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Drugging the world

Indian pharma industry is emerging as a global leader

MANTO BANERJEE

Why is the United States so particular about its concerns over off-alleged laxity in manufacturing processes and practices followed by India's drug manufacturers? Can India's drug industry afford to take the concerns of the powerful US Food and Drug Administration (FDA) lightly? These broad questions along with several more specific and less trivial others are crucial to the future progress and survival of India's roughly Rs 1,70,000-crore drugs and pharmaceuticals industry leaning stably on export with the US being the most important destination. Export accounts for nearly 45 per cent of the industry's turnover. Lately, exporting India-made drugs to the US market is becoming increasingly difficult with the US continuously raising procedural and legal hurdles affecting the trade. Fighting legal disputes in the US for a market space could be really expensive and struggle some in future.

India is concerned because the growing list of its pharma companies under the US FDA scanner for alleged non-compliance of good manufacturing practices covers some of the biggest names in the industry, it includes Ranbaxy, Wockhardt, Strides Aristo, RPG Life Sciences, Dr. Reddy's, Sun Pharma, Zydus Cadila and Lupin. If some issues get resolved, others crop up. The US has been blowing hot and cold with Indian Pharma majors, not always on rational grounds, as Indian companies dealing with the US are fully aware of stringent rules, regulations, inspection regimes and requirements of FDA which have made the US as one of the most difficult pharmaceutical markets for outsiders to enter.

One of the reasons that could be responsible for the US trying to keep Indian pharmaceutical exporters constantly on tenterhooks is India's growing clout in the American drug market as a quality generic drugs supplier at low prices, which US drug firms and their subsidiaries abroad find difficult to match. The costs of clinical trials and therapeutic research conducted in India are much lower than those in any other part of the world. Ironically, the US drug industry is one of the biggest beneficiaries of this. Indian pharmaceutical companies have made tremendous strides in the US market. Indian companies are exploiting their cost advantages, their strength in reverse engineering, and boasting till now of having the largest number of FDA-approved plants - nearly 100 - outside the US. Indian companies can manufacture pharmaceuticals for less than half what it costs to manufacture them in the US, conduct clinical trials for approximately one-tenth the US cost, and conduct R&D for less than one-eighth the US cost.

The pharmaceutical industry in India ranks third in the world in terms of volume and contributes over 12 per cent to the global pharmaceutical production. It is the world's 12th largest in terms of value per cent of the global pharmaceutical market. The industry has a lower share in the global market because Indian products are available at prices that are 5-50 per cent lower than those in developed countries.

The Indian pharma industry comprises around 250 large and about 80,000 small-scale units that operate across the pharmaceutical value chain ranging from new drug discovery to marketing and distribution. Last year, the country's pharmaceutical export was estimated at Rs 75,000 crore (\$12 billion), up by 25 per cent over the previous year. Almost 80 per cent of the exports belong to the medium and small-scale

gan of strong exports to the US and the depreciation of Rupee against US\$. In fact, the industry's growth story is more of a long-term phenomenon showing a consistent compounded annual growth rate (CAGR) of over 15 per cent in the last five years.

This robust growth, not only indicates the industry's inherent strengths in the global landscape, but is also a reflection of improving healthcare stan-

dards in India. Exports have been the cornerstone of growth of the Indian pharma industry, with the global pharmaceutical market offering strong opportunities to Indian players. By 2020, drugs with sales of more than \$100 billion are expected to lose patent exclusivity and



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open up to generic competition. India's key strengths being its cost-competitiveness and advanced process technology skills. Indian players are poised to tap this opportunity and increase their presence in the generics market.

Hopefully, the US will continue to be India's most critical export market. Wockhardt, for instance, earns more than 75 per cent of its revenues from global markets, with US operations contributing 40 per cent. Similarly, Sun Pharma and Lupin have strong presence in the US market, earning 35-40 per cent of revenues from there.

US healthcare reforms aims primarily at reducing healthcare spending and extending public healthcare to a larger portion of the population are expected to continue driving growth in the generics market. Unfortunately, the US FDA,

after having reposed faith in Indian drug industry's capability to serve its market with high quality products at low prices and having approved the largest number of manufacturing units in any country, seems to be more comfortable using a carrot-and-stick policy than being a guide and mentor in dealing with its licensed pharmaceutical exporters to the best advantage of each other.

This is creating an unnecessary bad blood between the two business partners. Its surprise inspection regime and post-inspection posturing are often unwinning to Indian manufacturers. FDA inspections should be done in the presence of Indian authorities.

One only hopes that the latest visit by US FDA Commissioner Margaret Hamburg, her first to India in official capacity, should be able to lighten, if not erase, the unhealthy atmosphere of distrust existing between the two important buyer and seller. Indian pharma exporters deserve to be treated with respect and not like a bunch of thieves.

Frequent policing, surprise swoops, imposition of penalties disproportionate to the offence, delayed approvals and harsh actions are permeating the trade climate between the two countries.

At the same time, it must be said that Indian export manufacturers and its drug control administration must attach the highest importance to best manufacturing practices to win the confidence of all importers, including the US, considering the fact that the global export market is extremely sensitive, especially for food and drugs.

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