



PHARMACEUTICALS EXPORT PROMOTION COUNCIL

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Drug majors may get easier access to Japan's \$60-b market

Tokyo likely to offer `national treatment' to Indian generic firms.

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<http://www.thehindubusinessline.com/2010/05/14/stories/2010051454120100.htm>

In a big boost to drug majors such as Ranbaxy, Lupin and Zydus Cadila, Tokyo has given an in-principle nod to New Delhi's demand for according `national treatment' to Indian pharmaceutical companies on registration and approvals in Japan.

Official sources told Business Line that the two countries have come to an understanding on attaching a `legally enforceable text' on pharmaceuticals to the final document on the proposed India-Japan Comprehensive Economic Partnership Agreement (CEPA). The `national treatment' clause would find a place in the `text'.

This means, post the pact, Japanese authorities will treat Indian pharma firms and local Japanese companies equally on registration and approvals. Indian pharma makers and drugs will have to obtain clearances from Japanese authorities just like their local counterparts but they will not face any discrimination. **Entry difficult**

This will effectively grant Indian generic firms faster and greater access to Japan - the world's second largest pharma market worth around \$60 billion. Japan is a tough market to enter due to its stringent registration norms.

Dr P. V. Appaji, Executive Director, Pharmaceuticals Export Promotion Council, said currently it takes between 11 months to two years for foreign companies to get registration in Japan. To get registered, one has to comply with additional norms such as having a local office and a local agent.

The drug approval requirements involve huge costs and the mandated sample size for testing is very big, he said, adding that all these rules make entry difficult.

The negotiations on the pharma sector were causing a delay in concluding the CEPA talks. Japan was earlier reluctant to include such a `text' and was only ready for a joint committee or a legally non-enforceable letter on the matter. However, sources said Japan may now agree to make the text legally binding.

This gesture would be reciprocated by New Delhi, meaning India too would offer `national treatment' to Japanese drug companies on registration and approvals. This could lead to a successful conclusion of the CEPA soon.

Dr Appaji said the share of pharma exports to Japan (in India's total pharma exports) is minuscule because a majority of India's pharma exports to Japan currently is of bulk drugs. "Once they allow easier entry to generic drugs and give us national treatment, pharma exports to Japan will rise significantly," he said.

Japan's plans to increase its share in the global generics market from the current 15 per cent to 50 per cent will also help Indian generics. **More presence**

Drug firms such as Ranbaxy Laboratories want to ramp up their presence in Japan. Ranbaxy has so far launched eight products in Japan. Its parent company has set up a new firm, Daiichi Sankyo Espha Company (DSECL), for marketing generic drugs in Japan.

"Japan is a focus area for us. Ranbaxy will have the opportunity to develop, manufacture and supply generic drugs to Japan through DSECL," said Ranbaxy Managing Director and Chief Executive Officer, Mr Atul Sobti. Ranbaxy may set up a dedicated manufacturing unit for exporting drugs to Japan.

Lupin too is betting big on Japan through its acquisition Kyowa. A Lupin spokesperson said, "The Japanese market holds immense potential for us. We believe it will grow very fast in the next three years."

India's pharma exports to Japan had declined by 7 per cent in April-December 2009 to \$53.85 million from \$57.95 million in April-December 2008. The country's pharma exports to Japan had fallen by 30 per cent to \$72.7 million in 2008-09 from \$94.45 million in 2007-08. The share of India's pharma exports to Japan as a percentage of its total pharma exports also had fallen from 1.23 per cent in 2007-08 to 0.84 per cent in 2008-09 and remained at 0.85 per cent in April-December 2009.