

FAQs for Barcode implementation as per DGFT guidelines

1. *What is the objective of the DGFT notification on implementation of barcoding on export consignments of pharmaceuticals?*

The objective is to facilitate track & trace of export consignments of pharmaceutical products using barcode technology.

2. *At which packaging levels is barcoding required to be implemented?*

Barcoding is required to be implemented at primary, secondary and tertiary packaging levels.

A primary pack is defined as the first level of packaging in direct contact with the product and marked with an AIDC (Automatic Identification and Data Capture) data carrier either on the packaging or on a label affixed to the packaging. It may consist of a single item or group of items for a single therapy such as a Kit.

A secondary pack is defined as a level of packaging that may contain one or more primary packages or a group of primary packages containing a single item.

A tertiary pack comprises of multiple secondary packs or secondary pack levels. Tertiary packs are normally the ones which are dispatched as logistic units/shipments.

3. *Is exemption from implementation of the DGFT notification on barcoding permitted in any instance?*

Exemptions are listed in the DGFT notification. As per the notification, in case the importing country has mandated a specific requirement, the exporter can adhere to the same and it would not be necessary to comply with the stipulations for primary, secondary and tertiary packaging level barcoding as articulated in the DGFT notification.

It may be noted that exemption is allowed only if the specific requirement is from the Government/Regulator in the importing country. Such exemption is not permitted based on importer/buyer requirements only.

4. *On which medicines/drugs are barcodes as stipulated by DGFT required to be implemented?*

Clarification may be sought from Pharmexcil, the export promotion body for pharmaceuticals under the Ministry of Commerce. Contact details of the same are available at www.pharmexcil.org

5. *What information is required to be encoded in barcodes at various packaging levels of medicines for exports?*

The requirements for the same are detailed in the DGFT notification. For details on implementation of barcoding at different packaging levels, access the same under “Barcoding on exported consignments” at www.pharmexcil.org

6. *What is GTIN and what is unique serial number and how are they created and assigned?*

GTIN (Global Trade Identification Number) is the unique product identification code which comprises of 14 digits. These are created by the brand owner for each product type/variant/SKU using the GS1 company prefix number allocated to a company by GS1. For details on how to create GTINs using the company prefix number, look at the implementation guideline available under “Barcoding on exported consignments” at www.pharmexcil.org.

Unique serial numbers are used in addition to GTIN to uniquely identify different packages at the primary, secondary and tertiary pack levels. At the tertiary level packaging, unique serial nos. should be created using the SSCC format as provided in implementation guidelines.

7. *What barcode symbologies are to be adopted at different packaging levels?*

As per the DGFT notification, the following symbologies are to be used at different packaging levels:

Primary level packaging: GS1 Datamatrix which is a 2D barcode symbology.

Secondary level packaging: GS1 128 linear (1D) barcode symbology or GS1 Datamatrix (2D) barcode symbology.

Tertiary level packaging: GS1 128 linear (1D) barcode symbology.

No other barcode symbology is permitted at any packaging level except that stipulated above.

8. *What is a homogeneous and heterogeneous pack?*

Homogenous package: Is defined as a package containing multiple units of the same (only one) product packaging type. If a Shipper/Carton/Tertiary level packaging is a homogenous package then there shall be two barcodes on the label containing GTIN, Expiry Date, Batch no. encoded in the first barcode and SSCC encoded in the second barcode.

Heterogeneous package: Is defined as a package containing multiple units of different (more than one) product packaging type. If a Shipper/Carton/Tertiary level packaging is a heterogeneous package then there shall be only one barcode on the label encoding SSCC.

9. How is the barcode to be implemented on very small packs like those of vials etc?

As per the DGFT notification, if the space for printing the stipulated size of barcode is not sufficient, the same information should be printed on the pack in human readable form.

10. *I already have an EAN 13 digit product code printed on my product packaging. What do I need to do to comply with the DGFT notification?*

You need to affix a “0” in front of the EAN 13 code being currently used by you to convert it into a 14-digit code (GTIN-14) as required under the DGFT notification for unique product identification.

11. *Does the GTIN for a medicine change with different packaging levels?*

Yes, GTIN of the medicine changes at each packaging level and packaging configuration. For details on how to generate, look up under “Barcoding on exported consignments” at www.pharmexcil.org

12. *Does the GTIN for a medicine change with a packaging configuration at the same packaging level?*

Yes, GTIN of the medicine changes with its packaging configuration. For e.g. XYZ product may have packaging configuration of 10 or 20 pills as options. Different and unique GTIN is needed to be created for each packaging configuration.

13. *For the same GTIN, is the serial number the same as well?*

No, serial numbers are required to be unique for each item even if the GTIN (product variant/SKU) is the same.

14. *What is the data-structure of the serial number and batch number to be adopted for primary and secondary packaging levels?*

Serial number of the product is a variable data structure and can have 1 to 20 alphanumeric characters given by manufacturer/brand owner. It is preceded by GS1 Application identifier (AI) 21. The purpose of the AI is to indicate the nature of information that follows it.

Batch number of the product is a variable data structure and can have 1 to 20 alphanumeric characters given by manufacturer/brand owner. It is preceded by GS1 AI 10. The purpose of the AI is to indicate the nature of information that follows it.
