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

Public Notice No.21 (RE-2011)/2009-2014
New Delhi, Dated the 10th January, 2011

Sub: Procedure relating to tracing and tracking of export consignment of pharmaceuticals and drugs- regarding

In exercise of the powers conferred under Paragraph 2.4 of the Foreign Trade Policy, 2009-14, as amended from time to time, the following shall be added and in supersession of Public Notice No. 173 dt. 13th April,2009, henceforth the following procedure for strengthening the enforcement mechanism available under the Drugs and Cosmetics Act, 1940 will be followed.

1. 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.

Where required the officials of the Drug Control Department posted at the port offices shall retain a sample of the subject consignment for the purpose of reference and tracking of the manufacturer/ exporter of the subject product.

3. Exporter of Pharmaceutical products will build track and trace capability for their exported medicines using barcode technology as per GS 1 global standards. The same will need to be done at primary, secondary and tertiary level packaging labels as per details below:-

a. Primary Level packaging:

Incorporation of 2D (GS 1 Data matrix) barcodes on medicines at strip/vial/bottle level encoding unique product identification code (GTIN), Batch Number, Expiry Date and Serial Number of the Primary pack.

b. Secondary Level packaging

Incorporation of barcodes (1D or 2 D) encoding unique product identification code (GTIN), Batch Number, Expiry Date and Serial Number of the Secondary pack.

c. Tertiary Level packaging

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

1. The trace and track technology as per Serial Number 3 above, will come into effect from 1st July, 2011.

2. Effect of this Public Notice:

(a) Exporters of pharmaceutical products will be required to affix barcodes on their export products to facilitate tracing and tracking of their products. In order to enable exporters of pharmaceutical products for incorporation of this technology, adequate time is being given and that is why para 3 will be made applicable on 1st July 2011.

(b) Exporters would also be required to submit certificate of analysis as per Para 2. (This is not a new stipulation, it was included in Public Notice of 13th April, 2009)

Sd/-
(Anup K.Pujari)
Director General of Foreign Trade
E-mail : dgft@nic.in

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