

Pharma & Healthcare Update

July 13, 2015

PHARMA ALERT

- Barcoding on mono cartons containing one primary pack for export made optional until further notice
- India mulling over new regulations for online sale of drugs
- India exempts AIDS related drugs, diagnostics and equipment used in its national AIDS control programme from import duty

BARCODING ON MONO CARTONS CONTAINING ONE PRIMARY PACK FOR EXPORT MADE OPTIONAL UNTIL FURTHER NOTICE

On 22 May 2015, the Director General of Foreign Trade (DGFT) announced that it will now be optional for drug formulations manufactured for export to incorporate one or two dimensional (1D or 2D) barcodes on mono cartons which contain one primary pack. 'Primary pack' means the package which is in direct physical contact with the drug formulation.

Earlier this year, the DGFT made it mandatory for drugs manufactured for export on or after 1 April 2015 to incorporate 1D or 2D barcodes on mono cartons which contain one primary pack. The barcodes would encode the unique and universal global product identification code in the format of a 14 digit Global Trade Item Number (GTIN) along with the batch number, expiry date and a unique serial number. If the barcode did not exist, then the drugs were not permitted to be exported.

It is believed that the requirement was relaxed because small-size manufacturers and exporters were finding it difficult to bear the cost of the barcoding process.

INDIA MULLING OVER NEW REGULATIONS FOR ONLINE SALE OF DRUGS

It has been reported that the Ministry of Health is mulling over new regulations to govern the retail sale of drugs on the internet.

Numerous e-pharmacies and online marketplaces have been served with a show cause notice for committing violations or abetting violations concerning the retail sale of drugs without a licence and without obtaining valid prescriptions. The biggest concern appears to relate to the sale of prescription drugs using a scanned copy of the prescription.

Due to the alleged lack of clarity in law, numerous industry organisations have made a demand for official guidelines, whilst brick and mortar retailers have vehemently opposed the online sale of drugs.

The development appears to be a step in the right direction as online pharmacies are operational in other mature regulatory jurisdictions such as the US, UK and Europe.

INDIA EXEMPTS AIDS RELATED DRUGS, DIAGNOSTICS AND EQUIPMENT USED IN ITS NATIONAL AIDS CONTROL PROGRAMME FROM IMPORT DUTY

On 10 June 2015, the Central Board of Excise and Customs exempted a long list of anti-retroviral drugs, diagnostics and equipment from basic custom duty and additional customs duty until 1 April 2016.

In order to avail the exemption, the importer has to produce a certificate from an officer of a rank no less than Deputy Secretary to the Government of India in the Ministry of Health and Family Welfare to the effect that the relevant products are required for the National AIDS Control Programme funded by the Global Fund to fight AIDS, TB and Malaria.

This step is directed at reducing the cost burden on stakeholders involved in seeking to control AIDS.

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— Anay Shukla & Khushboo Baxi

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September 22, 2024