	How many reports have been submitted in the last two years? 	40	2008	JFDA; RDU
5.10.09	Are ADR reports sent to the WHO database in Uppsala?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	JFDA; RDU
5.10.09.01	If yes, number of reports sent in the last two years 	36	2008	JFDA; RDU
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 checked="" type="checkbox"/>	2010	JFDA; RDU
5.10.13	Please describe how you intend to enhance the Pharmacovigilance system			
5.10.14	Comments and References			
<b>Supplementary questions (<a href="#">click here for help</a>)</b>				
			Year	Source
5.10.15S	Feedback is provided to reporters	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		*
5.10.16S	The ADR database is computerized	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		*
5.10.17S	<a href="#">Medication errors (MEs)</a> are reported	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		*

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5.10.18S	How many MEs are there in the ADRs database?			*
5.10.19S	There is a <a href="#">risk management plan</a> presented as part of product dossier submitted for Marketing Authorization?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
5.10.20S	In the past two years, who has reported ADRs? *			
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			
5.10.21S	Was there any regulatory decision based on local pharmacovigilance data in the last 2 years?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		*
5.10.22S	Are there training courses in pharmacovigilance?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		*
5.10.22.01S	If yes, how many people have been trained in the last two years?	50		*
5.10.23S	Comments and References	*These answers were provided by Nidaa Bawaresh, who is in charge of the pharmacovigilance center of the JFDA and are not referenced to any published material. While an ADR bulletin is published, it has not been on a regular basis due to "funding constraints".		

## 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:	2004	MoH Regulation of Health Insurance (2004); MoH Rules and Regulations (2007)
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		
6.01.02	Is there a public health system or <a href="#">social health insurance</a> scheme or public programme providing medicines free of charge for :	2007	WHO Level I
6.01.02.01	All medicines included in the <a href="#">EML</a>	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	



6.01.02.02	Any non-communicable diseases	Yes <input 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 <a href="#">sickness fund</a> provide at least partial <a href="#">medicines coverage</a> ?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2002	MoH Regulation of Health Insurance
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/ <a href="#">social insurance schemes</a>			
6.01.04	Do private health insurance schemes provide any medicines coverage?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
6.01.04.01	If yes, is it required to provide coverage for medicines that are on the <a href="#">EML</a> ?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
6.01.05	Comments and References	It is widely known that private insurance companies provide medical coverage depending on the policy purchased		

## 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 <a href="#">co-payment</a> /fee requirements for consultations	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2007	WHO Level I
6.02.02	In your health system, at the point of delivery, are there any co-payment/fee requirements for medicines	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2007	WHO Level I
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"/>	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 <input checked="" type="checkbox"/> No <input type="checkbox"/>	2007	JFDA Laws and Regulations
6.03.01.01	If yes, are the provisions aimed at <a href="#">Manufacturers</a>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
6.03.01.02	If yes, are the provisions aimed at <a href="#">Wholesalers</a>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
6.03.01.03	If yes, are the provisions aimed at <a href="#">Retailers</a>	Yes <input checked="" 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.)	Differing pricing provisions for generic vs. originator medicines			
6.03.02	Government runs an active national medicines price monitoring system for retail prices	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>			JFDA Inspection Dept.
6.03.03	Regulations exists mandating that retail medicine price information should be publicly accessible	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>			
6.03.03.01	-if yes, please explain how the information is made publically available	While not mandatory, prices are made available at the JFDA website.			
6.03.04	Comments and References				

## 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.  <b>If yes</b> , please indicate the year of the survey and use the results to fill in this table  <b>If no</b> , 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 <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>				
	<b>Basket Of key medicines</b>			Public procurement	Public patient	Private patient		
	<b>Availability</b> (one	<b>Mean</b>	<b>Orig</b>		6.04.01.01	6.04.01.03		

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	or both of)	(%)					
			LPG		6.04.01.02	6.04.01.04	
		Median (%)	Orig		6.04.02.01 0.0	6.04.02.03 60.0	
			LPG		6.04.02.02 27.8	6.04.02.04 80.0	
	Price	Median Price Ratio	Orig	6.04.03.01 1.38	6.04.03.03 5.95	6.04.03.05 17.05	
			LPG	6.04.03.02 0.57	6.04.03.04 0.85	6.04.03.06 10.50	
	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 0.9	
			LPG		6.04.04.02 0.1	6.04.04.04 0.3	
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 <a href="#">mark-up</a> between Manufacturer Selling Price (MSP)/ Cost Insurance and Freight (CIF) price and final medicine price for a basket of key medicines in			

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	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	
<b>Supplementary questions (<a href="#">click here for help</a>)</b>		
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 <a href="#">mark-up</a> or <a href="#">dispensing fee</a> as percent of retail price for a basket of key medicines (%)	
6.05.10S	Median percentage contribution of the <a href="#">wholesale mark-up</a> to final medicine price for a basket of key medicines (in the public and private sectors) (%)	
6.05.11S	Median percentage contribution of the <a href="#">retail mark-up</a> to final medicine price for a basket of key medicines (in the	

	public and private sectors) (%)			
6.05.12S	Comment and References			
<b>6.06 Duties and Taxes on Pharmaceuticals (Market)</b>				
<b>Core Questions (<a href="#">click here for help</a>)</b>				
			Year	Source
6.06.01	There are <a href="#">duties</a> on imported <a href="#">active pharmaceutical ingredients (APIs)</a>	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2007	WHO Level I
6.06.02	There are duties on imported <a href="#">finished products</a>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2007	WHO Level I
6.06.03	<a href="#">VAT (value-added tax)</a> or any other tax is levied on finished pharmaceuticals products	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2011	JFDA
6.06.04	There are provisions for tax exceptions or waivers for pharmaceuticals and health products	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2011	JFDA
6.06.05	Please specify categories of pharmaceuticals on which the taxes are applied and describe the exemptions and waivers that exist	There is no duty tax for medicines, but there is a VAT of 4% for medicines. For pharmaceutical products which are not classified as medicines VAT is 16%.		
6.06.06	Comments and References			
<b>Supplementary questions (<a href="#">click here for help</a>)</b>				
			Year	Source
6.06.07S	<a href="#">Duty</a> on imported active pharmaceutical ingredients, APIs (%)	0	2011	JFDA
6.06.08S	Duty on imported finished products (%)	0	2011	JFDA
6.06.09S	<a href="#">VAT</a> on pharmaceutical products (%)	4	2011	JFDA
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:		Joint Procurement Law
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	Board of Directors of Joint Procurement Department (JPD) is headed by Prime Minister. Procurement for MoH, Royal Med Services, and public university hospitals.	
7.01.02 If public sector <a href="#">procurement</a> is wholly or partially centralized, it is under the responsibility of a <a href="#">procurement agency</a> which  is:		
7.01.02.01 Part of MoH	Yes <input type="checkbox"/> No <input type="checkbox"/>	

7.01.02.02	Semi-Autonomous	Yes <input type="checkbox"/> No <input type="checkbox"/>		
7.01.02.03	Autonomous	Yes <input type="checkbox"/> No <input type="checkbox"/>		
7.01.02.04	A government procurement agency which procures all public goods	Yes <input type="checkbox"/> No <input type="checkbox"/>		
7.01.03	Public sector requests for tender documents are publicly available	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Joint Procurement Department ; Tenders
7.01.04	Public sector tender awards are publicly available	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Joint Procurement Department ; Tenders
7.01.05	Procurement is based on prequalification of suppliers	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.01.05.01	If yes, please describe how it works	As outlined in governing Procedures and the tender invitation form, the JPD requires that any bidder for medicine tender be registered and would be subsequently need to abide by JFDA rules and regulations and therefore WHO prequalifications (section 4 and 4.2)		
7.01.06	Comments and References			
<b>Supplementary questions (<a href="#">click here for help</a>)</b>				
			Year	Source
7.01.07S	Is there a written public sector <a href="#">procurement</a> policy?. If yes, please write the year of approval in the "year" field	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2002	JP Law (enacted 2004)
7.01.08S	Are there legal provisions giving priority in public procurement to goods produced by local manufacturers?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2004	JPD Governing Procedures / General Terms Article 48, 54



7.01.09S	The key functions of the procurement unit and those of the tender committee are clearly separated	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2002	JP Law (2002); JPD Governing Procedures (2004)
7.01.10S	A process exists to ensure the quality of products procured	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2004	JPD Governing Procedures and Tender Invitation Form
7.01.10.01S	If yes, the quality assurance process includes <a href="#">pre-qualification</a> 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 checked="" 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 checked="" type="checkbox"/>		
7.01.12S	Which of the following <a href="#">tender</a> methods are used in public sector procurement:		2007	WHO Level I
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 type="checkbox"/> No <input checked="" type="checkbox"/>		
7.01.12.03S	Direct purchasing	Yes <input type="checkbox"/> No <input checked="" 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	MoH Supply & Procurement Dept.
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 <a href="#">Good Distribution Practices (GDP)</a>	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
7.02.04	There is a licensing authority that issues GDP licenses	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
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:			
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 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	83	2011	JFDA
7.02.10S	Average stock-out duration for a basket of medicines at the Central Medical Store, in days	41		
7.02.11S	Routine Procedure exists to track the expiry dates of medicines at the Central Medical Store	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2011	JFDA
7.02.12S	The Public Central Medical Store is GDP certified by a licensing authority	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	JFDA
7.02.13S	The Public Central Medical Store is <a href="#">ISO</a> certified	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	JFDA
7.02.14S	The second tier public warehouses are GDP certified by a licensing authority	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	JFDA
7.02.15S	The second tier public warehouses are ISO certified	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	JFDA
7.02.16S	Comments and References			
<b>7.03 Private Sector Distribution</b>				
<b>Core Questions (<a href="#">click here for help</a>)</b>				
			Year	Source

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7.03.01	Legal provisions exist for licensing wholesalers in the private sector	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2001	Drug and Pharmacy Law; JFDA Registration Criteria
7.03.02	Legal provisions exist for licensing distributors in the private sector	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2001	Drug and Pharmacy Law; JFDA Registration Criteria
7.03.03	List of <a href="#">GDP</a> 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 <a href="#">essential medicines list (EML)</a> exists. If yes, please write year of last update of EML in the "year" field	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2006	JFDA
8.01.01.01	If yes, number of medicines on the EML (no. of <a href="#">INN</a> )	680		
8.01.01.02	If yes, there is a written process for selecting medicines on the EML	Yes <input checked="" type="checkbox"/> No <input 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 <a href="#">Standard Treatment Guidelines (STG)</a>	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"/>	2007	WHO Level I
8.01.03	STGs specific to Primary care exist. Please use the "year" field to	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		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 <input type="checkbox"/> No <input checked="" type="checkbox"/>	2007	WHO Level I
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 checked="" type="checkbox"/>	2007	WHO Level I
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"/>	2007	WHO Level I
8.01.09	Public education campaigns on <a href="#">rational medicine use</a> topics have been conducted in the previous two years	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2009	MeTA Initiative
8.01.10	A survey on rational medicine use has been conducted in the previous two years	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	WHO Level II
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 checked="" type="checkbox"/> No <input type="checkbox"/>	2007	WHO Level I
8.01.12	A written National strategy exists to contain <a href="#">antimicrobial resistance</a> . If yes, please write year of last update of the strategy in the "year"	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		

	field			
8.01.13	Comments and References	The number of medicines on the EML in 2006 was 613, and that is the last published list (the 2006 JRDL and 2006 JRDF, which is the reference manual for the EML is attached). However, currently there are 1312 medicines on the rational drug list which is not published.		
<b>Supplementary questions (<a href="#">click here for help</a>)</b>				
			Year	Source
8.01.14S	The <a href="#">Essential Medicines List (EML)</a> includes formulations specific for children	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2006	Jordan Rational Drug List 2006
8.01.15S	There are explicitly documented criteria for the selection of medicines in the EML	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		JFDA Registration Criteria and JRDL
8.01.16S	There is a formal committee or other equivalent structure for the selection of products on the National EML	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2006	JRDL Introduction and Annexes 1-3
8.01.16.01S	If yes, <a href="#">conflict of interest</a> 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 checked="" type="checkbox"/> No <input type="checkbox"/>	2006	Jordan National Drug Formulary
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"/>		
8.01.19S	A national reference laboratory/or any other institution has responsibility for coordinating epidemiological surveillance of	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		

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	<a href="#">antimicrobial resistance</a>			
8.01.20S	Comments and References	<p>Legal or legislative documentation not available. However, there exists a National Formulary Advisory Board, a National Pharmacy and Therapeutics Committee, and a Rational Drug List Technical Committee according to the JFDA document "JRDL 2006" (attached) in addition to a Rational Drug Unit in the JFDA. The Drug and Pharmacy Law 2001 stipulates that Higher Committee (prior to JFDA) must rationalize the use of medicines.</p> <p>There exists a National Formular Advisor Board, a National Pharmacy and Therapeutics Committee, and a Rational Drug List Technical Committee according to the JFDA document "JRDL 2006" (attached).</p>		

## 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 <a href="#">prescriber</a>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2009	JFDA Medical Prescription Guidelines (2009); MoH Laws and Regulations (1972)
8.02.02	Legal provisions exist to restrict dispensing by prescribers	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2009	JFDA Medical Prescription Guidelines (2009); MoH Laws and Regulations (1972)
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 <a href="#">Drug and Therapeutics Committees (DTCs)</a>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2007	WHO Level I
8.02.05	Do more than half of <a href="#">referral hospitals</a> have a DTC?	Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>		
8.02.06	Do more than half of <a href="#">general hospitals</a> 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:		2007	WHO Level I
8.02.08.01	Concept of <a href="#">EML</a>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
8.02.08.02	Use of <a href="#">STGs</a>	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
8.02.08.03	<a href="#">Pharmacovigilance</a>	Yes <input type="checkbox"/> No <input checked="" 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 <a href="#">physician</a> )	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2007	WHO Level I
8.02.10	Mandatory continuing education that includes pharmaceutical issues is required for <a href="#">nurses</a>	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
8.02.11	Mandatory continuing education that includes pharmaceutical issues is required for paramedical staff	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2007	WHO Level I
8.02.12	Prescribing by <a href="#">INN</a> 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)	2.2	1999	Rational Use Survey
8.02.14	% of medicines prescribed in outpatient public health care facilities that are in the national EML (mean)		2009	WHO Level II (Ongoing)
8.02.15	% of medicines in outpatient public health care facilities that are prescribed by INN name (mean)		2009	WHO Level II (Ongoing)
8.02.16	% of patients in outpatient public health care facilities receiving antibiotics (mean)		2009	WHO Level II (Ongoing)
8.02.17	% of patients in outpatient public health care facilities receiving injections (mean)		2009	WHO Level II (Ongoing)
8.02.18	% of prescribed drugs dispensed to patients (mean)		2009	WHO Level II (Ongoing)
8.02.19	% of medicines adequately labelled in public health facilities (mean)		2009	WHO Level II (Ongoing)
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 <input checked="" type="checkbox"/> No <input type="checkbox"/>	1972	MoH/ Jordanian Union for Doctors/ Nurses
8.02.22S	A professional association code of conduct exists governing professional behaviour of nurses	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
8.02.23S	Diarrhoea in children treated with Oral Rehydration Solution (ORS)			

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	(%)			
8.02.24S	Comments and References			
<b>8.03 Dispensing</b>				
<b>Core Questions (<a href="#">click here for help</a>)</b>				
			Year	Source
8.03.01	Legal provisions exist to govern dispensing practices of pharmaceutical personnel	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2001	Drug and Pharmacy Law
8.03.02	The basic pharmacist training curriculum includes components on:		2007	WHO Level I (2007); Jordan University Faculty of Pharmacy (2010)
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 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 type="checkbox"/> No <input type="checkbox"/>		
8.03.03	Mandatory continuing education that includes rational use of medicines is required for pharmacists	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2007	WHO Level I
8.03.04	<a href="#">Generic substitution</a> at the point of dispensing in public sector facilities is allowed	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		*
8.03.05	<a href="#">Generic substitution</a> at the point of dispensing in private sector facilities is allowed	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		*

8.03.06	In practice, (even though this may be contrary to regulations) are antibiotics sometimes <a href="#">sold over-the-counter</a> without any prescription?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>	2007	WHO Level I
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 checked="" type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>	2007	WHO Level I
8.03.08	Comments and References	No regulations that prohibit exist		
<b>Supplementary questions (<a href="#">click here for help</a>)</b>				
			Year	Source
8.03.09S	A professional association <a href="#">code of conduct</a> exists governing professional behaviour of pharmacists	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	1972	MoH / Jordanian Union for Pharmacists
8.03.10S	In practice, (even though this may be contrary to regulations) do the following groups of staff <i>sometimes</i> prescribe <a href="#">prescription-only medicines</a> at the primary care level in the public sector?		2011	JFDA
8.03.10.01S	Nurses 	Yes <input checked="" type="checkbox"/> No <input 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 checked="" 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?	WHO Level II Assessment, Household Medicines Survey (2011 DRAFT)		
9.01.02	Adults with acute condition in two-week recall period who took all medicines prescribed by an authorized prescriber (%)	76.9	2011	Household Medicines Survey Household Medicines Survey
9.01.03	Adults with acute conditions not taking all medicines because they cannot afford them (%)	0.11	2011	Household Medicines Survey
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	0.04	2011	Household Medicines Survey

	afford them (%)			
9.01.06	Adults with chronic conditions taking all medicines prescribed by an authorized <a href="#">prescriber</a> (%)	89	2011	Household Medicines Survey
9.01.07	Adults (from poor households) with chronic conditions not taking all medicines because they cannot afford them (%)	0	2011	Household Medicines Survey
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 (%)	43	2011	Household Medicines Survey
9.01.12	Comments and References	<p>For all questions "from poor household", the survey does aggregate the data by different income levels but does not categorise the poor, mediocre and rich households. Therefore for filling in these questions, data from the "poorest income level (&lt;50 JOD 4-week spending/person) was used as the "poor household".</p> <p>9.01.02 Calculated from the data in the survey (table 3-17) because it was disaggregated into sick persons with an acute illness perceived as very serious, moderately serious and not serious. The survey does not say whether this is for within the two-week recall period.</p> <p>9.01.03 + 9.01.05 Calculated from the data in the survey (fig 3.18). Total population of survey is 5597 (table 3-3).</p> <p>9.01.11 This is the % of persons with recent acute illness who obtained medicines free of charge. Not stated whether this was in the</p>		

		15 days before the interview.		
<b>Supplementary questions (<a href="#">click here for help</a>)</b>				
			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					

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