# Nordic & National article numbers

Country specific information

# Sweden

Version 1.2

# History

Date	Version	Comment	Author
2013-03-25	1.0	New document	Hans Andersson
2013-11-25	1.1	Section 3.4 and 4.2-#6 Updated with information that TLV requires the company to send a new application for reimbursement if the package is changed.	Hans Andersson
2014-01-22	1.2	Changed names from Apotekens Service to eHälsomyndigheten in the whole document. The e-mail address has been changed to <u>registrator@ehalsomyndigheten.se</u> and the webpage to <u>www.ehalsomyndigheten.se</u>	Hans Andersson

# Index

Art	Article numbers - Country specific information - Sweden		
1	The flow of product and article information	5	
2	Vnr – stakeholders' different needs	7	
2.1	Medical Product Agency - Läkemedelsverket (regulatory control)	7	
2.2	TLV (prices)	8	
2.3	eHälsomyndigheten (VARA – a national product and article register)	8	
2.4	Wholesale distributors (distribute)	8	
2.5	Health care (prescribe)	9	
2.6	Pharmacies (logistics and dispensing)	9	
3	Impact on Vnr when an article and/or its package changes	10	
3.1	What happens when an incorrect Vnr has been saved in NPL?	10	
3.2	Change of trade name	11	
3.3	Change of marketing authorisation holder (MAH)	12	
3.4	Change of package type	12	
3.5	Change of Rx / OTC	12	
3.6	Can old Vnrs be removed from NPL for articles, which are not marketed?	13	
3.7	May a Vnr be reused?	13	
3.8	How is the previous Vnr handled in NPL when a Vnr is changed?	13	

Version: 1.2 Document name: Nordic & National article numbers – Country specific information (Sweden)

have the same Vnr in a country and in different countries?	13
4 Checklists	14
4.1 New Vnr	14
4.2 Change of Vnr	14
4.3 Withdrawal of Vnr	17
5 Vnr – layout and allocation	18
5.1 Layout of the Vnr	18
5.2 Allocation of the Vnr	18
6 Pricing of Nordic Article Numbers	18
7 Use of article number series	19
8 Läkemedelsbranschens nummernämnd, LNN	21
9 Contact information	22
9.1 Sweden	22
9.2 Country specific information – other Nordic countries	22
10 Definitions	23

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

## Article numbers - Country specific information - Sweden

In this document information related to the handling of article numbers in Sweden is presented.

The common Nordic guidelines of Vnr is presented in Vnr – Nordic instruction booklet - see <a href="http://wiki.vnr.fi/">http://wiki.vnr.fi/</a>

Country specific information for the other Nordic countries can be found in separate documents per country:

- Denmark Not yet available
- Finland see <u>http://wiki.vnr.fi/</u>
- Iceland
   Not yet available
- Norway see <u>http://wiki.vnr.fi/</u>

Definitions of keywords are found in chapter 10.

## 1 The flow of product and article information

eHälsomyndigheten has the national responsibility to compile and supply a national product and article register to the Swedish market. The purpose of the register, called VARA, is to supply the Swedish market with up to date and quality assured product and article information for the approved pharmaceuticals on the market in Sweden and consumer products within the reimbursement system.

VARA is distributed to all pharmacies, veterinarian health care systems, system suppliers, statistics stakeholders and SIL, Svensk Informationsdatabas för Läkemedel. SIL in turn distributes the VARA information to health care actors. All health care systems should be integrated with SIL.

Figure 1 shows the VARA system at eHälsomyndigheten and its sources. VARA daily collects and compiles updates from NPL.

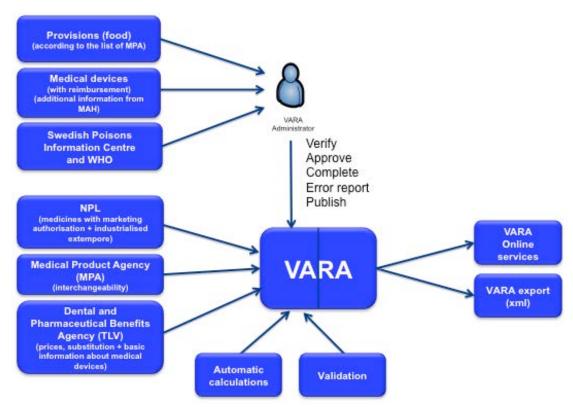


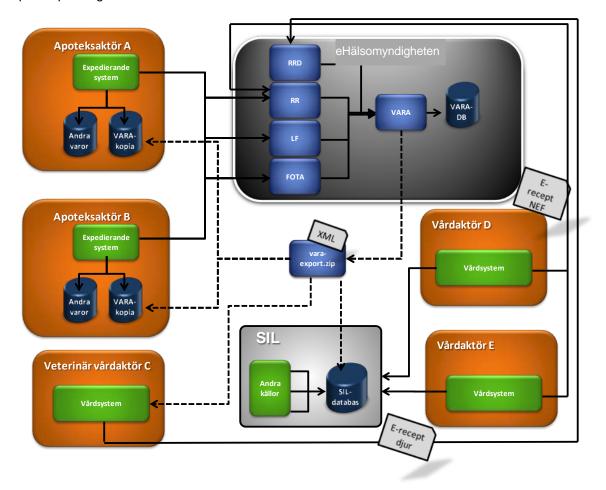
Figure 1 The VARA system and its sources

The quality of data in VARA is vital, and the information in VARA is therefore updated in accordance with a well-defined input process. All changes are validated with automatic validity checks, and are thereafter reviewed and approved by pharmacists before they are published once a day.

It is the responsibility of the information owners, such as TLV, MPA (LV) and pharma companies to deliver quality assured information to VARA and quickly correct any deviations.

Pharmacies are required to update their systems with information from VARA daily in order to be able to file prescriptions from Receptdepån at eHälsomyndigheten. Currently SIL and health care systems are updated with VARA information approximately once a week.

Date: 2013-03-25 Last updated: 2014-01-21 Version: 1.2 Document name: Nordic & National article numbers – Country specific information (Sweden) Figure 2 shows how dispensing systems at pharmacies use a local copy of VARA and how central systems such as Receptdepå (RR)/receptdepå djur (RRD), Läkemedelsförteckningen (LF), and Försäljningstransaktionsregistret (FOTA) at eHälsomyndigheten are directly linked to VARA. The figure schematically also shows how health care actors have access to VARA via SIL alternatively for veterinarian health care systems directly from eHälsomyndigheten, and how electronic prescriptions get into RR/RRD.



Swedish	English
SIL	SIL
SIL-databas	SIL database
Andra källor	Other sources
E-recept djur	E-presription animals
Apoteksaktör A-B	Pharmacy Actor A-B
Expedierande system	Dispensing system
Andra varor	Other articles
VARA-kopia	VARA (copy)
Veterinär vårdaktör C	Veterinarian health care actor C
Vårdsystem	Health care system
Vårdaktör D-E	Health care actor D-E
Vårdsystem	Health care system

Figure 2 VARA, pharmacies and health care actors

Date: 2013-03-25 Last updated: 2014-01-21 Version: 1.2 Document name: Nordic & National article numbers – Country specific information (Sweden)

## 2 Vnr – stakeholders' different needs

This chapter describes how different stakeholders use, and are dependent on, Vnrs in the handling of pharmaceuticals and reimbursed consumer products on the Swedish market.

In Sweden there is not a single identification code, which provides a unique identity for all pharmaceuticals, medical devices, and consumer products. However, the Vnr has, in combination with other identification codes, a very important function in the handling of pharmaceuticals on the Swedish market.

It is extremely important that manufacturers working with products on the Swedish market are aware 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, storage and information regarding 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 or incorrect.

In order for the distribution chain to function safely, it is important to know when and how an article should change Vnrs.

An error in a Vnr may result in unexpected and serious consequences. The result of an incorrect Vnr can be that a pharmaceutical loses its identification or is identified as a completely different pharmaceutical. After the reregulation of the pharmacy market the systems of the stakeholders have became highly automated and integrated, which further increases the need for correct Vnrs in order for the management of pharmaceuticals to function efficiently and safely.

In Sweden, the handling of Vnrs is funded through the FASS-charge and therefore there is no direct cost associated with acquiring a Vnr.

The administration of the Vnr system is under responsibility of the Nordic Number Centre, (NNC)<sup>1</sup>, <u>vnr@vnr.fi</u>, located at Pharmaceutical Information centre Ltd. (Lääketietokeskus Oy), Helsinki, Finland.

## 2.1 Medical Product Agency - Läkemedelsverket (regulatory control)

The Medical Product Agency (Läkemedelsverket) use NPL id and NPL pack id as identification codes. Vnrs are not used, but in NPL there is a field for Vnr, which the responsible company adds together with other information.

<sup>&</sup>lt;sup>1</sup> On behalf of the Nordic country organisations Dansk Lægemiddel Information A/S in Denmark, Pharmaceutical Information Centre Ltd in Finland, Lyfjastofnun in Iceland, Legemiddelindustriforeningen in Norway, and Läkemedelsindustriföreningens Service AB, LIF, in Sweden.

## 2.2 TLV (prices)

Please read TLV's document *Information om ändringar i NPL som kan beröra subvention av läkemedel.* The document is available on the website of TLV: <u>http://www.tlv.se/lakemedel/ansok-om-pris-eller-subvention/information-om-andringar-i-nationellt-produktregister-for-lakemedel-npl/</u>

#### 2.3 eHälsomyndigheten (VARA – a national product and article register)

eHälsomyndigheten has the national responsibility to compile and supply a national product and article register to the Swedish market. The purpose of the register, called VARA, is to supply the Swedish market with up to date and quality assured product and article information for the approved pharmaceuticals on the market in Sweden and consumer products within the reimbursement system.

It is the responsibility of the information owners, such as TLV, MPA (LV) and pharma companies to deliver quality assured information to VARA and quickly correct any deviations.

Since information in NPL is distributed via VARA to the various stakeholders in the market, which in turn uses the information in a variety of situations and systems, it is very important that the Vnrs saved in NPL are correct. Changes in NPL are transferred and updated automatically in subsequent systems. Please be very careful when entering the Vnr. Notify eHälsomyndigheten and correct immediately if an error occurs. When the flag "On the market" once has been set and saved to "yes" the article information will always be distributed from VARA.

If an incorrect Vnr has been saved in NPL, and it is discovered later, prescription on the Vnr may have occurred. In such a situation - always contact eHälsomyndigheten to discuss how the situation should be handled. It is very important not to delete, edit or otherwise modify the incorrect information without first consulting with eHälsomyndigheten, since it can have major consequences in subsequent systems.

When a pharma company is about to change a specific Vnr, it is important to make the change in NPL a couple of days before the new packages are available at the distributor. The reason for this is to synchronize the change of Vnr between the pharmacies and the distributor in order to maintain the whole distribution chain. If the change of Vnr is done too early or too late in NPL, there is a risk that the pharmacies purchase orders won't be recognized by the distributor.

#### 2.4 Wholesale distributors (distribute)

Currently the distribution systems of the two main distributors in the Swedish market, Oriola and Tamro, use Vnrs to identify articles.

Vnrs are used throughout the whole distribution chain from pharma companies to the patient, e.g. purchase orders, inventory management and traceability according to GDP. In addition, all pharmacies currently order on Vnrs.

When the same Vnr is used in several Nordic countries for an identical article where only the product information leaflet in the packages is different there are problems in the handling of the article, since it is not visible on the package for which country the package is intended. If an article is sent to the wrong country it results in withdrawals.

#### 2.5 Health care (prescribe)

Currently the handling of pharmaceuticals in health care would not function without Vnrs.

Most health care systems currently use Vnrs to identify pharmaceuticals when medicines are prescribed. It is therefore important that the Vnrs are updated and correct.

To be able to follow the information about a pharmaceutical over time, it is important that the article history of Vnrs is complete and clear, and that as few changes as possible are made to the article.

#### 2.6 Pharmacies (logistics and dispensing)

Vnrs are necessary for many of the processes in pharmacies. They play a central role in

- Ordering from different pharmaceutical distributors and all parts of stock management in all kinds of pharmacies
- Dispensing with the support of the IT-systems for prescription dispensing in retail pharmacies, dose dispensing pharmacies, hospital pharmacies and distance pharmacies
- Ordering and dispensing of e-prescriptions, customer service etc.
- Management of article information in article repositories and article information in intra- as well as internet information systems
- Ordering systems for hospitals

The Vnrs are the information carriers between different IT-systems. This can be exemplified by the situation when a doctor is prescribing electronically to the national e-prescription database. The doctor prescribes a certain product and the information sent from his computer to the e-prescription database is *only the Vnr* for this product.

When the pharmacist dispenses this product the prescription is picked up from the e-prescription database and again the information about the selected product is transferred between the two systems *in the form of the Vnr* for the product. Also in the work with dispensing, handling reimbursement and payment etc. it is the Vnr that is used for transferring information between different systems.

Due to the important role of Vnrs in the management of prescribed drugs it is crucial that the Vnr is correct, showing the article it belongs to and being transferred in a safe and correct way between systems.

## 3 Impact on Vnr when an article and/or its package changes

For the common Nordic guidelines on changes, see Vnr – Nordic instruction booklet, chapter 6. Listed below is additional country specific information for Sweden on how a change in an article and/or its package should be handled. Any questions can be directed to eHälsomyndigheten registrator@ehalsomyndigheten.se

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 the Vnr – Instruction booklet, 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 when other criteria than the six basic changes. By changing Vnr it will be obvious to all stakeholders that a change has been made to the article.

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.

Pharmaceutical companies have a responsibility to always inform about changes in trade name, marketing authorisation holder, and Vnr to all pharmacies, see chapter 9 *Contact information*.

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

Please also read TLV's document *Information om ändringar i NPL som kan beröra subvention av läkemedel.* The document is available on the website of TLV: <u>http://www.tlv.se/lakemedel/ansok-om-pris-eller-subvention/information-om-andringar-i-nationellt-produktregister-for-lakemedel-npl/</u>

#### 3.1 What happens when an incorrect Vnr has been saved in NPL?

Since information in NPL is automatically distributed via VARA to the various stakeholders in the market, which in turn uses the information in a variety of situations and systems, it is very important that the Vnrs saved in NPL are correct. Changes in NPL are transferred and updated automatically in subsequent systems. Please be very careful when entering the Vnr. Notify eHälsomyndigheten and correct immediately if an error occurs. When the flag "On the market" once has been set and saved to "yes" the article information will always be distributed from VARA.

It takes two business days until a change in NPL is available in the dispensing systems. In health care systems it takes approximately 1-2 weeks before the updated information becomes available to prescribers. Information in FASS.se is updated from NPL several times a day. See Chapter 2, *Flow of product and article information*.

If an incorrect Vnr has been saved in NPL, and it is discovered later, prescription on the Vnr may have occurred. In such a situation - always contact eHälsomyndigheten to discuss how the information should be handled. It is very important not to delete, edit or otherwise modify the incorrect information without first consulting with eHälsomyndigheten, since it can have major consequences in subsequent systems.

When a pharma company is about to change a specific Vnr, it is important to make the change in NPL a couple of days before the new packages are available at the distributor. The reason for this is to synchronize the change of Vnr between the pharmacies and the distributor in order to maintain the whole distribution chain. If the change of Vnr is done too early or too late in NPL, there is a risk that the pharmacies purchase orders won't be recognized by the distributor.

## 3.2 Change of trade name

It is recommended that the Vnr is changed when the trade name of the product changes. It will thereby be obvious to all stakeholders that the article somehow has been changed.

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.

In cases when a Vnr is to be changed, packs with different trade names but with the same Vnr can be marketed in Sweden during a transition period (one month), when agreed with the MPA (LV).

If a company wants a longer period of parallel sale than a month it must be discussed and approved by the MPA contact person who administers the name change. A longer period is in principle never accepted unless it is a very small change, for instance that the suffix of "vet" is added to, or removed from, a vet. trade name.

For pharmaceuticals with generic names longer parallel sales can, in certain cases, be accepted.

The pharmaceutical company has a responsibility to inform all pharmacies about the change of a Vnr.

#### 3.3 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 may not be deleted from NPL.

When a Vnr is withdrawn there is no longer a cost associated with the Vnr. In Sweden, the handling of Vnrs is funded through the FASS-charge and therefore there is no direct cost associated with Vnrs.

Please contact NNC to discuss the specific situation.

The pharmaceutical company has a responsibility to inform about the change of Vnr to all pharmacies.

### 3.4 Change of package type

In most cases the Vnr needs to be changed. Please contact eHälsomyndigheten and/or NNC when considering changing package type or package material. A new package gets a new NPL pack id.

A change of NPL pack ID affects the price in the reimbursement system. If the old package was reimbursed, the company needs to send a new application for reimbursement for the new package to TLV. Information regarding the application procedure can be found in TLV's document Information om ändringar i NPL som kan beröra subvention av läkemedel. The document is available on the website of TLV: <u>http://www.tlv.se/lakemedel/ansok-om-pris-eller-subvention/information-om-andringar-i-nationellt-produktregister-for-lakemedel-npl/</u>

If a company, without applying for price within the reimbursement system and getting the price approved by TLV, moves a Vnr in NPL to a new NPL pack id, the price within the reimbursement system will not automatically be updated. This means that the package will be handled as if it is not reimbursed in the systems of the pharmacies.

In cases when a Vnr is not changed packs with different package type, but with the same Vnr, can be marketed in Sweden during a transition period (one month), when agreed with the MPA (LV).

## 3.5 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.

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

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

## 3.6 Can old Vnrs be removed from NPL for articles, which are not marketed?

Once an article has been set as "On the market = Yes" in NPL the specific Vnr of that article may not be removed / blanked out in NPL. Sales transactions are linked to the Vnrs in a many systems, such as receptdepån, läkemedelsförteckningen, and statistical systems within and outside eHälsomyndigheten. To mark a change for an article that is not sold, for instance when an article has been passed to another MAH, it is permissible to acquire a new Vnr, see Vnr – Nordic instruction booklet, chapter 3, *Application for Nordic Article Number*.

In Sweden, the handling of Vnr is funded through the FASS-charge and there is therefore no economic reason to refrain from acquiring a new Vnr.

### 3.7 May a Vnr be reused?

It is absolutely forbidden to reuse a Vnr for *another* article. An article, which has been prescribed and dispensed, is registered with the Vnr in a number of systems, e.g. receptregistret, läkemedelsförteckningen, statistics, distribution systems, order and supply systems, article history and invoicing.

For correct historical handling the Vnr must remain even though the article is not marketed.

If a company reuses a Vnr and already has printed packages, these packages may not under any circumstances be distributed on the Swedish market! The company must acquire a new Vnr, and thereafter print new packages.

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.

#### 3.8 How is the previous Vnr handled in NPL when a Vnr is changed?

When changing a Vnr in NPL, the previous Vnr should always be transferred to the field *"Previous item number"*.

The previous Vnr will be saved in VARA together with the new one. This makes it possible for the pharmacies to sell both the old and the new package simultaneously.

# 3.9 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 packages they could have the same Vnr in the different Nordic countries despite differing MT-numbers.

## 4 Checklists

#### 4.1 New Vnr

#	Activity	Comment	To do	Reference
1	New Vnr	Application for a Nordic Article Number	Order Vnr: <u>https://vnr.fi</u>	Application for Vnr:
		should be made when the MAH knows		Vnr – Nordic
		which packages will be marketed and		instruction booklet –
		really need Vnrs.		chapter 3
		Technically Vnrs can be applied for at		Status of Vnr:
		any time. However, a Vnr should be		Vnr – Nordic
		used on the market within three years.		instruction booklet -
		Otherwise the status of the Vnr will be		chapter 4
		changed to Withdrawn.		0 % · / //
				Criteria for Vnr:
		Six basic criteria are mandatory and		Vnr – Nordic
		need to be met equally in all countries		instruction booklet –
		concerned if a Vnr is to be used in		chapter 5
		more than one country.		

#### 4.2 Change of Vnr

#	Activity	Comment	Todo	Reference
# 1	Activity Change Vnr?	Comment Changes can easily be made for articles and Vnrs, which never have been on the market (status Assigned) in <i>any</i> 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. All changes of an article and its package must be informed to, and confirmed with, NNC/PIC in advance. Six basic criteria are mandatory and need to be met equally in all countries concerned if a Nordic Article Number is to be used in more than one country.	Todo Contact eHälsomyndigheten and/or NNC/PIC to discuss if the Vnr should/ought to be changed when an article or its package is changed. Order Vnr: https://vnr.fi Pharmaceutical companies have a responsibility always to inform about changes in trade name, MAH, and Vnr to all pharmacies. Send a mail to TLV with information about which Vnr is changed, to which number it is changed and which NPL pack id it has. The mail should be sent to: registrator@tlv.se	Reference         Vnr – Nordic         instruction booklet –         chapter 6         Swedish guidelines         – chapter 3         TLV information:         Information om         ändringar i NPL som         kan beröra         subvention av         läkemedel.         http://www.tlv.se/lak         emedel/ansok-om-         pris-eller-         subvention/informati         on-om-andringar-i-         nationellt-
			to: registrator@tlv.se When changing a Vnr in NPL, the previous Vnr should always be transferred to the field "Previous item number".	

#	Activity	Comment	Todo	Reference
3		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	In cases when a Vnr is to be changed, packs with different trade names but with the same Vnr, can be marketed in Sweden during a transition period (one month) according to a routine at the MPA (LV). See "Todo" for "1. Change Vnr?"	Vnr – Nordic instruction booklet – chapter 6.3 Swedish guidelines – chapter 3.2
		<ul> <li>country</li> <li>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.</li> </ul>	above.	
4	Change of marketer/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 Vnr may not be deleted from NPL.	Please contact NNC to discuss the specific situation. See "Todo" for "1. Change Vnr?" above.	Vnr – Nordic instruction booklet – chapter 6.4 Swedish guidelines – chapter 3.3
5	Switch 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. If a switch is made from Rx to OTC the Vnr should be changed, since the requirements for package text, package leaflet etc. differ. If a change is made from OTC to Rx the Vnr can be maintained.	See "Todo" for "1. Change Vnr?" above.	Vnr – Nordic instruction booklet – chapter 6.10 Swedish guidelines – chapter 3.5

### 4.3 Withdrawal of Vnr

#	Activity	Comment	Todo	Reference
1	Withdrawal of	A withdrawal of an article/product is a	Contact MPA (LV) who registers	Vnr – Nordic
	an article or a	permanent action.	a date of withdrawal in NPL,	instruction booklet -
	product?		either for the product or an	chapter 6.11
		When the withdrawal date has passed	article.	
		the pharmaceutical or the article will		
		disappear automatically from the	Inform NNC/PIC that the	
		reimbursement system and is no	article/product has been	
		longer shown in the price- and decision	withdrawn in Sweden.	
		databases of TLV.		
2	Withdrawal of	A Vnr withdrawal can be notified at any	Notify by using the Vnr extranet	Vnr – Nordic
	a Vnr	time by using the withdrawal function	service: <u>https://vnr.fi</u>	instruction booklet -
		in the Vnr extranet service		chapter 4.3
3	Reuse of Vnr	It is absolutely forbidden to reuse a Vnr	A company, which reuses a Vnr	Swedish guidelines
		for another article.	and already has printed	<ul> <li>– chapter 3.7</li> </ul>
			packages, may not under any	
			circumstances distribute these	
			packages on the Swedish	
			market!	
			This means that the company	
			must acquire a new Vnr, and	
			thereafter print new packages.	

#### Vnr – layout and allocation 5

All pharmaceuticals with a marketing authorisation in Sweden should have a Vnr printed on the package.

#### Layout of the Vnr 5.1

The six-digit number must be in three groups of two digits. In front of the number it should read Vnr (without period).

#### Example: Vnr XX XX XX

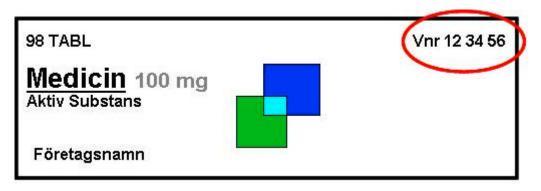
In order for the Vnr to be clearly legible, it should be of a type size of at least eight points.

#### 5.2 Allocation of the Vnr

The Vnr shall be placed:

- On a visible, and easily legible, place near the trade name •
- Normally, on all sides where a complete identification of the package occur.

The reason for this is that the Vnr is intended as an additional confirmation of the identity in the physical handling of the package. The Vnr must be easy to find and easy to read. An example of a good location and layout of a Vnr is in the top right corner on the front of the package.



#### **Pricing of Nordic Article Numbers** 6

The cost for NNC is divided between the Nordic countries.

In Sweden, the handling of Vnrs is funded through the FASS-charge and therefore there is no direct cost associated with acquiring a Vnr.

## 7 Use of article number series

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.

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.

Article number	Used for	Owner	Comment	Licens	Antidote
0 - 199999	Godkända läkemedel. (+ licenser och antidoter)	NNC		17	53
200000 - 2999999	Handelsvaror, Stomi, Diabetes, Läkemedelsnära,	Apoteket AB		22	20
	Livsmedel, VUM, Naturläkemedel, Gashyror,				
	APL-varor, (+ licenser och antidoter)				
300000 - 319999	Bruten förpackning till GOP	Apoteket AB			
320000 - 369999	APLs handelsvaror och läkemedel, PES-	APL	366401-366900		15
	läkemedel, Medicinsk gas (antidoter)		till Unimedic		
370000 - 599999	Godkända läkemedel (+ licenser)	NNC		23	
600000 - 665999 *	Sjukhusvaror och lågfrekventa licenser	Apoteket Farmaci		98	
666000 - 679999	ExTempore i SALT				
680000 - 680299	Handelsvaror	Kronans			
		Droghandel			
680300 - 680999	700 lediga varunr	Apoteket			
681000 - 681599	Handelsvaror	Apoteket Hjärtat			
681600 - 681999	400 lediga varunr	Apoteket AB			
682000 - 682699	Handelsvaror	Apoteksgruppen			
682700 - 682999	300 lediga varunr	Apoteket AB			
683000 - 683399	Handelsvaror	Vårdapoteket			
683400 - 683999	600 lediga varunr	Apoteket AB			
684000 - 684399	Handelsvaror	Medstop			
684400 - 684999	600 lediga varunr	Apoteket AB			
685000 - 685399	Handelsvaror	DocMorris			
685400 - 685999	600 lediga varunr	Apoteket AB			
686000 - 686699	Handelsvaror	Apoteksamariten			
686700 - 686999	300 lediga varunr	Apoteket AB			
687000 - 689999	3000 lediga varunr	Apoteket AB			
690000 - 690999	1000 varunr utlämnade till Apotekens Service för	Apotekens Service			
	Licenser				
691000 - 691199	200 varunr utlämnade till Apotekens Service för	Apotekens Service			
	Livsmedel	-			
691200 - 691999	800 lediga varunr	Apoteket AB			
692000 - 694199	2200 varunummer utlämnat till Apotekens	Apotekens Service			
	Service för Licenser				
694200 - 698999	56000 lediga varunr	Apoteket AB			
699000 - 699999	1 000 varunr utlämnade till Apotekens Service	Apotekens Service			
	för ExTempore				

In the table below all Swedish six-digit-codes are listed. It also shows what different number series are used for, and the owners of these series - October 25, 2012, version 3.0.

Article number	Used for	Owner	Comment	Licens	Antidote
700000 - 709999	Militärläkemedel, 79 varunr har använts i serien	Apoteket AB	9921 lediga		
	men har utgått år 2004		varunr		
710000 - 729999	Sjukhusvaror	Apoteket AB			
730000 - 740000	Varunummerserien utlämnad till TLV utom 14	TLV			
	varunr som har använts av Apoteket AB men som				
	har utgått år 2001				
740001 - 749999	7 varunr har använts i serien av Apoteket AB och	ingen	9992 lediga		
	alla har utgått år 2002		varunr		
750000 - 789999	KDs interna nummerserie (Licenser +	KD		432	12
	anskaffningar från KD)				
790000 - 799999	Sjukhusvaror och licenser (ca 400 vnr har	Apoteket AB			
	använts)				
800000 - 909999	Tamros interna nummerserie (Licenser +	Tamro		141	2
	anskaffningar från Tamro)				
910000 - 920008	Apotekets interna nummerserie som används till	Apoteket AB	919500-919722		8
	del av förpackning, rabatterade		919001-919997		
	apoteksförpackning samt tjänster. Gäller		APL extempore-		
	Handelsvaror, Läkemedelsnära och Livsmedel.		läkemedel		
920009 - 999999	Tamros interna nummerserie	Tamro			
Enstaka 70-vnr	Vilka ?	LIF	Matilda Holst på		
			LIF ska kolla		
Article number	Special	Owner			
* 630000	Gruppvnr utlämat till Apotekes Service	Apotekens Service			
* 640000	Teknisk sprit e-förskrivning	Apotekens Service			
* 650000	Livsmedel utan förmån e-förskr	Apoteket AB			
* 660000	Ex-Temporeläkemedel, e-förskrivning .	Apotekens Service			
* 670000	Licensförskrivet läkemedel, e-förskrivning	Apotekens Service			
920001 - 920008	Testvaror för att kunna testa i skarpt läge mellan ACA och ATS.	Apoteket AB			
919999	Informationsvaror (NLM och VUM) visas endast	Apoteket AB			
	på ApoNet, ej i ATS				
919200	Informationsvaror (Licenser) visas endast på	Apoteket AB			
	ApoNet, ej i ATS				
920000	Informationsvaror (Läkemedel) visas endast på	Apoteket AB			
	ApoNet, ej i ATS				
		Apoteket AB			
919800	Dospeng (andvänds inte idag)	Apolekel AB			
919800 919191	Dospeng (andvänds inte idag) "Fossiler" utgångna varor som är hämtade från	Apoteket AB			

Table 1 List of all article numbers used in Sweden

## 8 Läkemedelsbranschens nummernämnd, LNN

LNN is a forum in which the different stakeholders of the pharmaceutical and pharmacy industry can discuss the overall handling of article numbers. Currently, February 2013, it is discussed what the future purpose of LNN should be. After the next LNN meeting this chapter will be updated. LNN has the following members:

- LIF (Pharma companies)
- Medical Product Agency (Läkemedelsverket)
- eHälsomyndigheten
- Swedish Pharmacy Association
- Wholesale distributors
- Dental and Pharmaceutical Benefits Agency (TLV)
- Swedish Association of Local Authorities and Regions (SKL)
- Extempore pharmacies

## 9 Contact information

The Vnr system is administered by the Nordic Number Centre (NNC)<sup>2</sup>, located at Pharmaceutical Information Centre Ltd (PIC) (Lääketietokeskus Oy), Helsinki, Finland. <u>vnr@vnr.fi</u>

#### 9.1 Sweden

Läkemedelsindustriföreningens Service AB, LIF Box 17608 118 92 Stockholm Telephone: 08-462 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

Please also read TLV's document *Information om ändringar i NPL som kan beröra subvention av läkemedel.* The document is available on the website of TLV: <u>http://www.tlv.se/lakemedel/ansok-om-pris-eller-subvention/information-om-andringar-i-nationellt-produktregister-for-lakemedel-npl/</u>

Pharmacies approved by Medical Product Agency: <u>http://www.lakemedelsverket.se/malgrupp/Apotek--handel/Apotek/-Tillstand-for-apotek/</u>

Contact list to pharmacy chains when to inform about article information: http://www.sverigesapoteksforening.se/apoteksbranchen/varuinformation/

#### 9.2 Country specific information – other Nordic countries

•	Denmark	Not yet available
---	---------	-------------------

- Finland see <u>http://wiki.vnr.fi/</u>
- Iceland
   Not yet available
- Norway see <u>http://wiki.vnr.fi/</u>

<sup>&</sup>lt;sup>2</sup> On behalf of the Nordic country organisations Dansk Lægemiddel Information A/S in Denmark, Pharmaceutical Information Centre Ltd in Finland, Lyfjastofnun in Iceland, Legemiddelindustriforeningen in Norway, and Läkemedelsindustriföreningens Service AB, LIF, in Sweden.

# **10 Definitions**

FASS	The Swedish medicine compendium.
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. <u>www.gs1.se</u> or <u>www.gs1.com</u>
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 + serial number + check digit. Can be presented in a barcode for automatic reading.
LIF	Läkemedelsindustriföreningens Service AB, LIF, is the trade association for the research- based pharmaceutical industry in Sweden. LIF represents around 80 companies that produce 80 per cent of all the pharmaceuticals that are in Sweden. – <u>www.lif.se</u>
LV	Läkemedelsverket (MPA – Medical Product Agency)
MAH	Marketing Authorisation Holder
MPA	Medical Product Agency (LV – Läkemedelsverket)
Marketer	Company that represents the product (often the same as MAH)
National article number	A six-digit code (200000-369999 and 600000-999999) used 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 Nordic Article Number 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.
NPL	Nationellt Produktregister för Läkemedel – MPA is responsible for the development and administration of the product and article register NPL - <a href="https://npl.mpa.se/mpa.npl.services/home2.aspx">https://npl.mpa.se/mpa.npl.services/home2.aspx</a>
NPL id	An identification code for a product. It is generated and administered by MPA.
NPL pack id	An identification code for an article. It is generated and administered by MPA.

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
SIL	Svensk Informationsdatabas för läkemedel
SKL	Swedish Association of Local Authorities and Regions (SALAR) – Sveriges Kommuner och Landsting (SKL)
TLV	Tandvårds- och läkemedelsförmånsverket – Dental and Pharmaceutical Benefits Agency, administers the prices in the reimbursement system.
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.
VARA	The national product and article register for all pharmaceuticals, and consumer products within the reimbursement system. VARA is administered by eHälsomyndigheten <u>www.ehalsomyndigheten.se</u>