Information to manufactures on implementation of 2D Data Matrix according to FMD for packs released to the Norwegian market 2017 - 2019

NTIN to GTIN and linear barcode to 2D-Datamatrix

- As a consequence of implementation of 2D Data Matrix, many manufacturers wish to implement GTIN as product code. The transition from NTIN to GTIN must follow the principles stated below.
- When introducing a new Vnr in the IT systems, the pack may have GTIN in the linear barcode (EAN-13).
- Marketed packs: Avoid changing from NTIN to GTIN in linear barcode in 2017*.
- From 1 January 2018: You may change NTIN to GTIN in the linear barcode for marketed packs.
- Linear barcode will be the valid information carrier until 9 February 2019, but a 2D Data Matrix may also be printed on the packs.
- From 9 February 2019: 2D Data Matrix should be the only information carrier. The linear barcode must be removed.

*) If the manufacturer decides to introduce GTIN in 2017, a new Vnr is required. GTIN may be included in a 2D Data Matrix in addition to the linear barcode.

Following the implementation of the European Falsified Medicines Directive (FMD) pharmaceutical manufacturers wish to introduce Global Trade Item Number (GTIN) as product code on their packs. The IT systems in the Nordic countries may handle the transition differently. This information is for the situation in Norway.

IT systems at wholesalers and pharmacies can currently only handle one product code (as linear barcode, EAN-13 format) per Vnr/pack. The product code can be NTIN or GTIN, but GTIN only for new packs introduced to the market. The systems cannot handle a change of product code on marketed packs from NTIN to GTIN until 1 January 2018. On 9 February 2019 at the latest, the systems and scanners can also read product codes in 2D Data Matrix.
Products released to market/wholesalers in 2017

All packs should have the linear barcode on one side of the pack. The product code could be GTIN only for new packs and the GTIN should not change in 2017. Marketed packs should keep their NTIN. Avoid changing from NTIN to GTIN in 2017. However, if it is necessary to change the product code from NTIN to GTIN, the Vnr for the pack must change.

If 2D Data Matrix is printed on the pack in 2017, it should be printed with the product code that is to be used after Feb 2019, which is GTIN or unique NTIN. The linear barcode must be kept on the pack, and the product code in the linear barcode could be different from the product code in the 2D Data Matrix. The GTIN and NTIN will not refer to the same product in the IT systems until the GTIN is added to Vnrs at VareWeb, Farmaloggs web portal which will open in November 2017.

Note that this is not allowed in SE/FI. For packs shared with SE/FI, manufacturers could either change to a Norwegian specific pack (new Vnr with GTIN) or wait until 2018 to implement GTIN in the 2D Data Matrix.

Products released to market/wholesalers between 1 January 2018 and 9 February 2019

From 1 January 2018, the product code could change from NTIN to GTIN in the linear barcode. The linear barcode is the valid barcode in this period, but the 2D Data Matrix can also be added to the pack. The 2D Data Matrix should not be on the same side of the pack as the linear barcode.

The GTIN product codes must be added to Vnrs at VareWeb, Farmaloggs web portal.

Products released to the market/wholesalers after 9 February 2019

All packs must have the product code as GTIN or unique NTIN in a 2D Data Matrix. IT systems will support linear barcodes with both NTIN and GTIN information in a transitional period (for existing packages in the supply chain).

The information is presented visually in the enclosed poster.

June 2017

NOMVEC

Apotekforeningen

Legemiddelgrossistforeningen
# Implementation of 2D Datamatrix in Norway

<table>
<thead>
<tr>
<th>Released to Norwegian market</th>
<th>1 Jan 2018</th>
<th>1 Jan 2018</th>
<th>9 Feb 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Requirements according to FMD</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Linear barcode</td>
<td>2D Datamatrix</td>
<td>Linear barcode</td>
<td>2D Datamatrix</td>
</tr>
<tr>
<td>NTIN ¹</td>
<td>None</td>
<td>NTIN</td>
<td>None</td>
</tr>
<tr>
<td>GTIN ³</td>
<td>None</td>
<td>GTIN ², ³, ⁴</td>
<td>GTIN ³</td>
</tr>
</tbody>
</table>

| Optional implementation of 2D Datamatrix before 9. Feb 2019 | | |
|-------------------------------------------------------------|------------------------------------------------------|
| Linear barcode | 2D Datamatrix | Linear barcode | 2D Datamatrix | Linear barcode | 2D Datamatrix |
| NTIN (un) | NTIN (un) | NTIN (un) | NTIN (un) | NTIN (un) | NTIN (un) |
| NTIN ⁴ | GTIN ², ³, ⁴ | NTIN ⁴ | GTIN ⁴ | NTIN ⁴ | GTIN ⁴ |
| GTIN ³ | GTIN ³ | GTIN | GTIN | GTIN | GTIN |

May have 2D Datamatrix **Must** have linear barcode

May have 2D Datamatrix **Must** have linear barcode

Must have 2D **Cannot** have linear barcode

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1. If package has existing NTIN, a switch to GTIN is not allowed until 1 Jan 2018
2. GTIN not registered in Farmalogg
3. Not possible to change the GTIN before 1 Jan 2018
4. Not allowed on packs shared with SE/FI
5. NTIN must have been assigned before 9 Feb 2019. No new NTINs are assigned after this date

FMD - Falsified Medicines Directive
GTIN - Global Trade Item Number
NTIN - National Trade Item Number
NTIN (un) - Unique NTIN following the same rules as GTIN

Version 1: Feb 2017