

LÄÄKE  
TIETO  
KESKUS

*Reporting serialized packs in the  
Vnr Service*

*GTIN and Vnr*

Fimvo 1.2.2018

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## Reporting serialized packs in the Vnr Service

- Verification notification

Moving from NTINs to GTINs  
The role of Vnrs in the future

## *The aim of verification notifications*

- The need for notifications has come from the logistics chain operators
- The aim is to facilitate and speed up the work of different actors
  - The medical supply chain has clear information of which exact packages can/need be verified/decommissioned
    - Information will be used in IT systems to guide operations and workflows
  - The necessary information is available easily, reliably, timely and with minimal resources

# The process of verification notifications

- The same familiar principles as in other type of notification
  - The pharma company makes the verification notification in the Vnr Service utilizing the basic information already ready for use
    - Notifications are not “approve” by Lääketietokeskus, ie. the same approach as in product code notifications: the information in the notification is stored directly in the database
  - Lääketietokeskus forwards the notifications and necessary information to wholesalers, pharmacy and hospital IT system providers and the "2020" ePrescription pharmaceuticals database



# Verification notifications = temporary support

- Only once for each package covered by the FMD
  - From 9.2.2019 all new packages on market within FMD coverage need to be verified
  - Packages already on the market before 9.2.2019 theoretically after max 5 years
- Temporary need during the transition period to ensure efficient operation
  - Lääketietokeskus follows the market situation
    - Lääketietokeskus also follows significant changes in shelf life



2 different information types that Laaketietokeskus delivers to stakeholders

1. The package needs to be verified/decommissioned (=is covered by the FMD)  
(1/0)
2. The package contains 2D data matrix and safety features (from pharma companies)

Functions have been implemented in Vnr Service in 2017

- Tested by pharma companies
- Transfer to production environment 2.2.2018
- Introduction to use for pharma companies Q1/2018
  - Will be confirmed and communicated later on when Fimvo's system is taken into use

# Verification notifications in the Vnr Service

- The notification form is found where other notification types
  - Home > Notification forms > Medicines verification
- The Vnr Service performs following automatic checks
  - The Vnr belongs to the company whose user is logged into / to which the user has the user rights
  - The notification can be made only for packages covered by the FMD
  - The notification be made only for a product whose product code has been notified to the Vnr Service
  - The notification can be made only once for each package

## Notification forms:

- New product into the market
- Change in price
- Product withdrawal from the market
- KELA notification
- Other change
- Product code
- Medicines verification

## *Filling out verification notification*

- The package to be notified can be searched by Vnr or trade name
- After choosing the correct pack, basic information is visible and usable
- The product code (GTIN/unique NTIN) from drop-down list (mandatory)
  - If there are several product codes for the Vnr, they will all appear in the list, and the one associated with the notification in question needs to be selected
  - If the Vnr does not have the product code needed in the drop-down list (pharma company hasn't notified it), the product code needs to be notified first. For this purpose the notification has a direct link to the product code notification



## Filling out verification notification

- Batch (mandatory)
- Expiration date of the batch (voluntary)
- Date of entry into force (= **Estimated** date when the first batch of the package within in FMD coverage will be available)
  - If left empty, the date will automatically be the date of the notification

### Medicines verification

#### Finland

Product code	Batch	Batch expiration date	Effective date of the notification	Additional information	Notifier	Added
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## Verification notifications in the Vnr Service

- If the notification needs to be changed, Lääketietokeskus must be contacted
- Verification notifications report

Report: Medicines verification

Marketer <Select a Value> Country View Report

- Product code report
  - Home > Reports > Product codes
  - Listing of product codes of the company
    - If missing product codes, can also be uploaded as a file

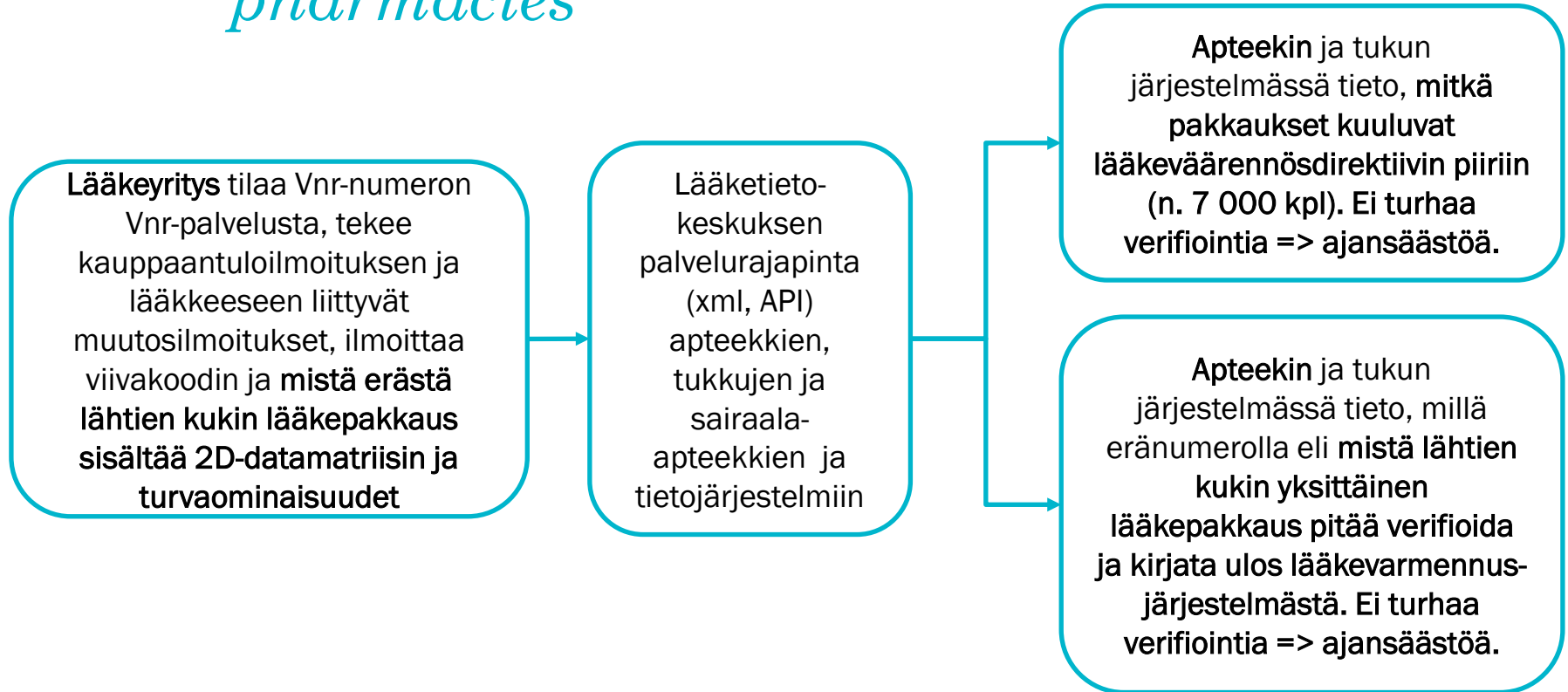
## *Verification notification*

- Co-operation partners receive verification notifications either via interface or as transfer file
  - Interface recommended
  - Information can be retrieved at any time automatically through the interface, eg. every night
  - Lääketietokeskus reminds co-operation partners of the retrieval of the transfer file along with product notification messages
  - Data cumulatively

# Data content of verification notifications to be delivered

Tietokentän nimi	Tietokentän kuvaus	Arvot	Tietotyyppi	Merkkimäärä
VNR	VNR-tunnus		string	7
TradeName	Kauppanimi		string	80
BatchId	Erän tunnus		string	50
BatchExp	Kertoo, milloin pakkaus on viimeistään käytettävä. Sisältää tiedon kuukausitasolla.	MM.yyyy	date	7
EffectiveDate	Voimaantulopäivämäärä	dd.MM.yyyy	date	10
AdditionalInformation	Lisätiedot		string	200
Strength	Vahvuus		string	80
DosageForm	Lääkemuoto		string	200
PackageSize	Pakkauksen koko		decimal	
PackageType	Pakkauksen tyyppi		string	80
ProductCode	Tuotekoodi, johon erä liittyy.		string	14
OtherProductCodes	Ilmoituksen jälkeen markkinoille tulleet kyseisen pakkauksen muut tuotekoodit.		string	200
ATC	ATC-koodi		string	7
MAH	Lääkevalmisteen myyntiluvan haltijan nimi.		string	80
MA-number	Fimean myyntilupanumero		string	80
Marketer	Yritys, joka vastaa valmisteen markkinoinnista Suomessa		string	80
Recipe	Valmisteen toimittaminen edellyttää reseptiä.	1 = reseptilääke, 0 = itsehoitovalmiste	boolean	1
Created	Ilmoituksen tekopäivämäärä.	dd.MM.yyyy	date	10

# *One-channel service for pharmaceutical companies: information for the use of pharmacies*






## Coding of medicines

## Identification of medicines

- Data carrier will be added to packages (2D datamatrix). Data carrier includes product code (now as a linear one dimensional barcode).

Product #:	09876543210982	
Batch:	A1C2E3G4I5	
Expiry:	140531	
S/N:	12345AZRQF1234567890	



- Product code needs to be standardized GTIN or unique NTIN
- Package is identified by the combination of product code & serial number
- Vnr will be kept on the package

## Identification of medicines

- Detailed information on codes, packages, data content, change situations and requirements for different Nordic countries can be found at VnrWiki ([wiki.vnr.fi](http://wiki.vnr.fi))
- The package may contain both a 2D data matrix and a linear barcode at the same time, but both must bear the same product code (GTIN/unique NTIN)
- The Vnr number can not be placed as a fifth element in the 2D data matrix
- Vnr does not disappear
- No new NTINs after 9.2.2019
- Needs must be taken into account extensively, not only from the point of view of FMD



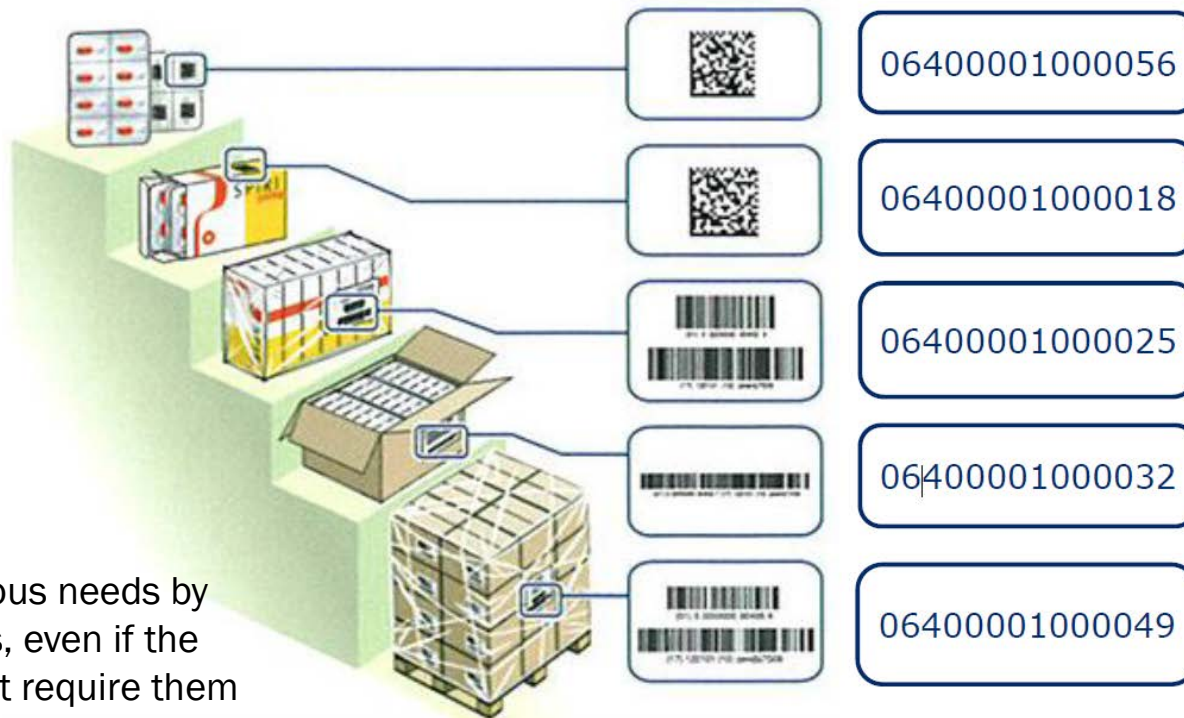


# *Importance of coding: code is the key to information*

- Unique product code is a key to information used and shown in data systems
- Different uses have different needs. The coding enables the use of relevant information
  - Pharma company makes a notification of a launch into the market
  - Pharmacy returns a product to wholesaler
  - Hospital pharmacy marks biological product as dispensed
  - Doctor prescribes a medicine
  - Nurse gives a pain relief for a patient
  - PPB updates a package size of a medicine
  - On line pharmacies, robots, authorities, logistic chain, home care solutions, storage control, eCabinets
- The information on the package has to be uniform with information in data systems
- Coding enables the connection of information from different databases



# Information needs vary– need to prepare



There are numerous needs by information users, even if the authority does not require them

# The need for information at different levels

Taso	Käyttöesimerkki	Lääke-esimerkki				
Geneerinen valmistaja	lääkeaineen valinta: päänsärky	<u>Ibuprofeeni</u> / Parasetamoli				
Lääkevalmiste	lääkkeen valinta: tuttu lääke allergiselle potilaalle	<u>Burana</u> / busal				
Myyntilupa	lääkemääräys: sooiva vahvuus ja lääkemuoto	Burana	<u>600 mg tabl</u> / 125 mg peräpuikko			
Pakkaus	lääketoimitus: varastossa oleva pakkaus koko	Burana	600 mg tabl	<u>100 kpl</u> / <u>vnr 552208</u> 30 kpl		
Yksittäinen pakkaus	lääketoimitus: varastoon jää parempi kesto aika	Burana	600 mg tabl	100 kpl	vnr 552208	<u>erä A12345B exp 01-2015</u> / erä A12345X exp 01-2017



**GTIN/NTIN/Vnr**  
**Product codes in Vnr Service**

# GTIN (Global Trade Item Number)

- Usually 13 digits (64xxxxxxx + yyy + z) + often pre-0 in data systems
  - 1) Company prefix (64xxxxxx)
    - 2-3 digits: country prefix (Finland 64) and company prefix (for example 7 or 5 digits)
    - Company = Manufacturer, importer/wholesaler etc.
    - Company prefix has to be in the used by the company. It may not be sold or given to any other user
  - 2) Numbering of the company (for example 3 or 5 digits) (yyy)
    - On the responsibility of the company
  - 3) Check digit (1 digit) (z)
    - Check calculator



## GTIN rules

- Determine when to change GTIN
- Significant change from the view of point of selling process
  - Dosage form change
  - Different language in different market
  - Significant size change of outer package
  - Change in storage conditions



**GS1 GTIN Allocation Rules**  
Pharmaceuticals

# NTIN (National Trade Item Number)

- When barcodes were taken into use it was decided to use uniform barcoding in the Nordic countries (NTIN 13 digits)
  - 704626 + Vnr + check number (always same Nordic prefix)
- NTIN is a GTIN
  - The company prefix belongs to Nordic Vnr administrator = Lääkietietokeskus
- Since Vnr is included in the NTIN, NTIN changes only when Vnr changes
  - 6 Data elements defining Vnr
    - Trade name, dosage form, strength, pack size, pack type, MAH
  - Does not separate packages for example with different PILs or different outer pack sizes -> NTIN is not necessary always unique
  - Important! Vnr change rules are different from GTIN rules

# *The aim is unique identification*

- Pharma company decides whether to use GTIN or unique NTIN codes
  - The prerequisite is **unique** product code
- Watch out for any change
  - See table CHANGE SITUATIONS VNR vs. GTIN from VnrWiki
  - **General rule: If Vnr changes → GTIN changes always and more often**
    - Since Vnr is included in NTIN, NTIN changes only when Vnr changes
- **One Vnr can have many different GTINs** (for example different PILs)
  - One Vnr can have only one NTIN
- **Linkege** between Vnrs and GTINs is very important (product code notifications!!!!)
- No new NTINs from 9 February 2019
  - For veterinary medicines still slightly open
- Old, unique NTINs can still be used





# LÄÄKE TIETO KESKUS

VnrWiki: <http://wiki.vnr.fi>



## Welcome to VnrWiki

### Latest updates

**19.1.2018**

The Norwegian Medicines Agency has now agreed to keeping both linear and 2D code on the packages after Feb 2019. The pdf on From NTIN to GTIN has been updated accordingly.

[NORDIC GUIDELINES \(PRINTABLE\)](#)

[Nordic Article Number \(Vnr\)](#)

[Nordic Number Centre \(NNC\)](#)

[Criteria for Vnr](#)

[Locked or unlocked Vnr](#)

[Vnr status](#)

[Vnr - layout and allocation](#)

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*Questions?  
Thank you!*

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