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OutBound Japan industry on the move

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Japan is the world's second largest economy and also the second highest spender in healthcare in the world. A rapidly aging population has burdened the healthcare system both in terms of funding and facilities there.

For life sciences companies globally, the massive size of the Japanese market is a considerable attraction. This gives Japan a distinct advantage over other countries in the region such as Australia, Korea and Singapore, where the industry is limited by their comparatively smaller domestic markets.

The last decade has seen the Japanese pharmaceutical players ranking in the top list of global pharmaceutical manufacturers. And in a bid to perform more competitively on the world stage, some of the biggest Japanese companies have merged to form Astellas Pharma, Dainippon Sumitomo and Daiichi Sankyo.

According to Japan Pharmaceutical Manufacturers Association, the global pharmaceutical market approximately doubled to $565.9 billion (Rs 26.19 lakh crore) between 1995 and 2005. Japan became the second largest market after North America, with a market size of over $111 billion (Rs 5.13 lakh crore). A breakdown of these sales indicates that prescription drugs consumed in Japan accounted for 64.4 percent of the market and exports of prescription drugs to other countries accounted for 15.8 percent. Thus, prescription drugs accounted for the bulk of the market.

As a result of decrease in drug prices in recent years, growth of the Japanese pharmaceutical market has been somewhat curtailed. Consequently, expectations are high for overseas markets, particularly the US, EU, China, India and other markets that are rapidly growing. According to a Business Monitor International (BMI) report, generic drugs account for less than 10 percent in Japan market. While China and India account for 65 percent and 37.1 percent respectively. However, BMI forecasts that the market share for these low-cost products in Japan will double by 2010, adding almost $5 billion (Rs 23,142 crore) in value to the sector.

The government too has implemented a generic substitution system to increase the market share of generics to 30 percentin volume terms by 2012. In 2009, generic companies such as Sawai Pharmaceutical, Towa Pharmaceutical and Nichi-Iko announced plans to introduce their versions of a number of blockbuster drugs whose patents expire this year. Foreign entrants to the generic market, such as Israel's Teva, which formed a joint venture with Kowa Pharma, are planning a more aggressive strategy that will involve marketing around 200 generic drugs by 2015.

In June 2009, the Pharmaceutical Affairs Law was also revised and the rule in regards to the sale of over the counter (OTC) drugs was relaxed. The relaxed rule has resulted in increased competition in the sector with reports of supermarkets and convenience stores reducing prices by up to 20 percent.
Additionally, various industrial policies have been drawn up and implemented that include 'Pharmaceutical Industry Vision', Biotechnology Strategy' and 'Intellectual Property Strategy', but many issues, including drug pricing system reform and consolidation of the clinical trial system remain unresolved.

Giving importance to the IP scenario, the government is very supportive in intellectual property. It has been laying more emphasis on increasing the number of patent attorneys specialized in the areas of life sciences and biotechnology. Major universities have liaison offices for technology transfers. Even the education ministry has been providing funds for intellectual property issues so as to support the university professors to file patents through foundations set up at the universities.

Biotechnology-a leading sector

The Japanese biotechnology industry too has been making good progress in recent years. Much of the impetus has come from the Japanese government which has been providing considerable support to foster this industry.

There are about 400 biotechnology companies in Japan. But the core biotech companies are about 100 that are doing very well in the stock market. The big pharmaceutical companies own these companies which have a diversified product range. Besides the leading companies, there are about 10â€“15 spin-off companies from the universities. To remain stable, these companies have opted for the services model. They are utilizing a part of their resources for the product development as a long-term goal.

The industry's rapid development is a visible result of the close cooperation between the Japanese public and private sectors and academia. In 2007, the total market size of the Japanese biotechnology industry was $19.5 billion (Rs 90,247 crore), a 10.8 percent increase over 2006.

Biopharmaceuticals continue to be the mainstay of the Japanese biotech market, accounting for 40 percent of the total market. Recombinant protein drugs such as erythropoietin and interferon have the highest market share in the biopharmaceuticals segment. Erythropoietin, the largest selling product with a market size of around $1 billion (Rs 4,628 crore), is expected to show continous growth.

Although most of these biopharmaceuticals are produced in technical collaboration with European and American companies, Japanese biotech companies are now investing heavily in research to bring out their own products and are eying various emerging areas. Regenerative medicine, which promises to grow organs and tissues to eliminate the problem of rejection that occurs with organ transplants, holds much interest for Japanese companies. The other potential areas of growth are expected to be protein drugs and glycobiology.

Currently, medical biotechnology is the leading sub-sector in Japan. Medical biotechnology products account for over 30 percent of the Japanese biotechnology market. Within medical biotechnology, therapeutic antibodies have the highest growth potential. Japanese pharmaceutical companies are eagerly seeking new drug candidates and pipelines, identified or developed by overseas biotech companies, which they can tap into in order to develop new drugs.

The restructuring and change

From 2008 onwards there has been a spate of mergers and takeovers, involving both foreign and local companies. Japan's acquisitions market has seen surprising growth in recent times, as generic drugs increase in popularity. Companies like Daiichi Sankyo, Eisai, Astellas Pharma and Takeda have been aggressively expanding their global operations.

The business integration from 2005 to 2007 of the two separate companies to form the joint Daiichi Sankyo created one of Japan's biggest pharmaceutical companies. Daiichi Sankyo's move to acquire India's top drug maker by revenues, Ranbaxy, is one of the biggest outbound M&As so far, with a deal worth $5,326 million (Rs 24,651 crore). In the past, new drug companies like Takeda and Sankyo did not have to care about generic drugs, but now, for example, Daiichi's Ranbaxy buy puts it onto the global generic drug market map. The move, which came in June 2008, also gives Japanese drugs maker Daiichi Sankyo a foothold in the US and Indian market.

The other biggest outbound deal in recent years is the Osaka-based Takeda's acquisition of Massachusetts, US-based Millennium Pharmaceuticals in 2008, a buyout worth $8.8 billion (Rs 40,730 crore). Takeda is the largest pharmaceutical company in Japan and its patent on stomach acid reducing drug Prevacid expired in November 2009 and while diabetes drug Actos is losing patent in 2011.

As Japanese companies become global forces, a key challenge is to integrate Japanese personnel with workforces overseas. Takeda Pharmaceutical last year reorganized its corporate structure, as part of its 2006-10 Medium-Term Plan vision to become a global pharmaceutical company with highly integrated global operations. In order to become more responsive to rapid changes in the global operating environment and to maximize the global market potential of new products and the company's global presence, the company is streamlining executive reporting relationships to Yasuchika Hasegawa, president, by creating corporate-level, center of excellence R&D, commercial and administrative functions.

â€œTakeda is making meaningful changes in structure and governance through this reorganization and the creation of the CSO, EVP, International Operations, and CAO roles, which we believe will further strengthen our global operations structure,â€? Hasegawa said, in a company release.

The company is also setting up new commercial subsidiaries covering Mexico, Turkey, Sweden, Norway, Denmark, Belgium and Luxembourg as part of its strategic global expansion effort. The new subsidiaries will strengthen Takeda's expansion efforts for products such as Actos (pioglitazone), which the company bought back in October 2009.

For most of the leading Japanese pharma players, overseas business comprises 45 to 60 percent of their revenue. For Astellas, overseas sales for FY08 was 48.6 percent and for the second quarter of FY09 it was 49.5 percent.

â€œAstellas' sales results for FY08 stood at $10.53 billion (Rs 48,731 crore), while our forecast is $10.64 billion (Rs 49,245 crore) (+1.1 percent). We plan to formulate a new five-year medium-term management plan to begin in FY2010 ending March 31, 2011. The scheduled announcement for the plan is May 2010. Therefore we are unable to provide the envisaged future growth,â€œsays a senior spokes person from Astellas Pharma Japan headquarter who did not wish to be named.

Sharing information about the regions providing better growth rates for Astellas, the person quotes, â€œWe had good sales performance in Japan, Asia, the US and EU on each currency basis in FY08. In addition, we are focusing on emerging market as well. We established our affiliates in India in November 2008 and in Brazil in July 2009.â€?

Eisai too seems to be on a globalization spree. The company acquired two US companies in recent years-Morphotek in 2007 and MGI Pharma in 2008. The company went on setting up two knowledge centers 2009-one in Europe and the other in India. The India facility, which is an investment of $50 million (Rs 231.41 crore), is the second facility after Japan that will cater to the global market.

The facility, which is scheduled to start full scale operations by September 2010, will be Eisai's first base to integrate active pharmaceutical ingredients (APIs), formulation manufacturing and API process research on one site.

According to Sanjit Singh Lamba, president, Eisai Pharmatechnology and Manufacturing India, â€œWe are operating a globalization strategy. This new facility would emerge as the global hub for R&D, formulations and API manufacturing. The center is aimed at stimulating the knowledge creation between the researchers and the production team.â€? Eisai has production facilities in Japan, UK, the US, China, Taiwan, Indonesia, and R&D facilities in Japan, UK and the US.

Therefore, after years of indifferent performances and an expiring product pipeline, the Japanese industry is on the move. The mergers, acquisitions and globalization strategies are an indicative of a corporate restructuring which has fundamentally changed the Japanese industry. Many see the future for the Japanese companies as that based on innovative R&D and in export markets. In a ranking of pharmaceutical companies that developed the top 100 products in terms of global sales, Japanese-based firms today are in the third position after those of the US and UK.

Jahanara Parveen in Bangalore