

Ind-Swift Labs gets approvals for two products from PMDA, Japan

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Ind-Swift Laboratories, a Rs.700 crore plus Chandigarh based pharma company, has received Pharmaceutical & Medical Devices Agency (PMDA) approval from Government of Japan for pioglitazone and risedronate sodium to be manufactured at its facilities at Derabassi, Punjab. With this approval, it has become the first Indian company to get Japanese Government approval without any observations. This is a significant development in the company's history as it is aiming at huge exports to Japan.

N R Munjal, vice-chairman cum managing director, said, The company has high regulatory standards where its facilities are already approved by US FDA/TGA/COS/KFDA and with this approval for pioglitazone which is an anti diabetic drug with market size worth US \$2.8 billion and risedronate sodium a drug for osteoporosis with market size worth US\$ 1.6 billion, the company is aiming at capturing 15-20 per cent of the market share of these products by 2013."

It is for the first time that a large number of drugs patented by Japanese companies are going off patent. With the healthcare market size of US\$ 350 billion and only US\$ 13 billion worth of pharma product imports, Japan is a promising market for Indian pharma manufacturers. The rapid pace of population aging and associated high healthcare expenditure is also increasing the popularity of generics in Japan. Japan's pharma imports from India are currently less that US\$ 10 million and these factors are likely to boost export prospects. Munjal added, "We are in the advance stage of negotiations to supply commercial quantities for these products to the Japanese market and the free trade pact between India and Japan will further strengthen company's export revenues."

Ind-Swift has already filed 4 DMFs in Jaoan including that of Atorvastatin a 12 billion market drug, PMDA approval for these products is expected shortly, that will take the total approved products to six. It has also filed 302 DMFs so far with various regulatory authorities including 4 DMFs filed in Japan.