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Action plan: serialisation of Nordic packages – focus on Product Codes

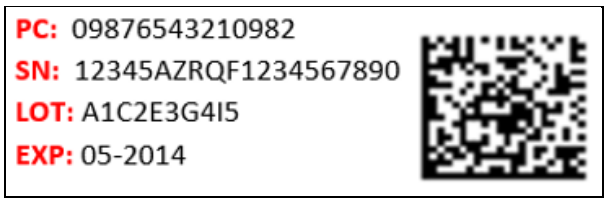
The aim of this document is to help pharma companies to prepare for product code changes and to be able to maintain product codes in an efficient manner also after the launch of medicines verification, which affects mainly prescription human medicines. This document has been prepared by LIF Sweden and verified by all Nordic countries. If you have change requests to this document, please send them to: vnr@vnr.fi.

The safety features required by the Falsified Medicines Directive (medicines verification) will consist of a unique package identity carried by a 2D Data Matrix combined with tamper evidence.

The 2D Data Matrix carries the following elements

- Product code (GTIN or unique NTIN)*
- Unique serial number (randomized) for every single physical package
- Batch number
- Expiry date

Example for EEA license plate:



A 2D Data Matrix is printed on the pack together with the same information in human readable format #

The order is flexible as long as the readability is not compromised (EFPIA, v1.o 18Oct2017, Layout of the Human Readable Unique Identifier Data Elements).

Please also refer to the Commission Questions & Answers document https://ec.europa.eu/health/sites/health/files/files/falsified_medicines/qa_safetyfeature_v9.pdf regarding the layout of the human readable format (questions 2.8,, 2.9., and 2.10.)

GTIN = Global Trade Item Number
NTIN = National Trade Item Number
GTIN[1] = GTIN or Unique NTIN in this document
Linear barcode = 1D code carrier, which can hold either NTIN or GTIN
2D Data matrix = 2D code carrier, which on the secondary pack, holds Product code (GTIN[1]), Serial no, Batch no and Expiry date.
Vnr = Nordic Article Number, not included in GTIN. Linkage between Vnr and GTIN[1]s is maintained in national data systems.
EEA = European Economic Area
QRD = The European Medicines Agency's Working Group on Quality Review of Documents
Hard cut = A cut-off date (old packages need to be recalled)

*registered with 14 digits (add a leading zero if GTIN 13 as shown in the example)
General information about labelling, https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-2/2016_12_packaging_guidelines_revision_14_4.pdf
[1] GTIN (Global Trade Item Number) in this document means GTIN/Unique NTIN
More information about abbreviations
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004426.pdf

Country requirements during pre-serialisation phase and post-serialisation phase

General principles in all Nordic countries

- One GTIN[1] per secondary pack per stock keeping unit (SKU).
- No hard cut is needed when changing from NTIN to GTIN on packs (hard cut: cut-off date, old packages need to be recalled).
- Packages in all countries must have a 2D matrix after 9 Feb 2019, in addition they can have a linear barcode.
- If a company uses NTIN in the 2D Data Matrix, the NTIN should be unique and it should follow the same rules for changing as a GTIN. The unique NTIN must have been assigned before February 9, 2019, as no new NTINs are assigned after this date. This means that the use of NTINs will diminish after 2019.
- Please see table on page 5.

DENMARK

- No Danish Medicines Agency submission or approval needed for change from NTIN to GTIN[1]. Submission to DKMAnet is needed if the Vnr is changed.
- Different GTIN[1] needed on the primary pack than on secondary pack (Amgros in DK). Please note, that linear barcode on the primary pack will not be affected by the serialisation project.

GTIN change on the primary pack should be reported to Amgros. As noted above, linear barcodes on the primary pack is not part of the serialisation project. For more information regarding the technical guide from Amgros in DK, please see:
https://levportal.amgros.dk/SiteCollectionDocuments/Hj%C3%A6lp%20og%20support/Technical%20guide%202017_Version3.pdf

Joint guidelines from the supply chain for the transition from linear barcodes (EAN-13) to 2D Data Matrix in the Danish market concerning medicines in the scope of Falsified Medicines Directive 2018 – 2019:

- NTINs can be changed to GTIN without changing the Vnr. No hard cut is needed.
- Linear barcode is the valid data carrier until 9 Feb 2019.
  - When a new package is introduced in the IT systems, it can have either GTIN or NTIN in the linear barcode.
- The manufacturers are asked to use 2D data Matrix in good time before Feb 2019.
- 2D Data Matrix is the only valid data carrier from 9 Feb 2019.
  - Linear barcode can be removed after 9 Feb 2019 (for instance in connection with a later update).

Supply chain IT systems in Denmark can only handle one product code (as linear barcode, EAN 13 format) per item number per each package at present. The product code can be either NTIN or GTIN. The supply chain IT systems and scanners can read 2D Data Matrix on 9 Feb 2019 at the latest. Therefore, the linear barcode is the valid data carrier until 9 Feb 2019, but 2D Data Matrix can be printed on the packages already now. 2D Data Matrix ought not to be on the same side of the package as the linear barcode. If the two data carriers are placed at the same side of the package, the space between them shall be min 2 cm.

From 9 Feb 2019 the only valid data carrier is 2D Data Matrix and the linear barcode can be removed, for instance in connection with a later update. If the linear barcode is retained, the two data carriers are not allowed to contain mutual conflicting information.

For further information, please see Implementation of 2D Datamatrix in Denmark - table.

FINLAND 

- No need to change Vnrs when changing from NTIN to GTIN[1].
- Inform new GTIN[1]s and changes of GTIN[1]s in the Vnr Service (can be done at any time). Product codes are delivered to the supply chain actors from the Vnr service.
- Many different GTIN[1]s are allowed for the same Vnr in the data system at the same time. This is a one-to-many relation.
- No need for Finnish Medicines Agency's (Fimea) submission or approval (if only the product code is changed).
- If the layout is changed, an Article 61(3) notification needs to be submitted and approved (3 months lead time).
- No need for labelling texts for nationally approved products in Finland. Mock-ups are sufficient.
- The Finnish Medicines Agency (Fimea) has added guidance on Introduction of safety features on their website, e.g. when a notification should be submitted for an approval http://www.fimea.fi/web/en/marketing_authorisations/safety-features"

ICELAND 

- No need to change Vnrs when changing from NTIN to GTIN[1].
- Two different product code carriers i.e. linear barcode / 2D Data Matrix are allowed on the packs at the same time (the pharmacies order primarily on Vnrs) but the code carriers are not allowed to contain mutual conflicting information.
- Submission of mock-ups to Icelandic Medicines Agency needed "for information" according to normal practice.

NORWAY 

Background: It is possible to register more than one product code (NTIN or GTIN) to the same Vnr, also known as one-to-many relation. Packages can have both linear barcode and 2D Data Matrix. New product codes must be registered at the Farmalogg website VareWeb. An artwork pdf must also be submitted at the Farmalogg website.

- NTINs can be changed to GTIN without changing the Vnr. No hard cut is needed.
- If the layout is changed due to the introduction of 2D Data Matrix, an Article 61(3) notification must be submitted to the Norwegian Medicines Agency.
- The Norwegian Medicines Agency has confirmed that it is possible to have both linear barcode and 2D Data Matrix on the same pack, provided that the inclusion of both data carriers does not negatively impact the legibility of the outer package.
- As the IT systems have implemented the one-to-many relations, it is technically possible to keep both NTIN in the linear barcode and GTIN in the 2D Data Matrix on the same pack. However, it is encouraged to only have one product code on each package if possible, as the product code represent the identity of the package.

- If a product has multiple packing levels/package hierarchy with product codes on each level, the product code must be unique for each hierarchy level. One product code for each hierarchy level is encouraged for hospital packages.

SWEDEN 

- No need to change Vnrs when changing from NTIN to GTIN[1].
- When changing from NTIN to GTIN[1] add the new product code in LiiV (Leverantörernas information i VARA).
- Many different GTIN[1]s are allowed for the same Vnr in the data system at the same time (product codes are just added in LiiV and the VARA-file stores them as previous/historical product codes). This is a one-to-many relation.
- If only GTIN[1] is changed no notification/variation needed.
- If the layout is changed, an Article 61(3) notification needs to be submitted and approved (3 months lead time).
- To update labelling: notification “for information only” or an Article 61(3) notification is needed

  Please note! A labelling text needs to be created for all national packs that do not have a labelling text. https://lakemedelsverket.se/malgrupp/Foretag/Lakemedel/Nya-godkannanden-andringar-och-fornyelser/Krav-pa-sakerhetsdetaljer-pa-lakemedelsforpackningar/)

Country requirements regarding changes from NTIN to GTIN[1]	**DK**	**FI**	**IS**	**NO**	**SE**
New Vnr required	No*	No	No	No	No
Hard cut required (cut-off date, old packages need to be recalled) when no change of Vnr, only change of NTIN to GTIN[1]	No	No	No	No	No
National data system updates required (change NTIN to GTIN[1])	Wholesaler	PIC	Will be updated later	Farmalogg	LiiV
Many different product codes (GTIN[1]s) for the same Vnr can be handled by the national data system (one-to-many relation)	Yes	Yes	Yes	Yes	Yes
Two different product code carriers (linear barcode and 2D Data Matrix) with **the same GTIN[1]** are allowed to be printed on the secondary pack at the same time	Yes	Yes	Yes	Yes	Yes
Two different product code carriers (linear barcode and 2D Data Matrix) with **different GTIN[1]** are allowed to be printed on the secondary pack at the same time	Yes	No	Yes	Yes	No
Art 61(3) needed if layout change	No, if there is an approved variation	Yes	No**	Yes	Yes
Information from side/bottom panel can be deleted without an Article 61(3), if the same text is already written somewhere else	Yes	Yes	Yes	No	Yes
National competent authority notification including mock-up required for change in barcode, Vnr or 2D Data Matrix	No	No	No	Yes	No
Labeling text (QRD) required for nationally approved products	Yes	No	No	No	Yes

*For further information see country specific text above.

** Submission of Art 61(3) is not a requirement, but if required in the pack-sharing country, it is recommended by Icelandic authorities.

For more information regarding eVerification, see VnrWiki or contact:
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