



Bangalore Chamber of Industry and Commerce

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INTERNATIONAL TRADE

Circular No.04

17.01.2011

All Members

Dear Sirs,

Please find enclose herewith the following Public Notice and Policy Circular issued by Directorate General of Foreign Trade, New Delhi – for your reference and record.

1. Public Notice No.21 (RE-2011)/2009-2014 dated 10.11.2010, (Issued from F.No. 01/91/180/648/AM09/Export Cell) - Procedure relating to tracing and tracking of export consignment of pharmaceuticals and drugs- regarding
2. Policy Circular No.10 (RE-2010)/2009-14, dated the 31st December,2010-(Issued from File No.01/02/150/AM-11/EDI) - Provision of additional facility for filing Importer Exporter Code (IEC) applications “on-line”.

Thanking you,

Yours faithfully

T.S. Sampath Kumar
Secretary General

Public Notice No.21 (RE-2011)/2009-2014 dated 10.11.2010, (Issued from F.No. 01/91/180/648/AM09/Export Cell)

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

Policy Circular No.10 (RE-2010)/2009-14, dated the 31st December,2010-
(Issued from File No.01/02/150/AM-11/EDI)

Provision of additional facility for filing Importer Exporter Code (IEC) applications “on-line”.

DGFT is introducing additional facility on DGFT’s website (<http://dgft.gov.in>) for enabling members of trade to file their IEC applications ‘on-line’ with effect from 1.1.2011.

2. Presently, the applications for obtaining an IEC are filed manually with the concerned Regional Authority of DGFT. The applications are filed in hard copy in the prescribed proforma with stipulated documents.

3. The additional facility of filing “on-line” application for obtaining IEC will reduce the transaction cost and time for the applicant, would ensure easy, flexible filing of application and reduce human interface and paper work in the process.

4. The existing system of filing the IEC application manually would simultaneously continue till further orders i.e. the applicant will have an option to prefer his application either manually or “on-line” as per his/her convenience.

5. The following guidelines and procedures are stipulated for the “on-line” system of filing, processing and issuance of IEC:-

- (i) The applicant may file the IEC application for “on-line” through the link available on the DGFT’s website.
- (ii) The fee in case “on-line” application for IEC has to be paid through Electronic Fund Transfer (EFT) mode only. The EFT link with necessary guidance for making payment through EFT is already available on DGFT’s website.

- (iii) The prescribed documents, i.e. the Bank certificate, PAN copy and photograph, are to be scanned and attached with the 'on-line' application. Any other relevant documents for example Authority letter in respect of authorized representative, should be attached in the 'pdf' format.
- (iv) Physical copy of application is not required to be submitted to the concerned Regional Authority(RA) in case of "on-line" applications.
- (v) The status of IEC "on-line" application i.e. IEC number granted for accepted applications and deficiency in case of other approved applications will be available on DGFT's website.
- (vi) In case, an "on-line" application is found to be deficient and such deficiencies indicated 'on-line', additional information/documents against such deficiencies would need to be submitted physically (in hard copies) to the concerned RA.
- (vii) The applicants are advised to be very careful while selecting jurisdictional RA for sending their applications, as selection of a wrong RA would require retransmission of application to the correct destination and it is likely to cause delay in processing.
- (vii) Comprehensive guidelines regarding filing of "on-line" IEC applications are available on DGFT's server under the IEC "on-line" Help Icon.

6. Members of Trade are encouraged to take advantage of the "on-line" facility for IEC application and RAs are requested to disseminate the information about the facility among the Trade.

Sd/-
(Rajiv Arora)
Jt. Director General of Foreign Trade.

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