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

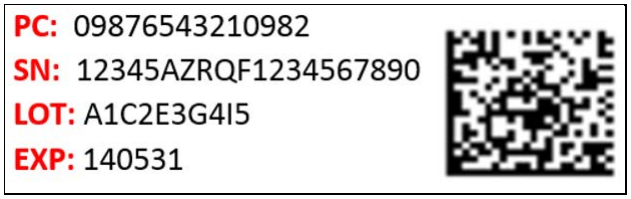
The aim of this document is to help pharma companies to prepare for product code changes and to be able to maintain product codes in an efficient manner also after the launch of eVerification. This document has been prepared by LIF Sweden and verified by all Nordic countries. If you have change requests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

The safety features required by the Falsified Medicines Directive (eVerification) 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

EEA license plate:



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

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)

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

[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

[#]General information about labelling, https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-2/2016_12_packaging_guidelines_revision_14_4.pdf

General principles

One GTIN[1] per secondary pack per stock keeping unit (SKU).

DENMARK

- Possibility: Keep current Vnr, keep current unique NTIN.
- Hard cut is needed at the moment when changing from NTIN to GTIN[1] on packs (hard cut: cut-off date, old packages need to be recalled).
- Pharmacy systems however can NOT handle two or more GTIN[1]s for the same Vnr at the moment.
    - It is expected, that there will be a transition phase, where there might be different solutions or workarounds at the pharmacies. It is expected, that the timeframe for this transition phase will be during Q2/Q3 2017.
- The legislation in Denmark allows two product code carriers i.e. linear barcode / 2D Data Matrix on the same pack. The Danish Medicines Agency (DKMA) in Denmark has confirmed, that it is allowed to have a NTIN and a GTIN containing different number sequences (=product code) on the secondary packaging.
- No DKMA 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).
  No need to add a linear barcode / 2D Data Matrix on the primary packs for other countries. 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.
- 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 also see table on page 5.

FINLAND

- No need to change Vnrs when changing from NTIN to GTIN[1].
- No hard cut is needed when changing from NTIN to GTIN[1] on packs (hard cut: cut-off date, old packages need to be recalled).
- 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"
- 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 also see table on page 5.

ICELAND

- No need to change Vnrs when changing from NTIN to GTIN[1].
- Check where to inform product code changes.
- 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). The product code carriers must have the same content i.e. product code.
- Submission to Icelandic Medicines Agency needed "for information" according to normal practice.
- 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 also see table on page 5.

NORWAY

Background: In 2017 Norwegian IT systems are based on one Vnr linked to one product code (linear barcode). The linear barcode is used by wholesalers and pharmacies as an identifier in the physical handling of the product in many different processes and are vital for correct dispensing. It is possible to use either a NTIN or a GTIN[1], but the data systems are not able to manage the transfer of one code (e.g. NTIN) to another code (e.g. GTIN) without manual changes (by Farmalogg, the wholesalers and the pharmacies) and corresponding risks and workload. The problem is not the introduction of GTIN but a seamless handling of more than one product code per Vnr.

- If NTIN is changed to GTIN in 2017, a new Vnr is required. No hard cut is needed (hard cut: cut-off date, old packages need to be recalled).
    - The new Vnr must be enrolled in Farmalogg as "substitutional Vnr". The sales of the old Vnr will continue until last pack is sold by the wholesaler. The sales will be transferred to the new Vnr when each wholesaler is out of stock of the old Vnr. When all wholesalers are out of stock, the old Vnr will be removed from the register.
- Any new pack (Vnr) may have a GTIN. Changing NTIN to GTIN on a marketed pack (Vnr) should be avoided until this can be handled by the data system. This change will occur 1 Jan 2018.
- From 1 Jan 2018, new product codes may be added to the data system by the pharma companies. This functionality will be added on Farmaloggs websites, VareWeb. An artwork pdf must also be submitted at the website.
- If NTIN is changed to GTIN after January 1, 2018, several different product codes are allowed in the data systems for the same Vnr (one-to-many relation).

- Packs released to the Norwegian market before 9 Feb 2019 must have a linear barcode, and may have 2D Data Matrix. Packs released to the Norwegian market after 9 Feb 2019 must have 2D Data Matrix and must not have linear barcode. Companies who need time to remove the linear barcode after 9 Feb 2019 should agree this with the Norwegian Medicines Agency.
- If the layout of artwork is changed due to the introduction of 2D Data Matrix, an Article 61(3) notification must be submitted to the Norwegian Medicines Agency.
- If GTIN is included on the primary pack, it must be different to the GTIN on the secondary pack. From the beginning of 2018, product codes for primary packs may be added to the data system by the pharma companies. This functionality will be added on Farmaloggs website, VareWeb. An artwork pdf must also be submitted at the website.
- If a phama 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 also see table on page 5.

SWEDEN

- No need to change Vnrs when changing from NTIN to GTIN[1].
- No hard cut is needed when changing from NTIN to GTIN[1] on packs (hard cut: cut-off date, old packages need to be recalled).
- Change NTIN to GTIN[1] by adding the new product code in Leverantörernas information i VARA (LiiV).
- 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/)
- 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 also see table on page 5.

Country requirements regarding changes from NTIN to GTIN[1]	**DK**	**FI**	**IS**	**NO**	**SE**
New Vnr required	No*	No	No	Yes in 2017 No from 2018	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]	Yes* at the moment	No	No	Yes* in 2017 No from 2018	No
Hard cut required (cut-off date, old packages need to be recalled) when change of Vnr + change of NTIN to GTIN[1]	Yes*	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)	No* (not for the same Vnr) at the moment	Yes	Yes	No in 2017 Yes in 2018	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
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	No	No	Yes
National competent authority notification including mock-up required for change in barcode, Vnr or 2D Data Matrix	No	No	Yes (all updated artworks need to be submitted)	Yes	No
Labeling text (QRD) required for nationally approved products	Yes	No	Not known yet	No	Yes

*For further information see country specific text above.

For more information regarding eVerification, see VnrWiki or contact:
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