

To be published in the Gazette of India Extraordinary Part-I, Section-I
Government of India
Ministry of Commerce and Industry
Department of Commerce
Directorate General of Foreign Trade

Public Notice No. 4 /2015-2020
New Delhi, Dated the 1 April, 2015

Subject: Implementation of the Track and Trace system for export of Pharmaceuticals and drug consignments.

In exercise of the powers conferred under Paragraph 1.03 of the Foreign Trade Policy, 2015-2020, as amended from time to time, the Director General of Foreign Trade hereby inserts Para 2.89 A in Handbook of Procedure, 2015-2020, as under, for laying down the procedure for implementation of the Track and Trace system for export of Pharmaceuticals and drug consignments:

2. **“2.89 A**

Procedure for Implementation of the Track and Trace system for export of Pharmaceuticals and drug consignments

- (i) The manufacturer of drug for formulations will print the barcode as per GS1 Global Standard at different packaging levels to facilitate tracking and tracing of their products. The details are as follows:

(a) Primary Level:

Incorporation of two dimensional (2D) barcode encoding unique and universal global product identification code in the format of 14 digits Global Trade Item Number (GTIN) along with batch number, expiry date and a unique serial number of the primary pack. The bar code labelling at primary level is exempted till further notification, however the above mentioned details are required to be printed in human readable form.

(b) Secondary Level:

Incorporation of one or two dimensional (1D or 2D) barcode encoding unique and universal global product identification code in the format of 14 digits Global Trade Item Number (GTIN) along with batch number, expiry date and a unique serial number of the secondary pack.

(c) Tertiary Level:

Incorporation of one dimensional (1D) barcode encoding unique and universal global product identification code in the format of 14 digits Global Trade Item Number (GTIN) along with batch number, expiry date and a unique serial number [Serial Shipping Container Code (SSCC)] of the Tertiary pack.

- (ii) The manufacturer shall maintain the data in the parent-child relationship for all three level of packaging i.e. Primary, Secondary and Tertiary and their movement in its supply chain.
- (iii) The data mentioned in (ii) above, shall be uploaded on the central portal of the Government of India by the manufacturer or its designated agency before release of the drugs for sale or distribution.

- (iv) The responsibility of the correctness, completeness and ensuring timely upload of data on the central portal shall be with the manufacturer.

The above rules will not be applicable to those drug formulation manufactured for export purposes, where the government of the importing country has mandated a specific requirement and the exporter intends to avail the option of printing the barcodes in their format with the permission of licensing authority appointed under rule 21. However, the tertiary level of packaging will have additional printing of barcode as per (i)(c) above in addition to importing country's requirement, if any.

- (v) The exports of the drugs having manufacturing date prior to 01.04.2015 will be exempted for requirement of barcode labelling and data uploading on central portal.
- (vi) The drugs with manufacturing date on or after 01.04.2015 will compulsorily carry barcode on tertiary and secondary packages as per the Notification No. 68 dated 06.08.2014. However the requirement of data uploading on central portal will be exempted till 30.06.2015.
- (vii) With effect from 01.07.2015, all drugs with manufacturing date on or after 01.04.2015 can be exported only if both the tertiary and secondary packaging carry barcoding as applicable and the relevant data as prescribed by DGFT is uploaded on the central portal.

Explanation:

- (a) For the purpose of this rule, primary packaging means the package which is in direct physical contact with the drug, secondary packaging means the carton containing multiple primary packs including a mono carton and tertiary packaging means a shipper containing multiple secondary packs.
- (b) Separate guidelines shall be issued for data requirement, maintenance and upload on central portal.”

3. Effect of this Public Notice:

The procedure for implementation of the Track and Trace system for export of pharmaceutical and drug consignments has been notified.

(Pravir Kumar)
Director General of Foreign Trade
E-mail:dgft@nic.in

(Issued from F.No. 01/91/180/648/AM 09/Export Cell)