



Disclosure Status of Pharmaceutical Sector Data
Part of Component 1 of the MeTA Baseline Assessments

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The Medicines Transparency Alliance Jordan

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Data Collection Tool developed by:

WHO Harvard Collaborating Center in Pharmaceutical Policy
On behalf of
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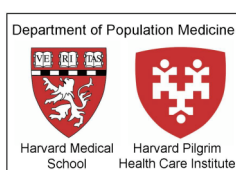


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ACRONYMS

HHC High Health Council

JAPM Jordan Association of Pharmaceutical Manufacturers

JFDA Jordan Food and Drug Authority

JP Joint Procurement

JPD Joint Procurement Department

JUH Jordan University Hospital

KAUH King Abdullah University Hospital

KHCC King Hussein Cancer Center

MOH Ministry of Health

QC Lab Quality Control Laboratory

RDL Rational Drug List

RMS Royal Medical Services

I. Introduction

MeTA pilot countries are developing strategies to promote greater transparency and accountability regarding policies, practices, and outcomes in the pharmaceutical sector. They have committed to disclosing, analyzing, and using over time data in the following four core areas described in the MeTA project document:

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

For each core area, disclosed information should cover **policies** – the laws and regulations that are in place; **practices** – suggested procedures to follow and actual practices; and **results** – achievements in the core area.¹ The objectives of describing the current disclosure status of information in the core areas are to: (1) enable the national MeTA stakeholders to prioritize potential MeTA country activities to facilitate progressive disclosure over time; and (2) create a baseline against which changes in transparency and disclosure during the MeTA pilot implementation can be measured.

This brief describes a process for accounting of data disclosures as envisioned by MeTA. The first section provides a brief framework for exploring disclosure status in a systematic way. The second section reviews the rationale for disclosing each type of pharmaceutical sector data and gives an overview of some possible data sources and key items to be disclosed in each area of disclosure. The third section provides a series of tables for collecting and presenting data on the disclosure status of key categories of pharmaceutical sector information.

To aid understanding, this information on data disclosure should be supplemented by contextual information on the medicines supply chain, access, price, affordability, and rational use of medicines. These data will be collected as part of an accompanying Pharmaceutical Sector Scan that will also be implemented as part of the baseline assessment. These contextual data will aid in the interpretation of the information on the status of disclosed data.

¹ Medicines Transparency Alliance. Implementing our pilot phase. Document presented at the MeTA launch, May 2008

II. Key Questions to Answer Related to Data Disclosure

In completing its baseline summary of disclosure, each MeTA country team should answer the questions below for each of the pharmaceutical sector topics targeted in the MeTA pilot phase project document. This information can be organized in a brief summary document (see Section 3) that will allow for convenient display of results for each topic.

The summary for each pharmaceutical sector topic will cover the following issues:

Policies

- Do relevant laws and/or policies exist?
- Are these laws and/or policies published?
- Do laws and/or policies exist to make the relevant data publicly available?

Practices

- Are required and/or recommended practices published?
- How are those practices implemented and enforced?
- What data sources exist and how are they organized?
- Where do the data reside and who has access?
- What is the quality of published data?

Results

- **Are results, achievements, or outcomes disclosed?**
- What are the disclosed data used for and by whom?
- What barriers exist to using the disclosed data more widely?
- Which strategies might encourage expanded data access and use?

During the process of conducting the baseline scan of data disclosures, MeTA country teams should obtain copies of any key pharmaceutical sector data that have already been publicly disclosed.. These disclosures may exist in the form of available publications, reports, lists, databases, or websites. The local team should append these disclosed data or their location to the summary report.

III. Information Categories and Possible Data Sources

1. Medicines Registration and Quality Assurance

1.1 Market registration procedures and registration status of all medicines

Rationale

Maintaining a transparent and organized process for registering medicines allowed to be used in a country is essential for ensuring that only high quality medicines are available on the local market. Through the registration process, manufacturers and importers demonstrate their compliance with pharmaceutical sector regulations on registered products. Drug supply managers and clinicians need to know which medicines are registered for use so that they can make appropriate therapeutic choices.

Possible data sources

- Explicit policies guiding registration along with decision making criteria (initial and renewal, patented and generic products)
- Information on registration fees, steps in registration process, regulations for general and/or restricted registration, for expedited review
- Policies and processes for de-registration of registered products
- Information on decision makers and potential conflicts of interest
- Dossiers submitted for medicines registration with dates and disposition

Key disclosure data

- Detailed information on process for registering and de-registering medicines
- List of registered products by therapeutic class, patent status, and registration date
- Average length of time required to register a product, both patented and generic
- Average cost to register a product, both patented and generic

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

Rationale

A key prerequisite to the production of safe medicines is adherence by manufacturers to Good Manufacturing Practices (GMP). Monitoring GMP adherence is a key function of the drug regulatory agency.

Possible data sources

- Regulations concerning GMP criteria and certification processes for domestic and foreign manufacturers
- GMP compliance monitoring procedures
- GMP certificates for domestic and foreign manufacturers
- Reports of inspections of manufacturing plants for compliance with GMP

Key disclosure data

- List of GMP compliant manufacturing plants of suppliers/manufacturers and dates of last inspection
- List of manufacturing plants that failed GMP inspection and dates of inspection and recommendations to plants

1.3 Quality assurance processes in public and non-profit tenders

Rationale

Making efficient, cost-effective, and safe procurement decisions requires information on the quality and reliability of medicines suppliers. Public disclosure of tender results can lead to more assured medicines quality and more cost-effective procurement.

Possible data sources

- Explicit criteria for supplier pre-qualification
- Procedures for pre-qualifying suppliers
- Ministry of Health, government procurement agency, or drug regulatory authority reports
- Non-profit medicine supply system reports

Key disclosure data

- List of pre-qualified suppliers for public, non-profit, or private sector tenders
- List of suppliers who failed to meet pre-qualification standards in the past
- Proportion of medicines by volume and value procured from prequalified suppliers in public sector and non-profit medicines supply systems

1.4 Quality assurance data during registration or procurement

Rationale

Prescribers, patients, and procurement agencies need to be able to trust the quality of medicines in the market place. Safe, appropriate, and cost-effective decisions depend on documented product quality assurance, specifically for generic products.

Possible data sources

- Regulations and procedures for assuring quality of domestic and imported products during registration or procurement processes
- Product quality assurance documents (both domestically produced and imported products)
- Bioavailability studies (generic products)
- Reports of violations of quality standards

Key disclosure data

- List of products that failed quality assurance procedures during registration or procurement processes and dates of failure and steps taken to address problems

1.5 Routine quality testing and adverse event monitoring

Rationale

Assuring safe use of medicines requires routine surveillance to detect substandard and counterfeit products, as well as routine reporting of adverse events identified after a drug has been marketed. The drug regulatory authority needs to establish systems to monitor drug quality and adverse events, and make these results publicly available.

Possible data sources

- Regulations and procedures for testing the quality of products in the market
- Regulations and procedures for monitoring and reporting adverse events
- Routine and ad hoc reports of products tested by quality testing laboratories
- Reports of adverse events identified in post-marketing surveillance studies
- Data and reports from voluntary adverse event reporting systems

Key disclosure data

- Number of samples from the market that were sent to quality control laboratories by government inspectors for routine testing in last year
- List of products that failed quality testing, date of testing, and steps taken to resolve problem
- Number of adverse event reports that were submitted to the government adverse event reporting system in last year

2. Medicine Availability

2.1 Standard treatment guidelines

Rationale

Standard treatment guidelines are one strategy for ensuring the availability of appropriate medicines to treat common health problems. Evidence-based and up-to-date standard treatment guidelines (STG) for key illnesses can guide the therapeutic decisions of health providers and the formulary decisions of health institutions and systems. STGs can be tailored for different levels of care and used as the basis for monitoring prescribing according to STGs.

Possible data sources

- Policies and procedures for creating and updating guidelines
- Procedures for selecting national STG committee members
- Processes to declare and document conflict of interest of STG committee members
- Processes for disseminating guidelines
- Policies and regulations to enforce or encourage guideline use (public and private sector)

Key disclosure data

- List of members of national STG committee with qualifications and affiliations

- Existing STGs for key adult and paediatric illnesses, including organization that created STG and year last updated

2.2 Essential medicines list

Rationale

A national or institutional essential medicines list (EML) provides guidance about the medicines recommended to treat common health problems seen in that setting. EMLs typically include all of the medicines recommended on STGs, as well as other medicines needed to address most of the clinical problems seen at a given level of care. By prescribing from an EML, health providers are more likely to offer the most cost-effective and affordable care. An essential medicines list also structures the process of procurement and pharmacy management, helping to ensure the availability of appropriate medicines.

Possible data sources

- Policies and procedures for creating and updating EML
- Procedures for selecting EML committee members
- Processes to declare and document conflict of interest of EML committee members and other stakeholders
- Processes for disseminating EMLs
- Policies and regulations to enforce or encourage EML use (in prescribing, procurement, supply management)

Key disclosure data

- List of members of national essential medicines committee with qualifications and affiliations
- Essential medicines lists for defined levels of care (primary health centre, secondary or district hospital, tertiary care centre) and year of last update

2.3 Pharmaceutical patents held in the country

Rationale

Policy makers and regulators need to be able to determine the patent status of products on the market to ensure compliance with intellectual property (IP) agreements and patent regulations, and to develop appropriate incentives for generic importation and manufacturing.

Possible data sources

- Laws and regulations governing IP, pharmaceutical patents, and market exclusivity
- Documentation of the status of relevant IP and trade agreements
- Explicit procedures governing filing for patents and market exclusivity arrangements

Key disclosure data

- List of registered medicines, their patent status, and the date of patent expiry (individually and by therapeutic class)

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

Rationale

Public sector policy makers and regulators need to know which products are used, in what volumes, and at what cost in order to project need, identify potential over- and underuse, and design policy interventions to increase use of desired and decrease use of undesired alternative products. Transparent procurement data are also useful for ensuring accountability of public resources. The non-profit health sector operates like a quasi-governmental system in many countries, filling gaps in the public health delivery system. Non-profit institutions also receive tax advantages in most countries in return for their role in promoting the public good. Disclosure of procurement data from non-profit institutions can encourage greater accountability.

Possible data sources

- Government budget documents
- Policies and regulations governing the disclosure of drug procurement or utilization data in the public and non-profit sectors
- Ministry of Health, Central Medical Stores, regional, or institutional medicines procurement or utilization reports
- Non-profit sector medicines procurement or utilization reports

Key disclosure data

- Government budgets for health care and pharmaceuticals for last fiscal year
- Type, volume, and value of medicines procured in the public and non-profit sectors (by region, by facility level, by innovator vs. generic, by therapeutic category)

2.5 Volume and value of medicines supplied in the private sector

Rationale

Policy makers and regulators need to know which products are used in the health system as a whole in order to understand trends in use, identify possible over- and underuse, and develop effective pharmaceutical policies. Detailed data on the quantity and price of medicines imported, manufactured, and sold in the private sector have commercial value and are generally considered confidential. However, some level of reporting of private sector pharmaceutical supply system data is often required to comply with drug regulatory and tax regulations.

Possible data sources:

- Policies and regulations governing the disclosure of drug supply data in the private sector
- Procedures and practices concerning release of private sector data on drug importation, manufacturing, and sales
- Data on type, volume and value of products imported, manufactured, or sold (by region; by therapeutic category, by level of the supply system)

Key disclosure data

- Type, volume, and value of medicines imported in the private sector (by innovator vs. generic, by therapeutic category)
- Type, volume, and value of medicines supplied in the private sector (at import vs. wholesale vs. retail level, by innovator vs. generic, by therapeutic category)

2.6 Availability of medicines to consumers

Rationale

To ensure effective treatment, appropriate medicines need to be available where and when patients seek care. Patients who seek care in public health facilities can expect that essential medicines recommended in relevant STGs and on the EML should be available at all times; poor availability of medicines is one common reason why patients bypass the public sector. Patients who seek care in the private or non-profit sector can expect adequate availability of medicines of reasonable quality.

Possible data sources

- Policies and procedures governing the procurement and stocking of essential medicines in public and non-profit health facilities
- Stock records for key medicines from public and non-profit health facilities (by region, by facility type, by therapeutic category)
- Documented follow-up on reports of pharmacy stock-outs in public health facilities, including time to resolution
- IMS data or other surveys of availability of medicines in private importers, wholesalers, or private retail pharmacies
- WHO-HAI medicines price or WHO Level II monitoring surveys

Key disclosure data

- Percent availability in public sector or non-profit health facilities of a list of key essential medicines (by region, by product, by innovator vs. generic, by therapeutic class, if available)
- Percent availability in private retail pharmacies of a list of key essential medicines (by region, by product, by innovator vs. generic, by therapeutic class, if available)

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

Rationale

Routine audits of medicines outlets are needed to ensure adequate compliance with laws and regulations concerning physical environment, types of products stored, staffing, record keeping, sales practices, and accounting.

Possible data sources

- Laws and regulations governing the operation of a pharmacy or medicines store (by public, non-profit, and private sector)
- Regulations and procedures for auditing practices in medicines stores
- Ministry of Health or drug regulatory agency reports

Key disclosure data

- Number, characteristics, training, and case load of drug regulatory agency auditors
- Number and percent of facilities audited in last year (by region, by type of facility)
- Number, type, and resolution of violations reported during audits

3. Medicine Prices

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

Rationale

Prices charged in public, non-profit, and private sector medicines outlets determine the affordability of medicines for consumers. End-user prices are a function both of the original price charged by a manufacturer (ex-manufacture price) and various mark-ups that are added on as the medicine proceeds through the supply system. Some countries regulate end-user price or allowable mark-ups at various points in the supply chain. Medicines are often provided free or with high levels of subsidy in public sector health facilities.

Knowledge about the comparative prices of alternative products, or about the prices of the same product in different outlets, can guide consumers to more cost-effective care.

Possible data sources

- Laws and regulations governing ex-manufacture and end-user pricing of medicines in the public, non-profit, and private sectors
- Procedures for auditing compliance with pricing regulations and procedures for handling violations
- Results of audits for compliance with pricing regulations
- Insurance program policies and procedures for medicines reimbursement
- Results of WHO-HAI medicines price surveys or of routine public or private medicines price monitoring systems
- Ex-manufacture price from manufacturers or importers/wholesalers² (both innovator and available generic versions)
- Insurance system reimbursement data

Key disclosure data

- Private sector retail prices for list of key essential medicines (by region, by innovator vs. generic versions)
- Private sector ex-manufacture price for a list of key essential medicines as above
- Prices charged to patients in public sector or non-profit health facilities for list of key essential medicines (by region, by level of facility, by innovator vs. generic versions), including visit fees or dispensing fees if applicable

² Disclosing ex-manufacturer prices by manufacturers or importers/wholesalers may be a sensitive issue in some circumstances. Aggregation of individual products into an average price per essential medicine, or the use of an intermediate agency (IMS, University, or consultant) might help obtain such data. Even if data cannot be disclosed, the arguments and potential process for disclosure could be discussed.

- Affordability of medicines to treat key acute and chronic health problems in public, private, and non-profit sectors, with prices expressed in relation to a standard metric such as the wages of the lowest paid government worker
- Amount charged and reimbursed to patients by insurance programs for list of key essential medicines (by insurance program type, by innovator vs. generic versions)

3.2 Public sector medicines procurement prices

Rationale

The prices that public sector agencies and health facilities pay to procure medicines are a key determinant of their ability to afford the medicines they need, and in some systems, of the prices charged to patients. Procuring medicines requires specialized technical skills that may not be present in all settings, especially in decentralized health systems. Transparent procurement processes, effective negotiation, and pooled procurement may decrease public procurement prices. Transparent procurement data enables public sector policy makers and system managers to benchmark bid prices, track prices over time, estimate budget requirements, and assess the overall efficiency of the procurement process.

Possible data sources

- Laws and regulations governing the disclosure of public sector medicines procurement prices
- Notifications about explicit procedures to be followed in handling bids in the public procurement process
- Audits for compliance with public medicines procurement regulations
- Ministry of Health medicines procurement records

Key disclosure data

- Public sector procurement prices for list of key essential medicines (by region, by level of care, by administrative unit, by product, by therapeutic class, if available)

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

Rationale

Taxes, tariffs, mark-ups, and other charges levied as medicines move through the supply chain can add substantially to the costs of medicines to consumers. To develop effective policies to make medicines more affordable, government policy makers need information about the levels and variations in medicines price components in both the public and non-profit sectors; countries that regulate private sector mark-ups need similar information from the private supply system.

Possible data sources

- Laws and regulations governing mark-ups of medicines in the public and non-profit sectors (and in the private sector, if applicable)
- Procedures for auditing compliance with regulations concerning mark-ups in the medicines supply chain and procedures for handling violations
- Results of audits for compliance with regulations concerning price mark-ups
- WHO-HAI price components studies

Key disclosure data

- Data on price components (duties, taxes, mark-ups and other charges) for key essential medicines, both domestically manufactured and imported (by region, by sector, by level of care, and by therapeutic class)

4. Medicine Promotion

4.1 Medicines promotion regulations, policies, and industry practices

Rationale

Through their promotional activities and materials, pharmaceutical manufacturers are the main source of information on medicines in many countries. Many countries have mandatory or voluntary codes of conduct governing the promotion of medicines to institutional purchasers, prescribers, retail sellers, and consumers. Some countries vet advertisements and promotional materials for accuracy. It is crucial that promotional activities comply with codes on ethical behaviour and balanced information content; inappropriate or unethical promotion can contribute to inefficient or unsafe patterns of care.

Possible data sources

- Laws and regulations on pharmaceutical industry promotion, including codes of conduct adopted by professional organizations
- International and domestic pharmaceutical manufacturers' codes of conduct
- Public procurement agencies' standard operating procedures related to relationships with representatives of pharmaceutical manufacturers and wholesalers
- Procedures for handling complaints, and for identifying, sanctioning, and publicizing violations of codes
- Documentation on the membership of monitoring committees and declarations of potential conflicts of interest

Key disclosure data

- List of manufacturers and distributors that subscribe to internationally or nationally recognized codes of conduct
- List of individuals with their affiliations who are on the national committee to monitor adherence to industry codes of conduct
- Reports of numbers and types of complaints submitted to the national monitoring committee regarding promotional practices, numbers of violations, and resolution of the complaints

IV. Forms for Summarizing Data Disclosure Status

1. Medicines Registration and Quality Assurance

1.1 Market registration procedures and registration status of all medicines

Sources:	Jordan FDA: www.jfd.jo
Policies: Do laws/policies exist? Are they published? Do associated regulations exist?	
<p>There are explicit Laws and policies (Drug and Pharmacy law No 80, 2001) that guide the registration process which are publicly available on the JFDA website along with regulations for registration and deregistration. The registration polices and regulations covers initial registration and renewal for both Original (Data protected) and Generics</p> <p>References:</p> <p>Drug and Pharmacy law No 80, (2001): http://www.jfda.jo/ar/Laws/details.aspx?id=60</p> <p>Registration and Deregistration Regulations: http://www.jfda.jo/ar/Laws/details.aspx?id=44</p>	
Practices: Are procedures published? How enforced? Which data exist? Who has access?	
<p>Registration procedures are published along with a manual that facilitate the stepwise process of registration on the website but there is no Online Tracking System for application for registration. The registration practices are enforced by drug and Pharmacy law , policies and regulations.</p> <p>Existed Data: procedures for registration of drugs, renewal of registration</p> <p>If any changes happen to already registered products, it should be re-registered and this is enforced by the law that governs tits registration. These changes might be one of the following:</p> <ul style="list-style-type: none">• Changes on country of Origin• Changes on manufacturing sites• Changes on manufacturing procedure• Changes of excipients• Changes of packaging• Changes of expiry date• Changes of the leaflet information• Changes of information on internal or external package	

- Changes of product criteria and analysis methods
- Changes of the trade name
- Changes of the manufacturing country address or name

The registration fees are covered within the registration manual according to each case. For example, the fee for renewal of a generic product is different from that of an original (data protected) product.

Requirement of Drug registration file are available and published as an annex in the registration criteria/regulations :<http://www.jfda.jo/EN/Laws/details.aspx?id=72>

Registration manual for applicants: <http://www.jfda.jo/ar/Forms/details.aspx?id=51>

The manual cover all procedures that an applier needs to follow according to cases as (registration of a new product, renewal, changes on already registered product)

Registration check list and required forms: <http://www.jfda.jo/ar/Forms/details.aspx?id=46>

All concerned stakeholders can access these data through entering the JFDA website

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

Detailed information on process for registration and re-registration, length of time and cost to register a product both patented and generics are available and disclosed.

length of time to register a patent product: within 180 days

<http://www.jfda.jo/ar/Laws/details.aspx?id=44>

Cost of registering a patent product: 1000 JD registration fees, 100 JD validity assessment study fees, 400 JD Bio-Availability study fees.

Length of time to register a generic product: within 180 days

<http://www.jfda.jo/ar/Laws/details.aspx?id=44>

Cost of registering a generic product: 100 JD registration fees, 100 JD validity assessment study fees, 400 JD Bio-equivalence study or 100 JD comparative dissolution study.

<http://www.jfda.jo/ar/Laws/details.aspx?id=44>

List of registered products by therapeutic class is provided to all pharmaceutical public sectors (JPD, MOH, RMS, JUH, and KAUH) for free. The same list is provided to the private sector and other stakeholders through a pre set fee (JD 1000 at the first year and JD 150 as a maintenance payment/year) or they can buy the required information through sending an SMS message to JFDA. The public can get an information regarding a specific registered medicine without date of registration and patency (data protection) status through the JFDA website by entering drug information link: http://www.jfda.jo/barcode_java/index.jsp?LangID=en (JFDA website bare code project)

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Through this link, the user need to write the generic or the brand name and then a list of that product with all alternatives will appear.

Who uses data: Available data can be used by all stakeholders (Public and private sector, CSO)

Barriers to use: paying fees to get some types of data. , and not easy to use by the public.

Wider use can be promoted by creating awareness regarding the available data based on the needs of each type of stakeholder which will save effort and time, also by making the website more user-friendly.

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

Sources:JFDA, www.jfda.jo**Policies:** Do laws/policies exist? Are they published? Do associated regulations exist?

GMP is covered by the Drug and pharmacy law, NO 80, 2001. Regulations concerning GMP criteria are available and published for both domestic and foreign manufactures. GMP guidelines is essential for improving the quality of pharmaceutical products, therefore Jordan is implementing the ARAB Guidelines on Current Good Manufacturing Practices (cGMP) for Pharmaceuticals. These Guidelines are binding to the Local and foreign pharmaceutical industries. The implementation of these essential guidelines is the responsibility of the health authorities in each Arab country, in Jordan it is the JFDA responsibility. Such guidelines should periodically be reviewed and, when necessary, revised by competent GMP Arab experts.

Drug and Pharmacy law No 80, (2001):

<http://www.jfda.jo/ar/Laws/details.aspx?id=60>

Arabic guidelines on cGMP:

<http://www.jfda.jo/ar/Laws/details.aspx?id=76>

Accreditation of Manufacturing sites regulations :

<http://www.jfda.jo/ar/Laws/details.aspx?id=46>

Practices: Are procedures published? How enforced? Which data exist? Who has access?

Procedures are covered and enforced by law. According to article (5A) of Drug and Pharmacy law no. (80) for the year 2001, and its amendments a valid certificate of good manufacturing practice issued by the concerned authority in the country of origin specifying the name of the manufacturing site, its address and its accredited production lines and stating that the company is following the instructions of good manufacturing practice guidelines of World Health Organization (WHO) as a minimum requirement. GMP certificate is issued upon request for domestic manufacturers. On the other hand, the GMP certificate is requested from foreign manufacturers. The monitoring procedures for compliance with GMP are available within the law, but not in a separate written document. The Accreditation of Manufacturing sites regulation contains an Annex that shows the requirements for manufacturing accreditation and evaluation.

Drug and Pharmacy law No 80, (2001):

<http://www.jfda.jo/ar/Laws/details.aspx?id=60>

Accreditation of Manufacturing sites regulations :

<http://www.jfda.jo/ar/Laws/details.aspx?id=46>

Manufacturing site Accreditation Forms: <http://www.jfda.jo/ar/Forms/details.aspx?id=46>

All stakeholders can access these data through the JFDA website.

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

Available data:

Laws and policies, regulations, forms and checklist that facilitate procedures. These data can be used by all interested stakeholders.

Barrier to use: unfriendly website.

Wider use can be reached by creating awareness and making the website easier for use.

Regarding key disclosure data:

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.

1.3 Quality assurance processes in public and non-profit tenders

Sources:	<p style="text-align: center;">www.jpd.gov.jo</p> <p style="text-align: center;">Public sectors: MOH, RMS, KAUH, JUH</p>
Policies: Do laws/policies exist? Are they published? Do associated regulations exist?	
<p>Regarding Quality assurance process in public tenders, laws and policies that covers tenders conditions and criteria for supplier prequalification is available and published on JPD website:</p> <p>http://www.jpd.gov.jo/ReadPaner_ar.php?id=63&sub_id=21</p> <p>Associated regulations are available and published on JPD website:</p> <p>http://www.jpd.gov.jo/ReadPaner_ar.php?id=97&sub_id=96 http://www.jpd.gov.jo/ReadPaner_ar.php?id=65&sub_id=21</p> <p>Regarding other public sector institutions available but not published</p>	
Practices: Are procedures published? How enforced? Which data exist? Who has access?	
<p>Procedures are published and enforced by law.</p> <p>All stakeholders have access through the JPD website.</p> <p>A workflow guide along with procurement steps and forms are available on the JPD website.</p> <p>Regarding other public sector institutions available but not published</p>	
Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?	
<p>Available data:</p> <p>Laws, instructions, regulations, polices, procedures and reference guide,</p> <p>Key disclosure data:</p> <p>There is no list of prequalified suppliers, but prequalification criteria and procedure are available and disclosed, while Performance criteria are not currently available, but the JPD is working on developing these criteria</p> <p>List of suppliers who failed to meet pre-qualification standards in the past is not available.</p> <p>The value and volume of tenders procured by MOH, JUH, KHCC, RMS and KAUH are disclosed and published on JPD website</p> <p>http://www.jpd.gov.jo/ReadPaner_ar.php?id=72&sub_id=22</p>	

Jordan Assessment of Pharmaceutical Data Disclosure

Proportion of medicine from pre-qualified suppliers can't be calculated as there is no list of the pre- or post qualified suppliers.

Data is used by concerned stakeholders.

Barriers to use: Lack of access and non-friendly JPD website can serve as barriers to users.

Wider use can be promoted by creating awareness regarding available data.

1.4 Quality assurance data during registration or

Sources:	JFDA, www.jfda.jo
Policies: Do laws/policies exist? Are they published? Do associated regulations exist?	
<p>The drug & pharmacy law & drug testing by-law that are published on the JFDA web site covers quality assurance processes for medicines. Medicines can't be registered nor distributed or used in the Jordanian market before passing Lab testing.</p> <p>Medicine testing By-law :</p> <p>http://www.jfda.jo/ar/Laws/details.aspx?id=62</p>	
Practices: Are procedures published? How enforced? Which data exist? Who has access?	
<p>Procedures of testing are within the drug regulations and are published. They are enforced upon registration by laws and regulations and by lab testing</p> <p>A manual that guides importers and local manufacturers is also available on JFDA website.</p> <p>http://www.jfda.jo/ar/Forms/details.aspx?id=51</p> <p>All concerned stakeholders have access to this information.</p>	
Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?	
<p>Laws, regulation, procedures, forms and manuals to guide applicants are available and can be used by all interested stakeholders.</p> <p>Barriers to use: non friendly user website and lack of access to key disclosure data</p> <p>Recommended: Wider use can be promoted by creating awareness.</p> <p>Regarding Key disclosure data:</p> <p>List of products that failed quality assurance testing procedures during registration process and dates of failure and steps taken to address problems are available at JFDA but Not disclosed neither published.</p> <p>List of products that either passed or failed quality assurance procedures during procurement processes and dates of failure and steps taken to address problems is not available at the JPD</p> <p>There is no List of products that either passed or failed quality assurance procedures For the local market (Private sector)</p>	

1.5 Routine quality testing and adverse event monitoring

Sources:	JFDA, www.jfda.jo
Policies: Do laws/policies exist? Are they published? Do associated regulations exist?	
<p>The Drug and pharmacy law, Drug Testing Bylaw, regulations and procedures for testing the quality of products in the market are available and published on the JFDA website.</p> <p>Drug and Pharmacy law No 80, (2001): http://www.jfda.jo/ar/Laws/details.aspx?id=60 Drug Testing Bylaw: http://www.jfda.jo/ar/Laws/details.aspx?id=62 Regulations and procedures for monitoring and reporting adverse events are available and disclosed on the JFDA website. The directorate of pharmaco-vigilance was established by the Drug and Pharmacy higher committee of according to Article 5/A of the Drug and Pharmacy law No 80 and its amendments for year 2006</p>	
Practices: Are procedures published? How enforced? Which data exist? Who has access?	
<p>Procedures of testing are within the regulations and they are enforced by the law and its Bylaw.</p> <p>Pharmaco-vigilance guidelines for adverse reaction and drug related problems are available and published http://www.jfda.jo/ar/Laws/details.aspx?id=44/(go back to website)</p> <p>Forms for reporting adverse reaction and drug related problems are available and published http://www.jfda.jo/ar/Forms/details.aspx?id=46</p> <p>Data accessibility is for all stakeholders</p>	
Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?	
<p>Laws, regulations, procedures, guidelines and forms are available and disclosed.</p> <p>Available and disclosed data can be used by all stakeholders.</p> <p>Key disclosure data:</p> <p>Number of samples from the market that were sent to quality control laboratories by government inspectors for routine testing in last year are publicly available and published within the JFDA annual report for 2009</p> <p>List of products that failed quality testing, date of testing, and steps taken to resolve the problem are available but not disclosed neither published.</p> <p>Number of adverse event reports that were submitted to the government adverse event reporting system in the last year is available but not disclosed neither published.</p> <p>Barriers to use: lack of Information and awareness of laws, regulations concerning</p>	

Pharmco-vigilanc

Recommended:

Promoting wider use by creating awareness regarding available data and disclose more statistical data.

2. Medicine Availability

2.1 Standard treatment guidelines

Sources:

JFDA, JUH, KAUH, MOH, RMS

Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

At a National Level:

There are no policies and procedures for creating and updating STG guidelines, there is only missions like the PHR plus project and some USAID project which supported developing some STGs

Creating and updating STG is part of the technical committees of RDL , and the Clinical Pharmacy Directorate at the MoH.

There are no procedures for selecting national STG committee members as there is no Specific National STG committee.

There are no polices for disseminating guidelines, also there are no polices and regulations neither incentives to enforce guidelines use.

At an Institution level:

The **Royal Medical Services** (RMS) had STGs from 1990 which is updated regularly and managed, implemented and monitored by committees and incentives are introduced.

At the RMS, the STG are enforced and incentives are introduced and if the medication is not under the specified guidelines it wouldn't be prescribed

JUH: There are no specific STGs each physician follow a different school

Practices: Are procedures published? How enforced? Which data exist? Who has access?

Not available.

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

Key Disclosure data:

List of members of the national STG Committee with qualifications and affiliations is not available as there is no national STG committee.

There are no national STGs but there are specific STGs at the institutional level (like RMS) which available but not disclosed nor published outside the RMS.

see annex 1)

RMS have STGs for the following disease categories:

- Glaucoma
- Osteoporosis
- Hepatitis B, C
- H. Pylori
- Hypertension (JNC7: It was recently updated)
- Antibiotics protocols
- Cytotoxic protocols these products should follow a chain process of approval even if it is available at the hospital pharmacy: (a physician , a specialist, the hospital director, the pharmacy director, and the RMS director)
- Systematic antifungal
- Diabetes
- Interferon
- Human Albumen
- Medications for Nephrology surgeries

2.2 Essential medicines list

Sources:

JFDA, www.jfda.jo
JUH,MOH,RMS

Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

Policies and procedures for creating and updating **EDL (RDL)** are available along with list of selecting RDL committee members.

In 2006, the government has officially adopted Jordan Rational Drug List (JRDL)

JRDL is available in a printed format and at the website of the JFDA/ at the RDU Unit site

Guidelines for addition-deletion for medicines from the list to update the list periodically are available as well.

A selection committee is appointed to give technical advice on the revision and updating of the RDL.

The form of conflict of interest of RDL committees is available but there is no conflict of interest management system neither practiced.

RDL is enforcing to all public sectors in procurement by an official letter signed by His Excellency the minister of health.

Practices: Are procedures published? How enforced? Which data exist? Who has access?

All related procedures are published in hard copies and at JFDA website.

It was enforced by an official letter from his Excellencies the Prime Minister and the Minister of Health that all medicines procured by JPD should be restricted to RDL.

Rational Drug Use Unit Website:

<http://www.jfda.jo/RDU/en-US/IndexPage.aspx>

Data accessibility is for all stakeholders

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

Within the RDL, Generic name of drugs, items number according to ATC code.

Jordan National Drug Formulary is available as a hard copy and at JFDA website.

It is used by all health providers in all health sector institutions, and all stakeholders.

Rational Drug Use Unit Website:

<http://www.jfda.jo/RDU/en-US/IndexPage.aspx>

Jordan National Drug Formulary is available through this link:

<http://www.jfda.jo/RDU/JNDFBook/All%20Chapters/All%20Chapters.htm>

Key Disclosure Data:

List of members of national RDL committed with qualification and affiliations is available and published within the Jordan national drug formulary, but not the reviewed, the committees members have been changed few times and the list is not published.

changes in RDL technical committees composition is not updated on the website nor the hard copy

EML for defined levels of care:

RMS: Available as VEN: Vital, Essential, Non-essential but not published neither disclosed.

Now the RMS is updating the **VEN** to become **ABC** system according to prescription authority.

MOH: EML for defined levels of care is available but not published.

JFDA: EML classified to restricted, unrestricted and authorized, it is available and published in the RDU Drug Use Unit Website but its not easy to use.

JUH: EML classified according to therapeutic area, It is available but not published

Recommendation on how to promote wider use:

1. increase awareness among health providers and consumers and patients groups
2. promote the pharmacy and therapeutics committees role in hospitals
3. introduce policy for generic substitution and increase awareness on this concept
4. adoption of standard treatment guidelines.
5. adoption of prescribing and dispensing policies and guidelines.

2.3 Pharmaceutical patents held in the country: Data Protection

Sources:

Ministry of Trade and industry <http://www.mit.gov.jo/>

Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

Laws and regulations governing, pharmaceutical patents are available.

Patent law and regulations are published at the ministry of trade and industry website.

Patent Law: <http://www.mit.gov.jo/portals/0/tabid/507/patent%20law.aspx>

Patent Regulations: <http://www.mit.gov.jo/portals/0/tabid/537/patent%20regulation.aspx>

patents applications are not published

granted patents are published in official gazettes-only summary, there is no electronic records

patent research is manual, not accurate , no electronic search

no classification of patents

access to details of granted patents is for free

Practices: Are procedures published? How enforced? Which data exist? Who has access?

Procedures for filing of patents are published and accessible

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

Available data:

Laws, regulations , procedures and Foreign agreements at the Ministry of Trade and Industry website

Recommended:

List of patent applications sorted and classified per filed of invention, patent owner and other details

List of granted patents sorted and classified per field of invention, patent owner and other patent details

Search engines for patents.

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

Sources:

JPD, www.jpdc.gov.jo
MOH, JUH, KAUH, RMS,

Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

Laws/ Policies and regulations governing the disclosure of drug procurement at the public sector are available.

http://www.jpdc.gov.jo/ReadPaner_ar.php?id=63&sub_id=21

http://www.jpdc.gov.jo/ReadPaner_ar.php?id=97&sub_id=96

Practices: Are procedures published? How enforced? Which data exist? Who has access?

Procedures are within the law and are enforced and published

All stakeholders have access

In some situations public institutions purchase medications based on Public price that is private price set by the JFDA not tender prices

Data regarding value and volume of local purchases is available but not publicly disclosed

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

Key Disclosure Data:

Government budget for health care and pharmaceuticals for the last year :

MOH: Available and Published.

http://www.moh.gov.jo/reports/headermain.jsp?firstjsp=budjetmain&lang_parameter=arabic

JUH: Available and it was published at the time of getting the data during December 2009 but now it is not publicly disclosed (Based on a conversation with JUH representative at the MeTA Council at the time of conducting the survey, the budget for pharmaceuticals at JUH is 12 Million for 2009. www.ju.edu.jo

KAUH: Available but not publicly disclosed (Based on a conversation with KAUH representative at the MeTA Council at time of conducting the survey, the budget for pharmaceuticals at KAUH is between 8-10 Million for 2009.

<http://www.kauh.jo/kauh/arabic/tender/Companies.aspx>

RMS: Available but not Publicly disclosed.

The Budget is not available but the JPD website shows how much each sector procured of medicine according to therapeutic class.

Type, volume and value of medicines procured in the public are available (by therapeutic category and sector) and published on JPD website

Generics versus Originators should be extracted from the list of procured medicines.

Barrier to use: lacking knowledge of available data , not easy to access and use data

Recommended:

Wider use: by creating awareness and make the website more user friendly

2.5 Volume and value of medicines supplied in the private sector

Sources:

Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

Not applicable- there is no laws and polices usually exist for volume and value of medicines supplied in the private sector.

Practices: Are procedures published? How enforced? Which data exist? Who has access?

Not applicable- no procedures usually exist for volume and value of medicines supplied in the private sector.

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

Type, volume and value of medicines **imported** in the private sector (originators and generics: available but not disclosed

Type, volume and value of medicines **supplied** (imported and manufactured) in the **private sector** :Available but not disclosed

Barrier to use: Data is accessible only for certain parties and it is available for fees, not free

There is private company IMS which does estimation-extrapolation from a sample of private sector pharmacies- for volume and value of medicines supplied in the private sector which is not very accurate and very expensive to get

2.6 Availability of medicines to consumers

Sources:

MOH, RMS, JUH, KAUH, WHO-HAI Survey

Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

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 KAUH

Stock records are available but not accessible

Documented follow up reports are available at RMS, and JUH but it is not available at MOH

Practices: Are procedures published? How enforced? Which data exist? Who has access?

Procedures governing stocking is available and are enforcing by law

Exist data:

JUH:

<http://www.ju.edu.jo/tenders/tenders/Pages/SystemsandLows.aspx>

RMS: Military Supplies Bylaw number 3 and its amendments for the year 1995 and the Military regulations supplies number 1

1()3() 1995

The RMS laws and regulation regarding stocking is not disclosed

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

% of availability of essential medicines for the public: Not Available now, will be available once WHO-HAI medicines price survey is completed and published.

% of availability of essential medicines in the private retail pharmacies: Not Available now, will be available once WHO-HAI medicines price survey is completed and published.

IMS : fees are required to access IMS data.

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

Sources:

JFDA, www.ifda.jo

Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

Laws and regulations governing the inspection and auditing of pharmacies and Drug stores (are available. Have been published within the the Drug & Pharmacy Law No.80 for 2001 / MAKE SURE OF THIS DATA(pharmacies of public hospitals are subjected to auditing)

Regulations and procedures for auditing practices in pharmacies are available, also Hospitals has its own internal audit system.

MOH: Laws and regulations governing the public pharmacies are available. Been published through the Supplies act Law No 32 for 1993 and internal auditing regulations

Auditing at the RMS takes place over many levels.

Representative from Jordan Audit Bureau attend the tender committee meetings as an observer to monitor the tendering procedure at JPD.

<http://www.ab.gov.jo/>

Practices: Are procedures published? How enforced? Which data exist? Who has access?

Procedures are available and are enforced by law

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

Number, characteristics, training and case load of drug regulatory agency auditors:
available but not published

Number and percent of facilities audited in last year:
available but not published

Number, type and resolution of violations reported during audit:
available but not published

Who uses data: related parties

3. Medicine Prices

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

Sources:

JPD,JFDA, www.jfda.jo

Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

Laws and regulations governing ex-manufacturing and end user pricing of medicines in the private sector are available and disclosed.

Drug and Pharmacy Law, NO 80, (2001)

<http://www.jfda.jo/ar/Laws/details.aspx?id=60>

Pricing Criteria:

<http://www.jfda.jo/ar/Laws/details.aspx?id=47>

Practices: Are procedures published? How enforced? Which data exist? Who has access?

Procedures of pricing are within pricing criteria which is published

Pricing Criteria:

<http://www.jfda.jo/ar/Laws/details.aspx?id=47>

They are enforcing by law

Access to the public

Pricing Forms:

<http://www.jfda.jo/ar/Forms/details.aspx?id=47>

A pricing manual is available to applicant (importers, local industry) to facilitate the pricing procedure: <http://www.jfda.jo/ar/Forms/details.aspx?id=51>

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

Private sector retail prices for list of key essential medicines: Available

All medicines prices are disclosed but not a friendly user website

<http://www.jfda.jo/RDU/ar-JO/HomeSearch.aspx>

<http://www.jfda.jo/RDU/ar-JO/IndexPage.aspx>

http://www.jfda.jo/barcode_java/index.jsp?LangID=en

Any price can be obtained through paid SMS message or through subscription to medicines prices program (a fee is needed for the medicines prices program in order to get the excel sheet for prices that shows price components)

Private sector ex-manufacture price for a list of key essential (Rational Drug List): Available but is not publicly disclosed. Getting this information is not free of charge, it needs subscription.

Co-payment to patients in public sector or non-profit health facilities for list of key essential medicines: Available but not published/disclosed

Affordability of medicines to treat key acute and chronic health problems in public, private, and non-profit sectors: This key data can be obtained once the WHO-HAI pricing and availability survey is completed. Mean while the 2004 survey is available on:

http://www.haiweb.org/medicineprices/surveys/200405JO/survey_report.pdf

3.2 Public sector medicines procurement prices

Sources:

JPD, www.jpd.gov.jo

Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

Laws and policies along with regulations are available and disclosed on JPD website.

http://www.jpd.gov.jo/ReadPaner_ar.php?id=63&sub_id=21

http://www.jpd.gov.jo/ReadPaner_ar.php?id=97&sub_id=96

Practices: Are procedures published? How enforced? Which data exist? Who has access?

Procedure are enforcing by law and published on JPD website

All stakeholders have access

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

Public sector procurement prices for list of key EML (Rational Drug List): available and disclosed

All stakeholders have access

Barriers to use: unfriendly website and lack of knowledge regarding data availability

Wider use: by creating awareness and developing the website to be more friendly user

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

Sources:

JFDA, www.jfda.jo

Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

Laws and regulations covering pricing components in the public and the private sector are available and disclosed within the drug and pharmacy law

Drug and Pharmacy Law, NO 80, (2001)

<http://www.jfda.jo/ar/Laws/details.aspx?id=60>

Practices: Are procedures published? How enforced? Which data exist? Who has access?

Procedures of pricing are within pricing criteria which is published

Pricing Criteria: <http://www.jfda.jo/ar/Laws/details.aspx?id=47>

They are enforced by law

Access are for public

Pricing Forms:

<http://www.jfda.jo/ar/Forms/details.aspx?id=47>

There is a pricing manual to guide applicants (local industry, importers) through the process: <http://www.jfda.jo/ar/Forms/details.aspx?id=51>

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

Data on price components (duties, taxes, mark-ups and other charges) for key essential medicines both domestically manufactured and imported: Available at JFDA by sector and therapeutic class but not published,

Information about medicines and prices/ the bare code project.

http://www.jfda.jo/barcode_java/index.jsp?LangID=en

4. Medicine Promotion

4.1 Medicines promotion regulations, policies, and industry practices

Sources:

JFDA, www.jfd.jo

Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

Recently drug promotion regulations were officially published.

They were published in the official gazette 2009 and available at JFDA website.

Drug promotion guidelines are issued according to Article (88) of the drug and pharmacy law (No. 80) for the year 2001

promotion guidelines:

<http://www.jfda.jo/ar/Laws/details.aspx?id=100>

Practices: Are procedures published? How enforced? Which data exist? Who has access?

Procedures are published at JFDA website.

It is not enforcing by the law

It can be enforced by adoption of this regulation and procedure for complains and sanction on reprehensible actions, and evaluation and monitoring by assigned body to follow up and monitoring.

For example, medicine advertising through TV is prohibited according to **Provisional Law No. (80) for the year 2001 .Drugs & Pharmacy Law , Article (35)**

- ▶ It shall be prohibited to advertise, for promotion purposes, any drug or substance that has medicinal characteristic, or infants milk formula or their special formula and supplementary food, in any of the readable, or visual or audible media or in any other mean unless by approval of both the Minister and the Association with the exception of medicinal publication and information directed to Health Authorities on condition that such information are authenticated.

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

Guidelines cover all drug promotion activities like: use of quotations in drug promotions, acceptability, distribution and transparency of drug promotion, events and hospitality, gifts and incentives, medical samples, the use of consultants, pharmaceutical company staff and the activities of medical representatives.

It is used by PHRMA, pharmaceutical companies and the industry.

Recommendation for promotion by:

1. 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.
2. Increase the awareness among consumers.
3. Introduce it in the curriculum of medical faculties.

List of manufacturers and distributors that subscribe to internationally or nationally recognized codes of conduct: Not available

List of individuals with their affiliations who are on the national committee to monitor adherence to industry codes of conducts: Not available as there is no national committee for monitoring.

Reports of numbers and types of complaints submitted to the national monitoring committee regarding promotional practices, numbers of violations, and resolution of the compliant: Not available as there isn't any system in place to cover complains.

Jordan Assessment of Pharmaceutical Data Disclosure

Disease	Group producing guideline
Hypertension	<ul style="list-style-type: none">- National Committee for Rational Use of Drugs, 1999- PHCI (USAID), 2003- MoH, Directorate of Disease Control & Prevention, Non-Communicable Disease Division, 2004 (PHC)
Diabetes	<ul style="list-style-type: none">- PHCI (USAID), 2003- MoH, Directorate of Disease Control & Prevention, Non-Communicable Disease Division, 2004 (PHC)
Asthma	- PHCI (USAID), 2003
Acute respiratory infections	- PHCI (USAID), 2003
Diarrhoeal disease	- PHCI (USAID), 2003

Annex (1)

