Pharmaceutical industry in the Middle East: challenges, controversies and strategies

'there is no question that a drug discovery and R&D platform is the essential component of a strategic solution'

The ratification, in 1994, of the General Agreement on Tariffs and Trade (GATT) and its associated agreement, TRIPS (Trade-Related aspects of Intellectual Property Rights), by the world community has introduced one of the most significant changes to the way the world, especially developing nations, will manufacture drugs and conduct international trade in the future.

The pharmaceutical industry in the Middle East (which, for the purposes of this editorial, include the Arab world and Israel) will be hard hit by this agreement unless certain steps and strategies are implemented. This industry is particularly vulnerable because it is research based. Nations and companies that do not invest in R&D today will find themselves empty-handed once the GATT takes full effect in the year 2005.

The past

Historically, the Middle East region has witnessed one of the earliest advances in the area of science and medicine from the time of the ancient Egyptians and throughout the Islamic civilization. Avicenna (980–1037 AD), one of the greatest scientists of all time, wrote 276 textbooks including *Al-Qanoon* (The Canon of Medicine), a five volume encyclopedia of Greek, Roman and Arabic medical achievement. However, their first modern attempt to produce pharmaceuticals was the establishment of Hegazi laboratories in Egypt in 1933, and the first pharmaceutical plant built using standardized criteria was the Egyptian Company for Medical Preparations in 1939. The pharmaceutical industry has continued to grow, and there are >150 companies in the Middle East today. These companies are either private, state-owned, joint ventures, or foreign-owned.

The present

The pharmaceutical industry in the Middle East is primarily production-oriented, and 90–95% of the raw materials are imported from outside the region. Most drugs manufactured in the region are either generics, under license or variations of drugs still covered under patent in their native countries. Current patent laws, where present, in countries of the Middle East only protect the process of manufacturing, not the final product. This allows pharmaceutical companies to modify the manufacturing process to avoid violating local patent laws when producing drugs still protected by patents.

In brief, the industry in the Middle East depends on foreign-research-based novel technologies as the source of new drugs. R&D activity is rare among companies of the region.

According to a study by the Arab Federation for Drug Producers, the drug market in the Arab world was $3.144 billion in 1993, and the countries with the largest market shares were Saudi Arabia ($650 million) and Egypt ($565 million). The study estimates that the drug market will reach $4.2 billion by the year 2000. In 1993, drugs manufactured in the region had a 43% market share, equivalent to $1.315 billion. In some countries the drugs manufactured locally contribute most of its total needs (e.g. Egypt produces 93% of its drug requirement). In 1997, the top three markets in the Middle East were: Saudi Arabia ($950 million), Israel ($850 million) and Egypt ($800 million).

In spite of profit margins averaging 25–30%, the observed fast growth in the number of companies and profit figures is more quantitative with no strategic 'added value'.

Challenges and controversies

The current manufacturing practices of the pharmaceutical companies in the region will have to be modified to comply with the letter and spirit of the GATT.

To conform with these agreements, protective import regulations and restrictions must be lifted to allow free trade among nations, which will be guided by certain international quality standards and measurements (not national requirements). Prices will be set competitively and according to how much the market can bear. Clearly, companies marketing new drugs will have the upper hand in determining price.

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Based on a 1997 report by the Centre for Medicines Research in the UK, companies in the USA account for 36% of the R&D conducted worldwide, followed by companies in Japan (19%), Germany (10%), France (9%), the UK (7%), Switzerland (5%), Sweden (3%), Italy (3%) and other countries (8%). Pharmaceutical Research and Manufacturers of America (PhRMA) has projected that pharmaceutical firms in the USA will invest $19 billion in R&D in 1997. According to various sources, the estimated R&D costs of developing a new drug is in the range of $350–500 million and it takes 10–12 years for a drug to reach the market. However, these figures could be reduced significantly in the Middle East because of a low-cost economic environment.

Another important change brought about by the GATT is the extension of the life of a patent to 20 years in countries that have not yet adopted such an extension. In addition, patent laws will have to be revised to protect not just the process of invention but also the final product. Implementation of such changes will deal a serious blow to the pharmaceutical industry in the Middle East if it does not respond by changing its work ethic. Currently, several countries in the region lack patent protection altogether. For countries with patent laws, the effective patent life does not exceed 10 years (Egypt) or 8 years (Israel). In fact, according to a report submitted by PhRMA to the office of the US Trade representative in 1996, the government of Israel is considering several amendments to its patent law that would allow Israeli manufacturers without any rights to the patent to conduct large-scale manufacturing in Israel during the life of the originator's patent. This draft proposal could permit the manufacture and export of patented products before patent expiry.

Most Middle East companies are dependant on technology acquired from multinational pharmaceutical giants, and this absence of ownership of know-how confers a lack of significant added value. With protection of national industries in each country, as provided by current laws, the pharmaceutical companies are able to manufacture and sell drugs locally and export to other countries without true competition because of cheap labor, favorable demographics and an absence of development costs. Thus, there is very little incentive to conduct R&D in the wake of profitability arising from existing low-cost manufacturing of drugs innovated elsewhere.

This led to an R&D 'hibernation' period where companies and governments in the region became complacent about R&D issues. In addition, they tried to acquire as much market share for their local drug industry as possible. Very little strategic planning to acquire R&D capabilities in the pharmaceutical, medical and related fields took place. No serious efforts were made to forge strategic R&D and manufacturing alliances among countries of the region, in order to capitalize on individual strengths and build an industry capable of competing worldwide with real added value and net worth.

In the 1997 monograph *The Future of the Drug Industry in Egypt and the Arab Region*, Rauf Hamed describes the consequences of the GATT on the drug industry in the region as enormous. He mentions that several reports have indicated that the cost of drugs in Egypt will rise six fold if drugs are imported rather than manufactured locally. The Arab Federation for Drug Producers projects the losses to the drug industry and its member countries resulting from implementation of GATT to be $1.24 billion by the year 2000 ($400 million from reduction in production volume, $500 million through investment losses and $400 million through indirect losses).

The future

In spite of the presence of many highly qualified and educated scientists in several Middle Eastern countries, no concerted effort has been made to apply their expertise and knowledge to building an R&D base for the pharmaceutical industry. This bleak picture has led drug industry leaders and government officials in several Middle Eastern countries to call for an immediate action plan to save their fledgling industry. Some have called for taking full advantage of the 10-year grace period allowed following the GATT ratification in 1994, to implement policies aimed at preparing them for 'life after GATT'. In 1996, the Egyptian government established a pharmaceutical R&D company with a capital of $33 million to spearhead its efforts for filling the R&D void.

The multinational pharmaceutical giants are resisting the efforts to delay implementation of the GATT and TRIPS agreement, arguing that by implementing the agreements now, technology transfer and investment dollars will flow into abiding countries thereby overcoming the biggest hurdle in advancing pharmaceutical R&D. Countries of the region are skeptical about this offer, claiming that these companies have accumulated enormous wealth from selling products in the region and that it is time for them to reciprocate by fully committing to the development of the pharmaceutical industry of the region.

Whatever the motive, there is no question that a drug discovery and R&D platform is the essential component of a strategic solution for the future. Significant R&D budgets must be allocated. According to Hamed, if Middle Eastern countries assign just 10% of their drug sales revenues to R&D it will be a relatively respectable starting point. In this respect, it is worth mentioning that Israel has spent $135 million on pharmaceutical R&D in 1995. In the industrialized world, 20–25% of drug sales revenues are earmarked for the pharmaceutical R&D budget.

It is not impossible to develop innovative pharmaceutical products given adequate funding and proper corporate and governmental support. Such support should come by modifying existing lax patent laws and facilitating R&D for local and international pharmaceutical companies. Companies should be allowed to conduct scientific studies and clinical trials without restricting the performance of such studies by appointing them to government facilities and subjecting them to government bureaucracy and red tape. This will encourage innovation and enhance productivity.

The important message here is not the allocation of several hundred million dollars for R&D but the need to adjust the priorities of the drug companies and government regulators in the Middle East from 'assemble and sell' to 'innovate and sell'.

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