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Ageing Japan beckons Indian generic drug companies

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Mumbai: Though the recent visit of Prime Minister Narendra Modi to Japan ended on a not-so-eventful note for the Indian pharma sector, the industry is hopeful that the Japanese market will slowly turn to India for exports of generics.

Japan, which was so far had been a market for patented and innovative drugs, is slowly realising the importance of low-cost generics, due to growing ageing population.

S V Veerramani, president, Indian Drug Manufacturers' Association (IDMA) and chairman and managing director, Fourrts (India) Laboratories, told dna, "Japanese market was earlier a more innovator and research-based market, and only allowed patent-based products. But they are slowly turning to generics because they have realised that prices of generics are lower and also that Japan has a large ageing population." The government there is giving added benefits, such as tax incentives, etc, to hospitals and doctors who are prescribing generics, he said.

P V Appaji, director general, Pharmaceuticals Export Promotion Council of India, said if Japan has to reduce its healthcare burden, it must depend on generics, adding that the Japanese government also has announced policy for increasing share of generic usage in the country.

"So far, the Japanese industry and government were not in a position to draw any understanding of the capabilities of the Indian pharma industry. Therefore, Indian industry was not able to get the entry through collaborations in Japan or through Japanese FDA approval. Besides, Japanese government and local medical authorities prefer branded and innovator drugs."

But with increasing ageing population in Japan, there is now an increasing burden of healthcare on the government and so Japan is slowly understanding the need for generic drugs, he said.

Except for Lupin and Zydus Cadila, no other pharma companies have been able to really enter the Japanese market.

In an earlier interaction with dna, Lupin managing director Nilesh Gupta had said, "One cannot treat Japan like any other generic market which is a limitation in itself. There must be a strong local understanding about the quality. The biggest challenge is to have products of right qualities."

In Japan, for any international company to do business, it is compulsory to partner with a local manufacturer. Besides, the bioequivalence studies, if the generic drug is for Japanese market, must also be conducted in Japan.

"For the US and the UK, they have accredited laboratories in India and those studies can be done in India as per requirements. But in case of Japan, they want all studies to be done only in Japan and on Japanese population. This automatically increases the cost," said Veerramani.

At present, Japan accounts for only 1% of the country's $16 billion overall pharma export. In rupee terms, it is about Rs 900-1000 crore. Of this, around Rs 600-700 crore is active pharmaceutical ingredients (APIs) export to Japan.

"They are more interested in API. It is also relatively easier to enter the Japanese market with API than with generic formulations since no bioequivalence study is required in case of API. Only in case of formulations, we have to do bioequivalence 3 in Japan which takes more time," said IDMA president.

Appaji said that that out of the overall exports to Japan, formulation exports value has increased from 10% to 30-35%.

"From our recent visit to Japan, we could see a lot of understanding by Japanese pharma manufacturers and increasing acceptance of India's pharmaceutical capabilities. We are hopeful that the approval of drug formulations by Japanese FDA will be faster in the coming days," he said.

Miscellaneous