



## PHARMACEUTICALS EXPORT PROMOTION COUNCIL

(Set up by Ministry of Commerce, Govt. of India)

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### **Pharmexcil raises concern over Sri Lanka's new approval procedure for bio-similars**

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The Pharmaceutical Exports Promotion Council (Pharmexcil) has urged the Union Ministry of Commerce and Industry to initiate talks with Sri Lanka on its revised policy in approving bio generics. Indian biopharma industry has already complained that the new procedure to enter the Sri Lankan market is unjustified.

The Sri Lankan government, in the beginning of February 2010, has issued a circular revising its procedures for registration of bio-similar products stipulating that bio-similar products marketed in Sri Lanka would need registration in at least one single reference country (in developed countries like UK, USA etc) as per the specified list. It also specifies compulsory submission of clinical trial data with reference to the innovator products, for such approvals.

The council, which works under the aegis of the Ministry of Commerce & Industry to promote the Indian pharma exports, has sent a letter to the department seeking early action on the issue. It has also forwarded a representation received from the Mumbai-based Wockhardt Ltd to the Department of Commerce, which appeals the council and the central government to take up the issue with the Sri Lankan government to ensure that status quo is maintained.

The council, in its letter to the joint secretary of Department of Commerce early this month, pointed out that the Indian companies are growing strong in bio-similar business and holds good potential in the international market and companies like Wockhardt, Biocon and Serum Institute are currently marketing bio-similar products including products like insulin and erythropoetin in international markets at affordable prices. The council also hints that the act from Sri Lanka appears to be due to influence of vested interests.

Considering the request from the industry and the goodwill towards the bio- similar exports market of India, the council requested the department to take up the matter with the Sri Lankan government after due consultation with the Drug Controller General of India (DCGI), if necessary.

Though the bio-similar market in Sri Lanka is comparatively small, the revised procedure in this country may set a trend for other similar countries to follow, says an expert from the industry. The government has to act promptly on any such moves for the better growth of Indian bio-similar industry, he said on condition of anonymity.