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

Public Notice No. 56 (RE-2013)/2009-2014

New Delhi, Dated the 1 April, 2014

Sub: Self-certification regarding compliance of bar-coding requirements on secondary and tertiary level packaging on export consignment of pharmaceuticals and drugs.

In exercise of the powers conferred under Paragraph 2.4 of the Foreign Trade Policy, 2009-14, Director General of Foreign Trade hereby prescribes the procedure for self-certification regarding compliance of bar-coding requirements on secondary and tertiary level packaging on export consignment of pharmaceuticals and drugs.

2. Bar-coding on tertiary level packaging has come into effect from 1st October, 2011 as per Public Notice No. 59 of 30.06.2011. Similarly on secondary level packaging this has come into effect from 1st January, 2013 as per Public Notice No. 10 of 11.07.2012. The requirement of bar-coding on primary level packaging will come into effect from 1st July, 2014.

3. It has been decided that with effect from 01.04.2014, export of pharmaceuticals and drug consignment would be permitted through a self-certification process. In this process, the exporters would be required to furnish a written declaration to the custom authorities at the time of export [as per Annexure to this public notice] regarding compliance of the relevant provisions of bar-coding on secondary and tertiary level packaging on the consignment of pharmaceuticals and drugs being exported.

3. Effect of this Public Notice:

A self-certification process on compliance of bar-coding requirement on secondary and tertiary level packaging of pharmaceuticals and drugs has been introduced. This will be effective from 1st April, 2014

(Madhusudan Prasad)
Director General of Foreign Trade
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(Issued from F.No. 01/91/180/648/AM09/Export Cell)

Annexure to Public Notice No. 56 (RE-2013)/2009-14

dated 1 April, 2014

(On letter head of Exporter containing details of Company phone numbers, e-mail & website etc)

Exporter's Declaration to Customs Officer of the relevant port for Pharma Products relating to compliance of track and trace capability and product registration.

(The exporter's declaration, the text of which is given below, must be made out in accordance with the footnotes. However, the footnotes do not have to be reproduced.)

DECLARATION

1A. I, the undersigned, declare that the goods listed for export vide our invoice no. -----dated-----and Shipping Bill No.-----dated-----and No.----- dated-----satisfy/comply with the requirements of the Public Notices issued by the Directorate General of Foreign Trade (Department of Commerce) as listed below:

- 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 (applicable for tertiary level packaging)
- iii. Public Notice No. 60 (RE-2010)/2009-2014 dated 30.06.2011
- iv. Public Notice No. 10 (RE-2012)/2009-2014 dated 11.07.2012 (applicable for secondary level packaging)
- v. Public Notice No. 31 (RE-2013)/2009-2014 dated 17.10.2013

1B. I declare that the Government authority of importing country----- (name) has its own legislation/regime regarding track and trace capability and therefore GS1 Data Matrix for the packaging as required under para 3 of Public Notice No. 59 (RE-2010)/2009-2014 dated 30.06.2011, is not applicable in this consignment.

2A. I also declare that the goods in the consignment are being exported to ----- (name of country) and that the products being exported hold necessary registration/approval issued by the concerned government authorities of importing country.

2B. The product(s) being exported do not require any registration/approval of the Government Authority of the importing country.

I undertake to make available to the customs authorities any further supporting documents they require.

By

Place:

(Name of the Company/Exporter)

Date:

(Signature)

Name & Designation of Authorised Officer

(with Company seal)

(1) If only some of the goods listed on the document are concerned, they should be clearly indicated or marked and this marking entered in the declaration.

- (2) The Community, country, group of countries or territory, from which the goods originate to be indicated if the goods are not manufactured in India, in 1 above (if applicable)
- (3) Declaration at 1B and/or 2A to 2B to be scored out if not applicable for the goods/consignment.
