PHARMACEUTICALS EXPORT PROMOTION COUNCIL
(Set up by Ministry of Commerce, Govt. of India)

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DCGI, Pharmexcil to meet regularly to address problems of pharma exporters.

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http://www.pharmabiz.com/article/detnews.asp?articleid=54079

The DCGI has asked the Pharmexcil to suggest any policy changes, if needed, to help the pharmaceutical exporters, as both the sides decided to meet regularly to discuss and mitigate the problems faced by the exporting community.

A recent meeting of Pharmexcil representatives with the DCGI, while clearing many pending issues and clarifications, has decided to hold monthly meetings. A core group of the Pharmexcil will thus meet the DCGI to take up the issues of the exporters in general, sources said.

While assuring all cooperation to the exporters including speedy clearance of NoCs, the DCGI said more staff will be inducted in the CDSCO to settle all applications in time. During the last one year, the DCGI office received 38,466 applications from the industry and 13,493 letters from government offices. Though the US FDA Bhavan is heavily understaffed, all applications were cleared. The DCGI informed that within one year 250 inspectors will be added to CDSCO. Thus the department will have 19 DDCGI and 41 ADCs. This additional manpower will strengthen early disposal of applications and pending matters with CDSCO offices.

On the complaints that the NoC was getting delayed by two weeks sometimes, the DCGI said the NoC was usually given in ten days. He said his office will revise the checklist for NoCs with the help of the Pharmexcil as most of the applications were incomplete and thus causing delays.

Some of the members of the Pharmexcil pointed that obtaining import license for artemisinin from China, Vietnam and Africa and also for piperquine takes a month's time, thus affecting the import. The members suggest that license may be given for product only instead of manufacturers, by taking an undertaking from the importer. It has been decided at the meeting that the Pharmexcil will prepare a list of drugs which are used as intermediates and not as drugs for approval to DCGI. Intermediates such as erythromycin thiocyanate also may be taken up for removal as a drug.

Another concern was about stability data as CDSCO zonal office in Bangalore was asking for it on commercial batches. The DCGI clarified that the stability data for test license is not considered as stability data for commercial production.

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