

**Achievement of Market-Friendly Initiatives and Results Program  
(AMIR 2.0 Program)**

Funded By U.S. Agency for International Development

**The Jordanian Drug Administration:  
Analysis and Recommendations**

Final Report

**Deliverable for Private Sector Policy Initiative Component, Task No. 581.1.6  
Contract No. 278-C-00-02-00201-00**

December 2002

This report was prepared by Mr. William T. Lampkin, in collaboration with Chemonics International Inc., prime contractor to the U.S. Agency for International Development for the AMIR Program in Jordan.

# Table of Contents

---

<b>TABLE OF CONTENTS</b>	<b>i</b>
<b>ACRONYMS</b> .....	<b>ii</b>
<b>Executive Summary</b> .....	<b>1</b>
Organization of the Drug Directorate .....	1
Major Findings .....	1
Prioritized List Of Recommendations .....	1
<b>1. Introduction</b> .....	<b>4</b>
1.1 Objective .....	4
1.2 Methodology.....	4
1.3 Report Organization .....	4
<b>2.0 Organizational Background</b> .....	<b>6</b>
2.1 Drug Directorate .....	6
2.2 Administration.....	8
<b>3.0 Organizational Assessment of the Drug Directorate</b> .....	<b>11</b>
3.1 Inspection Department .....	11
3.2 Registration Department.....	13
3.3 Quality Control Department .....	15
3.4 Import and Export Department.....	16
3.5 Narcotics and Dangerous Drug Department.....	17
3.6 Information and Follow-up Department and Jordanian Pharmacovigilance Center.....	19
3.7 Pricing Department.....	20
3.8 Other Recommendations .....	21
<b>4. Building and Facilities</b> .....	<b>23</b>
4.1 Sanitary Services .....	23
4.2 Work Space .....	23
4.3 Security and Other Issues .....	24
<b>Annex A: Consultant’s Scope of Work</b> .....	<b>25</b>
<b>Annex B: Interviews Conducted</b> .....	<b>27</b>
<b>Annex C: Seminar in Current Good Manufacturing Practice Regulations</b> .....	<b>28</b>

## Acronyms

---

CGMP	Current Good Manufacturing Practices
FDA	Food and Drug Administration
GLP	Good laboratory practice
GOJ	Government of Jordan
JAPM	Jordanian Association of Pharmaceutical Manufacturers
LAN	Local area network
MOH	Ministry of Health
QCL	Quality Control Laboratory
WHO	World Health Organization

## **Executive Summary**

---

The purpose of this study is to examine the present organizational structure of the Drug Directorate of the Ministry of Health (MOH) of the Government of Jordan (GOJ) with a view towards establishing a modern drug regulatory agency such as the Food and Drug Administration (FDA) in the United States. Presently the Drug Directorate and the Quality Control Laboratory (QCL) Directorate regulate the drug sector in Jordan. The QCL reports to the Minister of Health through several ministerial layers, but not to the Drug Directorate. The QCL and the Drug Directorate have an excellent working relationship; however, it could improve if the QCL were under the direct control of the Drug Directorate. This will be discussed in more detail later in the body of this report.

### **Organization of the Drug Directorate**

The Drug Directorate presently has eight departments: (1) National Drug Policy Management and Implementation Unit, (2) Quality Control Department, (3) Narcotic Drug Department, (4) Inspection Department, (5) Import and Export Department, (6) Registration Department, (7) Pricing Department and (8) Information and Follow-Up Department. Personnel in all of these departments were interviewed in order to determine the functions of the various departments. If department functional statements were available, they were also reviewed, and, if available, individual job descriptions were examined.

### **Major Findings**

The organization of the Drug Directorate has been discussed in previous reports.<sup>1</sup> In general all reports have recommended that the QCL be under the direct control of the Drug Directorate. The present report also recommends this change as well as others, which will be discussed in subsequent chapters. In general, all departments in the Drug Directorate lack adequate functional statements or job descriptions. Personnel were found to be hard working. Their working conditions, however, are not good in that the space is inadequate and they have insufficient equipment and support personnel. Morale is also low because of the low pay and perceived lack of an opportunity to advance in the Directorate.

### **Prioritized List Of Recommendations**

- 1) Secure a new building for the Drug Directorate. The current building is inadequate in that it lacks sufficient space for the current staff. It cannot accommodate the need for more waiting, meeting and file rooms. It is not climate controlled and it cannot be easily wired for a local area network (LAN).
- 2) Establish functional statements, position descriptions and standard operating procedures for each department. Currently none of the departments have adequate written documents covering these areas. The absence of these documents allows

---

<sup>1</sup>Report presented to HE Dr. Faleh Al Nasser, Minister of Health, from William T. Lampkin, FDA Consultant, June 30, 2002.

- for overlapping of functions and inefficiency due to duplication of work. There is also a great deal of confusion with respect to employee's duties and responsibilities.
- 3) Establish a LAN that spans the entire directorate. All of the computers in the drug directorate would be connected. Each employee would have his own computer and would be able to communicate with others electronically. They would also be able to access data and devices anywhere in the Directorate such as laser printers. The ability to communicate with each other through the computer would greatly increase communication between the divisions. The access to a central electronically created database would eliminate a lot of inquiries to the Registration Department. Users would also have access to the Internet, which would greatly increase their information base.
  - 4) Computer training for all users. It does no good to provide a LAN and computers to the Drug Directorate without proper training. This training will upgrade computer and analytical skills that should lead to better reports. This training should be continuous.
  - 5) Establish a file room with a file clerk. Files are currently stored throughout the Directorate and personnel waste a lot of time looking for files. A file room with a file clerk would bring order to the filing system. A logging system for files needs to be established as well as a system for updating them when new information is submitted
  - 6) Hire additional staff (or transfer from other staff) for the Pricing Department. This department is definitely understaffed.
  - 7) Add a deputy or assistant director to the staff of the Director. The responsibilities of the director are too great for one person. The director needs an assistant. It is difficult for the staff to always discuss problems with the director because of her busy schedule of meetings and appointments. A deputy can take care of many of the personnel problems and fill in for the director during her absence.
  - 8) Add a legal and medical advisor to the staff of the director. Many times medical and legal advice is needed. For example, medical advice would be needed to determine the health hazard associated with a product recall. The level of the recall would depend on the health hazard. Only a medical doctor can give a health hazard evaluation. A legal advisor would be needed whenever there is a legal question or court challenge to a directorate decision.
  - 9) Increase the staff in the Inspection Department and promote specialization. This department is understaffed and needs additional training on how to perform Current Good Manufacturing Practices (CGMP) inspections in drug manufacturing plants. This training is especially important when the inspector is expected to perform pre-approval inspections of foreign drug manufacturers.

- 10) A training program should be developed whereby an experienced FDA inspector can come to Jordan and accompany the inspectors on drug inspections for some on-site training. In addition, the inspectors should be allowed to travel to the USA for some additional on-site training with FDA inspectors. Inspectors receiving this training should be specialized in drug inspections. A side benefit of this training would be that the expertise of the inspectors would be increased and they can do a better job of inspecting Jordanian drug firms. This in turn will force the drug industry in Jordan to meet the more stringent CGMP technical standards present in Europe and North America. Jordanian drug firms will have to meet these standards in order to be able to increase exports to these regions. Without proper training of the inspection staff, there cannot be any enforcement of the CGMP regulations. Without proper enforcement of the CGMP regulations, some drug firms will not comply because of the increased expense involved. Other self-motivated firms will comply and this leads to an uneven playing field for the drug manufacturers. A staff capable of performing CGMP inspections in Jordan and foreign drug firms wishing to export to Jordan would raise the quality of drugs manufactured and imported. The image of the drug industry in Jordan as well as the inspectors in the Drug Directorate would be enhanced. In addition, Jordanian firms would more easily be able to meet the international standards required to export drugs to Europe and the USA.
- 11) Stop the practice of testing each batch of drug products manufactured, exported or imported in Jordan. This practice is wasteful of resources, a hindrance to drug manufacturers and is totally unnecessary. As discussed before, the way to assure drug quality is through stringent enforcement of the CGMP regulations not finished product testing. The quality of the drugs in the market place should be determined through a marketed drugs surveillance program.

The remaining recommendations made for each department, as discussed in this report, have approximate equal priority.

## **1. Introduction**

---

### **1.1 Objective**

This study was undertaken to examine the present organizational structure and procedures of the Directorate and to recommend changes where appropriate. A comparison was made between the present structure and that of a modern drug regulatory agency such as the Food and Drug Administration (FDA) in the United States. A new organizational chart was proposed along with new staffing recommendations. The operating procedures of the different departments were reviewed and recommendations were made on how they may be improved. The staffing and the budget were also reviewed as well as the training needs. Constraints to overcome were identified. A suggested training program was prepared and training sites were identified.

### **1.2 Methodology**

This study is a follow-up to previous work performed by a volunteer executive for the International Executive Service Corps IESC and the Jordan-United States Business Partnership.<sup>2</sup> The results of that study pointed to the need to reorganize the Drug Directorate into the Jordanian Drug Administration rather than a Jordanian Food and Drug Administration. Because of the complexity of the food industry, the study recommended the addition of the infrastructure for regulating foods at a later date. The study also pointed to the need to add the Quality Control laboratory Directorate (QCL) to the Drug Directorate in order to better coordinate their activities.

At the request of the Ministry of Health (MOH), a seminar on the Current Good Manufacturing Practice (CGMP) regulations was given to eighty-six participants from the drug industry and the MOH. This seminar was not included in the scope of work; however, it was a very important training event for MOH and private industry on the requirements of the CGMPs. The seminar announcement and the list of participants are given in Annex C.

### **1.3 Report Organization**

The report is organized as follows:

Chapter 2 discusses the organizational background of the present Drug Directorate and makes recommendations for changes. Figure 1 gives the current structure of the Drug Directorate and Figure 2 proposes its reorganized structure.

---

Memo presented to HE Dr. Faleh Al Nasser, Minister of Health, on the organization of the Drug Directorate, June 23, 2002.

Chapter 3 gives an organizational assessment of the Drug Directorate and offers recommendations for each department. This section also discusses product testing and makes recommendations for changes in the present procedure.

Chapter 4 discusses the building and facilities and makes recommendations for improvements.

Annex A provides the scope of work for this consultancy. Annex B includes the list of interviews conducted. Annex C contains the announcement of the CGMP seminar and the list of participants.

## **2.0 Organizational Background**

---

### **2.1 Drug Directorate**

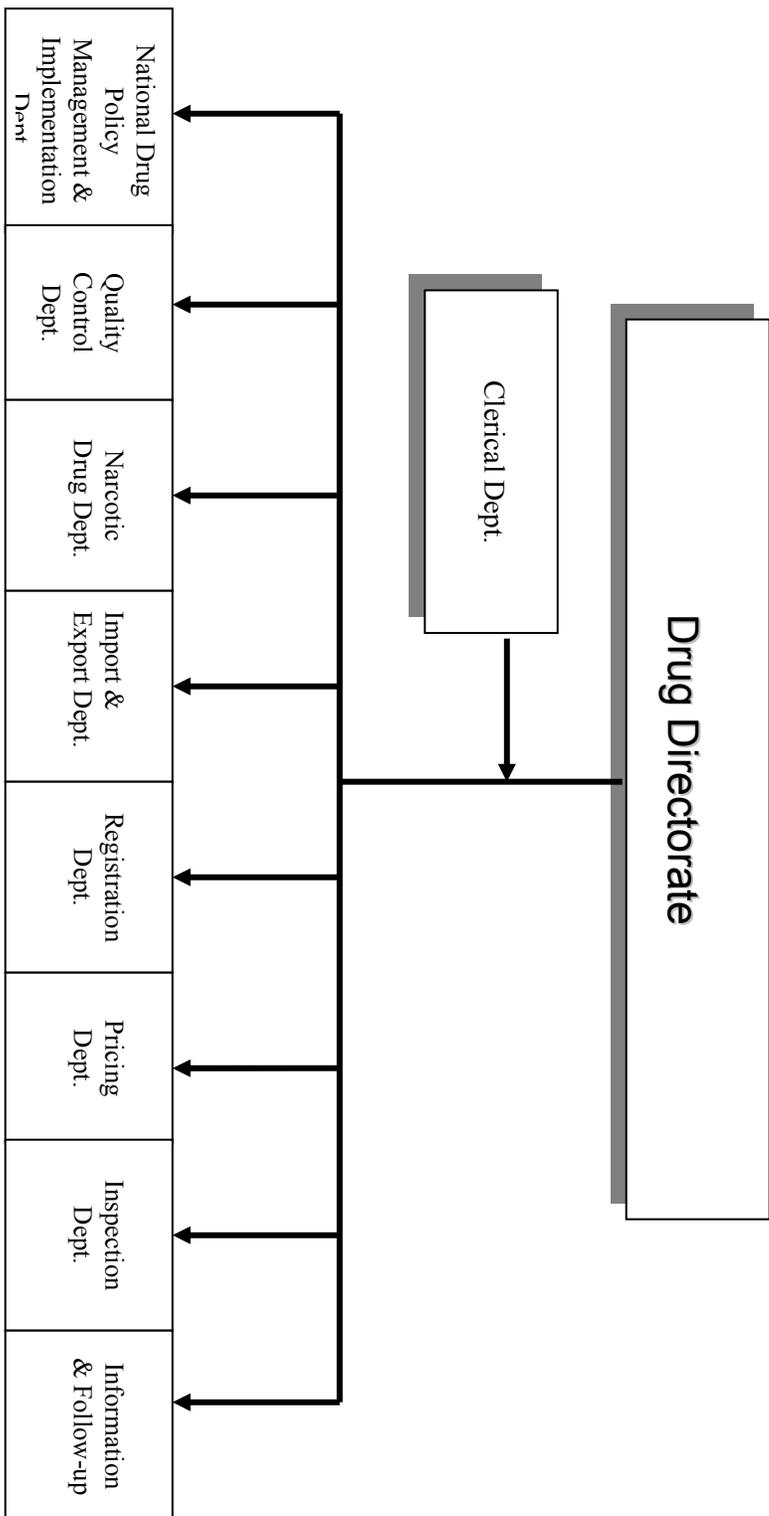
The Drug Directorate is one of the central directorates of the MOH that aims through its various sections to:

- 2) Ascertain the safety, efficacy and quality of drugs used in the Kingdom through registration and adequate pricing.
- 3) Control the importation of drugs in compliance with the registered drug information and ascertain their availability as well as controlling surgery necessities, medical equipment, vitamins, minerals, medicinal plants and medical products.
- 4) Assure drug safety through inspection control of drug importers and distributors as well as drug manufactures in order to ascertain the application of good manufacturing practice criteria.
- 5) Apply international agreements related to narcotics as well as Jordanian narcotics law in order to insure and control the circulation of dangerous drugs for legal medical use.
- 6) Control the quality of circulated drugs in terms of analysis.
- 7) Produce detailed statistical information on the Kingdom's consumption of drugs.
- 8) Follow up between the Drug Directorate and international agencies in relation to drugs.
- 9) Promote and support Jordanian drug manufacturing.

The current organizational structure of the Directorate is presented on the following page (Figure 1).

Figure 1

Present Structure of the Drug Directorate



## **2.2 Administration**

The Drug Directorate and the QCL regulate the drug sector in Jordan. The QCL is responsible for the testing of drugs, registration and marketing. This organizational setup is fragmented with the QCL reporting to the Minister of Health through several ministerial layers, but not to the Drug Directorate. Many of the regulatory and administrative procedures are based on the 1972 Pharmacy Law and are no longer consistent with the requirements of a modern drug regulatory agency.

The QCL interacts frequently with the Drug Directorate in the Quality Control, Drug Inspection, Drug Control, Import and Export, Registration and Pricing Departments. Organizationally the QCL should be under the control of the Drug Directorate, which would allow for better coordination of activities. For example, the laboratory personnel should review all scientific data in a registration file. Information such as process validation data, stability and expiration date data, manufacturing in process test data should be reviewed by laboratory personnel. Also once properly trained, laboratory personnel can accompany inspectors on drug manufacturing plant inspections in order to perform the inspection of the firm's quality control laboratory.

The auditing capability within the Drug Directorate and QCL needs improvement in areas related to CGMP and good laboratory practice (GLP).<sup>3</sup> Currently, the Drug Directorate lacks the knowledge required to perform CGMP and GLP audits at the levels seen in Europe and North America. The self-auditing standards of some of the better drug manufactures in Jordan are higher than those of the Drug Directorate drug inspectors. Therefore, there is a need to raise the bar in order to encourage all companies in Jordan to aim for higher international standards.

There is a relationship between the pharmaceutical enterprise and the MOH. When CGMP seminars were given by the MOH, industry participation outnumbered MOH personnel by more than three to one. Likewise, the industry works closely with the MOH and invites their personnel regularly to workshops ranging from validation, CGMP inspections, Intellectual Property, and water treatment. In addition, the Jordanian Association of Pharmaceutical Manufacturers (JAPM) has secured technical assistance to establish a pharmacovigilance center under the umbrella of the MOH. Such interactions are beneficial to the long-term relationship between regulators and the regulated industry. The drug industry can also play a key role in helping train Drug Directorate inspectors and laboratory personnel in CGMPs and GLPs.<sup>4</sup>

The following page contains a proposed re-organizational structure for the Drug Directorate. It reflects a name change to Director Drug Administration. It also includes a

---

<sup>3</sup>CGMPs are standards to which all drug manufacturers have to meet in order to market their products in Europe and North America. They are similar to the ISO 9000 standards.

<sup>4</sup>In other countries, representatives of the private sector provide government officials with training in CGMPs and GLPs. It is not considered a conflict of interest. It is recognized that the industry has the expertise in the production of drugs and performing clinical investigations.

legal advisor, a medical advisor and an assistant deputy director. The QCL has been moved to this new organization as an additional department and expanded into four units. The expected benefits of this reorganization are better coordination of activities between the Drug Directorate and the QCL. Names of certain departments have also been changed to better define their activities. Some departments have been combined when their activities are closely related. For example, the Inspection Department has been changed to the Drug Inspection and Drug Control Department. The Information and Follow-Up Department has been changed to the Information Management Department. The following page contains the proposed organizational chart (Figure 2).

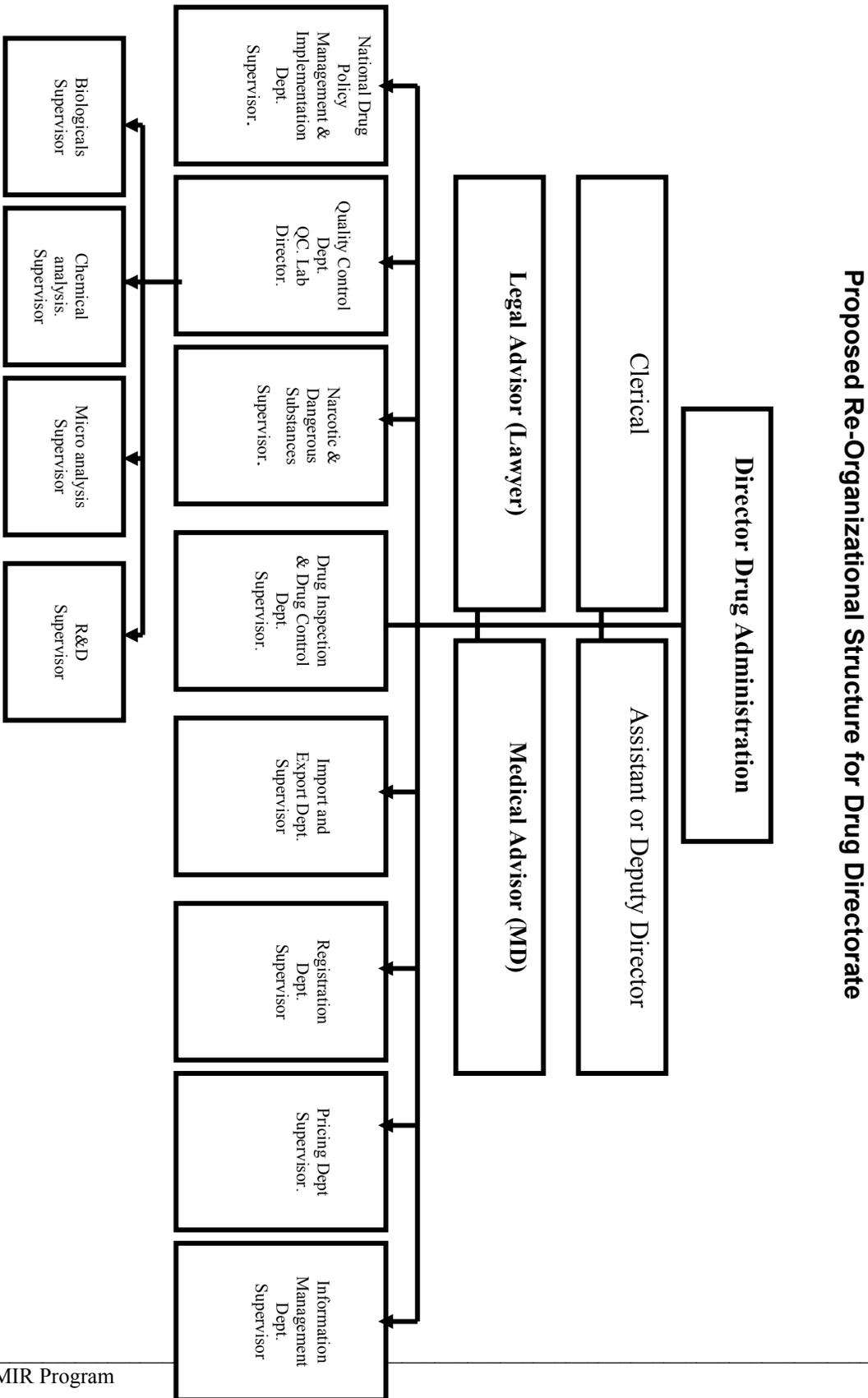


Figure 2

## **3.0 Organizational Assessment of the Drug Directorate**

---

### **3.1 Inspection Department**

#### **3.1.1 Responsibilities**

The Inspection Department is one of the most important departments in the Directorate. This department presently has nine inspectors and the department head. There is no clerical help assigned to this department. The main duties of the department are:

- 1) To inspect all pharmaceutical industries in Jordan such as (a) pharmacies, (b) drug stores, (c) hospitals and (d) drug manufacturing facilities.
- 2) To hold drugs that fail laboratory testing.
- 3) To randomly sample marketed drugs for testing by the quality control laboratory.
- 4) To investigation doctors and drug establishments after receiving complaints from patients or pharmacists.
- 5) To serve on different committees to help develop rules for compliance with CGMPs, GCPs and GLPs.
- 6) To supervise the destruction of certain drugs.
- 7) To verify the presence of the pharmacist or any other qualified person in the pharmacy.
- 8) To check the expiration date, storage conditions and registration of the drugs.
- 9) To check for the absence of free medical samples on the shelves.
- 10) To check for the absence of drugs that were officially sold to the MOH or any other governmental body.
- 11) To confirm that prescriptions are properly registered in the official records.
- 12) To verify a clean and healthy atmosphere in the pharmacy.
- 13) To check to see whether pharmaceutical preparations containing certain drugs such as codeine or dextropropoxyphene are correctly prescribed by authorized physicians and given correctly (according to MOH regulations) by the pharmacists.

- 14) To check to see that narcotic drugs are prescribed and dispensed according to MOH rules.
- 15) To randomly check invoices and certificates of analysis of certain drugs and free medical samples for correctness and completeness.

The Inspection Department is under-staffed and is unable to properly perform their many functions. In addition to being overcrowded, they lack the proper office equipment such as computers for each inspector and the proper training on how to use them effectively. They also need their own copy machine and additional staff. They would also benefit from specialization and a reduction of some of their more mundane duties.

### **3.1.2 Recommendations for the Inspection Department**

- 1) Increase the staff of this department, which will allow the inspectors more time to properly conduct CGMP inspections at drug manufacturers. They will also be better prepared to handle their new responsibilities such as inspections of clinical laboratories for compliance with GLP and conducting foreign inspections. This is especially important because the pharmaceutical industry is growing in Jordan at an annual growth rate of 15 percent and could well become Jordan's top export industry in the next ten years.<sup>5</sup> It is important that additional staff be hired as quickly as possible, since it will take three or four years before a new inspector becomes proficient in performing drug inspections.
- 2) Promote specialization within the Inspection Department. It takes a far different skill to inspect drug firms than it takes to inspect a pharmacy or drug store. It takes even greater skill to perform foreign drug inspections. The department should have their inspectors specialize in performing drug inspections and provide special training in this area. The inspector, once properly trained, must enforce the CGMP regulations evenly and take appropriate regulatory action against firms found out of compliance. Inspectors should also be trained to perform inspections of cosmetics and medical device firms.
- 3) Add two pharmacy assistants and a typist to the inspection staff. Pharmacy assistants can assist the inspectors in entering inspection data into the central computer.
- 4) Obtain identity cards for all Drug Directorate personnel. This is especially important for inspectors since they deal with the public. The Inspection Department should also consider issuing a notice of inspection to each establishment at the beginning of each inspection.
- 5) Computerize the Inspection Department. All inspectors should have a computer on their desk and all information from past inspections should be maintained in this

---

<sup>5</sup> For details on the pharmaceutical industry, see a recent AMIR report prepared by M. Desai, "The Jordanian Pharmaceutical Cluster: Analysis and Recommendations".

computer base. These computers should also be connected to the Internet so that they can perform data searches when needed. For example, the FDA has a large data on CGMP regulations and guidelines. These would be of enormous benefit to the investigator.

- 6) Establish a file room for the Inspection Department. This file room is essential in order to properly maintain the company files of all the firms inspected by this department. This room could be maintained by the clerk assigned to this department.
- 7) Establish a waiting area for visitors to this department. Outside persons who want to see an inspector simply walks into their office unannounced. They should be told to wait in a designated waiting area until the inspector can see them.
- 8) Equip all inspectors with cell phones so that they can be reached at all times. This is important from a safety as well as an efficiency point of view since the inspectors some times have to travel to remote areas of the country
- 9) Provide the inspection department with better vehicles. The inspector's job requires extensive travel, often to remote areas. They need reliable transportation. The vehicles also need to be air-conditioned.

## **3.2 Registration Department**

### **3.2.1 Responsibilities**

The Registration Department is also one of the most important departments in the Drug Directorate. The staffing currently consists of 15 pharmacists and 8 pharmacist assistants and the director. There is no clerical help assigned to this division. The functions of this division are as follows:

- 1) Receive and check documents from all drug stores and local manufacturers or importers of:
  - a) Drug products, infant milk and food.
  - b) Vaccines.
  - c) Dietary supplements, vitamins and minerals.
  - d) Medical plants files.
  - e) Cosmetics
  - f) Medical devices
  - g) Disinfectants and surgical scrubs.
  - h) Letters of objection on registration, pricing, etc.
  - i) Various inquiries on many different types of registration topics such as:
- 2) Post registration changes of manufacturers
- 3) Make all changes concerning registered drug products as well as those currently under registration.

- 4) Classify products
- 5) Update files as a result of World Health Organization (WHO) newsletters and FDA alerts.
- 6) Arrange, prepare for and take the minutes for the following committee meetings
  - a) Technical committee for registration of new drugs.
  - b) Technical committee for registration of generic drugs.
  - c) Approval of new plant manufacturing sites.
  - d) Pricing of products.
  - e) Assessment of serum and vaccines products files.
  - f) Assessment of infants' milk and food formulas.
  - g) Assessment of stability and bioequivalence studies.
  - h) Assessment of vitamins and minerals files.
  - i) Assessment of natural medicinal plants files.
  - j) Cosmetic products.
  - k) Allergy and allergens products.

### **3.2.2 Recommendations for the Registration Division**

- 1) Increase the staff of this department. This division handles one of the most important functions in the directorate. The speed and efficiency in which they perform their jobs can have a profound affect on the number and safety of the drugs registered in Jordan. The health of the Jordanian drug industry also depends on a speedy and accurate review of the files and the resulting registration of the drug. They do not have a sufficient number of personnel to perform their job in an expeditious manner. This increase in staff should allow for quicker and more accurate registrations.
- 2) Allot more space to reduce overcrowding. For example, there are usually three employees to a room. This should be reduced to no more than two to a room.
- 3) Computerize the department. This department could benefit greatly from computerization. A local network of computers containing all of the information derived from registering a product, committee meetings, inspection results, recalls would be invaluable in reducing the amount of time this department spends answering inquires.
- 4) Train the staff on the use of these computers. The staff must be properly trained so that they may effectively use these computers.
- 5) Establish a waiting area for visitors to this department. Currently there is no waiting area for visitors to this department and they receive numerous business visits every day. Visitors have to wait in other personnel's offices until the person they have come to see is free to see them. This disturbs other department personnel and is a security risk if other company's files are being worked on.

- 6) Add a clerk/typist to the staff. Currently there is no clerk/typist on the staff of this department. The pharmacist or pharmacy assistant has to make numerous copies of files in preparation for committee meetings. This is an inefficient use of personnel since this duty takes up a large part of their duties. They also have to type their own memos and make a lot of calls to schedule meetings. A clerk/typist would increase the efficiency of this department.
- 7) Establish a file room. Currently the files for this department are stored in no particular place with any particular order. Files can and do get lost because of this haphazard way files are stored. In addition, MOH personnel spend a lot of time looking for a particular file. With a file room and a file clerk the location of a file would always be known and file accountability would increase.
- 8) Establish a meeting room for this department. Often meetings have to be held in the office of the department head because this is the largest room available. This is disruptive to her work. This department has a lot of meeting and they need their own room.
- 9) Establish a database that can be used by the Jordanian Customs Administration to determine whether a drug offered for import into Jordan has been registered. This will save a lot of time and paperwork for this department. They will no longer have to respond to the many customs requests. The Quality Control Laboratory, procurement agencies and other departments in the government thereby reducing the department's inquiry answering workload can also use this database.
- 10) Develop standard operating procedures (SOPs) for the operation of this department. These SOPs are critically important for training new employees as well as for day-to-day operation of the department. These SOP's should include SOP's for all technical committee meeting. All forms used by this department should be numbered and dated. All revisions to these forms should be noted on the form and obsolete forms should be destroyed.

### **3.3 Quality Control Department**

#### **3.3.1 Responsibilities**

The functions of this department are as follows:

- 1) Inform local manufacturing and importing drug stores of the results of laboratory tests on their pharmaceutical products.
- 2) Inform Royal Medical Services, the Supply Directorate and the Purchase Directorate of the MOH, the UNRWA and the Jordan University Hospital of the laboratory tests on their local and imported pharmaceutical products.

- 3) Contact concerned authorities when there are notes on manufactured or imported products of interest.
- 4) Inform drug agents and provide them with a copy of laboratory test results on their products used for the registration application.
- 5) Inform concerned parties of the results of vaccines and serums tests.
- 6) Contact Royal Medical Services, Supply Directorate and Purchase Directorate / MOH for retention and informing Drug Directorate in the case of non-complying drugs for retention and informing Drug Directorate if returned to the agent.
- 7) Accept protests from concerned parties and resolving the dispute.

### **3.3.2 Recommendations for the Quality Control Department**

This department appears to be adequately staffed for their stated functions. They currently have three pharmacists, one pharmacist assistant and one data entry person. They do need more space. Their offices are overcrowded and they can benefit greatly by having computers for each employee. These computers also need to be connected to the quality control laboratory since a large part of their job entails informing clients of laboratory results.

This division has recently been given additional responsibilities. They now are responsible for all sampling of products that will be tested by the QCL. They are also responsible for preparing and maintaining the essential drug list. They also have been charged with the task of preparing regulations for the collection of fees due to the Drug Directorate.

The division needs to develop job descriptions and SOP's for all of their functions and they need computers and computer training.

## **3.4 Import and Export Department**

### **3.4.1 Responsibilities**

This department currently has seven pharmacists and four clerical positions. This department appears to be adequately staffed. The department is charged with the following responsibilities.

1. Processing permits to import the following products:
  - a) Raw material for local pharmaceutical industry
  - b) Pharmaceuticals for the local market

- c) Tenders pharmaceuticals.
  - d) Serums, vaccines and products containing human materials.
  - e) Infants and baby milk as well as baby food.
  - f) Radiological pharmaceutical products.
  - g) Contrasts media.
  - h) Vitamins, minerals and herbal products.
  - i) Contact lenses solutions.
  - j) IV media and solutions.
  - k) Surgery products.
  - l) Dentistry materials.
  - m) Materials planted in human bodies, intrauterine devices, condoms and surgical threads.
  - n) Surgical requirements (cotton, cloth, bandages, plaster, etc.).
  - o) Medical and laboratory equipment as well as medical disposables.
  - p) Laboratory reagents including AIDS reagents.
  - q) Personal use drugs.
  - r) Unregistered drugs for tenders, local market and personal use.
2. Processing permits to export the following:
- a) Locally manufactured drugs.
  - b) Pharmaceuticals not passing laboratory tests.
  - c) Personal use pharmaceuticals.
  - d) Drugs for export to other countries outside the kingdom.

### **3.4.2 Recommendations for the Import & Export Department**

This department is in dire need of a complete computer system. The department only has one computer and since a computer program to assist them with their work is lacking, all work is completed using a manual system. The most serious problem facing staff of this department is to determine whether the labeling on the product is the current approved label. This problem is most severe with medical devices, implants and raw materials. Computerization would also help if they had access to the Internet since a lot of required information can be found there. They also need training in the English language since many certificates are in English. Job descriptions and SOPs need to be developed and used.

## **3.5 Narcotics and Dangerous Drug Department**

### **3.5.1 Responsibilities**

This department is staffed with three pharmacists and the director, which appears adequate. It is responsible for controlling the legal trade in narcotics, mental affecting drugs and chemical isotopes in order to prevent their transfer to the illegal market. The department prepares all statistics and internal and external reports required by the International Association For Narcotic And Mental Affecting Drugs. It also inspects all medical and pharmaceutical institutions manufacturing or dealing with dangerous drugs.

### **3.5.2 Recommendations for the Narcotics and Dangerous Drug Department**

This department needs to develop functional statements as well as job descriptions for the employees. There seems to be a great deal of overlap between the stated functions of this department and that of the Inspection Department. They both seem to have the responsibility to inspect drug manufacturers, pharmacies, drug stores and hospital pharmacies. They both review records for accuracy and accountability and review the storage conditions and the pharmacist records. In addition, there also seems to be duplication of functions with the district pharmacist. They review the same activities and medications as the Drug Directorate inspectors. These overlapping functions need to be sorted out so that there will be less duplication and more efficiency in this department. More computers and computer training is needed. The inspectors need extensive training in CGMP regulations. They have the responsibility to perform inspections at narcotic drug manufacturers, yet they have never been trained on how to perform a CGMP inspection. They also need more office space.

### **3.6 Information and Follow-Up Department and Jordanian Pharmacovigilance Center**

#### **3.6.1 Responsibilities**

This department currently has nine employees: two pharmacists (one is the department head), one pharmacist assistant, three programmers and three data entry clerks. This department appears to be adequately staffed. This department is responsible for:

- 1) Pharmacovigilance (monitoring safety of products after marketing).
- 2) Preparation of annual reports of drug consumption in Jordan.
- 3) Preparation of annual index of pharmacies in Jordan.
- 4) Preparation of the annual report of drug directorate accomplishments.
- 5) Follow-up on drugs that failed drug quality control laboratory tests.
- 6) Preparation and provision of information related to drugs, local drug stores, drug companies and local pharmacies.
- 7) Preparation of software, support hardware, software network and training employees on programs.
- 8) Assistance to employees in using and searching for information on the Internet.

This division is crowded with three or more employees to a room. They have insufficient and/or in-appropriate tools such as computers, printers and copiers. The computers are outdated (486's, Pentium 1) with limited capacity. They do not have approved job descriptions with fixed responsibilities. They have inadequate training both technical and managerial. They have difficulty in supporting foreign computer programs due to the unavailability of the source code. An example would be the Microsoft Windows program. Their SOPs are inadequate.

#### **3.6.2 Recommendations for the Information and Follow-Up Department and the Pharmacovigilance Center**

Remove pharmacovigilance responsibilities from this department and add them to the Drug Control Department. This responsibility is a better fit in the Drug Control Department.

- 1) Give the current head of this department additional computer training or appoint a person with knowledge in computers to head this department.

- 2) Rename the department. One suggestion is “Information Management Department”. This more clearly defines their responsibilities.
- 3) Charge this department with the responsibility for computerizing the Drug Directorate using a local area network (LAN). All computers would be connected through this network. This will allow for all directorate personnel to communicate with each other through the computer.
- 4) Train all Drug Directorate personnel on the proper use of their computers. Set up a training program that will provide continuing computer training for all Drug Directorate personnel.
- 5) Purchase virus protection and other needed software for use by the Drug Directorate.
- 6) Prepare appropriate departmental functional statements and job descriptions for this department.
- 7) Allot more space for employees with no more than two to a room.
- 8) Design a program so that customs can access the Drug Directorate’s database in order to make decisions on the importation of drugs.

### **3.7 Pricing Department**

#### **3.7.1 Responsibilities**

This department was recently split off from the Registration Department. It currently has a head of the department without any permanent staff. This department is definitely under staffed. This division has the responsibility of determining the price of all drugs manufactured, imported and exported in Jordan. This is a very important function. Drug manufacturers have to obtain a fair return on their product in order to stay in business. To a large extent, the health of the drug industry in Jordan depends very much on the prices they can get for their products at home. Most countries set the price of the imported drug product based on some percentage of the price for the same drug sold in the country where it is manufactured. If the price is set too low in Jordan, the price that a Jordanian manufacturer can get for the exported product will not allow for the company to make a profit. This will hamper their export business.

This department does not have any SOPs for determining how a price is set. The director of this department has a procedure she uses but it is not written. There is no functional statement for the department and no job descriptions for the head or any of the employees.

### 3.7.2 Recommendations for the Pricing Department

- 1) Hire additional staff (or transfer from other departments) so that this department can function properly. The present situation cannot continue forever with only one person assigned to this department.
- 2) Develop functional statements, job descriptions and SOPs for this department. The functions of this department are too important to only have one person familiar with how prices are set.
- 3) Add a clerk to the staff. The person in charge has to make a lot of copies in order to prepare for the committee meetings on pricing.
- 4) Develop a computer program that will automatically make the required changes in the price of a product based on a change in the exchange rate. These type of calculations take up a large part of the duties of this department

### 3.8 Other Recommendations

#### 3.8.1 Product Testing

**Description --** Currently the Directorate of the Quality Control Laboratory tests each batch of a product before allowing it to be sold in Jordan, imported or exported. This practice is mandated by the Public Health Law of 1971 and is flawed in many ways. First of all, the samples are delivered to the laboratory by the firm. This is unacceptable since it allows the firm to always submit material from a batch that they know will always pass. Second, the laboratory does not undertake complete testing. If a product contains three ingredients, for example, the laboratory only tests for one ingredient. This practice gives a false impression when the laboratory says that a product passes. The assumption is that it passes for all specifications. Third, the CGMPs, which all firms should follow, do not depend on final product testing but rather on a firm's adherence to these regulations in order to assure quality. Lastly, one has to consider the MOH's responsibility if for some reason a lot that was accepted by the laboratory turns up bad. This situation raises the issue of liability and credibility on behalf of the MOH.

The practice of the Drug Directorate in notifying manufacturers of passing lots on a standard form containing results from other firm's passing lots should be avoided. There is no need for other firms to know the results of any test except its own. The letters should only contain the results of the firm.

#### **Recommendations for the Testing of Each Batch--**

- 1) Stop this practice and rely on the CGMP inspection of the firm to determine if they have correctly manufactured the product.

- 2) Train laboratory personnel to assist in performing CGMP inspections instead of wasting time testing each batch.
- 3) Start performing post marketing surveillance in order to get a better idea of the quality of the drugs in the market place.
- 4) Immediately stop notifying manufacturers of passing results on a form containing results from other manufacturers products.

## **4. Building and Facilities**

---

### **4.1 Sanitary Services**

The Drug Directorate is housed in an old building that is poorly maintained is not climate controlled. The windows can be opened for ventilation but they lack screens, which allows insects to enter. There is also the question of the possible effect of dust that enters through opened windows on sensitive computers and other office equipment. The sanitary facilities are poor and are inadequate given the number of employees who work in the building. As an example, male workers on the first floor have to go to the third floor in order to use facilities. None of the facilities have towels or air-drying for hands after washing. Some do not even have hot running water and sometimes the toilets do not flush properly, which leaves a terrible smell in the building. Soap is present in only some of the toilets and none are cleaned in an appropriate manner. This was a universal complaint heard from all employees. Female employees were especially vocal about the state of these toilets. Some employees state that they wait until they go home before using toilet facilities. The state of these facilities is so poor that this building would fail an FDA inspection if this were a drug/food manufacturing plant. The Current Good Manufacturing Practice regulations for drug manufacturers require clean and readily available facilities with hot and cold running water and adequate means of drying hands.

### **4.2 Work Space**

Employees have an inadequate amount of space to work. The offices are overcrowded often with three or more workers in one small office. There are an inadequate number of telephone lines in each office. Employees often have to use their personal cell phone to make official calls because of a lack of available phone lines. Currently there is only one phone in each office. It has to be shared between three people. In addition, all calls come to a central switchboard. This further limits the use of the phone. There is an inadequate number of copying machines in the directorate. For example, the Inspection Department does not have a copying machine for their own use. They have to go up two floors (to the third floor) in order to make copies. Since they don't have a clerk assigned to their department, the inspectors have to make the necessary copies. This is an inappropriate use of their valuable time.

There are an inadequate number of meeting rooms for each department. This is especially critical for the Inspection and Registration Departments since they have a lot of meetings with employees of industry. This is counterproductive since staff cannot do any work while their offices are being used. There is also a need for a waiting area for people waiting to see MOH employees. Currently they have to wait in a vacant office or the office of another employee until they can see the person they have to meet. This is disruptive for the other employees and is a potential security risk since they may see files that belong to other companies.

### **4.3 Security and Other Issues**

There is no security at the Drug Directorate building. People off the street can and do just walk in without challenge since there is no one at the desk at the entrance. Street vendors have been known to show up at employee's desks peddling their wares. The absence of security is troubling not only from a safety point but also from a security point. These offices contain a lot of confidential information that could be valuable to competing drug firms. Firms submitting these files to the MOH have a right to expect that only MOH personnel will see the files and the files will be secure.

The vehicles used by the Drug Directorate are old and do not have functioning air conditioners. They are also unreliable. This is a problem when employees have to travel to remote parts of the country. There is also the problem of the image presented when MOH personnel use these vehicles.

## **Annex A**

### **Consultant's Scope of Work**

---

#### **1. Specific Challenges Addressed by this Consultancy**

The Government of Jordan under King Abdullah II has continued the open economic policies started by the late King Hussein, has accelerated Jordan's entry into the global economy, and has recently adopted a new, socio-economic plan which, among other things, espouses private- sector led economic development based on private investment. However, a great deal of work remains to be done to assist various important economic-oriented ministries to move beyond their traditional roles as regulators of industry and commerce, and adopt more proactive roles as facilitators of an enabling environment attractive to investors and enterprises, and as knowledge managers for better informing government and private sector decisions. These new roles need to be consistent with international best practice in excellence in government and accelerated economic development.

One of the most important agencies in this regard is the Drugs Directorate of the Ministry of Health. While some streamlining has been undergone in the Directorate, significant re-engineering must be undertaken to enhance the overall quality of its operations, as well as specific functions and processes. In particular, the Directorate needs to adopt a systematic approach for regular review and improvement that enables it to enhance the effectiveness, efficiency and impact it has in establishing and implementing health-related industry, commercial and trade policies.

#### **II. Objective**

The objective of this consultancy is to review the current Drugs Directorate and develop an action plan for its transformation into a Drugs Agency.

#### **III. Specific Tasks of the Consultant**

Under this Scope of Work, the Consultant shall perform, but not be limited to, the tasks specified under the following categories:

##### **A. Background Reading Related to Understanding the Work and Its Context**

Consultant shall read, but is not limited to, the following materials related to fully understanding the work specified under this consultancy:

1. AMIR Investor Roadmap
2. Drugs Directorate Needs Assessment, World Bank
3. FDA Project Report, JUSBP
4. Drug and Pharmacology Law of 2001
5. Official Gazette 5507

**B. Background Interviews Related to Understanding the Work and It's Context.**

The consultant shall interview, but is not limited to, the following individuals or groups of individuals in order to fully understand the work specific under this consultancy:

1. Steve Wade, Chief of Party, AMIR 2.0 Program
2. Charles Krakoff, PSPI Component Leader, AMIR 2.0 Program
3. Tania Revaut d'Allonnes, Senior Policy Advisor, AMIR 2.0 Program
4. Dr Maisaa Al Saket, Drugs Directorate, MOH
5. Mr Maher Matalka, JAPM
6. Jon Lindborg, Jim Barnhart and Jamal Al-Jabiri, USAID

**C. Tasks Related to Achieving the Consultancy's Objective**

The Consultant shall use his education, considerable experience, and additional understanding gleaned from the tasks specified in A. and B. above to:

1. Review the current structure and operating procedures of the Drug Directorate (Drug Directorate) and Drug Control Laboratory and related MOH departments
2. Detail the appropriate organizational structure of the proposed Jordanian Drugs Agency (JDA), based on the Drug Directorate review and on best practices elsewhere (esp. the USFDA).
3. Detail the appropriate functions of the JDA, and the necessary processes and procedures to meet these functions (including strategizing testing).
4. Recommend appraisal and approval processes and procedures for drugs, equipment, biologics and cosmetics.
5. Provide written job descriptions in line with the proposed JDA functions and procedures, stressing responsibilities and reporting lines.
6. Clarify the appropriate modus operandi for relations between offices, in particular in terms of information sharing and likely IT links.
7. Identify knowledge and skills gap, including language and IT needs, and prepare a training program, with participants sets identified.
8. Prepare a detailed, timed action plan for the transformation of the existing Drug Directorate into the proposed JDA, including the adoption of the FDA system of rules and rules making, licensing, confidentiality, conduct and ethics (GMP), adjudication, etc.
9. Suggest a research agenda to review pricing policy and drugs-related policy-making.

## Annex B

### Interviews Conducted

---

- Maisaa Al Saket, Ministry of Health
- Dr. Laila Badran, Ministry of Health
- Maha Moakat, Ministry of Health
- Lama Al Hmoud, Ministry of Health
- Hebbah Innab, Ministry of Health
- Hiam Al Dabbas, Ministry of Health
- Ghassan Malkawi, Ministry of Health
- Nacy Ghabbon, Ministry of Health
- Suhad F Rabie, Ministry of Health
- Mayor A Hatoqueih, Ministry of Health
- Basil M Alturk, Ministry of Health
- Dr. Ayyad Rumman, Ministry of Health
- Mohammed Al Jaafreh, Ministry of Health
- Manal Zyoud, Ministry of Health
- Mohammed Shahroori, Ministry of Health
- Obaida Rafiq Sabha, Ministry of Health
- Neyam Wahbett Ibrahim, Ministry of Health
- Khawla Azmi Murrar, Ministry of Health
- Azza Al Asir, Ministry of Health
- Sohila Batarseh, Ministry of Health
- Aref Alfarra, Ministry of Industry and Trade
- Reem Suheimat, Ministry of Health
- Seham Rabad, Ministry of Health
- Majed Hammoudeh, Ministry of Industry and Trade
- Maher Matalaka, JAPM
- Jamal Al Jabiri, USAID Mission
- Charles Krakoff, PSPI Team Leader, AMIR 2.0 Program
- Greta Boye, Acting PSPI Team Leader, AMIR 2.0 Program
- Dr. Samir Qammaz, Ministry of Health
- Dr. Lina Kayyali, Ministry of Health
- Soumah A Al Qatub, Ministry of Health
- Monadel S. Mohaisin, Ministry of Health
- Hakimah I Hoseh, Ministry of Health

## **Annex C**

### **Seminar in Current Good Manufacturing Practice Regulations**

---

A seminar on CGMPR was given to Ministry of Health and industry representatives on 14 September 2002. The seminar was attended by over 86 participants. Attached are an announcement and a list of participants.

**The Hashemit Kingdom of Jordan  
Ministry Of Health**

Ref. No: Drug Directorate 5/12/15022.

Date:09/09/2002.

The Jordanian Association of Manufactures of Pharmaceuticals and Medical Appliance  
(JPAM)

Dear Sir;

**FDA Expert will present a seminar, taking about Good Manufacturing Practice (GMP),  
titled:**

Guideline on inspection of drug manufactories for compliance with GMP

The Act will take place at Jordanian Pharmaceutical Association, on the 14<sup>th</sup> of  
September at 13:00, please inform us with the expected number of audience during  
the next two days.

Regards,

Minister Of Health  
{Excellency signature}  
Dr.Faleh Al Naser

Cc\ General Directorate Of Curative Services  
Cc\ Narcotics and psychotropic substances department.

## Current Good Manufacturing Practice Seminar 14/9/2002

No.	NAME	TITLE	COMPANY
1	Dr.Laila Badran	Minister Advisor/Drug & Chief Specialist pharmacy	Ministry of Health
2	Dr.Maha Al Moakat	Narcotics & Psychotropic Substance 's Head Dept.	Ministry of Health
3	Dr.Heyam Wahbeh	Narcotics & Psychotropic Substance 's Dept.	Ministry of Health
4	Dr.Enas Hasan	Supervisor	Jordan Pharmaceutical Manufacture JPM
5	Dr.Mahmmod Zoghoul	Production Manager	Arabic Pharmaceutical Manufacture APM
6	Dr.Yousef A.Al Oqdeh	Assistant Manager/R&D	Arabic Pharmaceutical Manufacture APM
7	Nabeel S.Abdelrahim	Packaging Dept Manager	Arabic Pharmaceutical Manufacture APM
8	Ahmed Al Khatieb	Quality Control Manager	United Pharmaceutical Manufacture UPM
9	Bassam Ahmad A.R	Technical Director	Arabic Pharmaceutical Manufacture APM
10	Dr.Munir Haddadin	Deputy of G.D. of Curative services.	Ministry of Health
11	Dr.Munzir Al Shami	Advisor	Mid Pharmaceutical
12	Dr.Amal Al-Abouchi	Quality Control Advisor	Mid Pharmaceutical
13	Reem A.Abdulqader	Quality Control Manager	Mid Pharmaceutical
14	Rasheed Najjab	Head of stores section	Jordan Pharmaceutical Manufacture JPM
15	Ala Ahmad Saleh	Research & Development	Arabic Pharmaceutical Manufacture APM
16	Dr.Basil M Al Turk	Drug Quality Control Dept.	Ministry of Health
17	Rania Kawar	Deputy Regulatory Affairs Manager	Hikma Pharmaceutical
18	Dr.Khawla Murrar	Narcotics & Psychotropic Substance 's Dept.	Ministry of Health
19	Eng.Rudineh awinel	Research & Development	Arab Center for Pharmaceutical & Chemical
20	Dr.Reem gharib	Research & Development	Arab Center for Pharmaceutical & Chemical
21	Dr.Maha Mamarnah	Research & Development	Arab Center for Pharmaceutical & Chemical
22	Eng.Eman Abu Zaid	Quality Control	Arab Center for Pharmaceutical & Chemical
23	Eng.Wafa Al-Jouhari	Agricultural Eng. & Chemist	Ministry of Health
24	Na'eI Al Kilani	Quality Control	Arabic Pharmaceutical Manufacture APM
25	Yara Al Monti	Quality Control	Advanced Pharmaceutical
26	Tyseer Yaseen	Quality Control	Advanced Pharmaceutical
27	Enam Aead	Quality Control	Advanced Pharmaceutical
28	Dr.Samer Saleh	Quality Control	Arabic Pharmaceutical Manufacture APM
29	Reema Malhis	Quality Control	Jordan Pharmaceutical Manufacture JPM
30	Eqbal Kabash	Quality Control	Jordan Pharmaceutical Manufacture JPM
31	Sawsan Qasem	Quality Control	Jordan pharmaceutical Manufacture JPM

32	Asma Al Nsour	Drug Quality Control Laboratory	Ministry of Health
33	Amal El Falouji	Drug Quality Control Laboratory	Ministry of Health
34	Vivian Karmout	Drug Quality Control Laboratory	Ministry of Health
35	Samya Al Attal	Quality Control	Arabic Pharmaceutical Manufacture APM
36	Lana Jreisat	Quality Control	Arabic Pharmaceutical Manufacture APM
37	Mohammed Joudeh	Quality Control	Dar Al Dawa Pharma DAD
38	Mohammad Yahya	Drug Quality Control Laboratory	Ministry of Health
39	Adnan Shakhtour	Drug Quality Control Laboratory	Ministry of Health
40	Sami Najjer	Engineering	Arabic Pharmaceutical Manufacture APM
41	Moh'd Al araj	Drug Quality Control Laboratory	Ministry of Health
42	Khaled Ghaner	Drug Quality Control Laboratory	Ministry of Health
43	Hama Arafat	Production Plant	Arab Center for Pharmaceutical & Chemical
44	Raghda Al Kilani	Quality Control	Arabic Pharmaceutical Manufacture APM
45	Zeina Al Hadidi	Research & Development	Arabic Pharmaceutical Manufacture APM
46	Hassan Shafiq	Production Dept.	Hayat Pharmaceutical Industry HPI
47	Mohammad Mustafa	Production Dept.	Hayat Pharmaceutical Industry HPI
48	Khaled Hatar	Quality Control	Hayat Pharmaceutical Industry HPI
49	Ali Al Kouz	Production	Arab Center for Pharmaceutical & Chemical
50	Riad Khalaf	Production	Arab Center for Pharmaceutical & Chemical
51	Dr.Mariam Saber	Import Export Department	Ministry of Health
52	Mayor Hatoquech	Import Export Department	Ministry of Health
53	Azza Al Asir	Import Export Department	Ministry of Health
54	Ahmad Zalloum	Research & Development	Arabic Pharmaceutical Manufacture APM
55	Robin Jaber	Quality Control	Arabic Pharmaceutical Manufacture APM
56	Rawia Al Natoure	Registration officer	Al Razi Drug Store
57	Moutasim Ruz	Validation Supervisor	Arabic Pharmaceutical Manufacture APM
58	Haytham Jaradat	Quality Control Supervisor	Jordan Pharmaceutical Manufacture JPM
59	Manal Al Jaber	Research & Development	Hayat Pharmaceutical Industry HPI
60	Amsi Al Natour	Research & Development	Hayat Pharmaceutical Industry HPI
61	Maha Jardaneh	Quality Control	Arabic Pharmaceutical Manufacture APM
62	Ibrahim Khrais	Quality Control	Arabic Pharmaceutical Manufacture APM
63	Haitham Fouad	Research & Development	Dar Al Dawa DAD
64	Omar Dababneh	Engineering	Arabic Pharmaceutical Manufacture APM
65	Lina Tamimi	Quality Control	Arabic Pharmaceutical Manufacture APM
66	Gamal Afaneh	Production	Hayat Pharmaceutical Industry HPI
67	Mohammad Natshih	Production	Hayat Pharmaceutical Industry HPI
68	Mohammad Habush	Production	Hayat Pharmaceutical Industry HPI
69	Yasseen Alawnah	Research & Development	Arabic Pharmaceutical Manufacture APM
70	Ahmad Abu Ouff	Production	Arabic Pharmaceutical Manufacture APM

71	Sharhabeel Meswadeh	Quality Control	Pharma International
72	Abd Allah Bishtawi	Quality Control	Pharma International
73	Yaser Melhem	Quality Control	Advanced Pharmaceutical
74	Shaza Al Qasas	Controlled Drug	Al Razi Drug Store
75	Asaad Ali Shahin	Production Manager	Jordan Sweden Medical Pharmaceutical
76	Ziad Al Amayreh	Production Manager	Dar Al Dawa DAD
77	Ramzi Darrwazeh	Quality Control	Hikma
78	Ahmed Yousef	Quality Control	Hikma
79	Nofous Salman	Quality Control	Amman Pharmaceutical Industry
80	Majeda Saleh	Quality Control Manager	Amman Pharmaceutical Industry
81	Suzan Obeid	Research & development	Jordan Sweden Medical Pharmaceutical
82	Nidal Saleh	Production	United Pharmaceutical UPM
83	Jaber Jarrar	Production	United Pharmaceutical UPM
84	El Ham Yousef	Quality Control	United Pharmaceutical UPM
85	Amal Al sayyed	Production	United Pharmaceutical UPM
86	Mohannad Ratrouf	Research & Development	United Pharmaceutical UPM