

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 Statistics¹²), 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.

A handwritten signature in black ink, appearing to be 'M. Said', written over a horizontal dotted line.

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). 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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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 2009.³

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.³

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)

	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

Jordan: Mortality Country Fact Sheet 2006, WHO

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).⁴

The general governmentⁱ 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.⁴

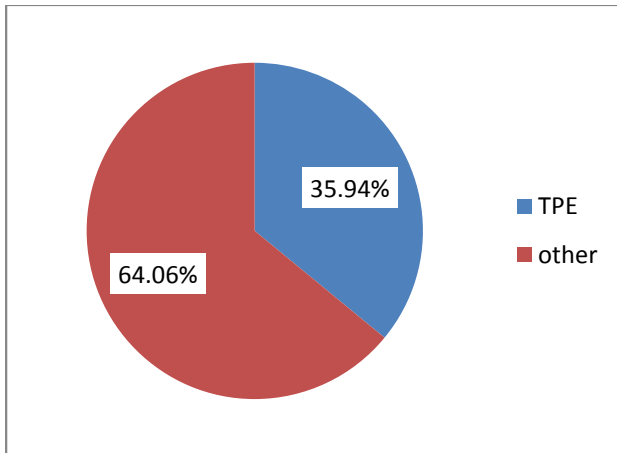
Of the total population, 75 % is covered by a public health service (MOH 34%, RMS 23%, UNRWA 9%, and Private Health Insurance 8%). the remaining 25% of population are without any form of health insurance. (Population covered by public insurance service is calculated from numbers reported in Jordan NHA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

ⁱ 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).⁴

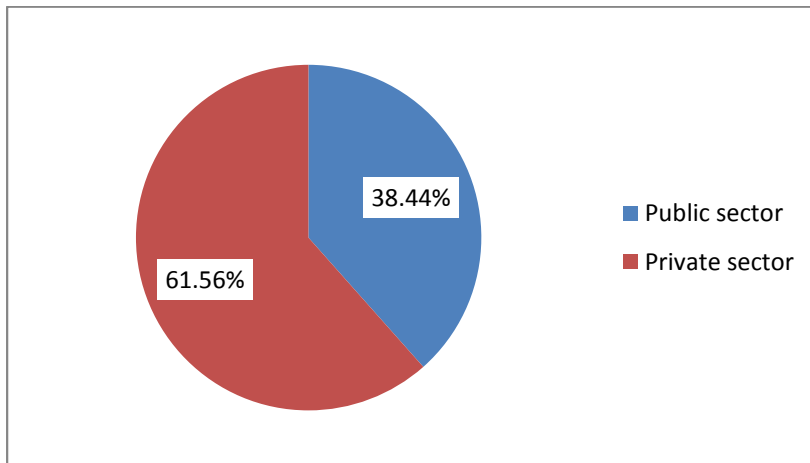
FIGURE 1: Share of Total Pharmaceutical Expenditure as percentage of the Total Health Expenditure (2008). The THE in 2008 was 1,381 million JOD (US\$ 1,951 million)



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.

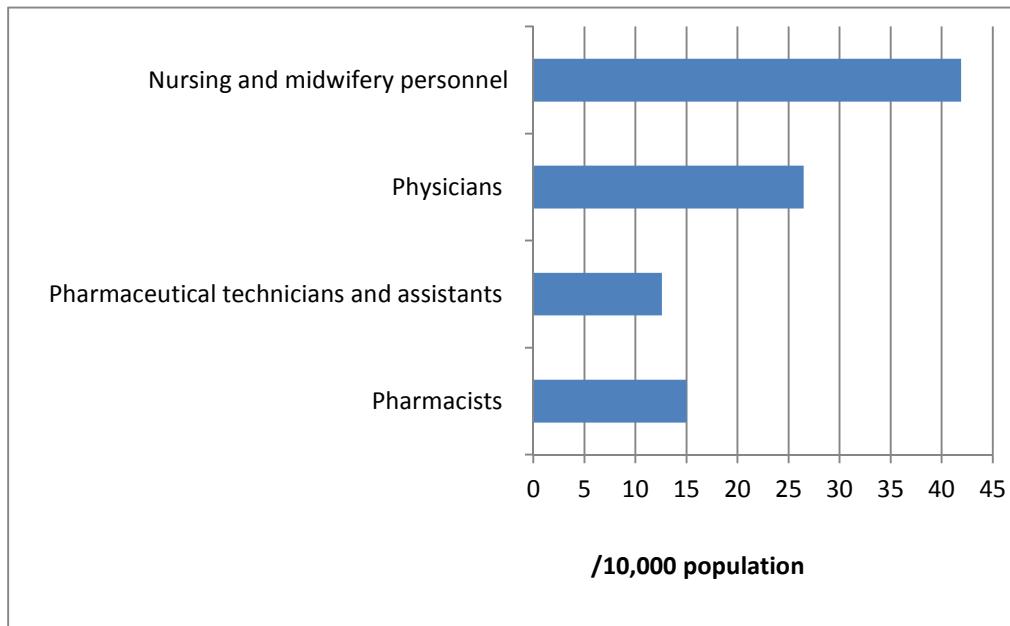
Table 1: Human resources for health in Jordan (Ministry of Health Report 2010)³

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. ³

Table 2: Health centre and hospital statistics (Ministry of Health Report 2010)³

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/

Human Resources for Health 2010, WHO 2009,

apps.who.int/medicinedocs/documents/s17239e/s17239e.pdf

Insurance Commission:

www.irc.gov.jo/doc/RSP/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/). 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.⁵ It was updated in 2009. An associated National Health Policy implementation plan does not exist.

An official National Medicines Policy document exists in Jordan.⁶

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 ⁶

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 constitution⁷, but it is included in national legislation¹⁵ (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".⁸

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

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 (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

Prime Ministry Code of conduct:

www.pm.gov.jo/uploads/Code_of_Conduct_english.pdf

Anti-Corruption Commission: www.jacc.gov.jo

Complaint form (Arabic only): 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.⁹ Legal provisions granting patents to manufacturers exist.¹⁰

National Legislation has been modified to implement the TRIPS Agreement and contains TRIPS-specific flexibilities and safeguards¹⁰, 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 ⁱⁱ	<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.¹¹

ⁱⁱ 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]



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.¹¹

Key reference documents:

Ministry of Industry and Trade, The Hashemite Kingdom of Jordan,
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

Trade Policy Review report by Jordan, World Trade Organization, WT/TPR/S/206,
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

4.2 Manufacturing

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

Table 5: Jordan manufacturing capabilities¹⁰

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.¹³

Key reference documents:

Prime Ministry Millennium Challenge Account:
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.io/EN/default/ .

The MRA is involved in harmonization/collaboration initiatives (such as “A Framework for good governance in the pharmaceutical sector”⁸). 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.¹⁴

Key reference documents:

MRA Website: www.jfda.io

JFDA Law: www.jfda.io/custom/law/22.doc

Drug and Pharmacy Law 2001: www.jfda.io/EN/Laws/LawInfo.aspx?id=507

Prime Ministry Code of conduct:

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.¹⁵ Explicit and publicly available criteria exist for assessing applications for marketing authorization of pharmaceutical products.¹⁴ ¹⁶ 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.¹⁶ 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.¹⁶

5.3 Regulatory Inspection

In Jordan, legal provisions exist allowing for appointment of government pharmaceutical inspectors.¹⁵ 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.^{15 17} 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.¹⁸

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.^{15 16}

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].¹⁹ Legal provisions exist requiring manufacturers (both domestic and international) to comply with Good Manufacturing Practices (GMP). Good Manufacturing Practices are published by the government.²⁰

Legal provisions exist requiring importers/wholesalers/distributors to be licensed.¹⁵ 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.¹⁵ 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.^{15 21}

A laboratory exists in Jordan for Quality Control testing.²²

Samples are collected by government inspectors for undertaking post-marketing surveillance testing.¹⁰

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.²³

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.²⁴

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.²⁴

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 signatory²⁵

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).^{10 26 27} The annual consumption of Morphine is 1.922 mg per capita.²⁵

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 Jordan²⁸

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.^{15 29} 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.³⁰ 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

Pharmacovigilance Directives, www.jfda.jo/custom/law/55.doc

Registration Criteria, 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^{31 32}

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

Table 13: Medications provided publicly, at no cost¹⁰

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.¹⁰

6.3 Pricing Regulation for the Private Sectorⁱⁱⁱ

In Jordan, there are legal or regulatory provisions affecting pricing of medicines.³³ 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.

ⁱⁱⁱ 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.³⁴ 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^{iv} 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

^{iv} 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). 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.



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.¹⁰

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%.⁴¹

Table 14S2: Duties and taxes applied to pharmaceuticals

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

^v 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 \(2nd Edition\)](#) 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.³⁵

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.^{36 37} As outlined in Governing Procedures³⁷ and the tender invitation form³⁸, 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 produced 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.¹⁵ 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

JP Law 2002: www.jpd.gov.jo/ReadPaner.php?id=110&sub_id=5

Current Tenders: www.jpd.gov.jo/ReadPaner.php?id=115&sub_id=6

Tender Invitation Form, Criteria:
www.jpd.gov.jo/images/pic/ZZ060402092259.pdf

Governing Procedures/General Terms:
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

Registration Criteria:
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.¹⁰

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.¹⁰

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.³⁹

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

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 curriculum¹⁰

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.¹⁰

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.⁴⁰

8.3 Dispensing

Legal provisions in Jordan exist to govern dispensing practices of pharmaceutical personnel.¹⁵ 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.⁴¹

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

MoH 1972 Laws and Regulations of the Jordanian Pharmacists' Union (Arabic): 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



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) ⁴²

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. ⁴²

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. ⁴²



List of key reference documents:

- ¹ World Health Statistics 2010, Geneva, World Health Organization, 2010; Available from: www.who.int/whosis/whostat/2010/en/index.html, 10-05-2011.
- ² World Health Statistics 2009, Geneva, World Health Organization, 2009; Available from: www.who.int/whosis/whostat/2009/en/index.html, 10-05-2011.
- ³ Ministry of Health Report 2010, Department of Statistics, available at: www.moh.gov.jo/MOH/En/publications.php
- ⁴ Jordan National Health accounts 2008 (Jordan NHA 2008), 2011; Available from: www.who.int/nha/country/jor/en/, 15-05-2011.
- ⁵ 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, 15-05-2011.
- ⁶ Jordan National Drug Policy (NDP), MoH Jordan, 2002;
- ⁷ The Constitution of The Hashemite Kingdom of Jordan; Available from: www.kinghussein.gov.jo/constitution_jo.html, 15-05-2011.
- ⁸ A Framework for Good Governance in the Pharmaceutical Sector. The Hashemite Kingdom of Jordan, 2010; Available from: <http://apps.who.int/medicinedocs/documents/s17057e/s17057e.pdf>, 15-05-2011.
- ⁹ World Trade Organization (WTO); Available from: www.wto.org, 10-05-2011
- ¹⁰ WHO Level I Survey, World Health Organization, Geneva. 2007;
- ¹¹ Ministry of Industry and Trade, The Hashemite Kingdom of Jordan. Available at: www.mit.gov.jo,
Trade Policy Review Report by the Secretariat, WT/TPR/G/206, World Trade Organization, 2008, Available at: www.mit.gov.jo/portals/0/g206.pdf.
Trade Policy Review report by Jordan, World Trade Organization, WT/TPR/S/206, Available at: www.mit.gov.jo/portals/0/s206-00.pdf.
- Patent Regulations official Gazette No. 4522 dated 13.12.2001. Available at: www.jfda.jo/custom/law/53.doc.
- ¹² JFDA Registration Department, unpublished, 2010; www.jfda.jo/;
- ¹³ 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, 15-05-2011.
- ¹⁴ JFDA; Available from: www.jfda.jo/Default.aspx, 15-05-2011.
- ¹⁵ JFDA Drug and Pharmacy Law 2001, JFDA, 2001. Available from: www.jfda.jo/EN/Laws/details.aspx?id=71, 15-05-2011.
- ¹⁶ JFDA Registration Criteria, JFDA. Available from: www.jfda.jo/EN/Laws/details.aspx?id=72, 15-05-2011.



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- ¹⁷ JFDA Law, JFDA, 2003. Available from: www.jfda.jo/custom/law/22.doc, 15-05-2011.
- ¹⁸ JFDA Inspection Department. unpublished. 2010;
- ¹⁹ Accreditation of Manufacturing Sites Regulations, Re-evaluation and Cancellation for the Year 2008, JFDA. Available from: www.jfda.jo/custom/law/52.doc, 15-05-2011.
- ²⁰ Arab Guidelines on Current Good Manufacturing Practices (cGMP) for Pharmaceutical Products, JFDA. Available from: www.jfda.jo/custom/law/35.doc, 15-05-2011.
- ²¹ JFDA Laws and Regulations, JFDA. Available from: www.jfda.jo/EN/Laws/details.aspx?id=507, 15-05-2011.
- ²² JFDA Organizational Structure, JFDA, 2010. Available from: www.jfda.jo/custom/topics/3.jpg, 15-05-2011.
- ²³ Drug Promotion Regulation (Arabic only), JFDA, 2009. Available from: www.jfda.jo/ar/Laws/details.aspx?id=100, 15-05-2011.
- ²⁴ Law of Clinical Studies, JFDA, 2001. Available from: www.jfda.jo/custom/law/23.doc, 15-05-2011.
- ²⁵ Report of the International Narcotics Control Board for 2009, INCB, 2009. Available from: www.incb.org/incb/en/annual-report-2009.html, 15-05-2011.
- ²⁶ Ministry of Health Rules and Regulations (Arabic), MoH Jordan, 1988. Available from: www.moh.gov.jo/MOH/En/rules_regulationsdetails.php?ruleid=95, 16-05-2011.
- ²⁷ JFDA Schedules and Lists, JFDA, 2006. Available from: www.jfda.jo/EN/Laws/details.aspx?id=87, 15-05-2011.
- ²⁸ INSERT reference for 5.09.01-5.09.02
- ²⁹ JFDA. The Directives of Pharmacovigilance [Internet]. 2006; Available from: www.jfda.jo/custom/law/55.doc
- ³⁰ JFDA. JFDA Rational Drug Use Unit (RDU) [Internet]. 2010 [cited 2011 May 16]; Available from: www.jfda.jo/RDU/en-US/IndexPage.aspx
- ³¹ MoH Regulations for Health Insurance, MoH Jordan, 2004. Available from: www.moh.gov.jo/MOH/En/rules_regulationsdetails.php?ruleid=116, 17-05-2011.
- ³² MoH Rules and Regulation, MoH Jordan. Available from: www.moh.gov.jo/MOH/En/rules_regulations.php, 17-05-2011.
- ³³ The Criteria and Standards related to Drugs Pricing, Repricing and Objections to Pricing Decisions, JFDA, 2007. Available from: www.jfda.jo/EN/Laws/details.aspx?id=73, 17-05-2011.
- ³⁴ HAI Survey Report Jordan - Year 2004. 2007;
- ³⁵ Joint Procurement Law 2002, JPD; Available from: www.jpd.gov.jo/ReadPaner.php?id=110&sub_id=5, 15-05-2011.



³⁶ JPD Current Tenders, Joint Procurement Department, 2010. Available from:

www.jpd.gov.jo/ReadPaner.php?id=115&sub_id=6, 17-05-2011.

³⁷ Governing Joint Procurements Procedures Of Drugs/General Terms, Joint Procurement Department. Available from: www.jpd.gov.jo/ReadPaner.php?id=184&sub_id=181, 17-05-2011.

³⁸ Tender Invitation Form, Criteria, Joint Procurement Department. Available from:

www.jpd.gov.jo/images/pic/ZZ060402092259.pdf, 17-05-2011.

³⁹ JFDA Medical Prescription Guidelines (Arabic), JFDA. 2009. Available from:

www.jfda.jo/ar/Laws/details.aspx?id=106, 22-05-2011.

⁴⁰ MoH / Jordanian Union for Doctors / Nurses (1972)

⁴¹ Ph. Adi Nuseirat, JFDA, 07-07-2011.

⁴² WHO Level II Assessment, Household Medicines Survey, 2011 DRAFT.