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India Pack Coding

1 DGFT Requirements

India regulations to implement a Track and Trace system for export of pharmaceuticals and drug consignments were introduced as a phased programme to address counterfeit and ineffective product recall challenges under the control of the Directorate General of Foreign Trade, Department of Commerce, Ministry of Commerce and Industry from 2011.

Core features are:

- Product Item serialisation and aggregate level to pallet
- Track & Trace reporting to Government Database: DAVA (Drugs Authentication and Verification Application)
- All exported drugs are in scope (Rx and OTC)
- Specific requirements on use of the Pack Level indicator (1st character of the GTIN-14 that are narrower than the GS1 standard)

2 Challenge for EU Markets

There are two problem with regards to the EU-FMD requirements in relation to Indian export packs: 1) treatment of GTINs and 2) OTC products.

1. GTINs

The GTINs applied to European packs will almost always present with a “0” as a first character in the 14-digit string. This is because GTINs in Europe are typically represented as EAN-13 i.e. the linear barcode that carries the 13-digit GTIN (or the NTIN in any NTIN markets).

When converting the GTIN-13 into the GTIN-14 format that is the standard representation in any database or in the EC-200 2D Datamatrix, the pack level indicator “0” is added in the first position of the 14-digit string. This has the effect that the 13 significant digits – including the check-digit – are identical between the GTIN-13 and GTIN-14 as the use of the “0” indicator will not affect the check digit.

However, the advise on GTIN allocation issued in India, in conjunction with the DGFT India Export requirements, deviates in this respect from the GS1 standard and prescribes a use of the GTIN Indicator Digit (1st position in the GTIN-14) that is more restrictive than the GS1 General specifications: For India pack coding, values "1", "2" and "3” are reserved, where "1" is to be used on innermost and “3" on outermost secondary package.

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This means that if a manufacturer were to use their "European" GTINs (i.e. EAN or NTIN) following these India-specific rules and use a pack level indicator other than "0" to generate the GTIN-14, this would force a re-calculation of the check digit. This means that the last digit would then also be different and the last digit of the code embedded in the GTIN -14 used in the 2D DM would be different to the code expressed in the 13-digit EAN.

2. OTC Products

On 2) OTC products, the problem is that the India Export requirements conflict with EU requirements: DGFT requirements also apply to OTC products which are out of scope of the EU-FMD.

This means that there will be packs in EU markets that carry a GS1 2D DM containing the same four data elements that are specified by the EU-FMD: Such packs will be indistinguishable from EU-FMD coded packs but when scanned the UI will not be found in the EMVS leading to a suspect pack alert.

Example of serialized packs of generic ibuprofen (UK market)

The fact that this may present a problem to exporting companies has been recognised by the Indian authorities and has been addressed: India guidance states

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that requirements of importing country take precedence, but requires an exemption, as clarified in Enforcement Notice PUBLIC NOTICE NO. 58/2018, issued on 13 April 2018:

> "If an exporter is seeking to avail such exemption from bar coding prescribed by the Government of India as above, the exporter is given the option to move an application to the Pharmaceuticals Export Promotion Council of India (Pharmexcil) for this purpose, clearly specifying the nature of such an exemption in the interest of the exports from the country. Pharmexcil shall dispose of such applications on case to case basis with prior approval of Government. However, the tertiary level of packaging will have additional printing of barcode as per Para 2 (i) (c) of this Public Notice in addition to importing country's requirement, if any. "

That would mean that coding on OTC products could be omitted as the importing country requirement (i.e. EU) specifies "no coding" for OTC products, but there will be an issue during the **transition period** that will present a challenge.

3 Practical suggestion

The practical - if not 100% foolproof - way of identifying such India OTC packs would be to check:

1. Does the GTIN in the 2D Data matrix start with a digit other than "0"?
2. If there is a linear EAN barcode on the pack, are the 13 numbers in the linear barcode different to the last 13 digits of the GTIN in the 2D DM?
3. Is the pack serialized but does not carry tamper-evidence?

If the answer to these questions is "Yes" then this is likely to be a pack that is serialised under India DGFT requirements rather than EU-FMD and it would therefore be expected that the UI is not uploaded to the EMVS.

The scan of the 2D DM will not be recognised and an alert will be generated.

However, it needs to be borne in mind that while this may work in the majority of cases but there will be exceptions.

