

Nordic Instructions for Nordic Article Numbers (Vnrs)

Supplementary information – Norway

This document presents an overview on the handling of Vnrs (Varenummer/article number) and information carried by the Vnr in Norway. Some supplementary information on issues addressed in the common Nordic regulatory framework is also presented, mainly concerning changes to a marketed Vnr and on the use of product codes (NTIN vs GTIN in Norway).

This document is prepared and maintained by Farmalogg AS. The Association of the Pharmaceutical Industry in Norway (LMI) is the national contracting party concerning the NNC (Nordic Number Centre, located at Pharmaceutical Information Centre Ltd (PIC) Helsinki, Finland) and the Nordic regulatory framework.

1. The flow of article information

Vareregisteret is the entry point for all new products in the Norwegian market. Vareregisteret is a common, national article register for all Norwegian pharmacies and pharmaceutical wholesalers in Norway. The register includes with few exceptions *all* products sold through pharmacies, and contains information necessary for a safe and efficient handling and dispensing of the products from manufacturer/supplier, via wholesaler and retailer, to consumer. Vareregisteret is maintained by Farmalogg AS, a joint stock company owned by the Norwegian Pharmacy Association.

The operation of Vareregisteret is carried out in cooperation with NoMA (Norwegian Medicines Agency), HELFO (The Norwegian Health Economics Administration), WHOCC (WHO Collaborating Centre for Drugs Statistics Methodology) and the pharmaceutical wholesalers. The information on the products listed in Vareregisteret is processed on data files exchanged between these partners twice a month.

FEST, maintained by NoMA, is a national database with all articles available for prescription in Norway, both first line- and specialized medicine (GPs, specialists, hospitals). FEST is available for the various systems for prescribing / EPJ (ElectronicPatientJournal). FEST is updated with information from Vareregisteret. Information from FEST, including information from the reimbursement system (HELFO), is included in Vareregisteret.

The management of the exchange of product information via FEST is essential for the coordination of information in the prescribing- and dispensing systems. This coordination is a prerequisite for the national system for electronic prescription. All information is carried by the Vnr, both the Nordic article numbers and national article numbers, as the sole identifier. Figure 1 gives an outline of the flow of information on medicines in Norway.

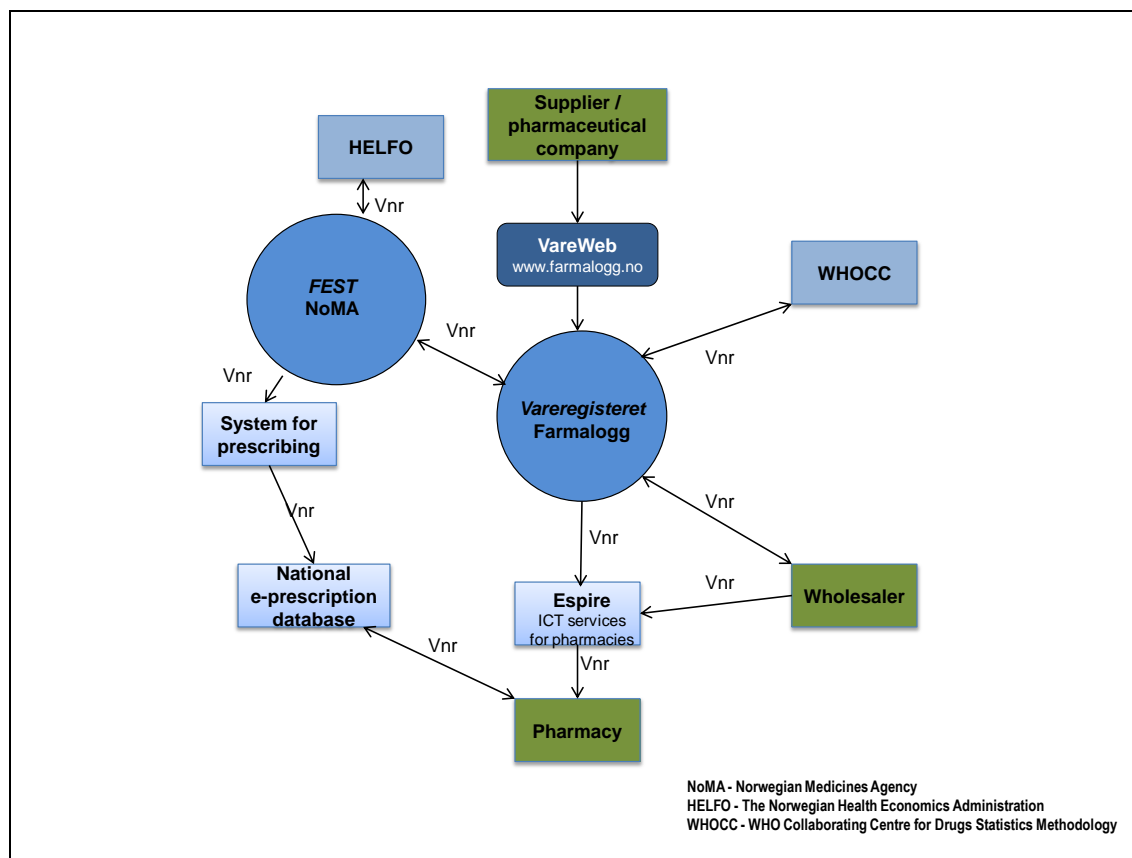


Fig.1

2. Vnr - the carrier of information

The information flow (fig 1) is based on the Vnr as identity and carrier of all information for prescription and dispensing in Norway. The Vnrs carry information to facilitate the handling of the products and as a structural basis for drug statistics.

Last line removed; . "The EPJsystems also use and keep patient drug history over time based on Vnrs ."

The stakeholders/operators receive customized updates from Farmalogg or NoMA as they may use different information elements linked to the Vnr or in some cases add their own elements. Some information elements which are coordinated between the systems are used by most operators. Information on pricing and reimbursement provided by NoMA and HELFO is used by many operators, as information on shelf life, storage and transportation mainly concern the wholesalers. Farmalogg add different types of information to the Vnrs for specific operators, as predefined labelling choices added for the pharmacies, subcategories for statistical use in addition to the statistical information provided by WHOCC.

Regardless of type of information element, it is of paramount importance to ensure that the Vnr represents a unique identity as defined by the Nordic instructions. As the Vnrs carry information for many different functions, changes must be handled with great care to avoid mix-ups.

Vnr vs. product code:

Each Vnr is linked to one product code. From 2018 more than one product code may be linked to each Vnr, thereby allowing easy transfer to new product code and corresponding barcode on the packs. The barcodes are used by wholesalers and pharmacies as the identifier in the physical handling of the medicines and is essential in the verification at the point of dispensing. This means that correct product codes and corresponding barcodes are vital for correct dispensing.

3. The Changes to an Vnr introduced to the market

For the common Nordic regulatory framework on changes, see Nordic Instructions.

On the topics of changes in the Nordic Instructions, please note the following elaborations:

Change of trade name

Any change of trade name that might introduce any doubts about the identity of the product, should be followed by a new Vnr. Adjustments or minor changes in the name may be allowed as long as the product appears principally unchanged.

Change of package type

A change of package type, eg from blister to container, is not acceptable and a new Vnr is required.. *Package materials* has not been a Vnr-issue in Norway as long as there is no impact on pricing, and the Vnr can be kept

Change of prescription group for medicines with MA

When changing the prescription group from C (prescription) to F (non-prescription), a new Nordic article number is required on the package. The package must be approved by the NoMA if the prescription group is to be changed from C to F to ensure correct patient information.

The need for separate Vnrs on packs intended for prescription- and non-prescription sales is an important issue in relation to logistics. The wholesaler and the retailer need separate Vnrs to differentiate these packages. With respect to medicine statistics, it is required to differentiate between prescription and non-prescription sales. This is also an issue because of the non-pharmacy sales of some OTC medicines. On this basis, a new article number is necessary when changing from prescription group F to C.

Change of product code

If the product code of a product is changed, the Vnr should be changed as well. The established systems in Norwegian pharmacies and at the wholesaler level can presently (2017) only handle one product code to each Vnr. The Vnr and the corresponding product code are mutually supportive identifiers on a one-to-one-basis. This will be amended from 1.1.2018. A separate document on implementation of 2D Data Matrix in Norway is available at Farmaloggs website. This contains information on change from NTIN to GTIN and from linear barcode to 2D Data Matrix.

Notification of change

Farmalogg is the entry point for maintaining the information linked to the identity of a Vnr. It is important to note that there is no link between the systems for NNC and Vareregisteret. Any change concerning the Vnr in the NNC-system must be communicated to Farmalogg by the responsible pharmaceutical company.

The pharmaceutical company must also notify Farmalogg on changes to other information elements maintained by Farmalogg. A guideline on what information the company must communicate is available at www.farmalogg.no after logging in.

Please note that any change in a product which entails a change of Vnr means that the new Vnr must be registered and processed as any *new* product in Vareregisteret.

4. Product codes in Norway

NTIN presented as EAN13, is the dominant product code in use in Norway. The NTIN is constructed from the Vnr and as a consequence a non-changeable unit. GTIN comply with the same 13 digit format as NTIN, EAN13, and may be used on *new Vnrs introduced to the market*. The GS1 GTIN Allocation Rules is available at <http://wiki.vnr.fi/>

NOTE the situation in Norway in **2017**;

All systems in Norway are based on one product code linked to one Vnr. The corresponding barcodes are used by wholesalers and pharmacies as an identifier in the physical handling of the medicines in many different processes and are vital for correct dispensing. It is possible to use either a NTIN or a GTIN as product code, but the systems are not able to manage the change of one code (ex NTIN) to another code (ex GTIN) without manual changes (by Farmalogg, the wholesalers and the pharmacies) and corresponding risks and workload. This will be amended by 1.1.2018.

Any new pack (Vnr) may carry a GTIN. Changing NTIN to GTIN on a marketed pack (Vnr) should be avoided until this can be handled by the systems in 2018.

A separate document on implementation of 2D Data Matrix in Norway is available at Farmalogs website. This contains information on change from NTIN to GTIN and from barcode to 2D Data Matrix. The subject is more fully covered at <http://wiki.vnr.fi/>.

5. Product groups and vnr-series in Norway

All products in Vareregisteret are grouped into 9 different product groups, and the article numbers are either *Nordic article number* or *National article number*:

No	Product group	Article number series	Type
1	Medicines with MA (marketing authorisation)	00 00 01 – 19 99 99 37 00 00 – 59 99 99	Nordic
2	Pharmacy produced medicines	20 00 00 – 36 99 99	National
3	Commodities incl. medical equipment and products approved for reimbursement by the Norwegian Health Economics	80 00 00 – 99 99 99	National
4	Chemicals	20 00 00 – 36 99 99	National
5	Medicinal herbs	20 00 00 – 36 99 99	National
6	Unlicensed medicines / Medicines without MA (marketing authorisation)	20 00 00 – 36 99 99	National
7	Homeopathic and anthroposophic medicines	20 00 00 – 36 99 99	National
8	Natural remedies and herbal medicinal products incl. traditional and well-established medicinal herbs	00 00 01 – 19 99 99 37 00 00 – 59 99 99	Nordic
9	Miscellaneous incl. work rates, packaging, publications, supplies	20 00 00 – 36 99 99	National

Nordic article numbers are assigned by the Pharmaceutical Information Centre for products with marketing authorisation.

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