



PHARMACEUTICALS EXPORT PROMOTION COUNCIL

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

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News / Story reproduced with thanks:- **Pharmabiz**

Exporters demand validity of CoPP to be raised from two to three years

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<http://www.pharmabiz.com/article/detnews.asp?articleid=54095§ionid=>

Even as the legal battle between the industry and the drug controller general of India (DCGI) over the centralization of Certificate of Pharmaceutical Products (CoPP) lingers on, the pharma exporters have demanded to increase the validity of CoPP from the existing two years to at least three years on the lines of European Union (EU) countries.

Exporters argue that they find it difficult while registering their products abroad due to the CoPP validity as they have to renew it in every two years. Given the complicated official procedures and the subsequent delays in issuing the CoPP by the drug officials, exporters very often lose their export orders as they have to present their CoPP while registering their products abroad. If the CoPP is issued for at least three years, there will be some solace, an exporter said.

The exporters have sought union commerce ministry's intervention in this regard to take up the matter with the health ministry. The exporters have recently met senior commerce ministry officials in this regard to apprise them of the difficulties being faced by the exporters due to the delay in issuing the CoPP. The commerce ministry officials are believed to have assured the industry of its intervention in the matter.

Presently, the CoPP has two years validity and is issued by the state licensing authorities (SLAs) after a joint inspection by the CDSCO (DCGI office) and state drug control department. After two years, the exporters have to renew the CoPP. The exporters plead that if the validity is raised to three years, if not five years, the industry can save a lot of time and energy wasted in every two years to get these certificates.

CoPP is a basic document required by the exporters to export their products to the countries where there is no regulatory system of their own. The importing countries accept the CoPP as the proof of quality of the product. CoPP is issued by the SLAs for individual products. While the US, European Union countries, Canada, Australia and other developed countries have their own regulatory system and they import the drugs from the plants inspected and approved by their own agencies like the US FDA, countries in Latin America, Africa, CIS countries and other developing countries accept CoPP as the proof of quality of the product.