



PHARMACEUTICALS EXPORT PROMOTION COUNCIL

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Pharma intending agents form Assn, to take up issue of delay in registration of import licenses

Friday, May 28, 2010 08:00 IST
Ramesh Shankar, Mumbai

Direct link to the News/Story:-

<http://www.pharmabiz.com/article/detnews.asp?articleid=55662§ionid=>

Even as the drug importers in the country are annoyed over the issue of inordinate delay in getting the registration and re-registration of import licenses from the DCGI office, the intending agents of the pharma industry in the country have come together to form an association to take up the matter with the DCGI office.

According to sources, around 50 intending agents in the country have come together and have formed the All India Pharma Intending Agents Association.

The intending agents are the mediators between the manufacturers and the importers. The DCGI issues Form 41 to the intending agents and against the Form 41 the intending agents issue Form 9 to the importers as per the Drugs and Cosmetics Act and then the importer applies to the DCGI for Form 10 which permits them to import the registered drugs. The validity of Form 41, Form 9 and Form 10 is for three years from the date of issuance.

BR Sikri has been selected as the president of the new association while Gautham Shah has been selected as the vice-president. Darshan Thakur is the treasurer and Rana is the general secretary of the new association which will be registered soon. The association had its first meeting in Mumbai recently.

Association president BR Sikri said that at present, there is no proper platform of the intending agents in the country to express their grievances with the drug authorities. The Association is intending to meet the DCGI on June 11 on the issue of delay in getting the registration and re-registration of import licenses from the DCGI office.

Sources in the industry said that there is a lot of delay in renewing the import registration by the DCGI office, adversely affecting the business. For the renewal of import registration licences a fresh application of registration certificate has to be made nine months before the expiry of the existing certificate. Ideally, the DCGI's office is bound to take action on the application within six weeks from the time they receive the application for renewal of re-registration of import licences. However, there are complaints that the importers are not getting the registration renewal even after one year of putting up the application.

Import registration is the registration of the manufacturing site of a foreign manufacturing unit and the products manufactured therein, intended for import into India under the Drugs & Cosmetics Rules. All the biological and non-biological drugs, including bulk drugs, finished formulations, vaccines, critical diagnostic kits, syringes, needles, sutures, catheters, medical devices and internal prosthetic implants fall under the purview of the import registration.