

# LIF's recommendation

## Transition from NTIN to GTIN

Version 1.0

# Index

<b>Transition from NTIN to GTIN</b>	<b>3</b>
<hr/>	
<b>1 Background</b>	<b>3</b>
<hr/>	
1.1 Product, article and package	3
1.1.1 <i>Product</i>	3
1.1.2 <i>Article</i>	3
1.1.3 <i>Package</i>	3
1.2 Nordic article number, Vnr	4
1.3 Barcode	4
1.4 Consequences of changed market requirements	4
1.5 Increased demands – e-verification	5
<b>2 Current situation</b>	<b>6</b>
<hr/>	
<b>3 LIF's recommendation</b>	<b>7</b>
<hr/>	
3.1 Planning the transition	7
3.2 Stepwise transition from NTIN to GTIN	7
<b>4 What can you do now?</b>	<b>8</b>
<hr/>	
<b>5 Contact information</b>	<b>9</b>
<hr/>	
<b>6 Definitions</b>	<b>11</b>
<hr/>	

# Transition from NTIN to GTIN

## 1 Background

Fundamental to understanding the need for change is how the use of identification concepts and the Nordic article number (Vnr) have changed over time for the concepts of product, article and package.

### 1.1 Product, article and package

#### 1.1.1 Product

The term "product" is used for all articles with the same trade name, strength, pharmaceutical dosage form and MAH, e.g.

Tablet X, 500 mg, film-coated tablet (Company X)

#### 1.1.2 Article

A product may have one or more articles.

The term "Article" is used for a specific package type and size of a product, e.g.

Tablet X, 500 mg, **blister** 20 film-coated tablets (Company X)

#### 1.1.3 Package

An article may have one or more packages.

The term "package" is used for the physical packages of an article. These may have:

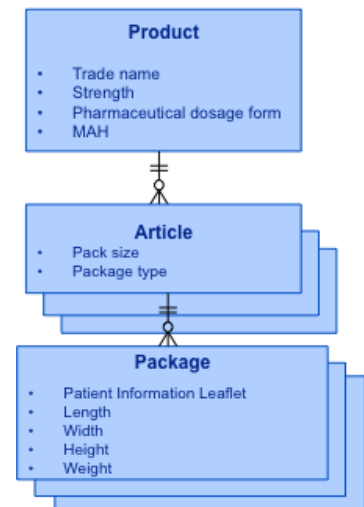
- Different measures
- Different external appearance
- Different patient information leaflets, PIL, in the Nordic countries, such as different languages and different information.
- Different content - different composition of the pharmaceutical e.g. colouring substance (parallel import)

Examples of the same article, but different packages:

- Swedish / Finnish package - Tablet Y, 500 mg, 20 blister
- Danish / Norwegian package - Tablet Y, 500 mg, 20 blister

Package material, including the patient information leaflet - different languages

- Paracetamol Parallel Importer Z - 500 mg, 20 blister originating from Bulgaria
  - Paracetamol Parallel Importer Z - 500 mg, 20 blister originating from Portugal
- Blister, package dimensions, colouring substance etc. can differ.



## 1.2 Nordic article number, Vnr

In the early 1970's, the possibility of creating a unique identification concept for pharmaceuticals was discussed. In 1977 the Nordic article number was launched, which made it possible for pharmaceutical companies to manage five small markets as one large, with less administration and lower costs.

The idea was that a package should be the same in all countries where the same Vnr was used, i.e. MAH, trade name, strength, pharmaceutical dosage form, pack size, package type, etc. This meant that the Vnr was unique for each article and package, i.e. 1 article = 1 package.

## 1.3 Barcode

In the 1980s, there was a need for machine-readable information (barcode) on packages for pharmaceuticals. The decision was that the leading format for barcodes, EAN, would be used. The barcode represents an identification code (GTIN) of a package. GTIN is a global standard for article numbering, administered by GS1, and consists of 13 digits (GTIN-13)

- Format (GTIN): Company prefix + article reference number + check digit

Since the Vnr was essential in the 1980s it was argued that the Vnr should be included in the barcode. To achieve this it was decided to modify the ID concept (GTIN) in the barcode for pharmaceuticals in the Nordic countries.

The Nordic format, called NTIN, has the same format as GTIN, 13 digits, but with a fixed prefix and a Vnr instead of a reference to the article.

- Format (NTIN): Nordic prefix (704626) + Vnr + check digit

## 1.4 Consequences of changed market requirements

Vnr and NTIN functioned well for a while, but the conditions have changed, e.g.

- Patient information leaflet was made mandatory
- Introduction of parallel import
- Computerisation of all steps in the processing of the prescription, from prescribing to dispensing to the patient at the pharmacy

When the market changed, the requirements changed as well but unfortunately not the guidelines for Nordic article numbers. Neither was there an actual supervision that the Vnr guidelines were adhered to. This led over time to that the guidelines have been interpreted differently by different companies, as well as between the Nordic countries.

The basic idea that 1 article = 1 package which has a Vnr and always is the same in the different Nordic countries therefore does not apply for all articles any longer. One example is that an article that is parallel imported from different countries may have:

- Same Vnr
- Different country of origin
- Different composition of the medicine – e.g. colouring substance
- Different packages - e.g. dimensions and appearance

An article may therefore today have several different packages with the same Vnr.

Since NTIN contains the Vnr, there can be only one NTIN per Vnr. The barcode will thereby be the same for all packages with the same Vnr, making it impossible to uniquely identify the different packages of an article.

A GTIN identifies a unique package. An NTIN identifies a unique package only if the article has only one package. Otherwise NTIN identifies the article, as the Vnr is a part of the NTIN format.

GTIN combined with Vnr makes it possible to uniquely identify the packages of an article, while the benefits of Vnr can be maintained, for example when prescribing.

	Possibility to uniquely identify			Would function with current	
	articles	packages	different packages of an article	prescribing routines (article & Vnr)	common Nordic articles
<b>Current situation</b>					
<b>Vnr + NTIN</b> (NTIN is not always unique)	Yes	No	No	Yes	Yes
<b>Possible scenario</b>					
<b>Vnr + GTIN / unique NTIN</b>	Yes	Yes	Yes	Yes	Yes

## 1.5 Increased demands – e-verification

The European directive<sup>1</sup> on falsified medicines prescribes mandatory, harmonised safety features on all prescription pharmaceuticals with certain exceptions. These safety features will consist of a unique package identity combined with tamper evidence. The goal is to prevent falsified medicines reaching patients in those cases where the falsified packages are not otherwise detected by authorities or other parts of the supply chain. The Directive was transposed into the Swedish Medicines Act<sup>2</sup> (*Läkemedelslagen*) on March 1, 2013.

EFPIA and LIF advocate a system for verification of pharmaceuticals (e-verification) based on GS1 2D DataMatrix, where GTIN is part of the identification. Most likely, this results in that most prescribed pharmaceutical packages in a few years will have GTIN. Each physical package will with e-verification have a unique combination of a serial number and GTIN entered into a European database at production. It thus becomes possible to verify and check off every single physical package at dispensing.

Note that in order to distinguish the different packages of an article it is necessary to always have a unique identity on package level (GTIN/unique NTIN). The reason for this is that there will be no database where it is shown to which of an article's different packages a serial number belongs. The serial number itself is thus not sufficient to identify the different packages of an article.

The introduction of e-verification will entail big changes and a lot of work. The barcode must be replaced with a 2D DataMatrix, and the production process needs to be changed so that a DataMatrix with a random serial number can be printed on each package. Manufacturing and often even the layout of the packages will be affected. The packages should also be tamper evident.

<sup>1</sup> 2011/62/EU  
[http://ec.europa.eu/health/files/eudralex/vol-1/dir\\_2011\\_62/dir\\_2011\\_62\\_sv.pdf](http://ec.europa.eu/health/files/eudralex/vol-1/dir_2011_62/dir_2011_62_sv.pdf)

<sup>2</sup> SFS 1992:859  
[http://www.riksdagen.se/sv/Dokument-Lagar/Lagar/Svenskforfattningssamling/Lakemedelslag-1992859\\_sfs-1992-859/?bet=1992:859](http://www.riksdagen.se/sv/Dokument-Lagar/Lagar/Svenskforfattningssamling/Lakemedelslag-1992859_sfs-1992-859/?bet=1992:859)

## 2 Current situation

If an article has only one package that is not changed, the Vnr/NTIN gives a unique identity. The problem is that the Vnr guidelines (<http://wiki.vnr.fi>) allow that an article that has several packages can have the same Vnr. It is not possible to change NTIN without changing the Vnr, which means that NTIN is not always changed even if the regulatory framework for GTIN so instructs, e.g. at modification of a package's dimensions. <http://www.gs1.org/1/gtinrules/index.php?lang=swedish>

From a patient safety perspective, it is important to identify the different packages of the same article, for example when:

- Prescribing and dispensing of prescriptions – such as parallel imported articles if the composition of the pharmaceutical differs e.g. colouring substance.
- Distribution – When the patient information leaflets are in different languages and with different content for the Nordic countries, but otherwise identical packages.

The use of identification concepts for articles and packages will continue to be adjusted to suit the needs. The only certainty is that the need to uniquely identify packages will increase.

A prerequisite for it to be possible to uniquely identify all packages of an article on the Nordic market is that the guidelines for Vnr (<http://wiki.vnr.fi>) and GTIN (<http://www.gs1.org/1/gtinrules/index.php?lang=swedish>) are followed.

## 3 LIF's recommendation

*From a patient safety perspective, it is important to be able to uniquely and easily identify an article and its packages. Therefore, it is LIF's recommendation to make a transition from NTIN to GTIN.*

It is no longer a requirement that the barcode for pharmaceutical products should contain a Vnr in the Nordic countries. This means that the identification concept in the barcode in the current situation may be an NTIN or a GTIN. Many articles, especially OTC, already have GTIN instead of NTIN as identity in the barcode.

LIF has set up a Task Force to monitor progress of the implementation of e-verification. It has also investigated how packages of an article should be uniquely identified. The recommendation is that a transition from NTIN to GTIN, combined with that the Vnr be printed on the package is the best option. This enables to change the code (GTIN) without changing the Vnr. In this way, a unique package ID is achieved, while at the same time the use of Vnr, for example when prescribing can continue undisturbed.

### 3.1 Planning the transition

*LIF's recommendation is for member companies to look into the situation regarding NTIN/GTIN, and investigate what a transition from NTIN to GTIN would entail – and subsequently decide when the transition should be implemented.*

It is up to each company to decide when the transition from NTIN to GTIN should take place. However, it may be advantageous to carry out the transition in the early stages. The introduction of e-verification will mean big changes and a lot of work. The barcode must be replaced with a 2D DataMatrix and production needs to be changed so that a DataMatrix with a random serial number can be printed on each package. Manufacturing and often even the layout of the packages will be affected. The packages should also be tamper evident.

An established number structure for GTIN and the processes for managing the GTIN at the company can facilitate the introduction of e-verification. Many companies already now use GTIN in other markets, which means that they in the future will not need to manage the Nordic market in a different way when it comes to GTIN.

### 3.2 Stepwise transition from NTIN to GTIN

*It is LIF's recommendation that the transition from NTIN to GTIN should be implemented no later than the entry into force of the EU directive on falsified medicines (e-verification), planned for the beginning of 2018.*

The transition from NTIN to GTIN can be done incrementally. A natural end date for non-unique NTIN is at the time of the introduction of e-verification, as e-verification requires unique NTIN/GTIN. In other words: Unique NTIN can continue to be used, but they must then be concordant with the guidelines for GTIN (<http://www.gs1.org/1/gtinrules/index.php?lang=swedish>) and thus changed when for example a package changes dimensions by more than 20 per cent.

The transition from NTIN to GTIN can begin now for articles with Nordic article numbers that are only used in Sweden, because the format (as defined in section 6) is the same for NTIN and GTIN and existing systems can handle both formats.

Until all pharmacies can read 2D DataMatrix, a change from NTIN to GTIN entails that the content of the barcode is changed. Thereafter, the change from NTIN to GTIN can be made by a transition from barcode to a 2D DataMatrix.

Even for articles with a common Nordic article number, transitions from NTIN to GTIN can begin now, but for those packages the transition must be synchronised in all countries affected.

By starting early, it is possible to make the transition from NTIN to GTIN gradually in conjunction with other changes, which saves time and resources.

## 4 What can you do now?

Since the fundamentals are different from company to company there are differences what a given company needs to do to achieve the transition from NTIN to GTIN. Many companies already use GTIN in markets outside the Nordic region. Even in the Nordic area, GTIN is used (Sweden and Finland 10 per cent, Denmark 5 per cent, Norway 4 per cent), especially when it concerns OTC.

In those cases where GTIN is already in use, for example in other markets, it is important to check with region and/or global HQ how GTIN should be managed and administered in Sweden.

Listed below are examples of activities that can be implemented within the company to plan the transition, and to be able to take decisions about when it is best for the company to make the switch NTIN/GTIN.

- Is GTIN today in use in Sweden 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; see contact information, to discuss how the transition from NTIN to GTIN for Nordic packages should be synchronised in the different markets.
- Check the conditions for when the 2D DataMatrix can begin to be printed on the company's packages.
- Make budget provision for the transition from NTIN to GTIN; see [www.gs1.se](http://www.gs1.se) for information on cost for GTIN.

The transition from NTIN to GTIN means that the company's entire article structure needs to be reviewed and verified. Different packages that in the current situation have the same Vnr and the same NTIN shall after the transition in some cases have the same Vnr but different GTIN. Such is the case for example for

- Parallel imported packages with different country of origin
- Common Nordic packages with different patient information leaflets for the different Nordic countries
- Packages that differ in dimensions and in other form of outer appearance
- Different composition of the medicine – e.g. colouring substance

In connection with that all items are verified, it is conducive to check that all the company's Nordic article numbers are correct. Contact PIC, Pharmaceutical Information Centre, which administers the Vnr system, and withdraw the Nordic article numbers that should no longer be active.



## 5 Contact information

The Vnr system is administered by the Nordic Number Centre (NNC)<sup>3</sup>, located at the Pharmaceutical Information Centre Ltd (PIC) (Lääketietokeskus Oy), Helsinki, Finland. [vnr@vnr.fi](mailto:vnr@vnr.fi)

**Sweden** Läkemedelsindustriföreningens Service AB, LIF

Tel: +46 8 462 37 00

E-mail: [info@lif.se](mailto:info@lif.se)

[www.lif.se](http://www.lif.se)

Questions regarding Nordic and national article numbers in Sweden can be directed to eHälsomyndigheten

Tel: +46 10 458 62 00

E-mail: [registrator@ehalsomyndigheten.se](mailto:registrator@ehalsomyndigheten.se)

[www.ehalsomyndigheten.se](http://www.ehalsomyndigheten.se)

**Finland** Pharmaceutical Information Centre Ltd

Tel. +358 9 6150 4950

E-mail: [vnr@vnr.fi](mailto:vnr@vnr.fi)

[www.laaketietokeskus.fi](http://www.laaketietokeskus.fi)

**Denmark** Dansk Lægemiddel Information A/S

Tel. +45 39 27 44 88

E-mail: [dli@dli.dk](mailto:dli@dli.dk)

[www.dli.dk](http://www.dli.dk)

**Norway** Legemiddelindustriforeningen

Tel. +47 23 16 15 00

E-mail: [lmi@lmi.no](mailto:lmi@lmi.no)

[www.lmi.no](http://www.lmi.no)

**Iceland** The Icelandic Federation of Trade

E-mail: [ift@ift.is](mailto:ift@ift.is)

[www.ift.is](http://www.ift.is)

---

<sup>3</sup> On behalf of the Nordic region's separate country associations: Dansk Lægemiddel Information A/S i Danmark, Pharmaceutical Information Centre Ltd i Finland, Lyfjastofnun på Island, Legemiddelindustriforeningen i Norge, and Läkemedelsindustriföreningens Service AB, i Sverige.

**GS1**

GS1 Sweden

Tel: +46 8 50 10 10 00

E-mail: [support@gs1.se](mailto:support@gs1.se)

GS1 Finland

Tel: +358 7 5756 3500

E-mail: [asiakaspalvelu@gs1.se](mailto:asiakaspalvelu@gs1.se)

GS1 Denmark

Tel: +45 39 27 85 27

E-mail: [info@gs1.dk](mailto:info@gs1.dk)

GS1 Iceland

Tel: +354 511 3011



E-mail: [info@gs1.is](mailto:info@gs1.is)

GS1 Norway

Tel: +47 22 97 13 20

E-mail: [firmapost@gs1.no](mailto:firmapost@gs1.no)

## 6 Definitions

Term	Definition
2D DataMatrix	<p>DataMatrix is a two-dimensional code, which most probably will be used in the e-verification system.</p> 
EAN	<p>The barcode EAN-13 is used to label consumer packages with a GTIN-13 (Global Trade Item Number, GS1-article number)</p> 
EFPIA	<p>European Federation of Pharmaceutical Industries and Associations – a European umbrella organisation for the pharmaceutical industry in Europe</p>
GS1	<p>GS1 is an international not-for-profit association with member organisations in over 100 countries. The GS1 standards, e.g. GTIN, are the most widely used supply chain standards in the world. <a href="http://www.gs1.se">www.gs1.se</a> or <a href="http://www.gs1.com">www.gs1.com</a></p>
GTIN	<p>Global Trade Item Number – A global standard for article numbering, which is administered by GS1.</p> <p>Format: Company prefix + article reference number + check digit</p> <p>May be presented in a barcode for automated reading.</p> <p>A GTIN in a database is an alphanumeric field with only numeric characters.</p> <p>In a database GTIN shall always have 14 digits. If the article refers to a consumer article, and has 13 digits; e.g. in an EAN-13 barcode the same article in the GS1 DataMatrix always has 14 digits. The first digit is then an "0" (zero).</p> <p>Guidelines for GTIN:  <a href="http://www.gs1.org/1/gtinrules/index.php?lang=swedish">http://www.gs1.org/1/gtinrules/index.php?lang=swedish</a></p>
LIF	<p>Läkemedelsindustriföreningens Service AB, LIF, is the trade association for the research-based pharmaceutical industry in Sweden. LIF represents around 80 companies that produces 80 per cent of all pharmaceuticals that are sold in Sweden – <a href="http://www.lif.se">www.lif.se</a></p>
MAH	<p>Marketing Authorisation Holder</p>

Term	Definition
NNC	Nordic Number Centre (Nordiska nummercentralen) administers the Nordic article numbers. It is located at the Pharmaceutical Information Centre Ltd (PIC) (Lääketietokeskus Oy), Helsinki, Finland. <a href="mailto:vnr@vnr.fi">vnr@vnr.fi</a>
Nordic article number (Vnr)	All marketed pharmaceuticals in Sweden must have a Nordic article number, Vnr, on the packages. The Nordic article number is a six-digit code (00 00 01-19 99 99 and 37 00 00-59 99 99), which is given to all human and veterinary medicines. The aim is that the package should be identifiable at all stages in the supply chain, from the producing company to wholesale distributors, pharmacies and governmental agencies.  Guidelines for Nordic article numbers: <a href="http://wiki.vnr.fi">http://wiki.vnr.fi</a>
NTIN	National/Nordic Trade Item Number – Presently used instead of GTIN for pharmaceuticals in the Nordic countries. NTIN has the same format as GTIN, but with a fixed prefix and a Vnr instead of a reference to an article.  Format: Prefix of Nordic Number Centre (704626) + Vnr + check digit
OTC	Over the counter - pharmaceuticals available without a prescription
PIC	Pharmaceutical Information Centre – <a href="http://www.laaketietokeskus.fi/en">http://www.laaketietokeskus.fi/en</a>  Administers the Nordic article number
Serial number	A unique randomised number – up to 20 alphanumeric characters
Vnr (Nordic article number)	All marketed pharmaceuticals in Sweden must have a Nordic article number, Vnr, on the packages. The Nordic article number is a six-digit code (00 00 01-19 99 99 and 37 00 00-59 99 99), which is given to all human and veterinary medicines. The aim is that the package should be identifiable at all stages in the supply chain, from the producing company to wholesale distributors, pharmacies and governmental agencies.  Guidelines for Nordic article numbers: <a href="http://wiki.vnr.fi">http://wiki.vnr.fi</a>