

DGFT PUBLIC NOTICE

-COPY OF-

PUBLIC NOTICE NO.13/2015-2020

Dated 22nd May, 2015

Implementation of the Track and Trace system for export of drug formulations.

In exercise of the powers conferred under Paragraph 2.04 of the Foreign Trade Policy, 2015-20, as amended from time to time, the Director General of Foreign Trade hereby amends Para 2.89 A of Handbook of Procedure, 2015-20, as notified vide Public Notice No.4/2015-20 dated 01.04.2015, as under, for laying down the procedure for implementation of the Track and Trace system for export consignments of drug formulations:

2. "2.89 A

Procedure for Implementation of the Track and Trace system for export of drug formulations

- (i) The manufacturer or the exporter of drug 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 on optional basis till further notification.

(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. However, manufacturer or exporter shall affix bar code on mono carton containing one primary pack on optional basis till further notification.

(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 of the tertiary pack i.e. Serial Shipping Container Code (SSCC).

- (ii) The manufacturer or exporter shall maintain the data in the parent-child relationship for three levels of packaging i.e. Primary, Secondary and Tertiary packaging and their movement in its supply chain. However, maintenance of parent-child relationship between primary and secondary packaging is optional till further notification.
- (iii) The data mentioned in (ii) above shall be uploaded on the central portal of the Government of India by the manufacturer or exporter or its designated agency before release of the drug formulations for sale or distribution.

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- (iv) The responsibility of the correctness, completeness and ensuring timely upload of data on the central portal shall be with the manufacturer or exporter.
- (v) The above rules (i) to (iv) will not be applicable to those drug formulations manufactured for export purposes, where the government of the importing country has mandated or formally notified its intention to mandate a specific requirement and the exporter intends to avail the option of printing the barcodes in their format after duly obtaining the permission of DCGI or its nominee. 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.
- (vi) The exports of the drugs having manufacturing date prior to 01.10.2015 will be exempted from requirement of data uploading on central portal.
- (vii) With effect from 01.10.2015, all drugs with manufacturing date on or after 01.10.2015 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,
- (i) Drug formulation means a formulation manufactured with a license from Drug Control Authority under the provisions of Drugs & Cosmetics Act and Rules made there under.
- (ii) Primary packaging means the package which is in direct physical contact with the active ingredient. Secondary packaging means a carton containing one or more primary packs and includes a mono carton containing one primary pack. The tertiary packaging means a shipper containing one or more secondary packs.
- (b) Separate guidelines shall be issued for grant of exemption (s), data requirement, maintenance and upload on central portal."

3. Effect of this Public Notice:

In supersession of the earlier Public Notice No.4/2015-20 dated 1st April, 2015, the procedure for implementation of the Track and Trace system for export of drug formulations has been modified.

Sd/-
(Pravir Kumar)
Director General of Foreign Trade

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Issued by:
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