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Life Sciences Law & Industry Report™

Life Sciences in the Middle East and North Africa

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The growth in demand for sophisticated pharmaceutical products in the Middle East and North Africa (MENA) region as witnessed in recent years shows no sign of abating.

Increased wealth, spurred by a liberalization of trade policies and the rise in oil and gas prices, has led to irreversible changes in the region's lifestyle and nutritional habits, and with it, a rise in the prevalence of lifestyle-related ailments and a corresponding demand for appropriate medicines.

While a number of not-insignificant obstacles to doing business in the region remain, improving sociodemographics, a continued preference for branded drugs, oft-found visionary leadership, improvements in the regulatory environment, and incentives offered to attract multinationals point towards a positive outlook for the life-sciences sector in the MENA region.

The MENA Pharmaceutical Market Today

Domestic production of pharmaceutical products in the MENA region is dominated by low-cost generic drugs, manufactured principally by locally based companies (including, in a certain number of instances, those producing foreign products under license), or, in a limited number of circumstances, by multinationals that have long-established subsidiaries or historic strategic joint ventures with local firms within the region.

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While domestic production is geared towards the production of low-cost basic medicines, these account for only a relatively small proportion of the regional pharmaceuticals market, which in the main comprises imports of patented and more valuable specialized pharmaceuticals and finished medicines (as do the vast majority of active ingredients required for the intraregional production of generics and biosimilars).

This dynamic is attributable in part to a generally historic absence of innovation and frequently seen restrictions on foreign ownership.

Add to this the falling away of time-bound patent protection from established products, and seismic changes to pharmas' business models, and the incentive for domestic producers to enter the field of innovation within the MENA region is likely to remain weak for some time.

Continued Growth Prospects

A combination of favorable sociodemographic factors and a reinvigorated focus on health care by governments within the region is expected to underpin positive growth prospects for the pharmaceutical market in the MENA region for the foreseeable future.

Socioeconomic Factors

Population growth in the MENA region in the decade before 2010 averaged around 2 percent per annum (compared to a global average of 1.3 percent), and increased life expectancy, lower mortality rates, and a growing elderly population (to say nothing of an influx of expatriate workers) is expected to see the region's population grow to 272 million by 2025. Further, as both states' and citizens' levels of income have increased, so too have education standards and literacy rates, the effect being a more ''health-conscious'' population, with greater expectations for better standards of health care.

Perhaps inevitably, these improved socioeconomic dynamics have led to an all too easy adoption of a more Western/sedentary lifestyle (although the region's climate also is an important contributory factor in this), and with it, the marked increase in lifestyle-related diseases. The World Health Organization (WHO) has estimated that 70 percent of United Arab Emirates (UAE) and Saudi Arabian nationals are medically obese, with the average rate of obesity amongst Gulf Cooperation Council (GCC) countries (Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, and the UAE) standing at 40 percent—one of the highest in the world.

Given such statistics, it is of little surprise that non-communicable diseases and afflictions associated with a sedentary lifestyle and poor diet (including type 2 diabetes; hypertension; cardiovascular disease; chronic respiratory diseases; cancers of the bladder, breast, bowel, and liver; and gastrointestinal and neuropsychiatric afflictions) are prevalent within the region. In certain cases, this prevalence has reached epidemic proportions—WHO estimates that the MENA region is home to more than 9 percent of all people (globally) living with diabetes.

Government Policies

It has long been common ground between citizen and state within much of the MENA region that the government will look after its citizens' health. While governments within the region continue to show admirable adherence to this unwritten arrangement, given that between 70 percent and 90 percent of health care financing (depending on the particular jurisdiction) currently is borne by governments, there is tacit recognition that ever-spiraling costs need to be arrested, particularly given the increased burden on spending created by lifestyle-related diseases.

Recent years have seen a surge in the number of proactive and sophisticated engagements by governments in the pharmaceutical and health care sectors, including immunization programs, campaigns to improve the awareness of the availability of generic products (in part, in an attempt to wean the population from their preference for branded products), and the introduction of policies intended to encourage the domestic manufacture of the same.

Compulsory Health Insurance

One of the most significant factors in reducing state spending on health care is likely to be the introduction of mandatory health insurance schemes throughout the region. While such schemes have long been in place for expatriate workers, particularly in the GCC, the recent roll-out to nationals employed by the private sector in Abu Dhabi, Sharjah, Kuwait, and Saudi Arabia is expected to be adopted by other jurisdictions in the coming years.

Critically, however, while the introduction of mandatory health insurance should reduce health ministries' spending, it nevertheless is likely to generate a net increase in spending on pharmaceutical products, as people take advantage of the benefits of having access to private health insurance.

Inward Investment

Adjunct to this are regional governments' policies intended to encourage multinationals to invest in the region, bringing with them the additional benefits of creating gainful employment, improved domestic know-how of pharmaceutical manufacturing processes, and going some way towards the long-term goals of diversifying their economies away from oil dependency (where applicable).

While these policies have some way to go before they could be considered a success, their introduction has seen (albeit, not universally across the region) revisions to manufacturing standards and intellectual property laws to bring them closer in line with their international counterparts, and, critically, amendments to foreign ownership laws so that overseas companies may now own 100 percent of local pharmaceutical companies (in particular, in ''free-zone'' clusters, such as Health Care City and DuBiotech in Dubai, KIZAD in Abu Dhabi, and King Abdullah Economic City in Saudi Arabia).

The competition between different countries or free-zones to be viewed as the dominant hub for the life sciences industry within the region has in turn led to other incentives being offered to multinationals, including preferential rates of debt and lease rates, government subsidies, and reduced utility costs for manufacturing facilities.

Ongoing Challenges

Despite the positive steps taken by governments within the region to improve the regulatory environment, relatively lengthy and disparate approval processes remain commonplace for both the establishment of manufacturing facilities and/or the distribution of products within the region, and as welcome as the government initiatives referred to above are, MENA is likely to remain a challenging region for multinationals for some time.

Perhaps the most frequent criticism is that leveled towards the regulations governing foreign ownership, which multinationals argue are anti-competitive and ultimately non-conducive towards the development of a knowledge-based economy. Coupled with this is the frequently seen requirement that drugs may be imported only into a country via an exclusive agency relationship, which inevitably brings with it issues associated with attempting to dissolve such relationships when they turn sour, and ongoing problems of adherence to international regulations and best practice.

Equally, government intervention in the prices charged for pharmaceutical products is frequently criticized. While methodology varies across the region, a typical (and often ad hoc) practice is for ministries of health to set the price of a product by reference to its sale price in other jurisdictions. Add to this the periodic application of downward price-escalator mechanisms, along with the practice of fixing product prices as CIF at the port of origin, and nonresident producers (or those domestic producers importing active ingredients) frequently find their profit margins slashed by a combination of aggressive price controls and unfavorable currency fluctuations.

Criticism also is leveled at the sophistication of IP protection available. While certain jurisdictions have taken steps to reduce the illegal trade of counterfeit and grey-market drugs in the region and to bring their IP protection more in line with international practice (with some, such as the UAE, gaining praise for the steps they have taken), multinationals continue to argue that even in those jurisdictions where such measures have been taken, they do not go far enough.

While such views prevail, inward investment (to say nothing of the development of a domestic pharmaceutical industry) will continue to be constrained.

Conclusion

The next 20 years are likely to see continued growth in demand for pharmaceutical products in the MENA region, and notwithstanding governments' valiant ef-

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forts to curtail their health care budgets, and the long-standing regulatory challenges facing the sector, the outlook for the pharmaceutical industry in the MENA region is almost certainly a strong one.

A rapidly growing population, increased incidence of lifestyle-related diseases, ever greater demand for higher standards of health care provision, a gradual improvement in the regulatory environment, and continued government efforts and incentives to attract multinationals to the region will underpin the business case for the life sciences sector in the MENA region in the foreseeable future.