



PHARMACEUTICALS EXPORT PROMOTION COUNCIL

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

Health ministry to allow drug imports through ICD of Tuticorin seaport soon

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Gireesh Babu, Mumbai

Direct link to the News/Story:-

<http://www.pharmabiz.com/article/detnews.asp?articleid=56205§ionid=>

The Union Ministry of Health & Family Welfare may soon allow imports of medicines and related products through one more Inland Container Depot (ICD), at Tuticorin, Tamil Nadu, by including the Depot as a clearance point in the Drugs and Cosmetics (2nd Amendment) Rules, 2010.

With this, the pharma industry, especially in South India, can import drugs through sea, not only through Chennai and Cochin which are the existing clearance centres for pharma imports, but also through Tuticorin, a major port city in the region. Tuticorin is an ICD with Container Freight Station (CFS), which allows an off dock facility located near the servicing port to help in decongesting the port by shifting cargo and Customs related activities outside the port area.

The Ministry, of late, has issued a draft notification announcing its proposal to include the ICD to the Rule 43-A of Drugs and Cosmetics Rules, 1945. The notification suggests that "in rule 43-A, for the words 'Chennai, Kolkata, Mumbai, Cochin, Nhava Sheva, Kandla and Inland Container Depots at Tuglakabad and Patparaganj, Delhi; in respect of drugs imported by sea into India.' the words 'Chennai, Kolkata, Mumbai, Cochin, Nhava Sheva, Kandla and Inland Container Depots at Tuglakabad and Patparaganj, Delhi and Tuticorin in Tamil Nadu; in respect of drugs imported by sea into India.' shall be substituted."

The sea port in Tuticorin, strategically located and very close to the East- West International sea-route on east coast, is well connected by broad gauge rail and road with all major cities and ICDs. This was the first port in India to attain ISO 9002 /94 standard certification, in 1996, according to sources. The district is also the home for many chemical and pharma small scale companies, they added.

Meanwhile, the draft notification has also made amendments in the Form 45 and 46 under the Schedule A of the Drugs and Cosmetics Rules, 1945, updating the norms of post marketing surveillance with details on submission of Periodic Safety Update Reports (PSUR).

While the earlier form had mandated the post marketing surveillance during the initial period of two years of marketing a new drug formulation, the amendment is in lines with the revised Schedule Y regulation, detailing that "...the applicant shall submit Periodic Safety Update Reports (PSUR) every six months for the first two years. For subsequent two years the Periodic Safety Update Reports (PSUR) need to be submitted annually."

The notification also has proposed to bring in amendment in Schedule F and Schedule K. Through this, the age barrier for blood donation would be extended from 60 years to 65 years under Schedule F and in item

number 33 of Schedule K, Nicotine lozanges would be included with extend and conditions of exemptions mandated for over the counter sales of Nicotine gum.