



## **DGFT PUBLIC NOTICE**

-COPY OF-

**PUBLIC NOTICE NO.62(RE-2013)/2009-2014**

**Dated 26<sup>th</sup> June, 2014**

### **Procedure relating to tracking and tracing of export consignment of pharmaceuticals and drugs.**

In exercise of the powers conferred under Paragraph 2.4 of the Foreign Trade Policy, 2009-14, as amended from time to time, and in supersession of the following Public Notices, Director General of Foreign Trade hereby prescribes the following procedure for tracking and tracing of export consignments of drugs and pharmaceutical products:

- (i) Public Notice No. 21(RE-2011)/2009-2014 dated 10.01.2011
- (ii) Public Notice No. 59(RE-2010)/2009-2014 dated 30.06.2011
- (iii) Public Notice No. 87(RE-2010)/2009-2014 dated 22.12.2011
- (iv) Public Notice No. 10(RE-2012)/2009-2014 dated 11.07.2012
- (v) Public Notice No. 54(RE-2012)/2009-2014 dated 05.04.2013
- (vi) Public Notice No. 31(RE-2013)/2009-2014 dated 17.10.2013

2. Every exporter of Drugs & Pharmaceuticals at the time of shipment shall submit, alongwith other required documents, the following:

- (i) A copy of Certificate of Analysis issued by the manufacturer for the subject products; or
- (ii) A copy of Certificate of Analysis issued by approved laboratory of the importing country/FDA; or
- (iii) A copy of Certificate of Analysis issued by a laboratory approved by Drugs Controller under Drugs & Cosmetics Act, 1940 and the rules made thereunder.

3.(i) Exporters of pharmaceutical products will adopt a track and trace system and incorporate its features for exported medicines using barcode technology as per GS 1 global standards. The following is needed to be done as detailed below:

**a. Primary Level packaging requirement:**

Incorporation of 2D (GS1 Data matrix) barcodes on medicines at strip/ vial/bottle, etc. encoding unique product identification code (GTIN) and Unique Serial Number of the Primary pack.

**b. Secondary Level packaging requirement :**

Incorporation of barcodes (1D or 2 D) encoding unique product identification code (GTIN), Batch Number, Expiry Date and Unique Serial Number of the Secondary pack. Mono cartons shall be treated as Secondary Level Packaging in line with prevalent global packaging nomenclature.

**c. Tertiary Level packaging requirement:**

Incorporation of barcodes (1 D) encoding unique product identification code (GTIN), Batch Number, Expiry Date and Unique Serial Number of the Tertiary pack (shipper/carton).

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(ii) The track and trace technology as per serial number 3(i) above will be effective as under:

- (a) Primary Level packaging :- Effective date will be notified later.
- (b) Secondary Level packaging :- 1<sup>st</sup> January, 2013 (already given effect to)
- (c) Tertiary Level packaging :- 1<sup>st</sup> October, 2011 (already given effect to)

4. 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 stipulations at serial number a, b & c of para 3(i) above and if an exporter is seeking to avail 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.

5. Under the track and trace system, manufacturers would be required to maintain serialized record of exported pharmaceutical products for a minimum period of six months after the expiry date of the product.

6. Authentication features will be added in due course and integrated with the track and trace system and Government will set up a Central Portal for tracking and tracing exported pharmaceutical products.

7. A self certification process has been mandated effective 15.05.2014, vide Public Notice No.56 (RE-2013)/2009-2014 dated 01.04.2014 read with Public Notice No.58(RE-2013)/2009-2014 dated 15.04.2014. This shall continue to be applicable without any change.

8. Effect of this Public Notice:

- (i) The requirement of affixing bar codes on Tertiary Level and Secondary Level Packaging already implemented w.e.f. 01.10.2011 and 01.01.2013 respectively continue to be in force.
- (ii) The requirement of affixing barcodes on Primary Level Packaging was to be effective from 01.07.2014. Now this date has been deferred till a new date is notified.
- (iii) Earlier through Public Notice No. 31 dated 17.10.2013, mono cartons were to be treated as part of Primary Level Packaging. Now this has been modified to treat mono cartons as Secondary Level Packaging.

Sd/-  
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**F.No.01/91/180/648/AM 09/Export Cell**

**Issued by:**

**Ministry of Commerce and Industry  
Department of Commerce  
Directorate General of Foreign Trade  
New Delhi**

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