

## 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](mailto: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:



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

### Definitions:

GTIN<sup>1</sup> = GTIN (Global Trade Item Number) in this document means GTIN/Unique NTIN

Linear barcode = 1D code, which can hold either NTIN = National Trade Item Number or GTIN = Global Trade Item Number.

2D Data matrix = 2D code, which on the secondary pack, holds Product code (GTIN<sup>1</sup>), Serial no, Batch no, and Expiry date.

Vnr = Nordic Article Number, not included in GTIN. Linkage between Vnr and GTIN<sup>1</sup>s is maintained in national data systems.

NCA = National Competent Authority

EEA = European Economic Area

SKU = Stock keeping unit

Hard cut = A cut-off date

QRD = The European Medicines Agency's Working Group on Quality Review of Documents

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<sup>1</sup> GTIN (Global Trade Item Number) in this document means GTIN/Unique NTIN

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

### General principles

One GTIN<sup>1</sup> per secondary pack per SKU.

### DENMARK

- Different GTIN<sup>1</sup> needed on the primary pack than on secondary pack (Amgros in DK).  
No need to add a linear barcode/2D Data Matrix code on the primary packs for other countries.  
Please note, that linear barcode on the primary pack will not be affected by the serialisation-project.
- Possibility: Keep current Vnr, keep current unique NTIN.
- Hard cut is needed at the moment when changing from NTIN to GTIN<sup>1</sup> on packs.
- The legislation in Denmark allows two product code carriers on the same pack, but they must have the same content. The NCA in Denmark has confirmed, that you are allowed to have a NTIN and GTIN code containing different number sequences on the secondary packaging.
- At the moment the pharmacies systems can however NOT handle two different product codes on the same pack.
- It is expected, that there will be a transition phase, where there might be different solutions or workaround at the pharmacies. It is expected, that the timeframe for this phase will be during Q2/Q3 2017.
- No NCA submission or approval needed for change from NTIN to GTIN. Submission to DKMAnet is needed if the Vnr is changed.
- Change the GTIN on the primary pack should be reported to Amgros. As noted above, barcodes on the primary pack is not a 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 NTIN must have been assigned before February 9, 2019, as no new NTINs are assigned after this date.
- Please also see table on page 5.

### FINLAND

- No need to change Vnrs when changing from NTIN to GTIN<sup>1</sup>.
- Many different GTINs<sup>1</sup> are allowed for the same Vnr in the data system at the same time. This is a one-to-many relation.
- No hard cut is needed when changing from NTIN to GTIN<sup>1</sup> on packs.
- No NCA submission or approval needed (for product code change only).
- 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.
- Change the new GTIN<sup>1</sup> in the Vnr Service (can be done at any time). Product codes are delivered to the supply chain actors from the Vnr service.

- “FIMEA has added guidance on Introduction of safety features on their website, e.g. when a notification should be submitted for an approval to FIMEA.  
[http://www.fimea.fi/web/en/marketing\\_authorisations/safety-features](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 NTIN must have been assigned before February 9, 2019, as no new NTINs are assigned after this date.
- Please also see table on page 5.

## ICELAND

- No need to change Vnrs when changing from NTIN to GTIN<sup>1</sup>.
- 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).
- Check where to inform product code changes
- NCA submission 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 NTIN must have been assigned before February 9, 2019, as no new NTINs are assigned after this date.
- 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, but the systems are not able to manage the transfer of one code (ex NTIN) to another code (ex GTIN) without manual changes (by Farmalogg, the wholesalers and the pharmacies) and corresponding risks and workload. The problem is not introduction of GTIN but a seamless handling of more than one product code per Vnr.

- 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 NTIN is changed to GTIN in 2017, a change of Vnr is required. No hard cut is needed. 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 systems. This change will occur 1 Jan 2018.
- From 1 Jan 2018, new product codes may be added to the system by the companies. This functionality will be added on Farmalogs websites, VareWeb. An artwork pdf must also be submitted at the website.






- If NTIN is changed to GTIN after 1 January 1th 2018, several different product codes are allowed in the systems for the same VNR (one to many relation).
- If a company uses NTIN in the 2D Data Matrix, the NTIN should be unique and should follow the same rules for changing as the GTIN. The NTIN must have been assigned before 9 Feb 2019, as no new NTINs are assigned after this date.
- If the layout of artwork is changed due to the introduction of 2DData 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 system by the companies. This functionality will be added on Farmalogs website, VareWeb. An artwork pdf must also be submitted at the website.
- Please also see table on page 5.

## SWEDEN

- No need to change Vnrs when changing from NTIN to GTIN<sup>1</sup>.
- If only GTIN<sup>1</sup> is changed no notification/variation needed.
- Many different GTINs<sup>1</sup> are allowed for the same Vnr in the 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.
- No hard cut is needed when changing from NTIN to GTIN<sup>1</sup> on packs.
- Notification “for information only” or Article 61(3) notification to update labelling. If the layout is changed, an Article 61(3) notification needs to be submitted and approved (3 months lead time).

Please note! 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-fornyselser/Krav-pa-sakerhetsdetaljer-pa-lakemedelsforpackningar/>

- Change NTIN to GTIN<sup>1</sup> by adding the new product code in LiiV.
- 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 NTIN must have been assigned before February 9, 2019, as no new NTINs are assigned after this date.
- Please also see table on page 5.

Country requirements regarding changes from NTIN to GTIN	DK 	FI 	IS 	NO 	SE 
New Vnr required	No*	No	No	Yes in 2017 No from 2018	No
Two different product carriers (linear barcode and 2D Data Matrix) with <b>the same GTIN<sup>1</sup></b> is allowed to be printed on the secondary pack at the same time.	Yes	Yes	Yes	Yes	Yes
Many different product codes (GTIN <sup>1</sup> ) 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 2017	Yes
Hard cut needed (no change of Vnr, only change of NTIN to GTIN <sup>1</sup> )	Yes* at the moment	No	No	Yes* in 2017 No from 2018	No
Hard cut needed (change of Vnr + change of NTIN to GTIN <sup>1</sup> )	Yes*	No	No	No	No
National data system updates required (change NTIN to GTIN <sup>1</sup> )	Wholesaler	PIC	Will be updated later	Farmalogg	LiiV
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
NCA notification incl. mock-up required for change in barcode or Vnr	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 the eVerification, see VnrWiki or contact:

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