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CDSCO to set up pharma zones at airports

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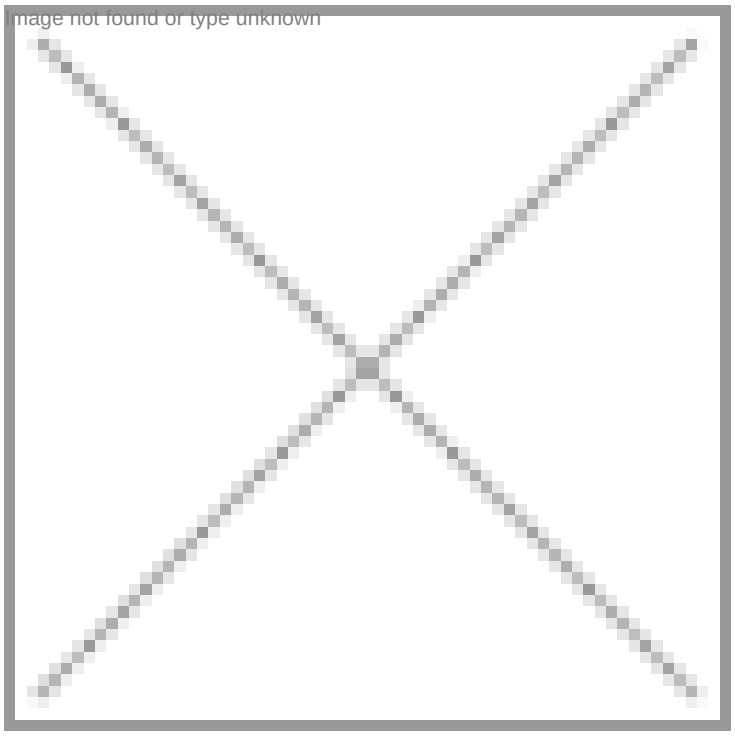

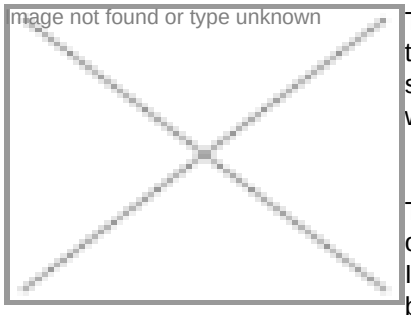

The Central Drugs Standard Control Organization (CDSCO) of India will set up dedicated temperature and atmosphere-controlled areas at airport terminals in India, to maintain the safety, efficacy, and quality of imported and exported drugs and pharma products, in line with the product requirements and good manufacturing practice (GMP) compliance, within

The Drugs Controller General of India (DCGI) Dr Surinder Singh, said, “We have a budget of 25 crore for this initiative, and the first pharma zone will be set up at the Indira Gandhi International Airport (IGIA), New Delhi.” Other terminals where similar pharma zones will be established, once initiated in New Delhi, include all the five international airports in India, plus the Nhava Sheva seaport. These pharma zones have been set up in the light of the increasing volumes of export and import of drugs from the country over the years.

The CDSCO zeroed in on New Delhi to establish its first pharma zone, primarily because of the increased number of new pharmaceutical companies mushrooming in north India, due to the government policy initiatives excise/ income tax incentives.

The current drugs exports from India is projected at 42,000 crore. India's pharmaceutical exports mainly comprise of formulations (over 55 percent) followed by bulk drugs (43 percent) and the remaining comprises of herbal exports.

Proposed US law may hit Indian exporters

The proposed Foreign Manufacturers Legal Accountability Act of 2010 (FMLAA) seeks to protect US consumers by requiring foreign manufacturers and producers to take direct responsibility on any liability arising out of such manufacturers’ or

producers' products.

Expressing disappointment at yet another protectionist measure emanating from the US, Chandrajit Banerjee, director general, Confederation of Indian Industry (CII), New Delhi said, "CII's preliminary estimates suggest that the additional cost of compliance with this new US law for Indian companies could be anywhere between ₹ 1,393 cr - 2,318 crore ($300 to $500 mn). This would significantly impact the competitiveness of Indian exports".

The act requires all foreign manufacturers exporting packaged products (that includes drugs, devices, cosmetics, biological products, consumer products, chemical substances, new chemical substances and pesticides, to establish a registered agent in the US, who would be in a position to take legal responsibility for the liabilities arising out of these products, thus also bringing Indian exporters into the ambit of US jurisdiction.

The FMLAA would prove to be very expensive for Indian exporters, especially for small and medium scale manufacturersand producers. For one, the cost of hiring registered agents on a permanent basis will prove prohibitive. Such a provision would be unjustified because many Indian exporters do not export to the US all year round; some, not even every year. This proposed law is also of grave concern because it applies not just to finished products, but also to intermediates.

Government to initiate inspection of clinical trial sites

The Drugs Controller General of India (DCGI) announced that India is soon to commence regular and on-the-spotinspections of clinical trial sites to ensure transparency and volunteer safety in the country. This could perhaps change the landscape of the clinical trial industry in India, which has been beset with lapses in adherence to safety guidelines.

Dr Surinder Singh, DCGI, said, "This will commence in September and we will begin by inspecting trial sites in Bangalore, Mumbai, Kolkata, Chennai and New Delhi. This will not just strengthen the clinical trial scenario in India, but also ensure that volunteers are in safe hands and there are no violations in protocols".
For this, there will be a collaboration with the US Food and Drug Administration, in terms of training of inspectors."Altogether, we have 169 inspectors. Out of this, 25 inspectors have been trained already, and 20 more will be trained to audit these sites," said Dr Singh.

In terms of conducting clinical trials, there have been a number of loopholes in India, volunteer safety being one of them. Off late, a number of big pharmaceutical companies have been conducting trials in India, without being reviewed by the Ethics Committee.

In April 2010, the Indian government suspended trials in Indian States for Merck's cervical cancer vaccine, Gardasil, after reports of the vaccine being allegedly tested on children, before being tested on adults. This is how, putting in place a system of stringent checks and balances becomes imperative.