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Government of India
Ministry of Commerce and Industry
Department of Commerce
Directorate General of Foreign Trade

Public Notice No.52/2015-2020
New Delhi, Dated the 5 January, 2016

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

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 2.89A of Handbook of Procedure, 2015-20, as notified vide Public Notice No. 4/2015-20 dated 1.04.2015 (as amended), 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 labeling 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, incase of monocartons 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) **Parent –Child Relationship/ Effective dates for SSI and Non-SSI Manufacturers:**

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.

a) All Manufacturers (SSI & Non- SSI Manufacturers):

As one time exemption all manufacturers are exempted from maintenance of Parent-Child relationship in packaging and its uploading on central portal (http://dava.gov.in) till 31.03.2016. However, the requirements of printing of barcoding on the different levels or packaging will be applicable as prescribed.

b) Extended Date of Exemption to SSI Manufacturers:

All SSI drug manufacturers are exempted from requirement of maintaining Parent-Child relationship in packaging levels for a further period up to 31.03.2017. However, they are required to upload Tertiary level data on the central portal mandatorily as prescribed in public notice no. 13/2015-2020 dated 22.05.2015.

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.

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. Export of drugs manufactured by non-SSI units and having manufacturing date prior to 31.03.2016 and export of the drugs manufactured by SSI units and having manufacturing date prior to 31.03.2017 are exempted from requirement of data uploading on Central Portal.

vii. All drugs manufactured by non SSI units with manufacturing date on or after 01.04.2016 and all drug manufactured by SSI units with manufacturing date on or after 01.04.2017 can be exported only if both 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 and registered as "Drug" with the FDA of importing country.

(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) All relevant guidelines regarding grant of specific exemption (s) if any, procedure of data requirement / maintenance / upload on central portal and clarifications issued under this notification etc. will be available on the central portal i.e. http://dava.gov.in

(c) It will be the responsibility of the drug manufactures/exporters as the case may be, to satisfy the customs authorities that the export consignment *satisfies the conditions of the notification".*

3. **Effect of this Public Notice:**

In suppression of the earlier Public Notice no. 13/2015-2020 dated 22.05.2015, the dates for implementation of Track and Trace system for export of drug formulations alongwith maintaining the Parent-Child relationship in packaging have been extended to 01.04.2016 for non SSI manufactured drugs and to 01.04.2017 for SSI manufactured drugs.

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