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ASIA EDITION

Unclear regulations dampen investment charm

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Singapore: Asian companies continued to attract global pharma and biotech giants to invest in regional markets to establish and expand their footprints. However, some of the global pharmaceutical companies redefined their strategies other way round and concluded to pack up from Asia on various grounds.

Earlier this year, global generics firm, Actavis announced to retreat from China and divested its assets to local firm Zhejiang Chiral Medicine Chemicals. Besides the promising generics market of China that projected to touch USD 100 billion (RMB 614 billion) by 2014 and growing at a CAGR of 13.8 percent, the multinational company did not find it lucrative enough to stay there and churn the opportunity. Actavis has reported unfavorable business environment as the reason of its exit from China.

Shortly after Actavis, AstraZeneca revealed its plan to shut down its Bangalore-based R&D center in order to consolidate its research base and move to western territory. AstraZeneca's decision to wind-up the Bangalore R&D base led to 170 manpower chop and halt of early stage research on neglected tropical diseases including TB and malaria.

China's aggressive attempt to crack-down on forgery in pharmaceutical industry and investigation into lowered drug prices in 2013 also influenced the expansion steps taken by pharma players in China. Investigation of GSK operation, regulatory norms for foreign players and lack of transparency in local policies alarmed other global drug players, such as Actavis, to further expand in China.

MNCs are often compelled to rethink of their investment strategy and took the decision to exit from countries that have so far lured them for cost efficiency. In case of Actavis, the company pointed at unsupportive business environment for foreign companies and low returns of investment in China's generic market to be the reason to pull its plug. Citing the same reason for exiting the generics market of China, India-based pharmaceutical company Orchid Pharma, that held a fifty percent stake in a joint venture with North China Pharmaceutical Corporation, ended the JV stating that the China generics market is reaching a stage of maturity.

Orchid's Chairman and Managing Director Mr K Raghavendra Rao had commented on the development that, "With the local

Chinese players fast integrating, the operating conditions have grown quite competitive in China. Moreover, the products that the JV manufactures and markets in the local Chinese market have reached a mature stage resulting in flat growth prospects going forward. Hence, it was a prudent decision to relinquish our stake to the partner and exit the JV".

Besides, frustrating regulatory structure and unclear policies in pharmaceutical industry are the prime reasons of investors losing their confidence in the two important countries of Asia, India and China.

In 2013, Central Drug Standard Control Organization of India amended the guidelines of clinical trials conducted in the county and made the procedure more stringent and tighter to enroll patients for clinical trial. In the same period, global contract research organization, Quintiles shut down its phase I clinical trial unit in Hyderabad, India, citing the reason to 'challenging external business environment'.

Drug approval in India has becomes much complicated and stringent process than it was before and approvals has come down drastically as over 25 drugs were approved in 2013 as compared to over 90 drugs in 2011. Low rate of drug approvals could be one of the reason for AstraZeneca to halt its research on neglected tropical diseases in India.

Finding the regulatory structure too difficult to comply or complicated to implement on practical grounds, many Indian companies are mending ways to conduct clinical trial outside India, even at a high price, and India may lose its investments to other south East Asian countries.

Multinationals firms state consolidation of operation as one of the reasons to exit from east so as to bring the operation closer to their customers. Custom manufacturing German company, Evotec closed its chemistry operations in Thane, India in 2013 and moved the operation to Abingdon (UK) facility, in order to stay closer to the principal R&D laboratories.

Dr Mario Polywka, Chief Operating Officer of Evotec, commented that, "Evotec were due to relocate its Indian chemistry operations in June 2014. During the due diligence in finding a new facility and because of growing customer requirements for European-based activities we came to the conclusion to exit our operations in India completely."

Analysis firm Deloitte mentions that life sciences companies are growing, restructuring, or refocusing their operations through making acquisitions to gain financial synergies and new products. They are diversifying into new product areas, divesting brands or business units to focus on their core strengths. Such companies need to align these transactions with long-term growth strategies.

The challenge for life sciences companies is to make their entrance and ongoing presence in emerging markets both safe and profitable, as each market can present unique operational and financial challenges; among them, significant pricing issues, insufficient and/or outdated distribution, networks, threats to IP protection, and problems with supply chain quality, cost, safety and security.

Drug makers should continue expanding in emerging markets to tap into the higher sales growth potential they offer versus developed countries. However, they will need to be selective about the products they choose to launch in these markets, based on market-specific disease profiles, patient affordability, operational infrastructure, and government patent protection policies, Deloitte concludes.

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