



सीमाशुल्क आयुक्त कार्यालय-एन.एस. IV
जवाहरलाल नेहरू सीमाशुल्क भवन, न्हावा शेवा
तालुका -उरण, जिला रायगड, महाराष्ट्र -400707

फ़ाइल F.No.S/12-Gen-07/2018-19 AM(X)

दिनांक Date:13.04.2018

सार्वजनिक सूचना / PUBLIC NOTICE NO. 58/2018

SUB: Implementation of the Track and Trace system for export of Pharmaceuticals and drug consignments.–reg.

Attention of the Exporters, Custom Brokers and all concerned is invited to the Notice No.52/2015-2020 dated 05.01.2016 issued by the DGFT on the above subject as amended by Public notice No. 03/2015-2020 dated 21.04.2016 (copies enclosed).

2. As per the aforesaid notice, all drugs manufactured by Non-SSI units with manufacturing date on or after 01.04.2016 and all drugs manufactured by SSI units with manufacturing date on or after 01.04.2017 can be exported only if both tertiary and secondary packaging carry 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 or tertiary pack. Further on, the relevant data is also required to be uploaded on the Central Portal. Further the said notification also stated that it will be the responsibility of the drug manufacturer/exporters as the case may be, to satisfy the customs authorities that the export consignment satisfies the condition of the notification.

3. During examination of the export pharmaceutical products, it has been found in some cases that the barcodes present on the cartons (tertiary level packaging) were submitted/ uploaded on <http://dava.gov.in> for verification but the verification was unsuccessful. It means that the data was not uploaded successfully on the central portal and therefore authenticity of the drugs being presented for export could not be verified by the officers (as required/stipulated in the said DGFT notification).

4. Para 2.89A of the Hand Book of Procedures (as amended) mandates that-

“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. 1312015-2020 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 In case, the Government of the importing country has mandated a specific requirement, the exporter has the option of adhering to the same and in such a case, it would not be necessary to comply with the stipulation under sub para (i) to (iv) of Para 2 of this Public Notice and if an exporter is seeking to avail such exemption from bar coding prescribed by the Government of India as above, the exporter is given the option to move an application to the Pharmaceuticals Export Promotion Council of India (Pharmexcil) for this purpose, clearly specifying the nature of such an exemption in the interest of the exports from the country. Pharmexcil shall dispose of such applications on case to case basis with prior approval of Government. However, the tertiary level of packaging will have additional printing of barcode as per Para 2 (i) (c) of this Public Notice 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."

5. In view of the foregoing, if the barcoding is not proper on secondary and tertiary packaging of export consignment, such consignments cannot be allowed to be exported and have to be ordered to back to town by the Proper officer/Competent Authority. Further, in case of such export consignments /shipping bills which comply with the proper barcoding as per the DGFT guidelines on secondary and tertiary packaging, but are short of verification of their data on <http://dava.gov.in> for want of uploading the same, the same cannot be allowed to be exported and have to be ordered to back to town by the Proper officer/Competent Authority.

6. All such exporters of pharmaceuticals/drugs are hereby advised to ensure that the requisite data has been successfully uploaded on the website <http://dava.gov.in> before despatch of the export goods from their factories/ warehouses.

7. Difficulty, if any may also be brought to the notice of Deputy / Assistant Commissioner in charge of Appraising Main (Export) through email / phones (email address: apmainexp@jawaharcustoms.gov.in, Phone No : 022-27244959).

8. Action to be taken in terms of decisions taken in this Public Notice should be considered as standing order for the purpose of officers and staff.

Sd/-

(सुभाष अग्रवाल)

आयुक्त- सीमाशुल्क, NS-IV, JNCH

प्रतिलिपि (By email only):

1. The Chief Commissioner of Customs, Mumbai Zone- II.
2. All the Commissioner of Customs, Mumbai Zone- II.
3. All Addl./Joint Commissioners of Customs, Mumbai Zone- II.
4. All Deputy/Asstt. Commissioners of Customs, Mumbai Zone- II.
5. The DC/EDI for uploading on the JNCH website.
6. BCBA/FIEO for circulation among their members, trade and industry.