



De forskande
Läkemedelsföretagen

Recommendations and guidelines - identifiers on primary packages in the Nordic countries

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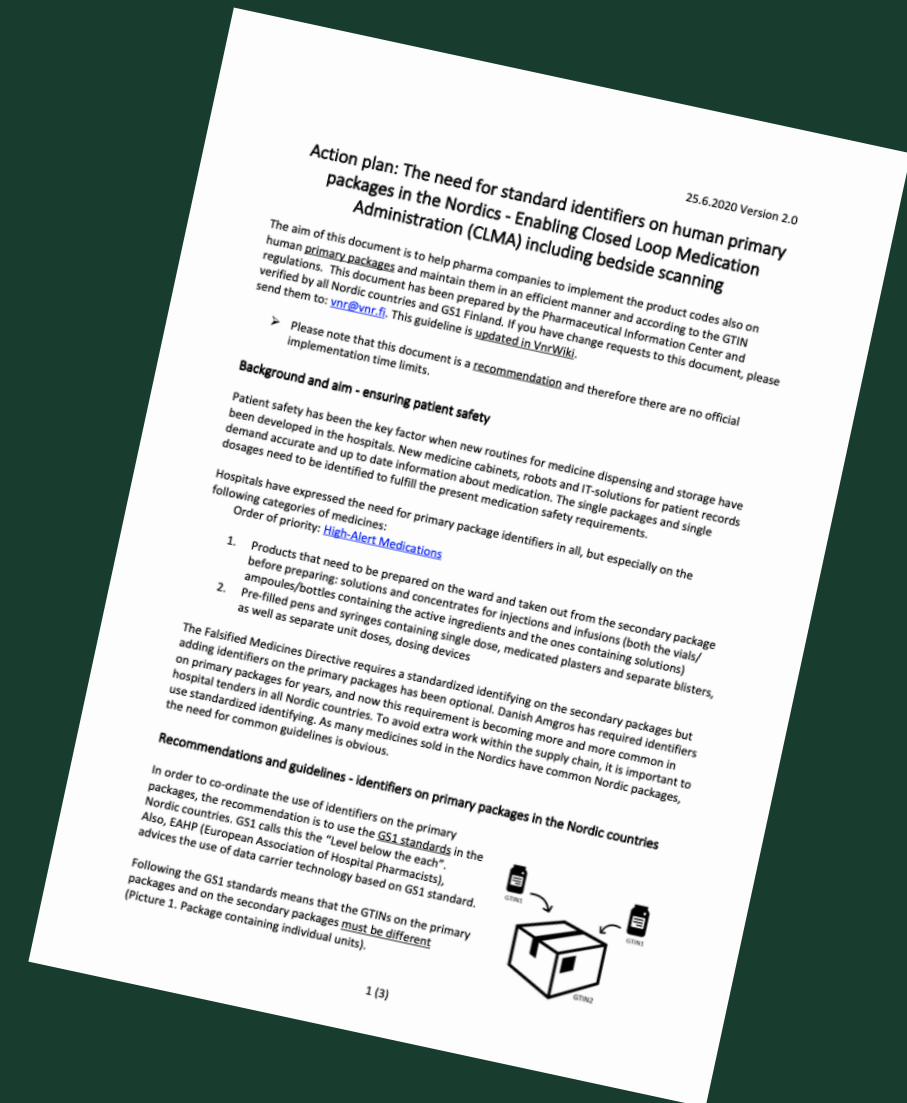
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Why a recommendation?

- Danish Amgros has required identifiers on primary packages for years, and now this requirement is becoming more and more common in hospital tenders in all Nordic countries
- The Nordic countries are often seen as one market and there are many common Nordic packages – need for common guidelines
- Important to use standardized identifying to avoid extra work within the supply chain
- A common standard is needed for CLMA (Closed Loop Medication Administration) including bedside scanning

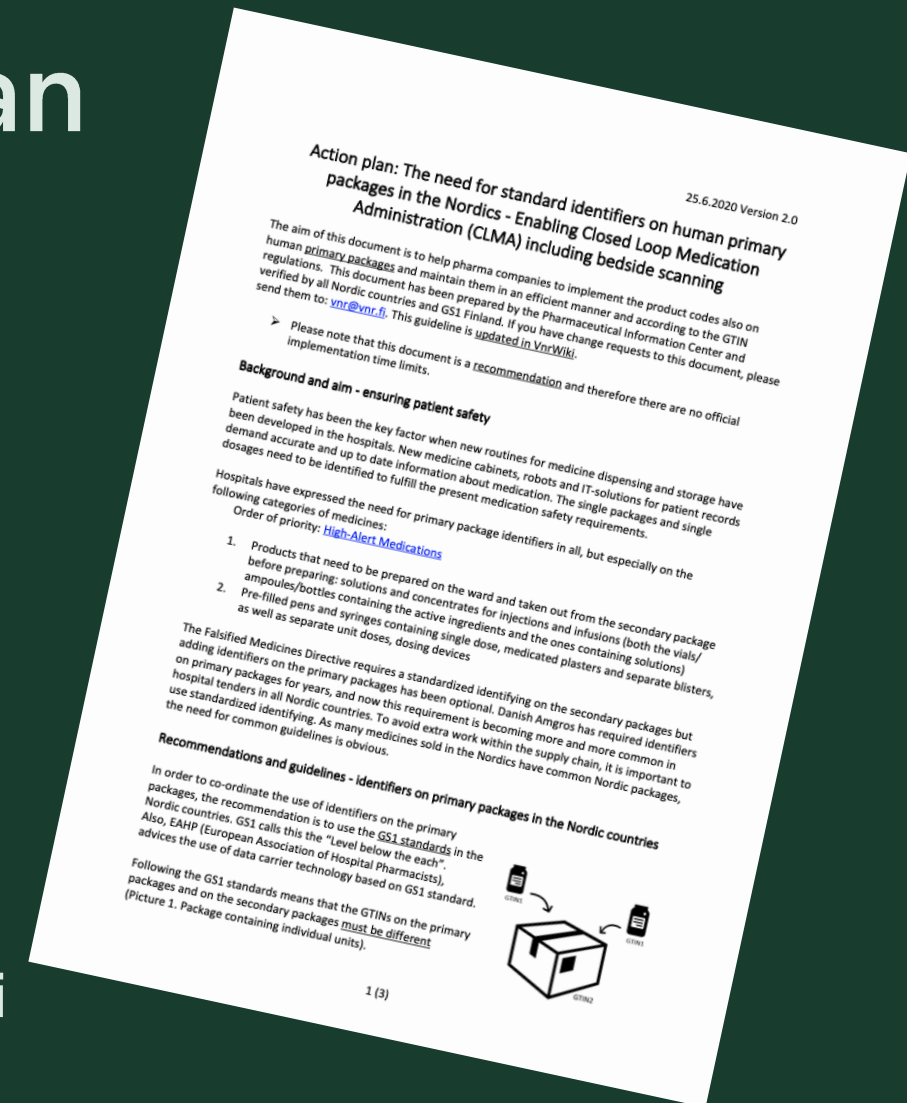
What has been done?

- Nordic meetings – discussions on
 - What is needed
 - Current status in the Nordic countries
- Decisions
 - Agreed on common Nordic guideline
 - Use GS1 standards (as for secondary packages, and recommended by the EAHP (European Association of Hospital Pharmacists) and Amgros
- Result
 - Common Nordic Action Plan - June 2020
 - Q&A - Primary pack identifiers – December 2021



Common Nordic Action Plan

- Prepared by Pharmaceutical Information Center (PIC) in Finland and verified by all Nordic countries and GS1
- Recommendation
 - No official implementation time limits
- Follow GS1 standard
 - GTIN
 - DataMatrix
- Latest version can always be found on VnrWiki

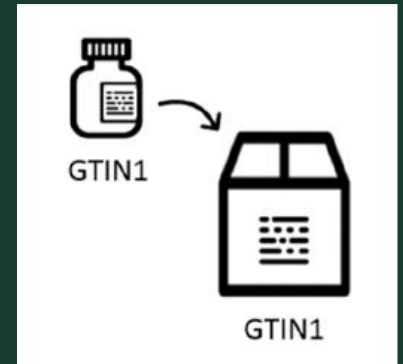
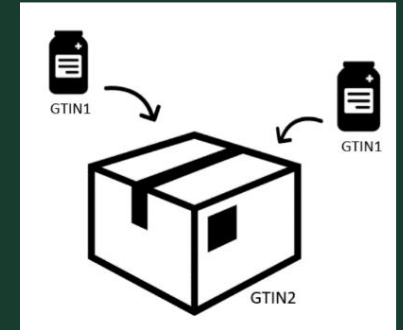


Which articles?

- Need for primary package identifiers on ALL packages
- Highest priority
 - High-Alert Medications , products that need to be prepared on the ward and taken out from the secondary package before preparing
 - Pre-filled pens and syringes containing single doses
 - Medicated plasters as well as separate unit doses, dosing devices

Recommendations

- GTINs on the primary packages and on the secondary package must be different
- If the package size is *one* (one vial, one ampoule, one pre-filled syringe etc.) the identifier on the possible secondary package can be the same as on the primary package.
- 2D data carrier with GTIN, batch and expiry date
 - if not possible, at least data carrier with GTIN



CLMA – Current questions

- Powdered medication and diluent – barcodes?



Single vials, or combinations of vials and their diluent, identified each with its own GTIN

- Reports where the patient has only received the diluent

2.6 When pharmaceutical products consist of powdered medication and a diluent

Some pharmaceutical products consist of powdered medication and a diluent. Amgro does not require barcodes on the diluent, however, it is allowed. Since the secondary package contains two vials, it is not a 1:1 relationship, and the vial with the powdered drug must have a GTIN, and the package, which contains the powdered drug + the diluent, must have another GTIN, see figure 9.

Figure 9: Allocation of GTINs to packages which contain powdered drug + diluent



CLMA – Current questions

- Human readable text?

Primary packages



Secondary packaging



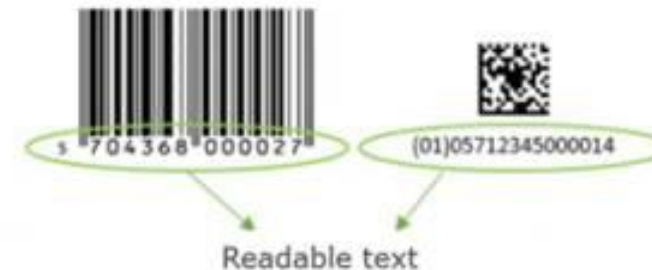
For information on serial number, expiry date, and batch-/lot number formats, see 13. Appendix.

5. Human readable text connected to the barcode (Human Readable Interpretation)

It is important that the information encoded in the barcode also can be found in readable text close to the barcode. This is to provide for cases in which the barcode cannot be scanned.

When an EAN-13 barcode is used, the readable text is placed below the barcode. The readable text encoded shall always be printed adjacent to the GS1 DataMatrix, while protecting the quiet zones. In circumstances with extreme space constraints it is possible to leave out some of the readable text or the entire text related to the barcode, however, if possible it is important to have the GTIN in readable text. For more information on human readable interpretation, see section 4.15 in [GS1 General Specifications](#).

Figure 7: Example of readable text. Note that Application Identifier (01) must be part of the readable text when a GS1 DataMatrix is used.



More information

[GS1 Healthcare GTIN Allocation Rules](#)

[Use of GS1 2D Matrix Data Carriers in Healthcare \(2019\)](#)

[Medicines identification requirements on primary level packaging using GS1 standards](#)

[EAHP - Bar coding medicines to the single unit](#)

[VnrWiki - Information regarding product codes](#)

Amgros: Technical guide to bar code labelling

(https://levportal.amgros.dk/SiteCollectionDocuments/Hjælp%20og%20support/20200108%20Technical%20guide%20to%20bar%20code%20labelling_2020_final.pdf)

Thank you for listening!

