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OPPORTUNITY IN CRISIS

No. of Indian facilities registered with the FDA has risen from less than 100 to 523 in 5 years

BY INVITATION

SREENIVASA PRASANNA
SENIOR DIRECTOR - CORPORATES, INDIA RATINGS & RESEARCH

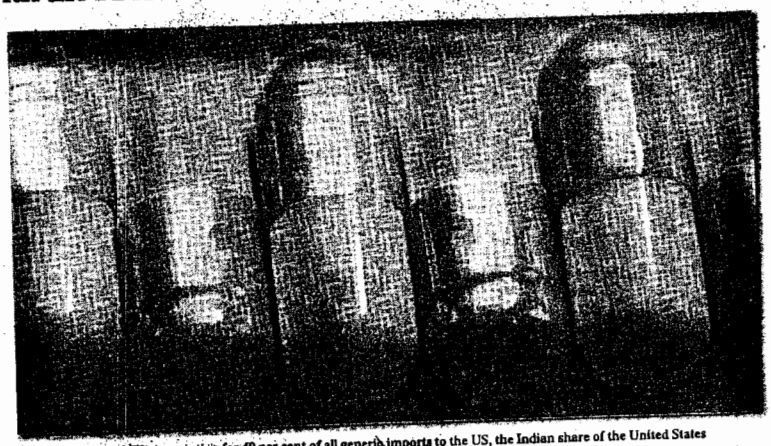
The year 2013 saw an increase in USFDA regulatory actions against Indian pharmaceutical manufacturers. Import alerts which ban import of drugs manufactured at a pharmaceutical facility were issued against 21 manufacturing facilities, and warning letters, which can lead to an import alert, if observed defects are not corrected, were issued to 10 facilities. In all, as on February 19, as many as 31 Indian manufacturing facilities were under import alert, the latest to join the list being Ranbaxy's Toansa facility on January 24.

Of these 21 joined the list during 2013. Although regulatory actions in 2013 denote a marked increase, Ind-Ra believes they do not weaken the industry's prospects.

This is not to downplay the importance of the US market or USFDA to the Indian pharmaceutical industry. Exports to the US have been the most important driver of growth for the industry over the last decade. Indian exports to the US have grown from Rs 2,937 crore in 2005 to Rs 22,463 crore in 2013 at a CARG of 29 per cent. The potential to grow remains high and we believe the CARG can be maintained at 20 per cent plus level at least for the next five years. The importance placed on generics by the Patient Protection and Affordable Care Act in the US (popularly called Obamacare) as well as the large number of drugs going off-patent over the next two years will continue to offer opportunities. And to capitalise on these opportunities, pharmaceutical companies have no choice but to manufacture them to US domestic standards as determined by the USFDA and in facilities whose manufacturing practices have been approved by the USFDA.

The Indian pharmaceutical industry has responded to this opportunity with commendable zeal. The number of manufacturing facilities registered with the USFDA has increased from less than 100 in 2008 to 523 as of February 19. This is the highest in any country outside of the US. The number of product approvals has also been very high. Indian companies accounted for 43 per cent of all ANDA approvals in 1H2013. It is this background of tremendous increase in activity that provides the context to assess the impact of the regulatory actions.

USFDA issued 43 import alerts against pharmaceutical facilities during 2013, of which 21 were facilities in India, making India's share 49 per cent of the total. This compares unfavourably with the total number of Indian facilities registered with USFDA, which was 523 as on February 19. This is about 17.4 per cent of the total 2,997 such facilities in the world outside the US. So India's share of import alerts is more than double the expected share, and on first sight is a definitely large and alarming proportion. However, considering the rapid growth of USFDA registered facilities in India, from less than 100 in 2008 to more than 500 now, we may be able to ascribe some of the lapses to the process of learning. The proportion is also comparatively similar in scale to those of other countries. The total number of Indian facilities currently under import alert is 31 which is about 5.9 per cent of USFDA registered facilities in India. This is slightly better than 6.1 per cent for China (31 out of 507) but somewhat higher than that for Germany (4.1 per cent) and UK (2.5 per cent).



CHEMICAL BOOST: Accounting for 40 per cent of all generic imports to the US, the Indian share of the United States pharmaceutical import pie increased from 2.5 per cent in 2008 to 5.6 per cent in 2012

The impact of the ban has also not been significant on the Indian pharmaceutical industry. If we look at the history of import alerts, they were always there. Seven Indian facilities were under import alert at the end of 2011, nine at the end of 2012 and 31 as on February 19. More importantly, many of those under import alert have set right their processes and have had the import alert lifted. Claris Life Sciences and Aurobindo Pharma both had import alert lifted on their facilities during 2012 and 2013 respectively. Such actions have been taken on MNCs exporting from India as well. Facilities of Hospira Healthcare India and Freesenelus Kabi Oncology were issued warning letters in 2012 and 2013, respectively, which were subsequently lifted. In all such cases there is an inevitable loss of revenue during the period of the ban/warning letter and additional expenses have to be incurred to set right the defects. Such losses can also be significant for the affected companies. Loss of revenue for Aurobindo was about $36m in 2012 or about only about 5 per cent of its total revenue FY13 revenues but the prospective loss for Wockhardt which has two facilities currently under import alert is expected by the company to be around $400m per annum or 40 per cent of their FY13 revenues. For the much smaller Smruti Organics, revenues decreased from Rs 180 crore in FY13 to Rs 41 crore in H1FY14, a fall of more than 50 per cent. However, given the overall size of exports from India, the loss of revenue is insignificant.

Also to be kept in mind is the importance of Indian pharmaceuticals to the US markets. Accounting for 40 per cent of all generics imports to the US, the Indian share of the US pharmaceutical import pie has increased from 2.5 per cent in 2008 to 5.6 per cent in 2012. Considering that India exports very little of the more expensive, under patent drugs, the increase in Indian exports with a lion's share of cheaper generics represents the contribution of India to affordable health care in the US. At a time when the demand for generics is poised to increase in the USA, the Indian pharmaceutical industry is expected to continue to be the leading supplier in this segment, as it has been registering the largest number of generic products with the USFDA in recent years.

Recognising the importance of the Indian pharmaceutical industry, the USFDA commissioner Margaret Hamburg, during her recent visit to India, announced the decision to increase the number of staff in the India office to 19 from 12. She also voiced her expectation that the ANDA approval backlog will be cleared quickly, underlying the importance US is placing on both, the need to increase the availability of generics as well as the expectation of a greater role of Indian manufacturers in meeting this need.

The Indian pharmaceutical industry will now have to install strong quality processes in its manufacturing facilities and inculcate a culture of compliance among its staff to ensure that the risk of import ban from USFDA is eliminated. The Indian players can then take full advantage of the market opportunity to become world class suppliers of drugs not only to the USA but also to the rest of the world.

Considering all these factors, including the rapid increase in product approvals and manufacturing facilities registered by the USFDA, the strong trend of growth in drug exports to the US, the considerable opportunities in the US and the correctible nature of the regulatory action, Ind-Ra believes that the potential for the Indian Pharmaceutical industry to grow at a 20 per cent plus CARG over the next five years is intact. We also believe that the Indian industry will be able to establish quality assurance processes as well as a compliance culture to reduce import alerts in the future.

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- Indian exports to the US grew from Rs 2,937 cr in 2005 to Rs 22,463 cr in 2013 at a CARG of 29 per cent
- The Indian pharmaceutical industry is expected to continue to be the leading supplier in this segment

Regulatory