



# PHARMACEUTICALS EXPORT PROMOTION COUNCIL

(Setup by Ministry of Commerce & Industry, Govt. of India)

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Dt. 2<sup>nd</sup> June, 2010

Shri Rajeev Kher, IAS  
Joint Secretary  
Department of Commerce.  
Ministry of Commerce & Industry  
Government of India  
New Delhi

Sir,

**Sub: Threat to Indian Bio-Similars Pharma market in Sri Lanka.**

As you are aware, India is growing strong in biological products and in the recent past, introduced several Bio-Similars (generics) from biological products, after patent expiry. Such Bio-Similars are being approved by DCGI and they are being marketed by Indian companies, both in India and outside, as per National requirements. There is good potential for Bio-similar products in international markets. It appears that due to influence of vested interests, one country, namely, Sri Lanka has revised its procedures for registration of Bio-Similar products in Sri Lanka. Their recently released circular dated 1<sup>st</sup> February, 2010 insists / stipulates 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 says that clinical trial data is to be carried with reference to the innovator products. As you may be aware, some of our member companies like M/s. Wockhardt, Biocon, Serum Institute, etc., are currently marketing Bio-Similar products, including products like Insulin, erythropoetin etc. in international markets at affordable prices.

We are herewith forwarding a representation received from M/s Wockhardt, requesting Pharmexcil/Govt. of India, to take up this unjustified proposal of Sri Lanka with the Sri Lankan Government and ensure that status quo is maintained.

In view of the above, we request you to kindly take up this matter with the Sri Lankan Government, after consultation with DCGI, if necessary.

Thanking you,

Yours sincerely,

A handwritten signature in black ink, appearing to read 'P. V. APPAJI', with a horizontal line underneath the name.

Dr. P.V. APPAJI  
Executive Director

Encl: as above.