

Public Notice No. 60(RE-2010) /2009-2014

New Delhi, Dated the 30th June, 2011

Subject: Procedure relating to export of pharmaceuticals and drugs.

In exercise of the powers conferred under Paragraph 2.4 of the Foreign Trade Policy, 2004-2009, as amended from time to time, Director General of Foreign Trade, notifies with immediate effect, procedures/guidelines to strengthen the enforcement mechanism available under the Drugs and Cosmetics Act, 1940 to ensure that counterfeit drugs do not get exported out of the country.

2. Procedure for export of Drugs & Pharmaceuticals, covered under the provisions of Drugs & Cosmetics Act, 1940 and the rules made there under, shall be as given below:

3. Every exporter of Drugs & Pharmaceuticals at the time of shipment shall submit, along with other required documents, the following:

(i) A copy of Certificate of Analysis issued by the manufacturer for the subject product;

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 there under.

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

(Anup K.Pujari)

Director General of Foreign Trade

(Issued from F.No 01/91/180/648/AM 09/ Export Cell)