Interview with Hanan Sboul, Secretary General, The Jordanian Association of Pharmaceutical Manufacturers

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You have extensive experience in the Jordanian pharmaceutical industry, knowing the industry both through your career at the Jordanian FDA and the Association. In your view, what have been the most important developments in the Jordanian pharmaceutical industry over the past years?

Pharmaceutical industry in Jordan has started in the early sixties. At that time the country witnessed the birth of its first pharmaceutical company; today Jordan is home to 17, as well as 8 CROs that conduct bioequivalence studies as well as phase I to IV clinical trials. The industry today is successfully exporting to some 60 countries around the globe, including highly regulated markets â?? about 80 percent of the production is exported. The industry produces almost all dosage forms and manufacture different therapeutic groups, including anti-biotics, cardiovascular drugs and oncology products.

One of the most important developments is the regulatory agency in Jordan; JFDA, which is very stringent and applies regulations which are in line with international standards. Compliance with these standards enables Jordanian pharmaceutical companies to meet the requirements of regulatory agencies in export markets. Our industry is one of the most developed industries in the region, and gained an excellent reputation based on the high quality attributes adopted.

What are today the Associationâ??s main priorities and objectives? What is currently your core agenda?

JAPM is the voice of the industry; it represents the industryâ??s unified position in front of the government. One of the top agencies that are regulating the industry is JFDA. JAPM; backed with the knowledge on international regulations, best practices and scientific evidences proved to be a reliable source for JFDA, and collaboratively worked with JFDA on draft regulations related to the industry. This collaborative relationship with JFAD has resulted in balanced practical regulations compatible with international ones and demonstrated a viable model of an excellent public private relationship.

JAPM also organizes demand driven activities, which build capacity at the industry, in the form of workshops, seminars and conferences.
We have furthermore made sure to increase the Jordanian industry presence at international pharmaceutical arena, in order to put Jordan on the global pharmaceutical industry map. Joining the International Generic Pharmaceutical Alliance as an observer was one of the platforms to achieve this goal.

What would you say are the biggest challenges that your members are facing today?

Emergence of domestic pharmaceutical industry is one of the major challenges, especially in the light of protection measures and technical barriers to trade taken by some of these countries.

The second challenge we are facing is price erosions; there is a continuous movement to reduce the prices even of medicines including generics, while costs are skyrocketing, on top of which are cost of compliance with regulatory requirements and cost of energy. This is ongoing and threatens the availability of affordable medicines, which would endanger the health of patients and put more pressure of the budgets of insurers including governments and national health insurance systems.

Upgrading the Jordanian pharmaceutical industry to world-class standards is of course of crucial importance to retain its competitive advantage when it comes to exports and entering new markets; how are the quality standards across the industry developing?

The high quality standards adopted by Jordanian pharmaceutical companies come from both sides â?? from the FDA as a strict regulatory agency and from the industry itself which adheres to cGMP standards,. JAPM implemented several projects to support its membersâ?? efforts in this direction. International experts are invited to review the systems; they conduct gap analyses at the industry, based on which JAPM conducts itâ??s activities to fill those gaps through targeted projects.

The Association follows the same plan with our CRO members; as generics producers we realize that the quality of the bioequivalence part of the dossier is as important as the other parts.. We executed many projects to build capacity at the CROs and assist them to comply with the international requirements regarding Good Laboratory Practices & Good Clinical Practices. Today Jordan is the hub for clinical trials and bioequivalence studies in the region; many MNCs also conduct their clinical studies at Jordanian CROs. JAPM efforts have also played a role in promoting Jordan as a destination for clinical research.

How would you rate the environment for CROs today?

Jordan was the first country in the region to have a regulatory framework for clinical trials conduct on human beings. Having the proper regulatory and legal infrastructure is a must; where roles and responsibilities are made very clear for all stakeholders; sponsors, CROs and volunteers. All clinical trials protocols have to be approved by the Clinical Trials Committee at JFDA; which also oversees the trials while conducted.

Contract manufacturing for large global pharmaceutical companies currently contributes to some 5% of the overall pharmaceutical sector revenue. Given the solid quality standards that the industry adheres to, do you expect manufacturers to look to increase this share and is this something you actively advocate?

Strategic expensive products are contractually manufactured in Jordan; yet this doesnâ??t make a high percentage of the products manufactured in Jordan. Such business activities are being executed because of the good quality systems applied at the Jordanian pharmaceutical facilities that are compliant with GMP, and not due to trade barriers which force MNCs to go through certain channels to get access to the market. JAPM has extensively worked with JFDA to have the proper regulations for contract manufacturing which encourages joint ventures and attracts MNCs to do business with Jordanian companies.

This is one of the reasons the Jordanian industry is looking to reach new markets and we see even an increasing focus on mature markets in the EU and US. What do you see as the most promising export markets for the industry?

While the industry is focusing on the MENA region, it also looks for expansion into the emerging markets. Jordanian companies have managed to get access to Europe, US, Africa, Russia, Kazakhstan, Azerbaijan, Armenia, and Ukraine and many other markets all over the globe..

What is your final message to the readers of Pharmaceutical Executive about the strength and developments perspectives of the Jordanian pharmaceutical industry?

Jordan has accumulated knowledge and experience over decades and gained good reputation in the pharmaceutical industry arena, explore the opportunities in making strategic partnerships with Jordanian companies. Great potential is there!

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