



Hashemite Kingdom of Jordan

Polices on Disclosure

2014



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Preface

The government of Jordan considers the pharmaceutical sector as a crucial part of health system, and is fully committed to continuously assessing and identifying areas of improvement and functions. As part of this quest for excellence, MeTA Jordan is developing strategies to promote greater transparency and accountability regarding policies, practices, and outcomes in the pharmaceutical sector. They have committed to disclosing, analysing, and using over time data in the following four core areas:

1. Medicines registration and quality assurance
2. Availability of medicines
3. Price of medicines
4. Policies and practices concerning the promotion of medicines.

The technical committee discussed the Information Categories and Possible Data Sources based on MeTA Jordan disclosure status of pharmaceutical sector scan. The committee collected all information related to the pharmaceutical sector including: studies, guidelines, lists, requirements, processes, standard operating procedures, members of national committees; and produce recommendations to make them publically available in an accessible & transparent way.

I would like to express my sincere appreciation to all those who have contributed to the preparation of this document and in particular to the MeTA Steering Committee, headed by Dr. Hayel Obeidat, and emphasize our commitment to endorse these recommendations in order to increase transparency along every link of the medicines supply chain.

Dr. Ali Hyasat



Minister of Health

Head of JFDA Board of directors



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1. Medicines Registration and Quality Assurance

1.1 Market registration procedures and registration status of all medicines

Sources:

Jordan FDA: www.jfd.jo

The length of time for medicines registration is within 180 days.

Recommendation:

1. Determine the period of time required for each procedure contained in the drug registration process.
2. Application of an electronic tracking system for all procedures related to drug registration stages
3. Website development to become more friendly-user.
4. Increase the awareness of the information available on the website (JFDA) in order to encourage its use by the public and recipient of the service.
5. Review mechanism and requirements for renewal of registration and subjected to electronic tracking system and determine the time period for the completion of renovation to achieve greater disclosure and transparency.
6. Disclosure of JFDA role in controlling clinical studies and protection of human volunteers

Justification:

1. To achieve greater disclosure and transparency.
2. Ease of follow-up by service providers and recipients to enhance disclosure and transparency.
3. Information is available and disclosed.
4. Information is available and disclosed.
5. Development and simplification of procedures and the availability of information and disclosed.

1.2 Good manufacturing practice (GMP) for domestic and foreign manufacturers

Sources:

Jordan FDA: www.jfd.jo

GMP compliant manufacturers and dates of last inspection are available within printed files but not published (not publicly available) also data regarding manufacturing plants that failed GMP inspection and dates of inspection and recommendation to plants are available but not published.

Recommendation:

1. Publish the names of the certified manufacturers by JFDA (GMP compliant)
2. Website development to become more friendly-user.
3. Increase the awareness of the information available on the website (JFDA) in order to encourage its use by the public and recipient of the service.
4. Publish the names of local factories and foreign manufacturers of raw materials which are certified by JFDA (GMP compliant).

Justification:

Information is available and disclosed.

1.3 Quality assurance processes in public and non-profit tenders

Sources:

www.jp.d.gov.jo

Public sectors: MOH, RMS, KAUH, JUH

1. The value and volume of tenders procured by MOH, JUH, KHCC, RMS and KAUH are disclosed and published on JPD website. There is no list of prequalified suppliers, but prequalification criteria and procedure are available and disclosed, while Performance criteria are not currently available.
2. Proportion of medicine from pre-qualified suppliers can't be calculated as there is no list of the pre- or post-qualified suppliers.

Recommendation:

1. Recommendation in the Annex (1).
2. Publish and disclose the list of prequalified suppliers.
3. Conduct a study to determine the cost of poor quality of supply (the delay in supply, the supply of non-matching material ...) And determine the social costs.

Justification:

Information is available and disclosed.

1.4 Quality assurance data during registration

Sources:	Jordan FDA: www.jfd.jo
1. Non friendly user website and lack of access to key disclosure data.	
Recommendation: 1. Website development to become more friendly-user. 2. Increase the awareness of the information available on the website (JFDA) in order to encourage its use by the public and recipient of the service.	
Justification: Information should be available and disclosed.	

1.5 Routine quality testing and adverse event monitoring

Sources:	JFDA, www.jfda.jo
Policies: 1. Number of samples from the market that were sent to quality control laboratories by government inspectors for routine testing are publicly available and published within the JFDA annual reports. List of products that failed quality testing, date of testing, and steps taken to resolve the problem are available but not disclosed neither published. 2. Number of adverse event reports that were submitted to the government adverse event reporting system in the last year is available but not disclosed nor published.	
Recommendation: 1. Publish a list of pharmaceutical products in post-marketing that have passed or failed quality tests with dates of testing, and steps taken to resolve the problem. 2. The announcement of the medicines that have failed quality tests for three days in the media. 3. Publish adverse event reports and the actions taken to resolve the problem. 4. Organize an awareness program on the importance of reporting side effects in the public and private sectors.	
Justification: Information should be available and disclosed and to protect the health of citizens.	

2. Medicine Availability

2.1 Standard treatment guidelines

Sources:	JFDA, JUH, KAUH, MOH, RMS
1. There are no policies and procedures for creating and updating standard treatment guidelines. 2. There are no national standard treatment guidelines committee.	
Recommendation: 1. Develop policies and procedures for creating and updating standard treatment guidelines. 2. Form national committees for developing standard treatment guidelines, with clear TOR and specific criteria for the selection of members, and publish the names of members and their specialties. 3. Dissemination and adoption of national standard treatment guidelines. 4. Develop the necessary legislations that make the enforcement of standard treatment guidelines.	
Justification: 1. Standardization of medical procedures. 2. Defining the responsibilities. 3. Disclose the information in order to achieve citizen's awareness of their rights and protect their health and increase confidence in the health services provided to him.	

2.2 Essential medicines list

Sources:	JFDA, www.jfda.jo JUH,MOH,RMS
1. The form of conflict of interest of RDL committees is available but there is no conflict of interest management system neither practiced. 2. List of updated members of national RDL is not published.	
Recommendation: 1. Creation of mechanisms to manage the conflict of interest. 2. Publishing a list of updated members of the technical committees. 3. Increase awareness of the importance of the existence of rational drug list. 4. Strengthening the role of the pharmacy and therapeutics committees in hospitals in the selection of rational drug list. 5. Introduce policy for generic substitution and increase awareness on this concept. 6. Issuing lists of OTC medicines and the medicines that only dispensed by prescribing.	
Justification: Achieve more credibility and transparency and increase citizen's confidence in the provided health services.	

2.3 Pharmaceutical patents held in the country

Sources:	Ministry of Trade and industry. http://www.mit.gov.jo/
1. patents applications are not published 2. Granted patents are published in official gazettes-only summary, there are no electronic records. patent research is manual, not accurate , no electronic search 3. No classification of pharmaceutical patents	
Recommendation: Laws and regulations governing, pharmaceutical patents are available. 1. Deployment of applications for patents and the date of submission and the name of its owner. 2. Publish a list of pharmaceutical patents detailed in an easy-to-use electronic manner. 3. Publish pharmaceutical patents with their classification electronically.	
Justification: To promote transparency, support and protection of innovation	

2.4 Volume and value of medicines procured in the public and non-profit sectors

Sources:	JPD, www.jpd.gov.jo MOH, JUH, KAUH, RMS
The budgets for the purchase of medicines in university hospitals and Royal Medical Services is not published neither available.	
Recommendation: 1. Disclose the budget for the purchase of medicines in each of the university hospitals and the Royal Medical Services and the Ministry of Health according to the type of medication, therapeutic classification, money value, the amount purchased and the purchase method. 2. Publish lists of procured medicines of the same active ingredient purchased (originator and generic).	
Justification: To enhance transparency and good governance.	

2.5 Volume and value of medicines supplied in the private sector

Sources:	Jordan FDA: www.jfd.jo
There is no laws and polices usually exist for volume and value of medicines supplied in the private sector.	
Recommendation: 1. Creating legislation and policies and mechanisms for disclosure for volume and value of medicines supplied in the private sector. 2. Publication types, volume and value of imported and supplied medicines in the private sector. 3. Development of policies and legislation to use this information in order to achieve drug security through lists of essential medicines and strategic medicine stocks in the public and private sector.	
Justification: To promote transparency.	

2.6 Availability of medicines to consumers

Sources:	MOH, RMS, JUH, KAUH, WHO-HAI Survey
<ol style="list-style-type: none">1. Availability of policies and procedures governing stocking of essential medicines in public health facilities differs according to sector: It is available at the RMS and JUH but not available at the MOH and KAUH2. Stock records are available but not accessible3. Documented follow up reports are available at RMS, and JUH but it is not available at MOH	
Recommendation: <ol style="list-style-type: none">1. Develop policies and procedures governing stocking of essential medicines in all public health facilities.2. Disclosure of Stock records in the public sector.3. Issue reports based on inventory balances for essential medicines in all public sectors.4. Adopt the results and recommendations of the two reports: (WHO Household Survey - LEVEL II -To Measure Access to and use of medicines in Jordan, report of a survey conducted October-December 2009). (Pharmaceutical Situation assessment – level II - , WHO Health facilities survey in Jordan, report of a survey conducted October-December 2009).	
Justification: <p>To promote transparency and achieve drug security.</p>	

2.7 Routine audits for public, private, and non-profit medicines outlets

Sources:	JFDA, www.jfda.jo
Laws and regulations governing the inspection and auditing of pharmacies and Drug stores are available	
Recommendation: <p>Disclosure of the violations that occurred in the medicines outlets.</p>	
Justification: <p>To promote transparency.</p>	

3. Medicine Prices

3.1 Consumer and ex-manufacture prices of medicines in the public, private, and non-profit sectors

Sources:	JFDA, www.jfda.jo
All medicines prices are disclosed but not a friendly user website.	
Recommendation: 1. Development of JFDA website to become more friendly-user. 2. Increase the awareness of the information available on the website (JFDA) in order to encourage its use by the public and recipient of the service. 3. Adopt the results and recommendations of the two reports: (WHO Household Survey - LEVEL II -To Measure Access to and use of medicines in Jordan, report of a survey conducted October-December 2009). (Pharmaceutical Situation assessment – level II - , WHO Health facilities survey in Jordan, report of a survey conducted October-December 2009).	
Justification: Information should be available and disclosed to increase transparency and credibility	

3.2 Public sector medicines procurement prices

Sources:	JPD, www.jpd.gov.jo
All medicines prices in the tenders are disclosed but not a friendly user website.	
Recommendation: 1. Development of JPD website to become more friendly-user. 2. Increase the awareness of the information available on the website (JPD) in order to encourage its use by the public and recipient of the service.	
Justification: Information should be available and disclosed	

3.3 Medicines price components in the public, non-profit, and private sectors

Sources:	JFDA, www.jfda.jo
Data on price components (duties, taxes, mark-ups and other charges) for key essential medicines both domestically manufactured and imported are available at JFDA by sector and therapeutic class but not published.	
Recommendation:	Publish the list of medicines with their prices according to pricing reference (median price, price at the origin country, price in Saudi Arabia,...etc.)
Justification:	Information should be available and disclosed

4. Medicine Promotion

4.1 Medicines promotion regulations, policies, and industry practices

Sources:	JFDA, www.jfda.jo
Drug promotion control guidelines are published.	
Recommendation:	<ol style="list-style-type: none">1. Review and update drug promotion control guidelines2. Insert legal reference to include sanctions against drug promotion violators.3. Formation of a national committee to monitor and implementation of drug promotion control guidelines and publish the names of the members.4. Prepare and publish classifications of the complaints and the decisions to be taken.5. Increase awareness among health providers about its effect on increasing irrational use of medicines which result in increasing expenditures on medicines and decreasing the availability of essential medicines.6. Increase the awareness among consumers.7. Introduce it in the curriculum of medical faculties
Justification:	Enhance transparency and provide the scientific non misleading information about medicines and promote rational use of medicines.

Annex 1:

Institution	Recommendation
Joint Procurement Department (JPD)	<ul style="list-style-type: none"> - Develop Website to get the information easily and conveniently. - Preparation of guidelines for evaluating the performance of suppliers and dissemination of results and update them periodically. - increase awareness of the need to use the site for the applicants of tenders.
Ministry of Health (MoH)	<ul style="list-style-type: none"> - The development of a website to publish tenders for the Ministry of Health and local purchases, and publishing laws, guidelines and instructions - develop guidelines for evaluating the performance of suppliers and dissemination of results and update them periodically. - increase awareness of the need to use the site for the applicants of tenders. - Dissemination of standard operating procedures for tenders.
Jordan University Hospital (JUH)	<ul style="list-style-type: none"> - The development of the hospital's website to include disclosure of tenders for medicines to include the following information: <ul style="list-style-type: none"> • prepare lists of medicines required bid. • comparison tables • the reasons for assignment • initial and final assignments - develop guidelines for evaluating the performance of suppliers and dissemination of results and update them periodically. - increase awareness of the need to use the site for the applicants of tenders. - Dissemination of regulations, instructions and policies. - Dissemination of standard operating procedures for tenders.
King Abdullah University Hospital (KAUH)	<ul style="list-style-type: none"> - The development of the hospital's website to include disclosure of tenders for medicines to include the following information: <ul style="list-style-type: none"> • prepare lists of medicines required bid. • comparison tables • the reasons for assignment • initial and final assignments - develop guidelines for evaluating the performance of suppliers and dissemination of results and update them periodically. - increase awareness of the need to use the site for the applicants of tenders. - Dissemination of regulations, instructions and policies. - Dissemination of standard operating procedures for tenders.
Royal Medical Services (RMS)	<ul style="list-style-type: none"> - The development of the hospital's website to include disclosure of tenders for medicines to include the following information: <ul style="list-style-type: none"> • prepare lists of medicines required bid. • comparison tables • the reasons for assignment • initial and final assignments - develop guidelines for evaluating the performance of suppliers and dissemination of results and update them periodically. - increase awareness of the need to use the site for the applicants of tenders. - Dissemination of regulations, instructions and policies. - Dissemination of standard operating procedures for tenders.