EXPRESS Pharma

www.expresspharmaonline.com FORTNIGHTLY INSIGHT FOR PHARMA PROFESSIONALS 1-15 February 2009

Mapping emerging markets

Making a mark in the MENA markets has been an uphill task for Indian pharmaceutical companies. ***Usha Sharma*** *analyses*

After India and China, many domestic and multinational pharmaceutical giants are planning to enter or are already running their businesses successfully in the Middle East and North Africa (MENA) region. The MENA pharma markets are growing aggressively both with respect to direct consumption as well as trading hubs. The total pharma products market size in the MENA region is close to $9 billion growing at 13 percent annually, which is a twice the global growth rate. The price realisation and margins are very high which makes this region very attractive for regulated pharma manufacturers. Various pharma industry experts believe that economic liberalisation alone will drive Middle East pharma market size to more than $12 billion by 2010. World Development Indicators in 2004 projected that the average annual population growth by 2015 in the region is set at 1.7 percent, a figure that is higher than the global average of one percent. Considering the anticipated healthcare burden in future years, it is no surprise that governments in the region have favoured healthcare policies focusing reforms on curbing expenditure and encouraging private sector participation in healthcare delivery.

Market players

At present major Indian pharma players like Ranbaxy Laboratories, Dr Reddy's Laboratories, Cipla, Wockhardt, Plethico Pharma, Unichem Laboratories, Lupin, Bal Pharma, Dabur, Mission Viva Care, Intas Biopharmaceuticals (IBPL) etc already have considerable presence in this region. To be part of the emerging pharma hub major multinational giants like Amgen, Roche, Sanofi, Teva, Sandoz and J&J also have strong presence across the region. Simultaneously, base players of the MENA market; (Julphar, Hikma, MEENA, Rhino, Sedico, Dar-Al-Dawa), are coming up very strongly which is thanks to government's preferential policy. Asian and Latino companies like Green Cross, LG, Bio-Sidus, NCPC have also entered into selective market due to its low cost manufacturing advantage.

The Middle East segment consists of Egypt, Turkey, Syria, Israel, Iran, Iraq, Jordan, Sudan, Oman, Saudi while the North Africa segment comprises Algeria, Egypt, Libya, Morocco, Sudan, Tunisia and Western Sahara as well as the Maghreb countries of Algeria, Morocco, Tunisia, and Libya. The Gulf countries are emerging as preferred industry destinations for pharma business with good reason after the formation of the Gulf Co-operation Council (GCC) as an economic and political policy co-ordinating forum for the six member states (Bahrain, Kuwait, Oman, Qatar, Saudi Arabia and the UAE). This Council has contributed substantially to improve investor confidence and attract long-term Foreign Direct Investment (FDI) in 'knowledge-based' industries like pharma. Another support to these emerging destinations is 'infrastructure' which is needed for the future growth in MENA region.

Growth drivers

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The growth potential for this region looks to be very positive based on growth drivers like growing economies in the region, high purchasing power, increased spend on healthcare facilities by governments, mandatory health insurance schemes and demographic trends like an increase in life expectancy, literacy rates and prevalence of life style related diseases like diabetes, cardiovascular, gastro and niche cancer therapies. These therapies constitute around 18-22 percent of total pharma volume. Besides this, nutrition segment is continuously growing and at a higher level along with the antibiotics segment, which is also growing with wider medical insurance overages.

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API and Exports
Bal Pharma

"GCC countries and Jordan due to its western influence is already member of the WTO, whereas countries like Syria, Yemen, Morocco, Egypt, and Libya are comparatively very liberal in IPR scenario"

- Simon Daniel
Chief Executive, Marketing
Intas Biopharmaceuticals

The market has seen a very good gross domestic product (GDP) growth in last couple of years due to increase in oil revenues leading to all around focus on healthcare and establishment of pharma manufacturing base in many countries in MENA region to serve local demand. The healthcare sector throughout the Middle East is experiencing significant growth following modernisation programmes and increased private participation in the health sector compounded with a higher than average population growth.

Another trend visible is that as more pharma manufacturing units come up, support services are following their user clients and expanding into these regions. For example, Bry Air, Asia, a manufacturer and supplier of environmental humidity control systems, is strengthening its presence in these markets aggressively through its UAE office. Commenting on the business opportunities in the MENA market, Dinesh Gupta, President, Bry-Air (Asia), says, "As economic activities will grow in the region, we will see continued focus by various governments in these regions for further encouragement of investments in healthcare segment which will have its own demand driven growth for pharma segment."

The increasing incidence of lifestyle disorders and a population with an increased life-expectancy account for growth in various therapeutic segments. Value added over the counter (OTC) products have wide potential as they are out of price control and have better opportunities with high levels of awareness about health related nutrition and supplements in MENA region. Dr P A Mody, Chairman and Managing Director, Unichem Laboratories, says, "In the Maghreb territory, especially in Algeria, Morocco and Tunisia, the total retail pharma market will be approximately $2.2 billion and it is growing at the rate of six to seven percent annually. Seeing future therapeutic explosion, the top therapeutic segments in the Maghreb region are antibiotics, anti-infective, non-steroidal anti-inflammatory drug (NSAIDS), gastro followed by cardio and diabetes products."

Sharing Unichem's strategy plan for Middle East, Mody comments, "In the Middle East, currently we have operations only in Oman and our plant has recently undergone a Saudi Ministry of Health (MOH) audit. In Oman we have three registered products and few more are in the pipeline. Our primary area of focus is the antibiotic and anti-histamine segment. Nutraceuticals/OTC are an interesting market segment which is being explored by us. We intend to expand actively in Sudan, Yemen and Libya."

Regulatory hindrances

The MENA region is believed to be one of the stringent regulatory approval systems across the globe. "Due to the stringent regulatory norms in most of the MENA markets, it is the big pharma players who are our competitors. Simultaneously, competition from domestic manufacturers in these countries and other growing companies from Europe, etc are increasing due to the lucrative nature of this market. This is a relatively more regulated area and the requirements are similar to US FDA and UK's Medicines and Healthcare products Regulatory Agency (MHRA) guideline, says Akkshay G Mehta, Managing Director, Mission Vivacare.

The regulatory environment is characterised by tough entry barriers largely to protect local industry, restrictive price controls and strict factory audits. The patents production, novel drug discovery and strong influence of Western world keeps alive the interest of MNC's in the MENA market. The regulated market remains high and MNCs have been enjoying monopoly with very high pricing. Indian pharma companies operating in these regions found that doing business here is more time consuming due to mandatory plant inspection and other stalwarts of the regulated market. There is also a preference for US FDA or UK MHRA labelled principle. As per the current norms, pricing is based on the price determined by the emerging country in the absence of a formal price regulating authority, which is another advantage enjoyed by MNCs.

Sharing details of the regulatory process, Mody points out, "The general regulatory route comprises a few steps. The first step is the submission of the dossier with all required documents for registration including approval of manufacturing site (if required by MOH of the country in question). It is followed by company registration and analysis of drugs applied for registration. And the last step is the pricing approval according to pricing norms of the country."

Gupta says, "It is important to be very careful of any adverse effects leading to legal cases. There have been no IPR issues that have come to light in the MENA region as general laws are very stringent; we can expect very limited ventures in this direction." Data exclusivity and protection of intellectual property remain key areas of concern in these regions. There is no uniformity in the product patent laws and as such there are large discrepancies in the way IPR is implemented across the region. Highlighting the hindrances posed by regulatory norms in the MENA market, Simon Daniel, Chief Executive, Marketing, IBPL, says, "The strong patent protection, high level GMP and mandatory bio-equivalence and clinical trials are the key elements of registration, which turned out to be high entry barriers in this region. The pharma companies deciding to enter this region are required to have deep pockets (in terms of high financial investment to fulfill regulatory requirements) and patience. GCC countries and Jordan due to the Western influence are already members of the WTO, where as countries like Syria, Yemen, Morocco, Egypt, and Libya are comparatively very liberal on IPR segment."

New junction

In MENA markets, manufacturing bases in Algeria and Egypt MNCs are looking to outsource complete dossiers from India to enable registration in their own brand names and as a trade-off active pharmaceutical ingredients (API) supply agreement is put in place. Archana Dubey Mitra, Associate Vice President, API and Exports, Bal Pharma, says, "Earlier these markets were predominantly import oriented and due to this high regulation imports were predominantly from Europe. Of late, the Government has opened up other markets as well as local manufacturing, thus getting recognised as a major pharma hub.

Mody informs, "The most potential country in the Maghreb territory is Algeria. In Algeria the registration activity is very strict and they follow US FDA norms. They accept products from US FDA approved plants and at the same time they want Common Technical Document (CTD) format dossier, with Drug Master Files (DMF) grade raw materials. Registration is a very long process and hence it is advisable to tie up with local manufacturers for co-branding registration."

Indian pharma companies are adopting several models for strengthening their presence in this region. Pharma manufacturers are moving towards joint ventures (JVs), technology transfer and licensing which are seen as ideal models by multinationals as well for this market. For example Lupin, Dishman Pharmaceuticals, Biocon and Mumbai-based Kopran established themselves in the Middle East region through JVs or other alliances to strengthen themselves in this market.

Exploring export opportunities in Middle East, companies like Cipla and Plethico Pharma have set up their own subsidiaries in this region. Cipla set up its wholly owned subsidiary--Cipla FZE--in Dubai and Plethico Pharma has finalised a manufacturing facility in Dubai, UAE. Proposed state-of-the-art manufacturing facility in the Middle East for medical lozenges and New Drug Development Services (NDDS) tablet, capsules, confectionary and the allied products shall cater to the demand of high volume emerging markets throughout the world subject to logistic viability.

Turkey, Israel, Saudi Arabia, Egypt and Iran stand out as the largest markets in terms of projected growth in the MENA region. Mody avers, "Most of the MNC pharma companies are already well-established in these markets. But Indian pharma companies with their strong generic capabilities can create a niche for themselves. Our major competitors would be Big Pharma and the prominent local, regional players, if they already have strong product baskets with offerings which extend beyond vanilla generics."

While the process is quite regulated in major markets like Saudi Arabia, UAE which insist on approvals from Europe or US, other countries like Oman, Muscut, Qatar etc are opening up to Indian pharma regulation products. North African countries like Algeria, Egypt, Libya, Morocco, Sudan, Tunisia and Western Sahara regulations are also as stringent as regulated markets and require a manufacturing unit to show compliance on parameters like bio equivalence and bio availability for plant approvals.

"We have already registered in a few MENA market countries and are adding thrust to develop new markets while consolidating present with more number of products. We are on a continuous lookout for the right associates to establish the Bal Pharma product range in the market," comments Mitra.

IBPL has adopted the out-licensing business model in MENA region. The company is also planning to open their representative office, subsidiary through partnership with local companies in Northern Africa, Arabic countries and Middle East. Sharing its business strategy in this region, Daniel mentions, "IBPL is in the process to register first bio-similar of Peg-Filgrastim in this region, we are exploring possibilities of technology transfer, JVs in the biopharmaceuticals and chemotherapy segments."

Along the same lines, Gupta says, "We have been supplying our products in this region for last about two decades. This led to the establishment of our regional sales office in UAE, to be closer to the market we serve. We are looking at establishing our office in Saudi Arabia."

"We are currently in the process of registering our products in the MENA markets. We are taking the MENA markets as an interesting area to do business and we will be having a strong focus in this region," adds Mehta.

Thus inspite of the obstacles, Indian pharma companies are not giving up the race to make a mark in the MENA markets. Their patience seems to have finally paid off as various countries in the Gulf region like Dubai and Bahrain have recently set up Economics Development Boards to help Indian companies navigate the complex regulatory landscape in these new markets. Pharma companies are hoping that this could well turn the tide in their favour.

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