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Action plan: The need for standard identifiers on human primary packages in the Nordics - Enabling Closed Loop Medication Administration (CLMA) including bedside scanning

The aim of this document is to help pharma companies to implement the product codes also on human primary packages and maintain them in an efficient manner and according to the GTIN regulations. This document has been prepared by the Pharmaceutical Information Center and verified by all Nordic countries and GS1 Finland. If you have change requests to this document, please send them to: vnr@vnr.fi. This guideline is updated in VnrWiki.

- Please note that this document is a recommendation and therefore there are no official implementation time limits.

Background and aim - ensuring patient safety

Patient safety has been the key factor when new routines for medicine dispensing and storage have been developed in the hospitals. New medicine cabinets, robots and IT-solutions for patient records demand accurate and up to date information about medication. The single packages and single dosages need to be identified to fulfill the present medication safety requirements.

Hospitals have expressed the need for primary package identifiers in all, but especially on the following categories of medicines:

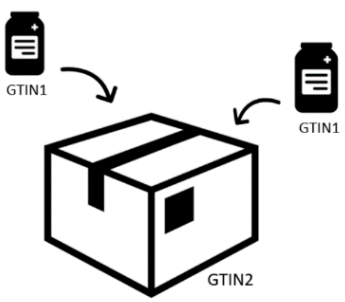
Order of priority: High-Alert Medications

1. Products that need to be prepared on the ward and taken out from the secondary package before preparing: solutions and concentrates for injections and infusions (both the vials/ ampoules/bottles containing the active ingredients and the ones containing solutions)
2. Pre-filled pens and syringes containing single dose, medicated plasters and separate blisters, as well as separate unit doses, dosing devices

The Falsified Medicines Directive requires a standardized identifying on the secondary packages but adding identifiers on the primary packages has been optional. 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. To avoid extra work within the supply chain, it is important to use standardized identifying. As many medicines sold in the Nordics have common Nordic packages, the need for common guidelines is obvious.

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

In order to co-ordinate the use of identifiers on the primary packages, the recommendation is to use the GS1 standards in the Nordic countries. GS1 calls this the “Level below the each”. Also, EAHP (European Association of Hospital Pharmacists), advices the use of data carrier technology based on GS1 standard.



Following the GS1 standards means that the GTINs on the primary packages and on the secondary packages must be different (Picture 1. Package containing individual units).

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. (Picture 2. Package containing one unit).

Recommendation – primary packages

- 2D data carrier with GTIN, batch and expiry date
  - if not possible, at least data carrier with GTIN
- Machine readability of the data carrier needs to be ensured

Please note that serialization is not needed for primary packages.

Important/needs from hospital pharmacies

- Preferably only one data carrier per outer package
  - Different 'packaging technical' data carriers/codes (codes indicating the material of the cardboard packaging, or color maps, in 1D or 2D format, etc.) are undesirable
  - The storage robots are sometimes disturbed by data carriers that are mainly hidden in the fold of the lid flap
- In the future there is also need for the corresponding data carriers for wholesale packaging and pallets (aggregation)

Please see also

- 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
- Amgros: Technical guide to bar code labelling (the guide is currently being updated; link will be added later)
- VnrWiki - Information regarding product codes

For more information on GS1 standards, please contact your local GS1 office

Denmark: www.gs1.dk
Finland: www.gs1.fi
Iceland: www.gs1.is
Norway: www.gs1.no
Sweden: www.gs1.se

For more information on the needs of the hospital pharmacies or Closed Loop Medication Administration (CLMA) including bedside scanning, please contact your local contact

Denmark:	Signum	info@signumlifescience.com
Finland:	HUS Pharmacy	laakehankinnat@hus.fi
	(STM:n julkaisu	Katkeamaton lääkehoito)
Norway:	Sykehusinnkjøp	Astrid.Johnsen@sykehusapotekene.no
Sweden:	Fass	fass@lif.se

The product codes for the primary packages can be informed to the following operators/registers. This informing will be specified and updated later, since some registers still require development to handle this information.

Denmark:	Signum	info@signumlifescience.com
Finland:	Vnr Service	www.vnr.fi (Notification: Other change)
Iceland:	Lyfjauðkenni	info@lyfjaaudkenni.is
Norway:	Farmalogg, VareWeb	www.farmalogg.no
Sweden:	E-hälsomyndigheten	www.ehalsomyndigheten.se