Vnr

Nordic Article Number

Instruction booklet

Version 1.7

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History

Date	Version	Comment	Author
2013-03-25	1.0	New document	Hans Andersson
2014-01-22	1.1	Changed names from Apotekens Service to eHälsomyndigheten. The e-mail address has been changed to registrator@ehalsomyndigheten.se	Hans Andersson
2014-08-13	1.2	Sentence changed: Vnrs are not needed for sample medicines and products on compassionate use programme, radiopharmaceuticals or, except for Iceland, immunological veterinary medicines	PIC
2014-09-09	1.3	Sentence changed: Vnrs are not needed for sample medicines, products on compassionate use programme or for radiopharmaceuticals. In Finland immunological veterinary medicines are also excluded from the Vnr requirement.	PIC
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2016-04-05	1.5	4.1 removed sentence “A Vnr is only allowed to have the status Assigned for three years. If the Vnr has not been marketed within this time period, the status of the Vnr will be changed to Withdrawn.“ 8.1.1 Added GS1 links	PIC
2016-09-26	1.6	6.4 removed sentence “Note that the instructions for Denmark differs from the other Nordic countries, see chapter 10.1.2 Denmark” Sections 10.1.2 and 10.1.3 regarding Denmark removed	PIC
2017-05-10	1.7	Section 5.7 made clearer and the notification regarding the need of different GTINs added	PIC

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Nordic Article Number (Vnr) – Instruction booklet

In this document the common Nordic instructions for Vnrs are described.

In addition to the Nordic instructions, there may be additional country specific guidelines, described in separate documents per country.

Definitions of keywords are found in chapter 13.

1 Nordic Article Number (Vnr)

The Nordic Article Number (Vnr) is an identification code for a specific article of medicine with marketing authorisation 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.

Vnrs are not needed for sample medicines, products on compassionate use programme or for radiopharmaceuticals. In Finland immunological veterinary medicines are also excluded from the Vnr requirement.

A Vnr can cover one, several, or even all Nordic countries if certain criteria are met, see chapter 5 *Criteria for Nordic Article Number*.

It is extremely important that manufacturers working with products on the market realize that the Vnr is a critical attribute. It functions as an information carrier between a number of IT-systems involved in the prescription, dispensing, ordering, supply, storage and information on medicines. The usage of the Vnr 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 Vnr is mixed with another Vnr or if it is incorrect in some way. Therefore, all Vnr changes must strictly follow these guidelines for management of Vnrs.

The labelling of transport and primary packages falls outside the instructions relating to Nordic article numbering.

1.1 National article number

The remaining six-digit-codes (200000-369999 and 600000-999999), which are not *Nordic* Article Numbers (000001-199999 and 370000-599999), are called *National* article numbers. They are used differently in the Nordic countries, for instance for consumer products (e.g. shampoo, etc.), medical devices (e.g. blood glucose test strips and colostomy bags), as well as for compounded drugs provided under special licence and extemporaneous preparations. This means that the same National article number is used for different articles in different countries.

2 Nordic Number Centre (NNC)

The administration of the Vnr system is under responsibility of the Nordic Number Centre (NNC)[1], located at Pharmaceutical Information Centre Ltd (PIC) (Lääketietokeskus Oy), Helsinki, Finland.

Each manufacturer with products on the Nordic pharmaceutical market is responsible for informing NNC/PIC of any changes regarding Nordic Article Numbers.

Routines for information and cooperation between manufacturers and NNC are specified by NNC, and available through the Vnr extranet service (https://vnr.fi) and e-mail vnr@vnr.fi.

[1] On behalf of the Nordic country organisations Dansk Lægemiddel Information A/S in Denmark, Pharmaceutical Information Centre Ltd in Finland, The Icelandic Federation of Trade, Legemiddelindustriforeningen in Norway, and Läkemedelsindustriföreningens Service AB, LIF, in Sweden.

3 Application for Nordic Article Number

Nordic Article Numbers can be ordered swiftly by using the Vnr extranet service: https://vnr.fi. A user name and a password can be obtained on the website https://vnr.fi.

In the Vnr extranet service companies can also see the current information of all their Nordic Article Numbers. The processing time for a Nordic Article Number order, when using the Vnr extranet service, is no more than three working days.

Application for a Nordic Article Number should be made when the Marketing Authorisation Holder (MAH) knows which packages will be marketed and really need Vnrs. Technically Vnrs can be applied for at any time. However, a Vnr should be used on the market within three years. Otherwise the status of the Vnr will be changed to Withdrawn, see chapter 4 *Vnr status administration*.

NNC will only provide Vnr information to the owner of the article in question. All other requests for article information will be referred to the National administrators of product- and article information, see chapter 12 *Contact information*.

Vnr information is undisclosed until the marketing authorisation has been approved.

Sometimes there is a need to specify for which markets a certain Vnr can be used. A Vnr can therefore be “unlocked” or “locked”.

- Unlocked — The Vnr can be used for the same article in any Nordic country, as long as the criteria for using the same Vnr in several countries are met.

  This means that the Vnr will automatically be allocated to a new country when a Vnr is applied for with the same article information.

  Unlocked is the default setting.

- Locked — The Vnr can only be used in the specified country/countries.

  This means that a new Vnr will be allocated to a new country when a Vnr is applied for with the same article information.

  If a Vnr is locked and it is desired to use the locked Vnr in another country, the holder of the Vnr in the country/countries, where the Vnr is locked, must approve the usage in the additional country in advance.

  It is the responsibility of the company to specifically confirm that the unlocking in the original country/countries can be performed.

When applying for a Vnr the applicant must select whether the Vnr should be unlocked or locked. Unlocked is the default setting.

4 Vnr status administration

An article can have three different statuses in the Vnr system:

- Assigned
- On market
- Withdrawn

In order for NNC to take correct decisions it is important that the status of an article in each country is correct in the Vnr system. It is therefore the responsibility of the company to inform NNC about changes in the status of an article for each country.

Note that the status of a Vnr can vary between countries.

4.1 Assigned

Assigned is the status of an article, which not yet has been marketed.

Normally this status should only be used for a short period of time, since Vnrs should be applied for when the marketing authorisation holder knows which packages will be marketed and really need Vnrs.

Since articles with the status Assigned have never been on the market, it is easier to change the information of these articles than for articles, which have been on the market.

When an article is to be marketed the status must be changed to On market. An article may not be marketed in a country where its Vnr has the status Assigned.

4.2 On market

When an article is marketed in a country, the status of the Vnr is “On market”.

NOTE - When an article has been launched on the market it is difficult to change the information without changing the Vnr. This is also true if an article has been on the market in another Nordic country with the same Vnr.

4.3 Withdrawn

A Vnr can have the status Withdrawn in one or several countries.

It is absolutely forbidden to reuse a withdrawn Vnr for *another* article.

In some cases NNC may reactivate a withdrawn Vnr if the article is exactly the same and if all the information is still relevant. This can only take place after direct contact with, and decision by, NNC.

5 Criteria for Nordic Article Number (Vnr)

A Nordic Article Number can be approved to cover one, several, or even all Nordic countries.

Six basic criteria are mandatory and need to be met equally in all countries concerned if a Vnr is to be used in more than one country.

- Trade name
- Marketing authorisation holder (MAH)
- Pharmaceutical dosage form
- Strength
- Pack size
- Type of package

5.1 Trade name

The trade name of the article must be *exactly* the same in all countries where a Vnr will be used. Even small differences in trade name are *not* permitted.

For example: Alvedon vs. Alvedone

5.2 Marketing authorisation holder (MAH)

The marketing authorisation holder does not necessarily have to be the same in all concerned countries where a Vnr is used, but the MAH must belong to the same group of companies (same consolidated corporation) or be an official representative for the MAH.

For example:	Group of companies:	Company group name	
	MAH:	Denmark:	Company name A/S
		Finland:	Company name Oy
		Iceland:	Company name hf
		Norway:	Company name AS
		Sweden:	Company name AB

5.3 Pharmaceutical dosage form

The pharmaceutical dosage form must be the same in all concerned Nordic countries where the same Vnr is used. However, linguistic differences in presenting the pharmaceutical dosage form can be approved as long as the composition of the product is the same and the term used complies with the EU Standard Terms.

For example:	*European standard term:*	*Tablet*
	Danish:	Tablet
	Finnish:	Tabletti
	Icelandic:	Tafla
	Norwegian:	Tablett
	Swedish:	Tablett

This means, for example, that it is not permitted to use the same Nordic Article Number for tablets in one country and capsules in another, or tablet in one country and film coated tablet in another.

5.4 Strength

The strength must be the same in all concerned Nordic countries where the same Vnr is used. However, some differences in presenting the strength might be approved after discussion with NNC.

5.5 Pack size

The pack size must be the same in all Nordic countries where the same Vnr is used for an article, for instance number of tablets or ml.

5.6 Type of package

The type of package must be the same in all Nordic countries where the same Vnr is used for an article, for instance blister, jar or bottle.

The package material must also be the same in all countries. It is not allowed to have a glass jar in one country and a plastic jar in another, or a glass vial in one country and a plastic vial in another.

5.7 Package appearance and/or package information leaflet

If the six criteria above are fully met, but the text on the package and/or the appearance of the package and/or the package information leaflet differs within the Nordic countries, an unlocked common Vnr can still be approved. However, in this case the packages with the same Vnr should be separated with different GTINs.

6 Impact on Vnr when an article and/or package is changed

NOTE - All changes of an article and its package must be informed to, and confirmed with, NNC/PIC in advance.

The general rule is that the Vnr must be changed if any of the six basic criteria described in chapter 5 has been changed, or no longer is valid.

In many cases it is not mandatory, but most often recommended, to change the Vnr, since it thereby will be obvious to all stakeholders that the article somehow has been changed.

Changes can easily be made for Vnrs, which never have been on the market (status Assigned) in *any* country. Only in very special cases and rarely can a Vnr be kept when an article or its package, which has been on a market, is changed. Usually a new Vnr is required.

It is absolutely forbidden to reuse a withdrawn Vnr for *another* article.

In some cases NNC may reactivate a withdrawn Vnr if the article is exactly the same and if all the information is still relevant. This can only take place after direct contact with, and decision by, NNC.

In order for NNC to take correct decisions it is important that the status of an article in each country is correct in the Vnr system. It is therefore the responsibility of the company to inform NNC about changes in the status of an article for each country.

6.1 Introduction of a new pharmaceutical product to the market

Nordic Article Numbers should be applied for as close to the marketing authorisation as possible.

If the article already has a Vnr NNC still must be informed before the introduction of the article to the market.

For further information, see chapter 3 *Application for Nordic Article Number*.

6.2 Change in the composition of the article

If the active substance of a product is altered in any way, a new Nordic Article Number must be assigned to the article.

If the change only concerns an excipient, the Vnr does not need to be changed. However, the Vnr may be changed to mark that the article has been changed. Please contact NNC to discuss the specific situation.

6.3 Change of trade name

It is recommended that the Vnr is changed when the trade name of the product changes.

If agreed upon in advance with NNC the Vnr, in certain situations, can be maintained:

- The article only exists in one country
- The trade name change takes place more or less at the same time (within a few months) in all Nordic countries. If it takes longer the Vnr must be changed.

Note that the instructions for Denmark differs from the other Nordic countries, see chapter 10.1.1 *Denmark*.

Note that there, for some countries, may be further country specific guidelines.

6.4 Change of marketing authorisation holder (MAH)

The same Vnr can be maintained if the MAH is changed at the same time in all Nordic countries and if the old and the new MAH agree on this. It should be noticed, that the sales statistical history moves to the new MAH together with the Vnr.

When a product changes MAH all other but withdrawn Vnrs associated with the product must be moved to the new MAH. Thereafter the Vnrs can be continuously used or changed. The status of not needed Vnrs may be changed to Withdrawn, but the Vnrs must *not* be directly deleted from the national product and article registers.

Please contact NNC to discuss the specific situation.

Note that there, for some countries, may be further country specific guidelines.

6.5 Change of the marketer

If all other article information remains the same, the same Vnr can be maintained. However, NNC must be informed about changes in marketer in advance.

Please note that Vnrs are found in the Vnr extranet service under marketer companies, but Vnrs belong to the MAH.

6.6 Change of pharmaceutical dosage form

NNC must be informed about all changes of the pharmaceutical dosage form.

Linguistic differences in presenting the pharmaceutical dosage form can be approved as long as the composition of the product is the same and the term used complies with the EU Standard Terms, see chapter 5.3 *Pharmaceutical dosage form*. However, NNC must be informed in advance for confirmation.

6.7 Change of strength

A change in strength always results in a new article that needs a new Vnr, see chapter 5.4 *Strength*.

6.8 Change of pack size

The pack size must be the same in all concerned Nordic countries where the same Vnr is used, for instance number of tablets or ml.

6.9 Change of package type

In most cases the Vnr needs to be changed.

Please contact NNC for further information, when considering changing package type or package material.

Note that there, for some countries, may be further country specific guidelines.

6.10 Change of Rx / OTC

An OTC-package is by definition a different package compared to the corresponding Rx-package and must therefore carry different Vnrs if both packages are on the market at the same time.

6.10.1 Switch Rx -> OTC

If a switch is made from RX to OTC the Vnr should be changed, since the requirements for package text, package leaflet etc. differ.

6.10.2 Switch OTC -> Rx

If a switch is made from OTC to Rx the Vnr can be maintained.

Note that the instructions for Norway differs from the other Nordic countries, see chapter 10.2 Norway.

6.11 Withdrawal of a Vnr

A Vnr can have the status Withdrawn in one or several countries.

It is absolutely forbidden to reuse a withdrawn Vnr.

Companies can notify Vnr withdrawals at any time by using the withdrawal function in the Vnr extranet service.

Note that there, for some countries, may be further country specific guidelines.

7 Frequently Asked Questions

7.1 May a Vnr, if it is already in use in one or several other Nordic countries, automatically be taken into use in another country?

No, NNC must confirm that the Vnr can be used in a new country.

In order for a Nordic Article Number to be used in several countries the article must meet the six basic criteria, see chapter 5 *Criteria for Nordic Article Number*.

A Vnr can be unlocked or locked. If the Vnr is unlocked the Vnr will automatically be allocated to a new country when a Vnr is applied for with the same article information.

If a Vnr is locked and it is desired to use the locked Vnr in another country, the holder of the Vnr in the country/countries, where the Vnr is locked, must approve the usage in the additional country in advance.

7.2 May a medical device have a Nordic Article Number?

A medical device cannot have a Vnr, as they are only used for pharmaceutical products.

However, medical devices can have *National* article numbers.

Note that there, for some countries, may be further country specific guidelines.

7.3 May a compounded drug provided under special licence have a Vnr?

An article without marketing authorisation cannot have a *Nordic* Article Number. However, a compounded drug provided under special licence and extemporaneous preparations can have a *National* article number.

Note that there, for some countries, may be further country specific guidelines.

7.4 May an identical parallel imported article originating from different export countries have *the same* Vnr in a country and in different countries?

Identical parallel imported pharmaceuticals originating from different export countries *should* have the same Nordic Article Number in a country.

If they fulfil the conditions for common Nordic packs they *could* have the same Vnr in the different Nordic countries despite differing MT-numbers.

7.5 Transport packages and primary packages

The labelling of transport packages and primary packages falls outside the rules relating to Vnrs.

8 Barcode

It is not mandatory, but highly recommended, that all pharmaceutical packages with a marketing authorisation should have a machine-readable barcode printed on the package.

The standard of the barcode on pharmaceuticals in the Nordic countries is EAN, which contains an identification number on the format GTIN (changed names from EAN in 2003).

8.1 Format of the barcode

The format of the barcode should be EAN-13, or where this is not possible EAN-8, i.e. the package is so small that there is not enough space for an EAN-13 barcode.

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 still handled manually. It was therefore argued 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.

8.1.1 GTIN

A GTIN-13 consists of 13 digits on the format:

Company's prefix + article reference number + check digit
A GTIN-8 consists of 8 digits on the format:

7 3 X X X X S C

- 73XXXX GS1-8-prefix – a six-digit company prefix allocated by GS1
- S one digit article reference number allocated by the company (1,2,3…0)
  This means that GTIN-8 can be used to number up to 10 packages.
- C Check digit calculated in accordance with a GS1 algorithm

For more information regarding GTINs, please see the local GS1 webpages

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

8.1.2 NTIN

An NTIN-13 has the same format as a GTIN-13, i.e. 13 digits, but with a fixed prefix and a Vnr instead of an article reference number.

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

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

8.2 Transfer from NTIN to GTIN

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.

The European directive on falsified medicines prescribes mandatory, harmonised safety features on all prescription pharmaceuticals. These safety features will consist of a unique package identity combined with tamper evidence. Only unique NTINs or GTINs should be used as barcodes.

For more information on GTINs, please see http://wiki.vnr.fi/?page_id=1671.

9 Multi packages

There are two kinds of multi packages.

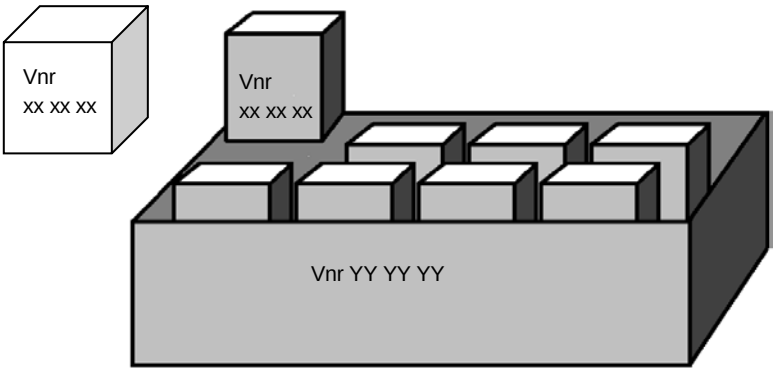
9.1 The single packages of a multi package have market authorisation

A registered multi package can contain units with marketing authorisation as separate packages, e.g. 10x100 tablets.

The single packages within a multi package may have the same Vnr (Vnr XX XX XX) as the registered separate single packages on the market.

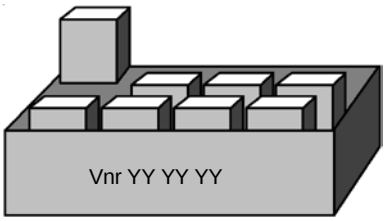
The Vnr of the multi package (Vnr YY YY YY) must differ, and may not appear on the single packages inside.

Note that the instructions for Denmark differs from the other Nordic countries, see chapter 10.1.3 *Denmark*.



9.2 Only the multi package has a market authorisation

A registered multi package can contain units, without market authorisation. In this case the single packages must not have a Vnr, but the multi package must have a Vnr number (Vnr YY YY YY).



10 Differences between the Nordic countries regarding Vnr

10.1 Denmark

10.1.1 Change of trade name

A new Vnr must always be applied for when the trade name of the product changes.

10.2 Norway

10.2.1 Change of Rx / OTC

In Norway the general view is that a Rx- and an OTC-pack always should carry different Vnrs regardless of the direction of the switch (Rx/OTC or OTC/Rx).

11 Pricing of Nordic Article Numbers

The cost for NNC is divided between the Nordic countries.

Each country decides how to cover its cost.

Therefore the charges for Vnrs may differ between Nordic counties. For more information please contact NNC.

12 Contact information

The administration of the Vnr system is under responsibility of the Nordic Number Centre (NNC)[2], located at Pharmaceutical Information Centre Ltd (PIC) (Lääketietokeskus Oy), Helsinki, Finland. vnr@vnr.fi

12.1 Denmark

Dansk Lægemiddel Information A/S
Strødamvej 50 A
2100 København Ø
Tel. +45 39 27 44 88
E-mail: dli@dli.dk

www.dli.dk

[2] On behalf of the Nordic country organisations Dansk Lægemiddel Information A/S in Denmark, Pharmaceutical Information Centre Ltd in Finland, The Icelandic Federation of Trade, Legemiddelindustriforeningen in Norway, and Läkemedelsindustriföreningens Service AB, LIF, in Sweden.

12.2 Finland

Pharmaceutical Information Centre Ltd
Korkeavuorenkatu 35
00130 Helsinki
FINLAND
Tel. +358 9 6150 4950
Fax. +358 9 6150 4941
E-mail: vnr@vnr.fi

www.laaketietokeskus.fi

12.3 Iceland

The Icelandic Federation of Trade
Hus verslunarinnar
Kringlan 7
103 Reykjavík, Iceland
E-mail: ift@ift.is
Website: www.ift.is

12.4 Norway

Legemiddelindustriforeningen
Postboks 5094 Majorstuen
NO-0301 Oslo
Tel. +47 23 16 15 00
E-mail: lmi@lmi.no

www.lmi.no

12.5 Sweden

Läkemedelsindustriföreningens Service AB, LIF
Box 17608
118 92 Stockholm
Tel: +46 8 462 37 00
E-mail: info@lif.se

www.lif.se

Any questions about Vnrs and National article numbers in Sweden can be directed to eHälsomyndigheten: registrator@ehalsomyndigheten.se

13 Definitions

GS1	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. www.gs1.se or www.gs1.com
GTIN	Global Trade Item Number – a global standard for article numbering administered by GS1. Consists of 13, maximum 14, digits on the format company´s prefix + article reference number + check digit. Can be presented in a barcode for automatic reading.
MAH	Marketing Authorisation Holder
Marketer	Company that represents the product (often the same as MAH)
National article number	A six-digit code (200000-369999 and 600000-999999) used in the pharmacies for articles, which are not human or veterinary medicines. The same article number can be used for different articles in different Nordic countries.
NNC	The administration of the Vnr system is under responsibility of the Nordic Number Centre (NNC), located at Pharmaceutical Information Centre Ltd (PIC) (Lääketietokeskus Oy), Helsinki, Finland. vnr@vnr.fi
Nordic Article Number	Vnr – a six-digit identification code (000001-199999 and 370000-599999) for a specific article of medicine with marketing authorisation in the Nordic countries. A Vnr is given to all human and veterinary medicines. It enables a simple verification of articles at all distribution stages.
NTIN	National/Nordic Trade Item Number – Used instead of GTIN for pharmaceuticals in the Nordic countries. Same format as GTIN (13, maximum 14, digits) but with a fixed prefix and a Vnr instead of an article reference number. Format: prefix of Nordic Number Centre (704626) + Vnr + check digit
OTC	Pharmaceuticals available without a prescription.
PIC	Pharmaceutical Information Centre – http://www.laaketietokeskus.fi/en
Rx	Pharmaceuticals only available with a prescription
Vnr	Nordic Article Number – a six-digit identification code (000001-199999 and 370000-599999) for a specific article of medicine with marketing authorisation in the Nordic countries. A Vnr is given to all human and veterinary medicines. It enables a simple verification of articles at all distribution stages.