LÄÄKE TIETO KESKUS

GTIN / NTIN / VNR

CODING OF MEDICINES

PREPARE AND ACT NOW

1.0 / 20.10.2015

Content

GTIN/NTIN/VNR - CODING OF MEDICINES - PREPARE AND ACT NOW

1 Falsified Medicines Directive and Specifying Delegated Acts

The main goal of the Falsified Medicines Directive (FMD) is to prevent the access of falsified medicines to the legal supply chain (Directive 2011/62/EU June 8, 2011). Details have been specified in Delegated Acts (adopted and content confirmed October 2nd, 2015). The implementation time of 3 years for the safety features begins after the publication of the Delegated Acts. The demanded changes will be therefore required from the beginning of 2019.

The achievement of the goal of the FMD requires unique identification of medicines by standardized coding and serialization of medicinal packages. Standardized 2D data matrix will be added to prescription medicines. 2D data matrix shall bear at least the four following data elements: product code, batch information, expiry date and serial number. The product is identified by the combination of product code and the serial number.

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

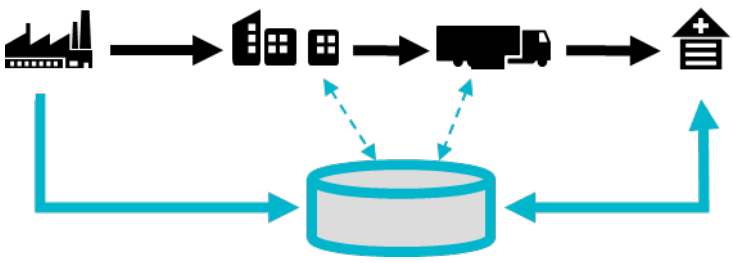
Coding and serialization are on the responsibility of the pharmaceutical company. Tamper evidence mechanism is also required to be added in outer packages at the same time.

The repository systems needed to take care of the verification requirements will be set up and governed by stakeholders under the supervision of the authorities. Pharmaceutical companies shall bear the costs of the repository systems.

2 European Medicines Verification System

In the European Medicines Verification System (EMVS) pharmaceutical company stores basic information of medicines and the master data to the EU Hub of the verification system. From the EU Hub the information will be transferred to national and local medicine verification systems.

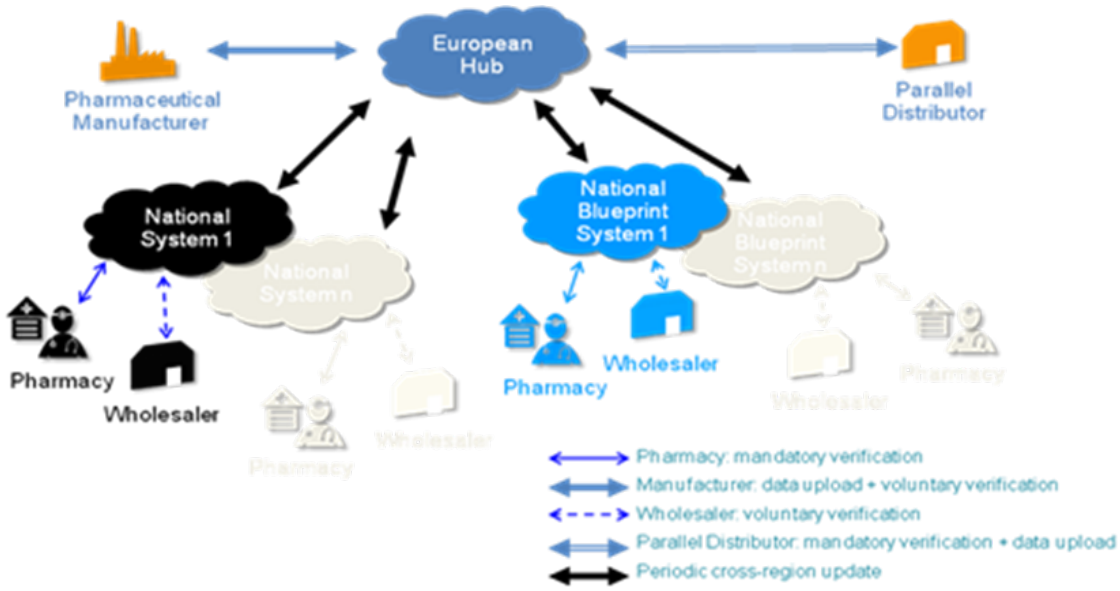
When the medicine is dispensed from a pharmacy to a patient the authenticity of the package is verified by comparing the information from the package to the information in the medicine verification system. Wholesalers implement risk-based authentication. The model is end-to-end system and point of dispense verification, not track and trace (Picture 1.).



Picture 1. End-to-end verification system

European Associations in the pharmaceutical field EAEPC, EFPIA, GIRP, EGA and PGEU have established European Medicines Verification Organization (EMVO) who administrates the EU Hub and has negotiated 3 Blueprint solution frame contracts.

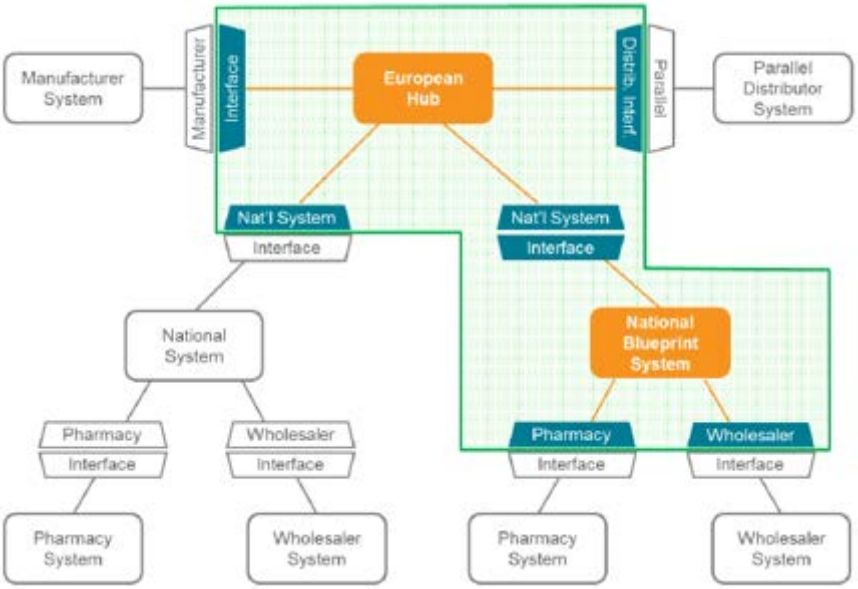
The integrity and the correctness of the data is essential in the supply chain. The data in the package and in the verification system has to respond to the other information used in the supply chain and IT systems. EMVS will contain only minimum data amount. Codes are part of master data.



Picture 2. European Medicines Verification System

The EU Hub enables the handling of multimarket or multinational packages and is the gateway to change information between national or local verification systems. The linkage between the original and re-packed batches is stored in the EU Hub.

The national Blueprint System is a cost efficient technical platform for national verifications and requirements and the channel to the EU Hub. It is the verification platform to pharmacies, wholesalers and others in ensuring the authenticity of the product. Package specific information is stored in the national or local systems and the product is marked as dispensed in the national system.



Picture 3. European Hub and National Blueprint System are on the responsibility of EMVO

3 Data elements and principles

Data elements in the EMVS include:

- Product code (+ national code)
- Shelf life
- Batch number
- Serial number
- Master data
- MAH
- Present status
- Status data changes (who, when)
- Time and date of previous changes

Master data is on the responsibility of the pharmaceutical company:

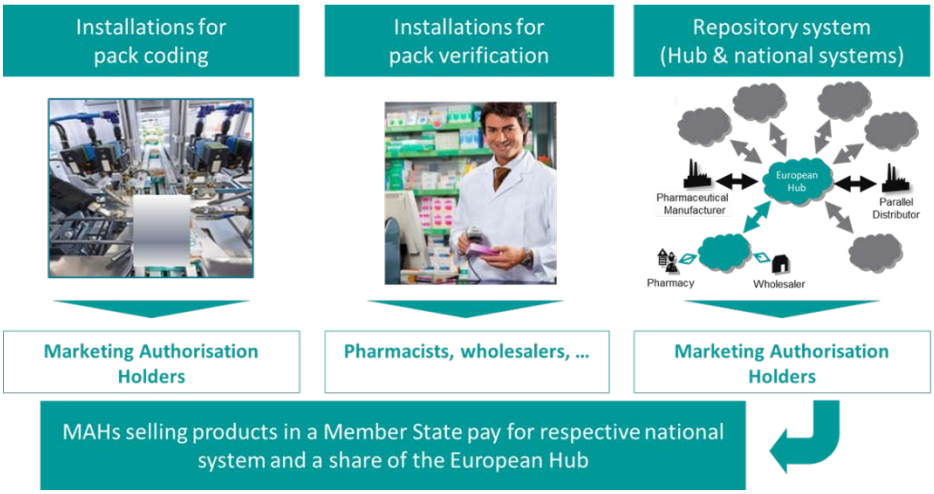
- Unique product code (+ national code)
- Product code version (original/update)
- Product name
- Dosage form
- Strength
- Package size
- Package type
- MAH id
- Market id
- Wholesaler id's
- Product code status
- National compensation number
- Black/white list – market specific flagging

The stakeholder proving the data owns the data. Every action in the repository system is

stored in log files and can be tracked. User rights are strictly monitored. The system shall not contain personal data.

4 Who will have to pay?

Pharmaceutical companies (Marketing authorization holders) bear the costs of the repository systems in Europe. The investments to package lines are also to be paid by pharmaceutical companies. Pharmacies, hospital pharmacies and wholesalers fund needed investments in the 2D readers and their IT software development.



Picture 2. Distribution of costs

5 Unique identification

Reliable verification requires unique identification of each medicinal package. Because of the FMD the packages shall have a unique product code within the 2D datamatrix instead of the current linear barcode. The used product code should be GTIN according to GS1 standards or unique NTIN.

Unique identification provides an opportunity to differentiate, in a machine readable form, an item's identification.

5.1 GTIN (Global Trade Item Number)

GTIN is used for the unique identification of trade items worldwide. GTINs may be 8, 12, 13 or 14-digits in length. Their data structures require up to 14-digit fields, and all GTIN processing software should allow for 14 digits.

A trade item is any item (product or service) upon which there is a need to retrieve pre-defined information and that may be priced, or ordered, or invoiced at any point in any supply chain. This includes individual items as well as their different types of packaging.

GTINs uniquely identify items that are traded in the Supply Chain. Integrity of these numbers throughout the item's lifetime is a key to maintaining uniqueness for manufacturers, wholesalers, distributors, hospitals, regulatory bodies and other Supply Chain stakeholders. A change to one aspect, characteristic, variant or formulation of a trade item may require the allocation of a new GTIN.

Brand Owners must properly allocate and maintain their GTINs to enable trading partners to distinguish products effectively for regulatory, Supply Chain and patient safety concerns.

GS1 Company Prefix →	← Item Reference	Check Digit
N_1 N_2 N_3 N_4 N_5 N_6 N_7 N_8 N_9 N_{10} N_{11} N_{12}		N_{13}

Picture 4. Example of GTIN-13

GS1 Company Prefix

- The GS1 Company Prefix consists of a GS1 Prefix and the Company Number both of which are allocated by GS1 Member Organisations. In general it comprises six to ten digits depending on the capacity needs of the company.
- The first two or three digits N1, N2, N3 constitute the GS1 Prefix allocated by GS1 Global Office to each GS1 Member Organisation (in Finland GS1 Finland). It does not mean that the item is produced or distributed in the country to which the prefix has been allocated.

Item Reference

- The Item Reference is a component of the Global Trade Item Number (GTIN) assigned by the owner of the GS1 Company Prefix to create a unique GTIN and is a non-significant number, which means that the individual digits in the number do not relate to any classification or convey any specific information. The simplest way to allocate Item References is sequentially, that is 000, 001, 002, 003, etc.

Check Digit

- The Check Digit is the last digit. It is calculated from all other digits in the GTIN. Calculator can be found for example www.gs1.fi.

Indicator	GTIN of the items contained (without Check Digit)	Check Digit
N_1	N_2 N_3 N_4 N_5 N_6 N_7 N_8 N_9 N_{10} N_{11} N_{12} N_{13}	N_{14}

Picture 5. GTIN-14 Data Structure/Example of GTIN-14

There are specific rules when GTIN has to be changed, for example when the size of the outer package changes significantly. Please get to know the change rules in depth.

See more information about GS1 www.gs1.fi.

See more information and check out the GS1 GTIN Allocation Rules for Pharmaceuticals: http://wiki.vnr.fi/

5.2 NTIN (National Trade Item Number)

When it was decided that a barcode should be printed on all pharmaceutical packages in the 1980's, the Vnr was central and dispensing was handled manually. It was therefore decided that it was important that the Vnr should be included in the new identification code represented by the barcode. In order to achieve this it was decided that pharmaceuticals in the Nordic countries should have modified formats of GTIN-13 and GTIN-8. This format was named NTIN.

However, the prerequisite that the barcode should include a Vnr is no longer valid from a logistical point of view. This means that the GTIN-13 and GTIN-8 formats of the barcode currently can be GTIN or NTIN.

An NTIN-13 has the same technical format as a GTIN-13, i.e. 13 digits, but with a fixed prefix and a Vnr instead of an article reference number. Actually it is a GTIN-13, but the prefix is owned by the Nordic Number Office.

Prefix of Nordic Number Centre (704626) + Vnr + check digit

704626 is the prefix of NNC used as a common Nordic company prefix for all pharmaceuticals.

An NTIN-8 has the format: 2 + Vnr + check digit.

Please note that there is a theoretical risk of mix-ups with articles other than pharmaceuticals. To reduce this risk NTIN-8 should only be used on prescription medicines.

NTINs can only be acquired from NNC by using the Vnr extranet service: https://vnr.fi. A confirmed barcode will then be visible in the detailed Vnr information section, for more information please contact NNC.

IMPORTANT:

1. The technical format of NTIN is correct, but the predetermined company prefix 704626 leads always to the Nordic Number Center (= Pharmaceutical Information Centre), not the pharmaceutical company in question

2. The company has to make sure that the NTIN is unique

5.3 Be sure to use GTIN or unique NTIN

Since the NTIN contains Vnr, NTIN can be changed only when Vnr changes.
There are 6 data elements that define Vnr:

- Trade name, dosage form, strength, pack size, pack type, MAH

If some of these changes, the Vnr has to be changed so the NTIN changes. NTIN allows individual identification only when the packages with the same Vnr are identical (since NTIN contains Vnr). NTIN cannot separate packages with different PILs or different outer packages since those are not the defining elements of Vnr. If there are PILs with different languages, the company should use GTIN, not NTIN. NTIN may be used only when it is unique. The ensuring of the uniqueness is on the responsibility of the pharmaceutical company.

Please note that the Vnr rules differ from GTIN rules. GTIN has to be changed in many situations when Vnr not.

One Vnr can have only one NTIN, but many GTINs (for example different PILs). The choice is GTIN or unique NTIN. Vnr and GTIN provide information on different level. They do not substitute each other.

6 From NTIN to GTIN along with FMD changes

Along with Falsified Medicines Directive 2D data matrix is added to the prescription medicine packages. 2D data matrix shall contain a unique product code. Pharmaceutical companies recommended to start using GTIN or to ensure that the NTIN is unique at the same time when the pack changes are made anyway.

Pharmaceutical company decides for itself what product code to use and how to administrate them. The aim is the individual and unique identification of the medicine package.

Check the quick help in VnrWiki: http://wiki.vnr.fi/?page_id=1671

7 VNR

The Nordic Article Number (Vnr) is an identification code for a specific article of medicine with marketing authorization in the Nordic countries. The Vnr is a six-digit-code (000001-199999 and 370000-599999) given to all human and veterinary medicines. It enables a simple verification of packages at all stages in the drug supply chain from prescription to the patient.

Vnr enables Nordic packages (remarkable cost savings). It is very widely used in the supply chain and IT systems to identify medicines and as a key to comprehensive information).

Vnr provides identification on different level than GTIN (since one Vnr can have many GTINs).

NOTE: Vnr will not disappear.

8 Why codes are important?

The code is the key to information shown and used in IT systems. Different users have different kind of needs in different situations, for example:

- company makes a notification of a new product into the market

- Pharmacy returns a package to wholesaler
- Hospital pharmacy dispenses a biological preparation
- Doctor prescribes a medicine
- Nurse doses painkiller for a patient
- Pharmaceutical pricing board updates a price for a medicine
- Online pharmacies, robots, services by authorities, supply chain, home care applications, storage control ect.

Information in the medicinal package and in the IT systems and supply chain must be the same. The codes are also the only manner to combine information from different sources and databases to one place.

It is extremely important that pharmaceutical companies are aware that the codes are critical attribute. They functions as an information carrier between a number of IT-systems involved in the prescription, dispensing, ordering, storage and information regarding medicines. The usage of the codes is therefore a matter of well-functioning management of articles as well as patient safety. In addition, electronic prescriptions as well as highly automated management systems in all parts of the distribution chain enhance the risk of fatal consequences if a codes are mixed or incorrect.

In order for the distribution chain to function safely, it is important to know when and how an article should change codes (Vnr/NTIN/GTIN).

8.1 Information on different levels for different purposes

In IT systems information is used on several different levels for different purposes depending on the needs of the users (doctor vs hospital pharmacist). Correct and uniform coding enables the useful information for different user cases.

Level	Usage example	Medicin example			
Generic product	medicine selection: headache	ibuprofen / parasetamol			
Medicinal product	medicine selection: familiar medicine for allergic patient	Burana / Ibusal			
Marketing authorization	prescription: suitable strength and dosage form	Burana	600 mg tabl / 125 mg suppository		
Package	medicine delivery: package size in stock	Burana	600 mg tabl	**100 pcs** / **Vnr 552208** 30 pcs	
Single package	medicine delivery: better duration stays in stock	Burana	600 mg tabl	100 pcs Vnr 552208	**batch A12345B exp 01-2015** batch A12345X exp 01-2017

Picture 6. Examples of information needs on different levels.

9 What to do now?

It is important to start preparing now. Especially concerning master data and code administration and communication in the pharmaceutical company.

1) Prepare: find out the current coding situation in your company
2) Start preparing for the required changes

- Is GTIN today in use in Finland and/or in the Nordic countries?

- Is GTIN in use in the rest of the world – contact region or global HQ.
- Coordinate with region or global HQ which GTIN company prefix should be used.
  New company prefix could be ordered from GS1.
- Coordinate with the region/global HQ and/or GS1 how a GTIN structure should be built, administered and managed.
- Coordinate with the other Nordic area administrators of Vnr/ID concepts; to discuss how the transition from NTIN to GTIN for Nordic packages should be synchronized in the different markets.
- Check the conditions for when the 2D data matrix can begin to be printed on the company´s packages.
- Make budget provision for the transition from NTIN to GTIN; see www.gs1.fi for information on cost for GTIN.

10 Questions and answers

To be updated.

11 Where to find information?

www.wiki.vnr.fi
vnr@vnr.fi
www.gs1.fi
GS1 GTIN Allocation Rules – Pharmaceuticals
European associations