The pharmaceutical industry in the Arab world: challenges, controversies and future outlook

'...the Arab world presents a unique opportunity to the multinational companies and the academic institutions of developed countries to collaborate in pharmaceutical and biomedical R&D...'

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A major challenge facing the pharmaceutical industries in the Arab world and other developing countries is to fulfill the obligations of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement by 1 January 2005, as mandated by the World Trade Organization (WTO; http://www.wto.org). Commitments to the funding of scientific research and drug discovery and to reaching an equitable arrangement with developed countries are essential to bridge the technology gap that currently exists between the developing and developed worlds.

Demographic background

The Arab world comprises the 22 countries that are members of the League of Arab States, which was formed in 1945. The majority of Arab countries are located in the Middle East, where 13 countries form the westernmost part of Asia. The remaining nine countries form part of northern and northeastern Africa. The majority of the population of the Arab world, which numbers ~300 million, share a common language, Arabic, and a common religion, Islam. Mineral production, particularly oil, and agriculture are the main sources of income of the Arab world. Although modern industrial manufacturing is still in its infancy, the pharmaceutical industry is one of the oldest industries of the Arab world.

History of the pharmaceutical industry in the Arab world

In the 7th century, Arab and Muslim scientists started to play major roles in advancing scientific knowledge at a time when medieval Europe was entering one of its darkest periods. Jabir Ibn Hayyan, who is considered the father of Arab alchemy, composed one of the first pharmacological texts *circa* AD 776. Avicenna (AD 980–1037) wrote 276 textbooks, with the highlight being a five-volume encyclopedia of medical achievement entitled *Al-Qanoon Filtib (The Canon of Medicine)*. According to David Tschanz [1], *Al-Qanoon Filtib* was used as a reference text in many European medical institutions until well into the 19th century and its *materia medica*, which described drugs derived from 760 plants, was the pharmacopoeia of Europe between the 12th and 17th centuries. In the 12th century, Arab pharmacists, particularly Ibn Albitar (AD 1179–1248), continued to be prolific in discovering new drugs from botanical sources. The first modern attempt by the Arab world to produce pharmaceuticals was the establishment of Hegazi laboratories in Egypt in 1933. In 1939, the Egyptian Company for Medical Preparations became the first Arab pharmaceutical factory to be built using standardized criteria.

Present state of the pharmaceutical industry in the Arab world

The latest statistics presented by the Union of Arab Manufacturers indicate that the Arab pharmaceutical market is worth US$6.20 billion, which accounts for 1.5% of the global pharmaceutical market. In 2003, the largest pharmaceutical market in the Arab world was that of Saudi Arabia, which was valued at US$1.17 billion (http://www.saudiembassy.net).

Pharmaceutical production in the Arab world constitutes ~50% of the total pharmaceutical market of the Arab world. The percentage of locally produced pharmaceuticals varies from country to country. For example, Egypt locally produces 93% of its pharmaceutical market. However, those countries that do not have the facilities for production, including Somalia, Qatar and Libya, import all their required pharmaceuticals. Jordan is the leading exporter of pharmaceuticals in the Arab world, registering sales of US$280 million in 2003 (http://www.mfa.gov.jo). The majority of exports were to Arab countries.

There are 230 pharmaceutical manufacturers in the Arab world today. These are either private or state-owned companies, or joint ventures between foreign and local partners.

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In an increasing number of countries, manufacturers are required to follow Good Manufacturing Practice (GMP) guidelines. However, these local guidelines are not necessarily as stringent as those practiced by Europe and the USA. In the Arab world, the industry is production-oriented and 90% of the raw materials are imported. The majority of the drugs manufactured are either generics, licensed or still under patent protection elsewhere. This means that the Arab pharmaceutical industry depends on foreign research-based novel technologies as the source for novel drugs. Furthermore, biopharmaceutical R&D and manufacturing is non-existent in the Arab pharmaceutical industry, although a handful of companies are attempting to enter this field.

In the Arab world, R&D expenditures account for less than 2% of sales revenue and almost exclusively involve R&D into the formulation of existing drugs rather than new innovations. Basic scientific and clinical research in the Arab world is unfortunately a low priority. Typically, research is carried out in academic institutions where the primary purpose of research is either to earn graduate degrees or promotion, rather than contribute to a discovery that could be marketable. Scientists are poorly paid, work without clear guidelines, recognition and incentives and must overcome tremendous obstacles to conduct their research, predominantly as a result of insufficient funding.

Regulatory procedures are somewhat comparable across the different Arab countries. On average, it takes anywhere from six months to two years to register a drug with the local Ministry of Health. This process involves several committees reviewing each application and assessing whether or not the drug is needed, whether or not the drug complies with pharmacological standards and the suitability of the drug for the local population. The applicant then provides samples of the drug for testing in government laboratories to verify that it conforms to the necessary specifications. Registration of biopharmaceuticals is challenging because this is a new category that is unfamiliar to the regulatory authorities. Registration of dietary supplements, or nutraceuticals, and cosmetic products, varies from country to country. For example, some countries, such as Egypt, require full registration and sample analysis of the product but not pricing, whereas others a simple application process rather than full registration.

Challenges and controversies

To meet the obligations of the TRIPS agreement, pharmaceutical industries in developing WTO member countries (most Arab countries are members, but Syria and Saudi Arabia are not) must implement product patent protection for a period of 20 years. Existing patent laws, where present, protect the drug manufacturing process, not the final product. This practice will leave many companies unable to produce new drugs unless they negotiate with the patent holders for the privilege of manufacturing and marketing a drug, or embark on a time- and resource-intensive R&D program to enable them to participate in the drug discovery process.

The implementation of TRIPS is not without its negative aspects. At present, there is a significant rift between developing and developed countries. Evidence for the existence of such a rift came with the collapse of the Doha round trade talks (launched in November 2001) in Cancun on 14 September 2003, which were described as supporting developing countries. An agreement was reached that enabled developing countries to enact compulsory licensing for generic drugs during public health crises. An article in *The Economist* [2] presented the argument that ultimately the developing world has the most to lose from the disruption of the Cancun talks because this breakdown might signal the replacement of multilateral talks with bilateral talks between developing and developed countries, which will reduce the bargaining power of developing countries. However, this article indicated that developing and developed countries were to blame for the breakdown in talks, the developed world for insisting on 'grotesque' subsidies to protect its own interests, and the developing world for making uncompromising demands. This article quoted the projection of the World Bank that a successful Doha round could raise global income by more than US$500 billion per year by 2015, with more than 60% of that gain going to poorer countries, thus helping to pull 144 million people out of poverty.

In a recent article, Foreman [3] states that the bulk of the profits accrued by pharmaceutical companies are made in the industrialized world; in 2002, 79% of the revenue generated by the industry was made in North America, Western Europe, Japan and Australasia. Foreman argues that because the majority of the profits of multinational companies are earned in developed countries, multinational companies have little to lose, and are likely to gain, if these companies permit the manufacturing of generic versions of all essential drugs under compulsory licensing schemes as described in the TRIPS agreement.

A view that is shared by many in the developing world is presented by Hamed [4], who argues that in its current format the TRIPS agreement is unfair to developing countries stating, for example, that the developed world is exaggerating the R&D expenses invested in making a new drug. Hamed states that US consumer groups have estimated the cost of developing a new drug to be US$57–71 million. The recently revised estimate from the Tufts Center for the

Study of Drug Development (http://csdd.tufts.edu) puts the cost of developing a novel drug at US$900 million. Hamed indicates that exaggerating the cost of drug development serves the interests of multinational companies in two ways – as a means of justifying price increases and to discourage pharmaceutical companies in developing countries from investing in drug discovery R&D because of prohibitive costs. To align the TRIPS agreement with the needs of the developing world, Hamed proposes the following reforms:

- Adjusting patent protection periods according to the life cycle of each product.
- Ensuring transparency and accuracy in presenting the economics of developing new products (through implementation of procedures of the WTO) to enable the accurate determination of a reasonable patent protection period that would encourage innovation and provide a fair return on an investment.
- National participation in ownership of patents of products derived from indigenous cultures and ingredients.
- Allowing patent applications from individuals or organizations from developing countries to be valid in all WTO member countries.
- Automatic acceptance of the compulsory licensing of drugs that international organizations determine to be life-saving products.

Opportunities and the future

Despite the pessimistic scenarios described, I remain optimistic about the future of the Arab pharmaceutical industry provided that the Arab world undertakes significant steps to bridge the current technology gap. The Arab world offers a convenient central location, a large number of educated multilingual scientists and technicians, inexpensive labor, an established pharmaceutical infrastructure, numerous academic institutions and a large population. Thus, the Arab world presents a unique opportunity to the multinational companies and the academic institutions of developed countries to collaborate in pharmaceutical and biomedical R&D and manufacturing, as well as basic and clinical research. With respect to the fulfillment of the TRIPS obligations, I believe that a compromise between the developed and developing countries that considers the comments of Foreman and Hamed would yield an ethically acceptable solution to the current impasse in the negotiations.

Arab pharmaceutical companies must earmark a significant percentage of their revenues for drug discovery and real R&D. Technology transfer, collaboration and investment from developed countries will expedite progress. With guaranteed adequate funding and proper corporate and government support, the development of novel pharmaceutical and nutraceutical products from synthetic or natural sources, or improvement of existing products is possible.

According to Abdalla Alnajjar, president of the non-profit Arab Science and Technology Foundation (http://194.170.95.27/index.htm), Arab countries invest 0.2% of their total Gross Domestic Product in R&D, compared to a 2.5% average in the European Union. Furthermore, only 3.0% of total R&D expenditure is invested by the private sector (http://www.dailystar.com.lb/article.asp?edition_ID=1&article_ID=2942&categ_id=3). Arab countries must dedicate a large portion of their budgets to basic and applied scientific research in their academic institutions to safeguard their future with a new generation of practical-minded scientists and executives. Qatar has embarked on an ambitious multibillion-dollar project guided by Egyptian-born Nobel laureate Ahmad Zewail to create a biomedical science and technology park that provides education, fosters innovation and promotes R&D. In October 2003, Zewail attended the inauguration of the new technology education city located in Dubai. These examples are two bright stars in the desert sky. The people of the Arab world must become proactive and demand change. They deserve to see many more bright stars because this is the only way to illuminate the path to progress and prosperity.

References

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