

F.No. 7-5/2016/BC/005
Directorate General of Health Services
Office of drugs Controller General(India)

07 MAR 2016

To

Director General Foreign Trade,
Department of Commerce,
Ministry of Commerce & Industry,
Udyog Bhawan, New Delhi

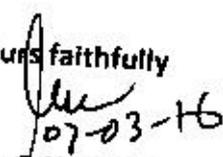
Subject: Implementation of track & trace system for export of pharmaceuticals and drug consignments – regarding

Sir,

Reference is invited to your public notice no. 52/2015-2020 dated 5.01.2016 pertaining to the captioned subject. The notification prescribes certain barcoding requirements for export of drug formulations. However, provisions from 2(i) to 2(iv) of the aforesaid notification will not be applicable to those drug formulation manufactured for export purposes, where the government of importing country has mandated or formally notified its intention to mandate a specific requirements and the exporter intends to avail the option of printing the barcode in their format after duly obtaining permission from the office of DCGI or its nominee. However, the tertiary level of packaging will have additional printing of barcode as per (i) (c) above in addition to importing country's requirement, if any.

We have received various applications from importer requesting waiver of the aforementioned barcoding requirements on formulations for export. The applications have been examined along with the provisions of the public notice issued by the DGFT. The aforesaid exemption has to be accorded under the provision of Handbook of Procedures, 2015-2020 regulated by the DGFT. Further, this office does not have a mechanism to verify the claim of the exporter that the Government of the importing country has actually issued a specific requirement for printing of the barcode. Therefore, it is opined that it would be appropriate if the exemptions are issued by the DGFT which is the competent authority rather than the DCGI. This office would extend all its cooperation required in this regard.

Yours faithfully


07-03-16
(Dr. G.N. Singh)

Drugs Controller General (India)

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