



### The Jordanian Association of Pharmaceutical Manufacturers

**JAPM** 

### Hanan Sboul Secretary General

The First Coordination Meeting of Pharmaceutical Manufacturers in GCC and Yemen

Doha - Qatar, 11th of April, 2011

JAPM



### **OUTLINE**

- Pharmaceutical Market in the Arab World Overview
- Challenges Facing Generic Pharmaceutical Industry
- The Jordanian Association of Pharmaceutical Manufacturers; JAPM





#### **Pharmaceutical market in the Arab World**

- 327 pharmaceutical manufacturers, mainly produce branded generics in different dosage forms and therapeutic categories
- Antibiotics are the leading therapeutic class followed by NSAID's – mostly in oral solid dosage forms
- Demand for pharmaceuticals is largely covered by importation
- Governments are the major health care providers





### **Total Pharmaceutical Market**

2009\*

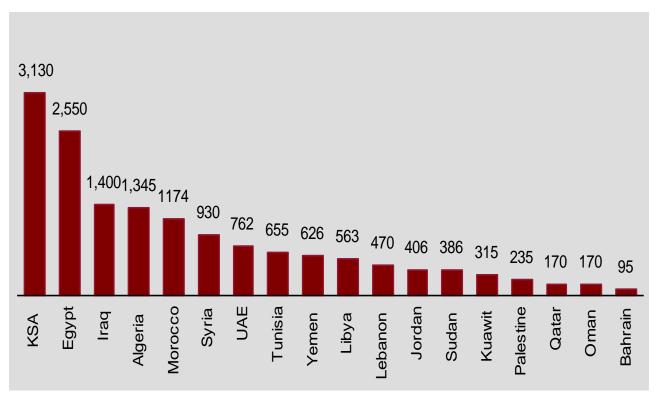
Country	Total Market (US\$)	Share of Local companies %	No. of Manufacturers
KSA	3,130,000,000	25.00%	17
Egypt	2,550,000,000	94.00%	85
Iraq	1,400,000,000	10.00%	10
UAE	762,000,000	20.00%	7
Algeria	1,345,000,000	48.00%	34
Morocco	1,174,000,000	93.00%	31
Syria	930,000,000	93.00%	62
Tunisia	655,000,000	48.00%	27
Yemen	626,000,000	15.00%	7
Libya	563,000,000	3.66%	1
Lebanon	470,000,000	12.00%	6
Sudan	386,000,000	49.00%	16
Jordan	406,000,000	29.00%	16
Kuwait	315,000,000	0.0%	1
Oman	170,000,000	10.50%	2
Qatar	170,000,000	0.0%	0
Bahrain	95,000,000	0.0%	0
Palestine	235,000,000	21.00%	5
Total	15,382,000,000		327



\* Source: AUPAM



### **Arab World Pharmaceutical Market 2009, Value (US\$ million)\***

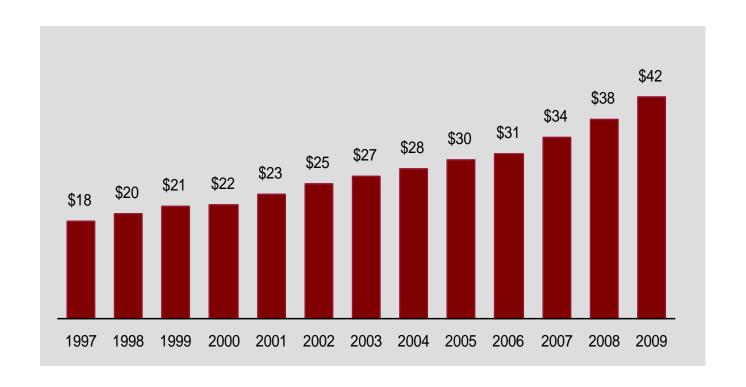


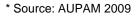


<sup>\*</sup> Source: AUPAM 2009



### **Average Consumption per Capita in the Arab World (\$)**

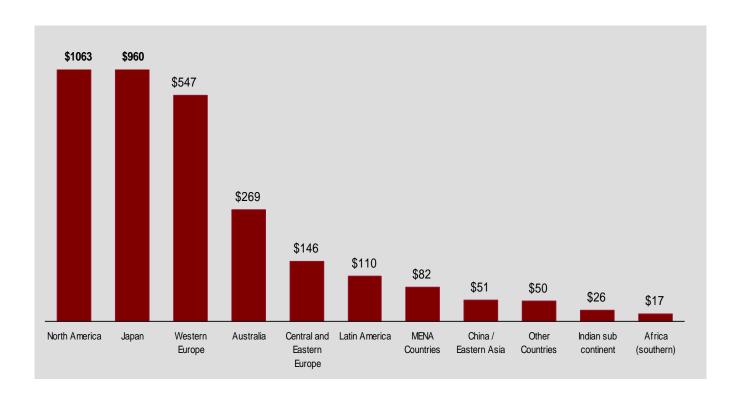








### **Average Consumption Per Capita in the World (\$) in 2009**



<sup>\*</sup> Source: AUPAM 2009





### **Jordanian Pharmaceutical Industry**

- Started in 1962
- 16 companies, 17 branches outside Jordan; in Europe, USA and Arab countries
- Export oriented; around 60 export markets. Major markets are Saudi Arabia, Algeria, Sudan, Lebanon & Iraq
- Local market share; 48% in volume & 29% in value
- Essential for Jordan economy; employment & export





# Challenges Facing Generic Pharmaceutical Industry





### **Main Challenges**

- Intellectual Property Rights Hurdles and Trade Agreements
- Regulatory Regimes; at National & Regional levels
- Increasing cost pressures; Rising Manufacturing Costs, Higher Regulatory Requirements such as BE, GMP, PV led to Increase in Cost of Compliance, Increase in Marketing Costs, etc..
- Pressure of Price Reductions
- Changes in Business Trends
- Originators into Generics
- Concentration of Retail





# The Jordanian Association of Pharmaceutical Manufacturers JAPM





### **JAPM**

A dedicated business association aims for developing Jordanian pharmaceutical industry into world class standards





### **JAPM**

Activities Are Member Driven
Yet
JAPM Takes Policy Initiatives





### **JAPM Main Activities**

### Lobbying & Advocacy

### Laws & Regulations

ΙP

Registration

Pricing

**Clinical Trials** 

BE

BS

### Upgrade the Industry

### **Compliance**

Gap Analysis & Provide Solutions to Fill the Gaps

#### **Building Capacities**

**GxP** 

PV

BE

### Representation of Industry

Local, Regional &
International
Organizations

**Joint Committees** 



### **JAPM Policy Initiatives - Examples**

Strengthen
Relations with
Academia

Orientation of Students

R&D Collaboration

Create
Awareness on
Generics

**Patients** 

Physicians Pharmacists **IP** Issues

Improve Awareness; Territoriality

Improve Access to Patent Information Granted & Applications

**Avoid Linkage** 



### **JAPM**

- Established in 1995
- Voluntary Membership
- Members:
  - Full Members (Manufacturers): 13 Companies
  - Associate members (Service Companies):
    - 7 Contract Research Organizations CROs
    - Two Pharmaceutical Services Providers: Accreditation, Calibration, etc..
    - Two Manufacturers of Medical Appliances, infant milk and food formulas
- Website: www.japm.com





### **JAPM Members**

### **Full Members**

- The Arab Pharm .Mfg. Co. Ltd.
- Dar Al-Dawa Develop& Invst.Co.
- Hikma Pharmaceuticals
- The Jordanian Pharm. Mfg. Co.
- Arab Center for Pharm. & Chem
- United Pharmaceuticals
- Hayat Pharm. Ind. Co. Ltd
- Philadelphia Pharm.Ind., Co.
- MID Pharma
- Pharma International
- Jordan Sweden Medical & Strz
- Al-Kindi, Pharm. Ind
- Jordan River Pharm. Ind

#### **Associate Members**

- Arab Pharmaceutical Industry Consulting Company PRU
- International Pharmaceutical Research Center IPRC
- ACDIMA Biocenter
- Jordan Center for Pharmaceutical Research Center JPRC
- Triumpharma Inc. Product Development & Clinical Evaluations Center
- Pharmaceutical Research Center PRC/ JUST
- PharmaQuest
- NutriDar
- EFADA/ Medical Industries Co. SUTCO





### **JAPM Bylaws - Structure**

- Name of Organization
- Purpose
- Membership
- Dues Structure
- Membership Meetings
  - General Membership Meetings
  - Special or Non-Regular
  - Quorum
  - Procedures

- Board of Directors
- Representation at the Board Meetings
- Term of Office
- Duties of Board Members
- Executive Committee
- Members of the Committee
- Term of Office
- Election of the Members
- Responsibilities of the Members
- Filling the Vacancies at the Committee





## Main Articles of JAPM's Bylaws

Non official translation





#### Article (1):

On the third of October 1995, the signatories of this Articles of Association agreed to form a not for profit ordinary association under the name of The Jordanian Association of Pharmaceutical Manufacturers, based in Amman.

#### Article 2:

The Association shall have financial and administrative independence. It shall be enabled to sign contracts, own transferable and non transferable funds, borrow, mortgage, sell, accept grants & donations. Also, it may assign any lawyer to exert legal procedures or other issues arising from its activities.

#### Article 3:

The Association shall contribute to the development of the pharmaceutical industry and to make medicines available and affordable through the promotion, coordination and protection of the scope of its members and strengthening the relations among the members in pursuit of the general goal through:

- Developing the technical standards of the pharmaceutical industry to produce high-quality medicines.
- Coordinating and cooperating with the competent authorities for the purpose of developing maintaining the technical standards of the pharmaceutical industry

in the manner that is conducive to achieving better health care solutions

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- Providing the members with scientific, regulatory & legal expertise and knowledge on matters related to the pharmaceutical industry.
- Urging the official authorities and / or non official authorities to encourage technology transfer and to adopt clear regulations in this regard
- Coordinating and cooperating with the entities which have goals, objectives, and interests in line with the Association's objectives.
- Lobbying the competent authorities to issue and amend the legislations to cope with the international legislations related to pharmaceutical industry.
- Making database available to serve the purposes and members of the Association.
- Supporting and coordinating projects relevant to the necessary infrastructure needed for the progress and development of the pharmaceutical industry.
- Issuing code of ethics that should govern the relationship among the member companies as well as relations between the member companies and other stakeholders in the manner that does not contradict with other legislations in force.
- Arbitrating whenever deemed necessary.



### **On Membership**

### ■ Membership categories:

- Full Members: manufacturers of any of the following:
- Drugs for human use.
- Veterinary Drugs.
- Pharmaceutical raw materials.
- Infants' food.
- Medical appliances.
- Herbal medicinal products and food supplements
- Diagnostics
- Affiliate Members: Industry Supporting Companies including but not limited to Pharmaceutical Research Centers.
- **☐** Acceptance of a new member
- Cancellation of a membership, and reapplication





### **On Financials**

- **☐** Fees Structure Categories:
  - Initiation Fees
  - Annual Subscription fees
- **☐** Bank Account and signatories
- ☐ Financial Records
- ☐ External Audit





### **On Management**

### **☐** Board of Directors:

- The Association shall be managed by a Board of Directors consisting of General Manager of member companies, where every member has one vote.
- The Board of Directors shall elect an Executive Committee from its members' consisting of a Chairman of the Board, Vice Chairman, Treasurer and Secretary, for a term of two years.
- ☐ Executive Committee; Roles and responsibilities
- ☐ Secretary General





### **On Meetings and Proceedings**

- **☐** Board Meetings
- ☐ General Assembly Meetings





### **On Dissolution**

- ☐ By Decision of Whom
- ☐ To whom goes the properties in case of dissolution



