

## 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.

*\* Reproduced from Practical Law with the permission of the publishers.*

— Anay Shukla & Khushboo Baxi

You can direct your queries or comments to the authors

### DISCLAIMER

The contents of this hotline should not be construed as legal opinion. View detailed disclaimer.

## Research Papers

### Structuring Platform Investments in India For Foreign Investors

March 31, 2025

### India's Oil & Gas Sector— at a Glance?

March 27, 2025

### Artificial Intelligence in Healthcare

March 27, 2025

## Research Articles

### Re-Evaluating Press Note 3 Of 2020: Should India's Land Borders Still Define Foreign Investment Boundaries?

February 04, 2025

### INDIA 2025: The Emerging Powerhouse for Private Equity and M&A Deals

January 15, 2025

### Key changes to Model Concession Agreements in the Road Sector

January 03, 2025

## Audio

### CCI's Deal Value Test

February 22, 2025

### Securities Market Regulator's Continued Quest Against "Unfiltered" Financial Advice

December 18, 2024

### Digital Lending - Part 1 - What's New with NBFC P2Ps

November 19, 2024

## NDA Connect

Connect with us at events, conferences and seminars.

## NDA Hotline

Click here to view Hotline archives.

## Video

Vyapak Desai speaking on the danger of deepfakes | Legally Speaking with Tarun Nangia | NewsX

This Hotline provides general information existing at the time of preparation. The Hotline is intended as a news update and Nishith Desai Associates neither assumes nor accepts any responsibility for any loss arising to any person acting or refraining from acting as a result of any material contained in this Hotline. It is recommended that professional advice be taken based on the specific facts and circumstances. This Hotline does not substitute the need to refer to the original pronouncements.

This is not a Spam mail. You have received this mail because you have either requested for it or someone must have suggested your name. Since India has no anti-spamming law, we refer to the US directive, which states that a mail cannot be considered Spam if it contains the sender's contact information, which this mail does. In case this mail doesn't concern you, please unsubscribe from mailing list.

April 01, 2025

**Vaibhav Parikh, Partner, Nishith Desai Associate on Tech, M&A, and Ease of Doing Business**

March 19, 2025

**SIAC 2025 Rules: Key changes & Implications**

February 18, 2025