

1. INTRODUCTION

Objectives

1.1 This Study falls within the United Nations “Regional Project to Support Arab States in their Pursuit of Economic and Social Reform and Multi-Lateral Economic Cooperation”. Its objectives are to identify major issues facing the Pharmaceutical Industry and to propose recommendations to minimize obstacles, successfully promote Lebanese products, and increase exports.

1.2 The Ministry of Economy and Trade conceived this project to be executed in two separate and distinct phases:

◆ **Phase I** (“MEMORANDUM OF AGREEMENT” No. C-97/1019 (UNDP)) commenced on October 1997 and was finalized on May 1998. The Scope of Services that were performed under Phase I of the Project concerned data collection regarding:

- The domestic pharmaceutical market
- Pharmaceutical production in neighboring countries: Syria and Jordan
- Quality control and production related methods
- Potential markets

◆ **Phase II** (“MEMORANDUM OF AGREEMENT” No. 99/007 (UNDP)) commenced on September 1999 and extended to June 2000. The objectives pursued under the established Scope of Services of Phase-II of the Project are recommendations for:

- The Pharmaceutical Industry
- Related Private Sector stakeholders (Consumers, Health Professionals, Health Institutions, etc.)
- Public Sector (Ministry of Economy and Trade, Ministry of Industry, Ministry of Public Health)

1.3 The entire Project is essentially oriented towards elucidating two categories of difficulties that the Lebanese pharmaceutical sector is experiencing. The first category of difficulties is related to internal malfunctions that are specific to the industry *per se* and to its regulating environment. The second category relates to extra-territorial exogenous factors, which are the result of the changing and evolving reorganization that is taking place in the Region.

1.4 Regarding the first category, the difficulty ranges from the internal organizations of local manufacturers to the interactions of these same manufacturers with their market and regulating environment. Some of the difficulties concern:

1. sources of inputs;
2. quality of products;
3. technical expertise;
4. consumer confidence in locally manufactured pharmaceutical products;

5. methods of production employed;
6. the auto quality control performed by manufacturers;
7. the deficiency of a viable central control body;
8. the availability and accessibility of information regarding the pharmaceutical market;
9. experience and information exchange between industry related parties;
10. human resources qualifications and expertise.

1.5 As for the second category of difficulties, the Project's preoccupation is in distinguishing and recognizing the following factors:

1. the drastic decline in exports of locally manufactured pharmaceutical specialties;
2. the growing competitiveness of pharmaceutical manufacturers in the Region focusing on Jordan and Syria. How to meet these ever growing challenges with all their accompanying constraints;
3. the pharmaceutical sector's best interest in light of the Intellectual Property Rights (IPR), and other trade agreements.

Beneficiaries

1.6 Main beneficiaries of the Project are:

1. the pharmaceutical industry through increased productive efficiency and increased domestic and regional market share;
2. the Lebanese consumer through higher product quality and lower prices;
3. the Lebanese industry through increased awareness from this study;
4. the Lebanese economy through increased trade volume.

Implementation Strategy

1.7 The Project is conducted according to a strict procedure consisting of several chronological tasks of different nature. These tasks are as follows:

1. Identification of sources of data
2. Direct contact with holders of required data
3. Collection of data
4. Data processing, editing, cleaning, coding, and storage
5. Analyses of robustness and explanatory capacity of data
6. Elaboration and distribution of questionnaires intended for local manufacturers
7. Feedback and data, processing, editing, cleaning and storage
8. Cross examinations of similar data originating from different sources
9. Meetings and work sessions with Industry, Public Sector, and Private Sector representatives
10. Elaboration and distribution of additional questionnaires intended for local manufacturers for data harmonization and completion of missing data
11. Feedback and data harmonization and completion

12. Organization of a Workshop¹ including manufacturers, authorities and orders, associations and committees: Identification of difficulties and Examination of solutions, Elaboration of recommendations, and Feedback
13. Issuance of the final report

Data Processing and Analyses

1.8 The data is processed and presented in a manner that would reflect the general and specific tendencies of the global Lebanese pharmaceutical sector. Individual data that is gathered from manufacturers is analyzed but not presented on a case-by-case basis. An aggregation of the data is carried out and elaboration of indicators and tendencies translate the status of the industry. The data processing and analyses provide precision to variables of two different natures, quantitative and qualitative:

◆ *Quantitative variables*

1. Production related variables such as maximum and actual production capacities
2. Volume and amounts of exports/imports
3. Market shares
4. Quality control methods employed
5. Size of the human resources
6. Investment and related variables
7. Potential markets for exportation

◆ *Qualitative variables*

1. List and types of locally manufactured pharmaceutical products
2. Origin of raw materials
3. Origin of imports
4. Sources of capitalization
5. Marketing strategies used
6. Quality control methods employed
7. Types of pharmacological test applied
8. Human resources qualifications and expertise
9. Potential markets

1.9 Efforts are made not to disclose any information that may lead to specific manufacturers. All data gathered is treated confidentially.

Expected Results of the Project

1.10 The final output of the Project is steered in a manner to mainly answer core questions such as the current status of the sector, the issues the Industry is facing, factors contributing to its stagnation, potential growth for market segments, and the essential

¹ The Workshop on Promoting Pharmaceutical Exports Based on a Regional Market Study was held at the UN-House (ESCWA) on June 16th, 2000 and was organized by the joint collaboration of the UNDP and Tomorrow's Advice.

responsibilities and duties of stakeholders; Consumers, Industry, Public Sector, Private Sector, as well as Orders, Associations, and Committees.

Meetings and Requested Data

1.11 Several meetings and contacts were arranged with local Manufacturers, officials, Orders' representatives and other concerned authorities and parties:

Lebanon

- ◆ Local pharmaceutical manufacturing firms
 - *General Manager of Mephico, Dr. Claude Lotfi*
 - *General Manager of Pharmaline, Dr. Carol Abi-Karam*
 - *Quality Assurance Manager at Serum Products, Dr. Yollande Abdallah*
 - *General Manager of Mediphar Laboratories, Dr. Fouad Fadel*
 - *General Manager of Algorithm, Mr. Selim Ghorayeb*
 - *Technical Director at Algorithm, Mr. Paul Henault*
 - *General Manager of Pharmadex, Mr. Fahed Hakim*
 - *Assistant General Manager of Alfa laboratories, Dr. Souad Akl*
 - *General Manager of Chalhoub Pharmaceuticals, Mr. Antoine Chalhoub*
- ◆ Ministry of Public Health (MOPH)
 - *Minister of Public Health, H.E. Dr. Karam Karam*
 - *Director General, Dr. Walid Ammar*
 - *Advisor to the Minister of Public Health, Dr. Nabil Kronfol*
 - *Advisor to the Minister of Public Health, Dr. Fadi Chammas*
 - *Former Advisor to the Former Minister of Public Health (H.E. Mr. Sleiman Franjeh), Dr. Albert Joe Khadar*
 - *Head of the Service of Pharmacy at the MOPH, Dr. Siham Tabbah*
 - *Head of Drug Import/Export Service, Ms. Houda Abbas*
 - *Head of Drug Inspection Service, Dr. Ilham Abou Jaoudeh*
 - *Former Director of the National Bureau of Medicine, Dr. Kassem Hamadeh*
- ◆ Central Laboratory
 - *Head of the Chemistry Division, Dr. Hala El Hout*
- ◆ Ministry of Economy and Trade (MET) and Ministry of Industry (MOI)
 - *Minister of Economy & Trade, and Minister of Industry, H.E. Dr. Nasser Saïdi*
 - *Former Minister of Economy & Trade, H.E. Mr. Yassine Jaber*
 - *Former Minister of Industry, H.E. Mr. Nadim Salem*
 - *Trade Information Officers at the Trade Information Center of the MET, Ms. Rouba Chalabi and Ms. Dana Bsar*
- ◆ Public Reimbursement Institutions

- *Director General of the Cooperative of Civil Servants, Mr. Richard Fabri*
- *Health Security Director at the National Social Security Fund, Mr. Jamil Malak*
- ◆ Orders and Associations
 - *President of the Lebanese Order of Pharmacists, Dr. Leila Khoury*
 - *Former Secretary General of the Lebanese Order of Pharmacists, Dr. Raymond Batrouni*
 - *Former Director of the Lebanese Order of Physicians, Dr. Antoine Coumair*
 - *Former Vice President of the Lebanese Order of Physicians, Dr. Rachid Kaddoura*
 - *President of the Association of Lebanese Industrialists, and Chairman of Pharmaline, Mr. Jacques Sarraf*
 - *President of the Lebanese Pharmaceutical Importers Association, Mr. Armand Phares*
- ◆ United States Embassy in Lebanon
 - *Former US Ambassador to Lebanon, Mr. Richard Jones*
 - *USAID Representative, Mr. James Stephenson*
- ◆ American University of Beirut
 - *Associate Dean of the Faculty of Medicine and Medical Center, Dr. Nadim Cortas*
 - *Professor of Physiology, Dr. Anwar Bikhazi*
- ◆ Lebanese University
 - *Professor in Pharmacy, Dr. Ahmad Yassine*
- ◆ Other Concerned Parties
 - *Deputy Member of the Lebanese Parliament, Dr. Ismail Sukkariéh*
 - *Team leader of the Cardio-Renal Drug Products at the U.S. Food and Drug Administration (FDA), Center for Drug Evaluation and Research, Dr. Patrick Marroum*
 - *Manager of the Information Medical Statistics (IMS-Lebanon), Mr. Meheddine Makkouk*
 - *Pharmacist at Hôtel Dieu de France Hospital , Ms. Mirella Khoury*
 - *A medical information expert in a scientific office for a major Swiss producer, Ms. Raymonde Gharzawi*

Jordan

- ◆ Local pharmaceutical manufacturing firms

- *General Director of the Jordanian Pharmaceutical Manufacturing Company, Dr. Adnan Badwan*
- *Director of the Technical Department at the Arab Company for Drug Industries and Medical Appliances (“ACDIMA”), Dr. Hussein Ibrahim*
- *Managing Director of Dar Al Dawa, Mr. Mohammad Fityani*
- *Director of the Development and Special Projects Department at Dar Al Dawa, Mr. Walid Finan*

◆ Other Concerned Parties

- *President of the Jordan International Consulting Group, H.E. Mr. Thabet Taher*
- *General Manager of Jordan International Team Consultants, Mr. Abdelraouf Thabet Al-Taher*
- *Deputy General Manager of Jordan International Team Consultants, Mr. Laith M. Barhoum*
- *Dean of the Faculty of Pharmacy and Medical Technology, Petraa University (Jordan University for Women formerly), Dr. Tawfic Arafat (He runs a Bioequivalence center)*
- *Professor of Pharmacology, Pharmaceutical Research Unit of the Royal Scientific Society, Dr. Hassan Mohammed Ali (He runs a Bioequivalence center)*

Syria

◆ Local pharmaceutical manufacturing firms

- *General Manager of Avenzor, Dr. Maged Koulsi*
- *Managing Director/Partner of the Mediterranean Pharmaceutical Industries, Dr. Ramez Haddad*
- *Registration and Market Development Manager at the Mediterranean Pharmaceutical Industries, Ms. Laila Nahhal*

◆ Ministry of Health

- *Director of the Pharmaceutical Affairs, Ms. Souheila Hakim*

◆ Other Concerned Parties

- *Secretary General of the Syrian-Lebanese Economic High Council, Dr. Nasri Khoury*

Other Contacts

- *UNDP Jordan, Mr. Jorgen Lessner*
- *UNDP Syria, Mr. Bou Allam Aktouf*
- *Deputy Minister of Health and National Project Director of the UNDP in Syria, Dr. Kawkab Dayeh*
- *Director Health Policy & Management, EMRO – Alexandria, Dr. A.A. Saleh*
- *Arab Trade Financing Program (“ATFP”), Dr. Jamel Zarrouk*

Additional Sources

1.12 In addition to our meetings, we exploited all available resources to gather information relevant to the objectives of the Project. Such sources include:

- ◆ The Internet

1.13 We selected studies and articles with information and data regarding the pharmaceutical markets of the Region and in particular Jordan and Syria.

- ◆ World Health Organization Library

1.14 Studies related to the Essential Drugs lists and concept, Good Manufacturing Practice, globalization and access to drugs, public and private roles in the pharmaceutical sector, and ethical criteria for drug promotion were gathered.

- ◆ Université Saint Joseph Library

1.15 We collected thesis studies conducted by graduate students on issues related to pharmaceutical industry in Lebanon, most consumed drugs, imports of drugs, etc.

- ◆ *MEDICA*, Lebanese Drug Reference, Second Edition

1.16 Lists of all generic products available in Lebanon next to the classification of drugs under therapeutic categories were gathered.

- ◆ Lebanese University, Library of the Faculty of Pharmacy

1.17 We collected thesis studies conducted by graduate students on issues related to pharmaceutical industry in Lebanon.

- ◆ Auto-Legal Encyclopedia (Compact Disk “CD”), the Legislation in Lebanon

1.18 We identified laws and regulations related to the manufacturing, import, export, and registration of medicine.

Main Limitations

1.19 Limitations that were experienced during this Study were mainly related to the consistency and availability of reliable data.

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