



## Information to manufacturers and parallel importers of prescription medicines for the Danish market regarding implementation of 2D Data Matrix in connection with FMD in 2017 - 2019

As a result of the implementation of the directive on falsified medicines (FMD) and 2D Data Matrix, representatives from the entire supply chain have prepared joint guidelines for the transition from linear barcodes (EAN-13) to 2D Data Matrix. We recommend that all manufacturers and parallel importers follow the principles mentioned below.

- The linear barcode is the valid information carrier until February 9, 2019.
- The manufacturers are asked to use 2D data Matrix in good time before February 2019.
- When a new item number is introduced in the IT systems, the package can have either GTIN or NTIN in the linear barcode.
- As of February 9, 2019, the 2D Data Matrix is the only valid information carrier. The linear barcode can be removed after this.

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### Background

In connection with the implementation of FMD, several pharmaceutical manufacturers wish to implement Global Trade Item Number (GTIN) as product code on their packages. The transition is handled differently in the individual EU countries. This information is inspired by principles from Norway and is applicable for Denmark.

IT systems at wholesalers, pharmacies and hospital pharmacies can at present only handle one product code (as linear barcode, EAN 13 format) per item number per each package.

The product code can be either NTIN or GTIN.

The systems cannot handle a change of product code on marketed packages from NTIN to GTIN before after January 1, 2018. The supply chain's systems and scanners can also read product codes in 2D Data Matrix on February 9, 2019 at the latest.

Therefore, the linear barcode is the valid information carrier until February 9, 2019, but you are free to print a 2D Data Matrix on the packages already now.

### Medicine packs for the Danish market in 2017

The linear barcode is the valid barcode in 2017, and all packs shall have the linear barcode on the one side of the package. The product code can be either GTIN or NTIN. If it is necessary to change the product code from NTIN to GTIN, the package shall have a new item number.

If 2D Data Matrix is printed on the package in 2017, it shall be printed with the product code to be used as of February 9, 2019, which is GTIN or unique NTIN. The linear barcode shall be retained on the package and the product code in the linear barcode can be different from the product code in 2D Data Matrix.

### Medicine packs for the Danish market as of January 1, 2018 and up until February 9, 2019

As of January 1, 2018, the linear barcode is the valid barcode during this period, but 2D Matrix shall also be added to the package in this period. 2D Data Matrix ought not to be on the same side of the package as the linear barcode. If the two barcodes are placed at the same side of the package, the space shall be minimum 2 cm.

### Medicine packs for the Danish market as of February 9, 2019

All packages shall have the product code GTIN or unique NTIN in a 2D Data Matrix as of February 9, 2019.

After this it is allowed to remove the linear barcode, for instance in connection with a later update. If the linear barcode is retained, the two barcodes are allowed to be different, but the barcodes are not allowed to contain mutual conflicting information or be misleading. Please take a look at the attached illustration that summarizes the rules.



## Sygehusapotekerne i Danmark

