Norwegian Medical Products Agency

FEST

Implementation guidelines

Norwegian Medical Products Agency

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Contents

Document history 6
1 Introduction 8
2 The purpose of FEST 9
2.1 Articles available in FEST 10
2.2 General prescription model 10
2.3 FEST catalogues 11
2.4 Quality in FEST 13
2.4.1 Data quality and ownership 13
2.4.2 Enquiries 14
2.4.3 Information from FEST concerning errors and non-conformances 14
2.4.4 Updates 15
2.4.5 Versions and filters of FEST 15
2.4.6 Staging file 15
3 Medicine 16
3.1 The «Legemiddel» class 16
3.2 Main catalogues for prescribing medicines 17
3.2.1 LegemiddelVirkestoff (MedicineActive substance) 18
3.2.2 LegemiddelMerkevare (MedicineBrandedProduct) 20
3.2.3 LegemiddelPakningMerkevare (MedicinePackageBrandedProduct) 22
3.2.4 LegemiddelDose (MedicineDose) 23
3.2.5 Information content in shared categories linked to Legemiddel (Medicine) 25
3.3 Mapping between main pharmaceutical catalogues 27
3.3.1 Mapping LegemiddelVirkestoff (MedicineActiveSubstance → LegemiddelMerkevare (MedicineBrandedProduct) 27
3.3.2 Mapping LegemiddelMerkevare (MedicineBrandedProduct) → LegemiddelPakningMerkevare (MedicinePackageBrandedProduct) 28
3.3.3 Mapping LegemiddelMerkevare (MedicineBrandedProduct) → LegemiddelDose (MedicineDose) 28
3.3.4 Mapping LegemiddelDose (MedicineDose) → LegemiddelPakningMerkevare (MedicinePackageBrandedProduct). 29
3.3.5 Relevant scenarios 29
3.4 Cardinality more restricted than indicated in the data model 31

4 Prescription of an active substance 32
4.1 Purpose of prescription of active substances 32
4.2 Prescription of an active substance in FEST 32
4.3 Prescription of an active substance unregistered medicines 33
4.4 Prescription of an active substance at the prescriber (generic prescription) 33
4.5 Dispensing medicines based on prescription of an active substance 34
5 Information about medicines 35
5.1 Dosage form 35
5.2 Active substance with and without indication of strength 36
5.3 Sorting of active substances without strength 37
5.4 Active substances in English 37
5.5 Indication of strength 37
5.5.1 Strength of liquid medication 38
5.5.2 Strength of powder etc. 38
5.5.3 Alternative strength 38
5.6 Active substances for magistral prescription 38
5.7 Vilkår (Conditions) 38
5.8 Structured conditions 40
5.8.1 Overview of structured conditions 42
5.8.2 Details concerning how each structured condition is to be implemented. 44
5.9 Prescription validity 47
5.10 Prescription groups 47
5.11 Opioid applications 48
5.12 Link to summary of product characteristics (SPC) 48
5.13 Taste (Smak) and other additional information 48
5.14 Animal species (Dyreart) 49
5.15 Medication review 49
5.16 Driving licences 49
5.17 “Svart trekant” 50
6 Packages 51
6.1 Incoming/outgoing packages in FEST 51
6.1.1 Marketing date 51

6.1.2 Withdrawal date 51
6.1.3 Temporarily discontinued date 51
6.2 Package information 52
6.2.1 Package size 52
6.2.2 Type of packaging 52
6.2.3 Bar code 53
6.2.4 Article number and discontinued article number (varenummer) 53
6.2.5 Special packages 53
6.2.6 Specific packages in FEST 2.5.1 for institutions 56
6.3 Prices 57
6.3.1 Validity dates 57
6.4 Reimbursement 57
6.4.1 Reimbursement validity 57
6.4.2 Preapproved reimbursement, Section 2 (blue prescription) 59
6.4.3 Individual reimbursement, Section 3 59
6.4.4 Magistral prescription reimbursement 59
6.4.5 Reimbursement by H-prescription (H-resept) 60
6.5 Substitution group 60
6.5.1 Substitution validity group 61
6.5.2 Technical information about substitution groups 61
6.5.3 Remarks regarding substitution 61
7 Administration 62
7.1 Administration information 62
7.2 Structured dosage 63
7.2.1 Short dose 63
7.2.2 Medicine consumption 63
8 Interactions 64
8.1 Interactions in FEST 64
8.1.1 Substance group 64
8.1.2 Information relating to the interaction 64
8.2 Interaction notification 66
8.3 Handling an interaction notification 66
8.4 Interaction searches 66

8.5 Non-assessed interaction 67
9 NOMA notifications 68
9.1 Notification types 68
9.2 Who should see the various notifications? 69
9.3 Duration of a notification 69
9.4 Link to case on NOMa's web pages 69
9.5 Linking a notification to one of the main catalogues in FEST 69
9.6 Notifications can be used as follows: 70
10 Unregistered medicines 71
10.1 Unregistered medicines in FEST 71
10.2 Labelling unregistered medicines in FEST 71
10.3 For prescription systems using FEST 71
11 Coding systems 72
11.1 Coding systems in the coding system catalogue in FEST 72
11.2 Coding system for reimbursement codes 72
11.3 The ATC registry as coding system in FEST 73
11.3.1 Structure of the ATC coding system vs. active substance 73
12 Commodities 75
12.1 Nutrients and Medical consumer products 75
12.2 How to populate what can be prescribed 76
12.3 Nutrients, breast prostheses and consumer articles (M30N) 80
13 Incremental downloads 81
13.1 Individual entry in FEST in M30 for incremental download 81
13.2 Incremental updates and Nutrients, Breast Prostheses and Medical consumer products (Commodities) 83
13.3 Dates in connection with incremental extraction 83
14 Glossary of terms 84
15 Preliminary missing content in FEST 88

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April 2024	Document version 3.5 - Updated text in chapter 2.3, 3.2, 3.2.2 og 4.4 with a clarification that as of 2024 it is no longer desirable that LegemidelMerkevare is used for prescription

1 Introduction

The Norwegian Electronic Prescription Support System (FEST) is an information service provided to expose common pharmaceutical data to all members of the prescription chain; physicians, hospitals, veterinary surgeons, pharmacies, manufacturers of surgical appliances and other health personnel receive updated information about all articles available for prescription/dispensing in Norway from one single source.

Basic data provided by the Norwegian Medical Products Agency (NOMA) through FEST can be used for different systems. It is not necessary to replace the systems to use FEST, only to adapt them to receive data in the correct format. The suppliers of the various systems are responsible for developing and providing the required functionality and use of the information. For more information about FEST and how to use it, please refer to the NOMA's web pages: https://www.dmp.no/om-oss/distribusjon-av-legemiddeldata/fest [Norwegian]

This document contains implementation guidelines. The purpose of the document is to provide extra support to system suppliers who want to implement FEST. The implementation guidelines describe connections, structure and business logic in more detail, and are intended as a supplement to the more technical description available on NOMA's web pages: Informasjonsmodell og XML-meldingsbeskrivelse (v. 2.5.0) / Informasjonsmodell og XML-meldingsbeskrivelse (v. 2.5.1) [Norwegian] (Information Model and XML notification description - hereinafter referred to as the Notification Description).

NOMA wishes to cooperate closely with system suppliers to prepare pharmaceutical information for practical use in the systems. Moreover, it is important that the user environments request that their suppliers use FEST in their systems and that FEST is used in a manner which ensures optimum functionality.

System suppliers can freely use the information in FEST in their systems in accordance with the Norwegian Licence for Open Government Data (NLOD) [Norwegian]. NOMA accepts no responsibility for integrations of FEST in the various systems.

2 The purpose of FEST

To promote safe and effective use of pharmaceuticals, NOMA has developed the data base and information service Prescription and Dispensing Support (FEST).

FEST is the key source of information about pharmaceuticals available through the Norwegian public health service. NOMA is the administrative agency for pharmaceuticals and processes and produces most of the content in FEST. The Agency also has partners who provide information from other relevant pharmaceutical fields. This is presented in a common data structure in FEST.

There are many benefits of providing pharmaceutical data from a single source. FEST will supply all health service providers with quality-assured and updated pharmaceutical information with a data structure suitable for optimum functionality in the various user systems. This entails:

- efficient use of resources in the form of centralised and correct information updates
- standardisation of information and format
- coordinated communication between stakeholders
- improved patient safety based on a correct and updated prescription and dispensing basis, etc.

FEST was developed as part of the national E-resept (*E-prescription*) programme. The programme was organised and managed by the Norwegian Directorate of Health. Other participants included NOMA, the Norwegian Medical Association, the Norwegian Pharmacy Association, Bandasjistenes næringspolitiske utvalg (*industry policy committee for manufacturers of surgical appliances*), the Norwegian Labour and Welfare Administration (NAV), the Norwegian Health Economics Administration (HELFO) as well as regional health enterprises. The participants cooperated with a wide range of ICT suppliers.

Responsibility for E-prescription was transferred to the Norwegian Directorate of eHealth with effect from 1 January 2016. Since 1.1.2020 the responsibility has been transferred to Norwegian Healthnet. Norwegian Healthnet supplies complete documentation for suppliers who want to prepare their systems for E-prescription. https://www.nhn.no/tjenester/e-resept/dokumentasjon-for-e-resept [Norwegian]

2.1 Articles available in FEST

FEST contains information about all products that can be prescribed and dispensed in Norway: pharmaceuticals, medical equipment and nutrients for medical use. Prerequisite: that they are on sale on the Norwegian market with a national article number

- Pharmaceuticals with marketing authorisation in Norway
- Pharmaceuticals produced by hospital pharmacies
- NAF medications
- Unregistered pharmaceuticals
- Nutrition supplements sold by pharmacies
- Commodities with reimbursement:
    - Medical consumables
    - Nutrients
    - Breast prostheses
- Unit dose packed in pharmacies (only version 2.5.1 Institution)
- Bulk-packages to repack as unit dose in pharmacies (only version 2.5.1 Institution)

2.2 General prescription model

To ensure consistency in all E-prescription notifications with the same or similar content, a general prescription model has been prepared. This will be reused for all notifications where this must be described. This applies to notifications M30 (FEST), M1 (the prescription), M2, M6, M8, M10, M20 and M25. These notifications have been collated in a single common prescription model (xsd) – Forskrivning (*Prescription*).

Two files must be used when loading xsd: One file for M30 containing the catalogue structure and some fields unique for FEST, and one file for *Prescription*.

Prescription contains certain categories that are irrelevant for M30 (FEST), but are used in the prescription and other E-prescription notifications. These have been circled in blue in Figure 1:

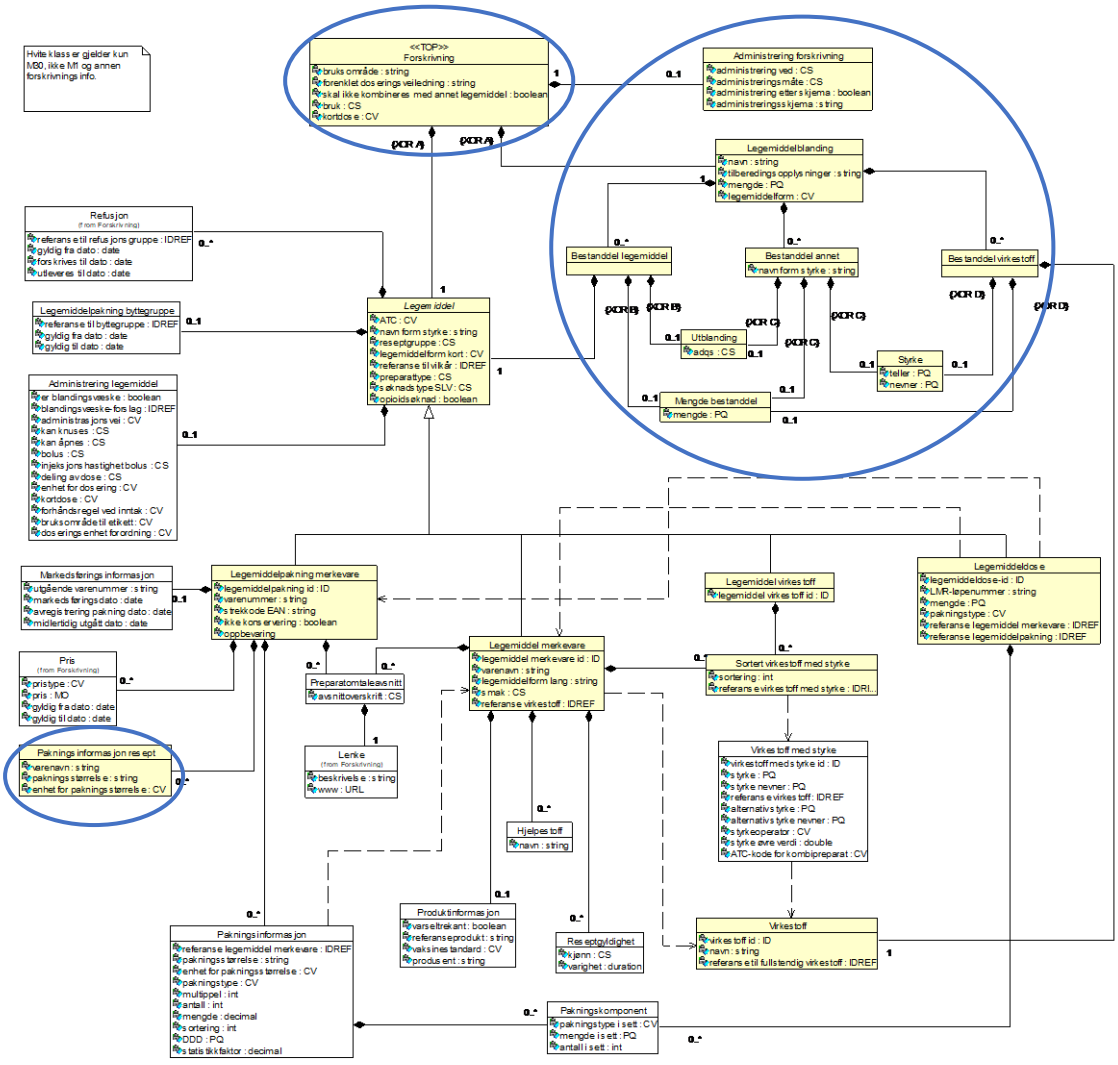

Figure 1 FEST - Notification Description 2.5.0

2.3 FEST catalogues

FEST was developed as part of E-prescription. The purpose was to expose common pharmaceutical data to all members of the prescription chain. Consequently, the FEST notification has been prepared to meet several needs. This means it also has several approaches for obtaining the required information.

These approaches are represented as various catalogues in FEST, making it possible to download those parts of FEST that are relevant. The catalogues in FEST are also referred to as different levels. Figure 2 shows the various catalogues in FEST:

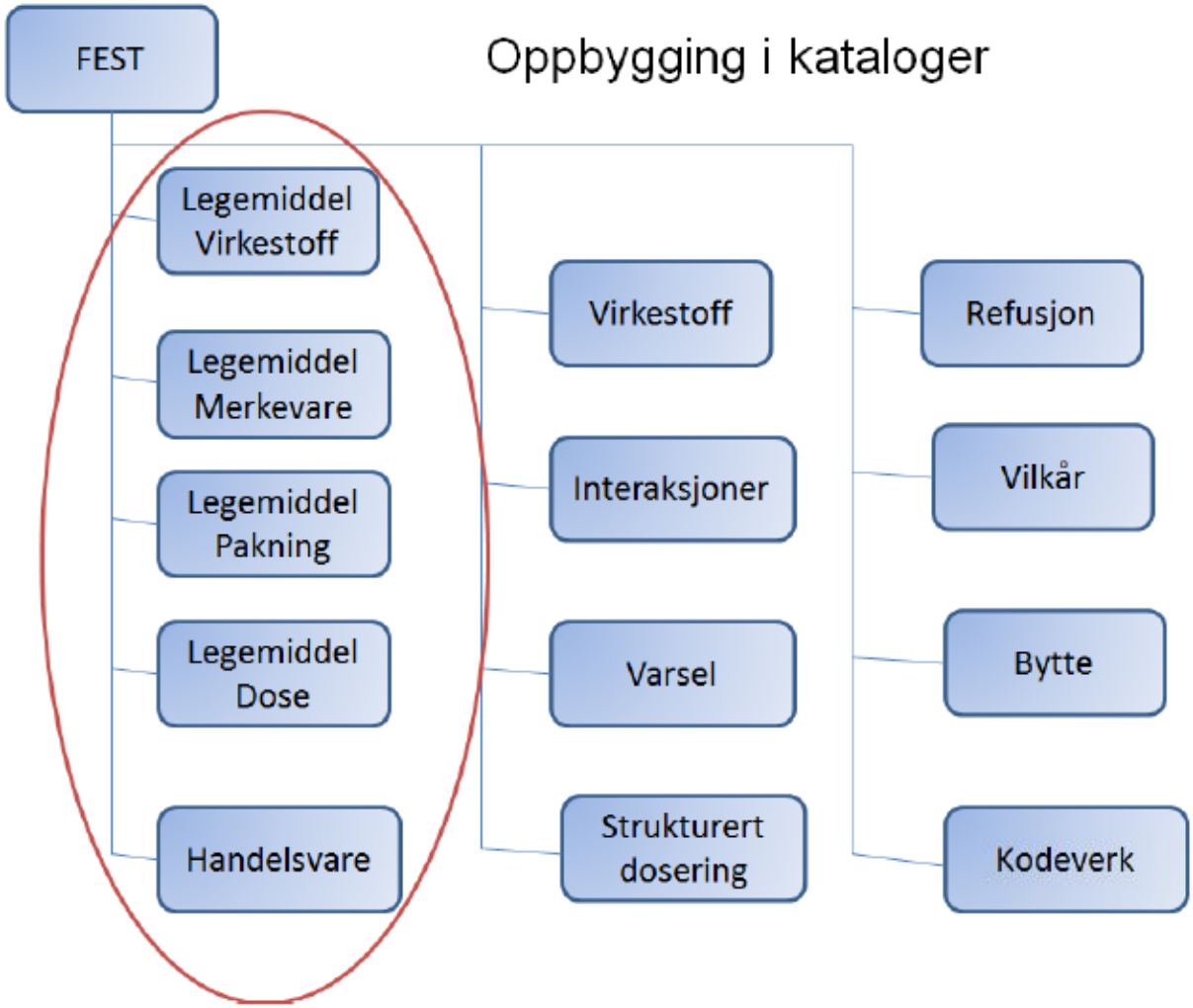

Figure 2 Catalogue structure in FEST

As shown in the figure above (Figure 2), there are five main catalogues for prescription. The four top ones are catalogues for prescription of pharmaceuticals, while the Handelsvare (Commodity) catalogue is the main catalogue for prescription of medical consumer products. Various information is linked to the different catalogues/levels. Much of this is through references to information in other categories, such as Byttegruppe (*Substitution Group*), Refusjon (*Reimbursement*) and Vilkår (*Conditions*).

- The catalogue LegemiddelVirkestoff (*MedicineActiveSubstance*): prescription of active pharmaceutical ingredients
- The catalogue LegemiddelMerkevare (*MedicineBrandedProduct*): prescription of a strength and form of a specific branded product. Per 2024 it is no longer desirable that LegemiddelMerkevare is used for prescription.
- The catalogue LegemiddelPakningMerkevare (*MedicinePackageBrandedProduct*): prescription of a specific package of a

branded product (article number). This catalogue has been abbreviated to LegemiddelPakning (*MedicinePackage*) in the figure.
- The catalogue LegemiddelDose (*MedicineDose*): prescription of a specific branded product with ID (LMR number) representing the smallest selectable unit, for instance one ampoule or one tablet.
- The catalogue Handelsvare (*Commodity*): commodities entitled for reimbursement, e.g. medical consumables, nutrients and breast prostheses.

The content of the four top catalogues is described in more detail in Chapters 4, 5, 6 and 7. The content in the catalogue Handelsvare (*Commodity*) has been described in Chapter 12. The other FEST categories contain information about pharmaceuticals and commodities.

2.4 Quality in FEST

2.4.1 *Data quality and ownership*

NOMA has a quality system which also encompasses FEST.

All procedures relating to operation of FEST and registration of information relating to FEST have been documented in a document control system. Change and non-conformance procedures have also been prepared.

Most of the information about pharmaceuticals has been obtained from NOMA's internal case processing system (Athene). Any pharmaceutical information made available in FEST will be quality-assured through both automatic and manual controls during authorisation of the marketing authorisation and marketing of the package.

Coding system values used in FEST are quality-assured before approval and the content in the coding system is updated regularly. Approved codes from Standard Terms are used where available. Norwegian pharmaceutical standards are used as a basis if a substance has an approved monograph.

External data sources

In addition to information from the Norwegian Medical Products Agency, FEST contains information from external sources. The Agency enters into agreements with third-party suppliers for supply of information. The agreements specify that data suppliers must have a quality system which secures quality of information, including non-conformance handling.

Table 1 Content in FEST with owner information

Content	Owner	Update frequency
ATC coding system	WHO collaborating centre	Annually and as and when necessary
Commodities, with reimbursement and conditions,	HELFO	Every quarter, with option for extraordinary updates every month.

as well as product group coding system		
Interactions	NOMA	As required by the 1st and 15th of each month
Pharmaceuticals manufactured by hospital pharmacies	Hospital pharmacies' administration	By the 1st and 15th of each month
"H-prescription" Reimbursement	Norwegian Directorate of Health	By the 1st and 15th of each month
"H-prescription" Maximum Reimbursement price	Sykehusinnkjøp HF, medicines division	By the 1st and 15th of each month
Unregistered pharmaceuticals	Farmalogg	By the 1st and 15th of each month
Food supplements	Farmalogg	By the 1st and 15th of each month
Structured dosage	Norwegian Directorate of Health	Each year
NOMA notifications	NOMA	As required by the 1st and 15th of each month in M30. NOMA notifications available as open data will be available on a daily basis.

2.4.2 *Enquiries*

Enquiries relating to FEST can be sent by email to fest@dmp.no or by phone via NOMA's switchboard on tel. +47 22 89 77 00

General information regarding enquiries:

- Emails will be answered within 24 hours Monday-Friday during regular working hours
- FEST uses HelseCIM, an electronic system for non-conformances and changes
- Non-conformances should preferably be reported by e-mail and will be answered according to their severity, as soon as possible.

2.4.3 *Information from FEST concerning errors and non-conformances*

Information from FEST concerning errors and non-conformances

- Operating reports and associated information are published on the NOMA's website and sent as e-mail to our contact lists from HelseCIM, with fest@dmp.no as the sender.
- In the case of critical errors, a text message will be sent to the contacts linked in the special distribution list for this purpose.

Contact lists

You should make sure we have your contact details as a FEST user in our contact lists, either as a personal user or through a joint contact. Send an e-mail with your

contact details, name, e-mail address, company and role, along with the system being used and the relevant FEST version to fest@dmp.no.

More information about FEST and the FEST section's work is available on the NOMA's web pages: https://www.dmp.no/om-oss/distribusjon-av-legemiddeldata/fest [Norwegian].

2.4.4 *Updates*

Ordinary updates take place every second week, normally two days before the updates become applicable. The dates for updates are available here: https://www.dmp.no/om-oss/distribusjon-av-legemiddeldata/fest/nedlasting-av-fest-og-safest [Norwegian]

Extraordinary updates may also take place in exceptional cases. Automatic updates should therefore be set to install every three days.

2.4.5 *Versions and filters of FEST*

FEST is available in versions 2.5.0 and 2.5.1. We recommend everyone to always use the latest version of FEST.

FEST comes with the following filters:

- Rekvirent: For prescribers of pharmaceutical products.
- Institusjon: For prescribers of pharmaceutical products in hospitals and nursing homes.
- Veterinær: Customised prescribers of pharmaceutical products for veterinary use.
- Bandasjist: To be used by bandagists. Contains only commodities with reimbursement.
- NAV: Customised financial settlement control in HELFO.
- Farmalogg: Used by Farmalogg for coordination with Vareregisteret for pharmacies.

2.4.6 *Staging file*

Before FEST files are published, they will be available in a Staging environment one week in advance. It is recommended that impending files be routinely imported into a test environment to ensure that changes in content do not have any consequences for EPJ systems and thereby the users. See the Technical interface documentation [Norwegian]

3 Medicine

This chapter is particularly technical in nature and is aimed at the technical resources of the system suppliers. The chapter contains descriptions of the Legemiddel (*Medicine*) class with associated catalogues, as well as the mapping procedure. See also Section 3.3.5 for examples of scenarios linked to mapping.

3.1 The «Legemiddel» class

The Legemiddel (*Medicine*) class is an abstract class in the FEST information model. It is the class shared by the four main catalogues. Information elements relating to the class Legemiddel (*Medicine*) are circled in red in Figure 3. These information elements are also referred to as shared categories. The four main catalogues for prescription of pharmaceuticals are circled in green.

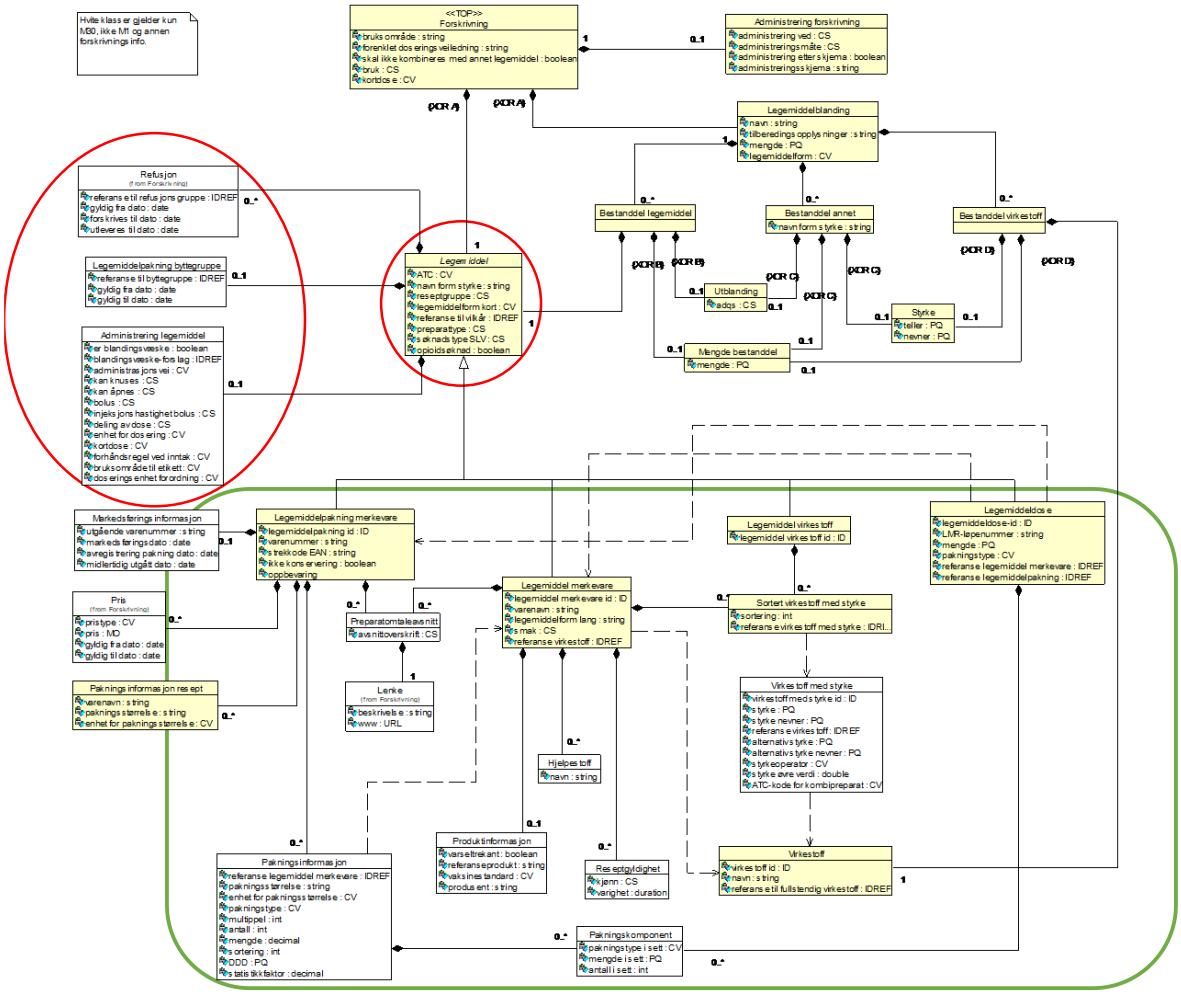

Figure 3 General class Legemiddel (Medicine) (version 2.5.0)

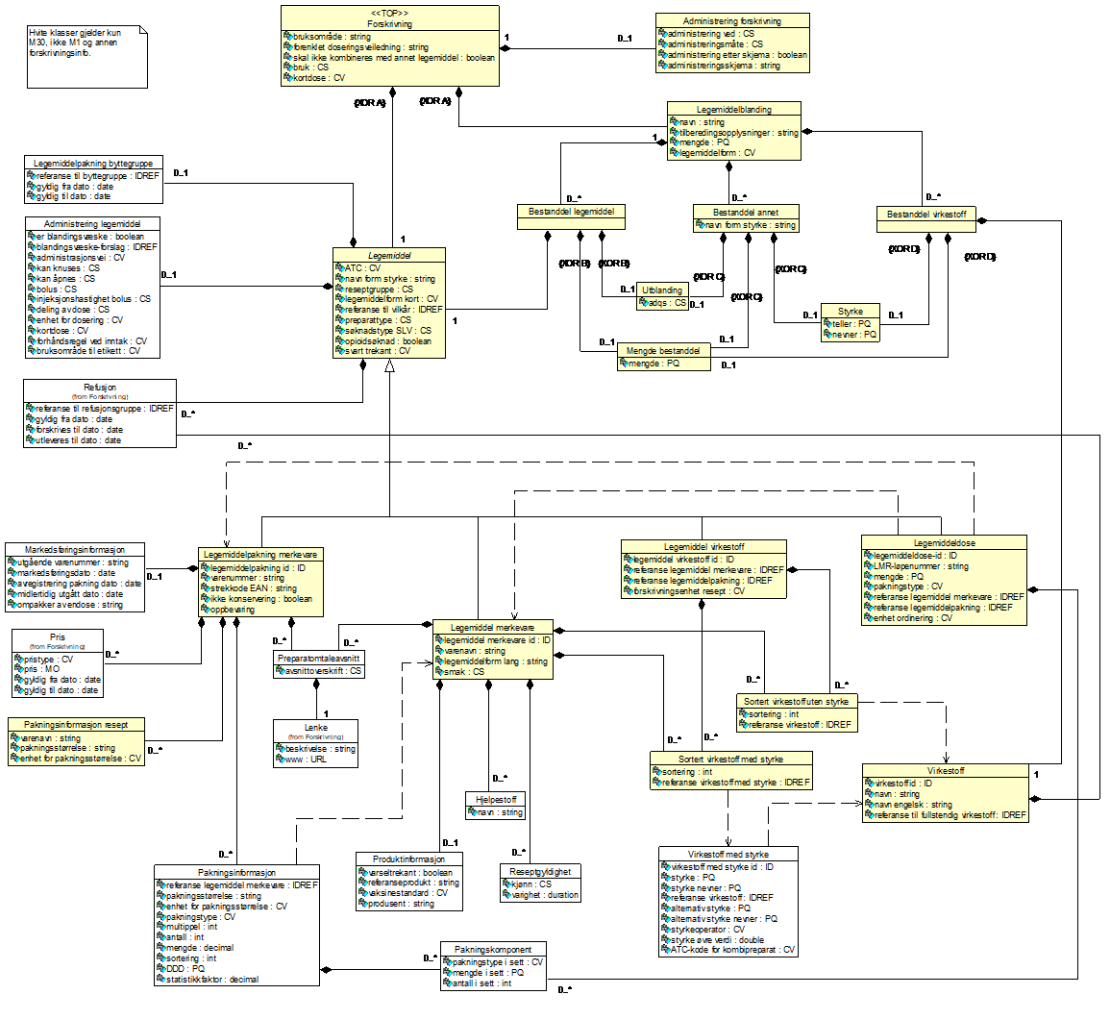

Figure 4 General class Legemiddel (Medicine) (version 2.5.1)

3.2 Main catalogues for information on medicinal products

The four main catalogs represent different approaches to extracting information about medicines.

- LegemiddelVirkestoff (*MedicineActiveSubstance)*,
- LegemiddelMerkevare (*MedicineBrandedProduct*),
- LegemiddelPakningMerkevare (*MedicinePackageBrandedProduct*), and
- LegemiddelDose (*MedicineDose*)

The four catalogues have a central class with the same name, which inherits the abstract class Legemiddel (*Medicine*). This means that the attributes in the class Legemiddel (*Medicine*) can be found in all incidences of the four categories.

The following subchapters describe the four main catalogues. There are information models for each of the catalogues representing the content of the catalogues, see figure 5-12. Even though the FEST Notification Description states that information elements should be available in all catalogues, information is in reality not available

in all attributes at all levels. Table 2 Information in shared categories linked to Legemiddel (Medicine) in Chapter 3.2.5 provides a good overview of what information is available in the various catalogues.

If information elements are required for a class where they are unavailable, one must map to one of the other categories containing this information. Chapter 3.3 explains in more detail how to map between the various categories.

Detailed information about the individual attribute, such as data type, cardinality and examples of attribute content is available in the FEST Notification Description.

3.2.1 *LegemiddelVirkestoff (MedicineActive substance)*

Prescription of active medicine ingredients is based on the catalogue LegemiddelVirkestoff (*MedicineActiveSubstance*). Figure 5 and 6 shows the content of this catalogue, including what has been inherited from the general class Legemiddel (*Medicine*).

All medicines found to be suitable for active substance prescription will exist as an incidence of the class LegemiddelVirkestoff (*MedicineActiveSubstance*). For one incidence of LegemiddelVirkestoff (*MedicineActiveSubstance*), one or several incidences (in practice one, two or three) can be linked to the class SortertVirkestoffMedStyrke (*SortedActiveSubstanceWithStrength*). Several incidences are available to enable prescription of active substances of combination medications.

In FEST, there is a reference which enables mapping of LegemiddelMerkevare (*MedicineBrandedProduct*) pertaining to an incidence of LegemiddelVirkestoff (*MedicineActiveSubstance*). Linked to a LegemiddelMerkevare (*MedicineBrandedProduct*) there are a number of incidences of LegemiddelPakningMerkevare (*MedicinePackageBrandedProduct*). Mapping is a bit different in version 2.5.0 and 2.5.1. This is described in Chapter 3.3.

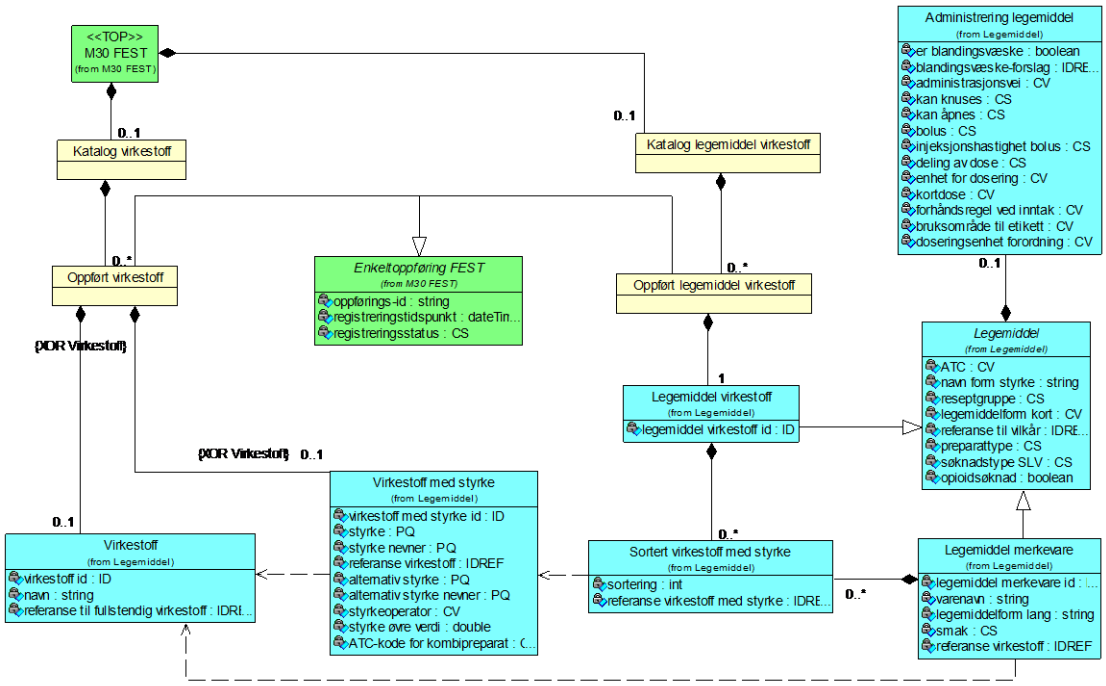

Figure 5 LegemiddelVirkestoff (MedicineActiveSubstance) (version 2.5.0)

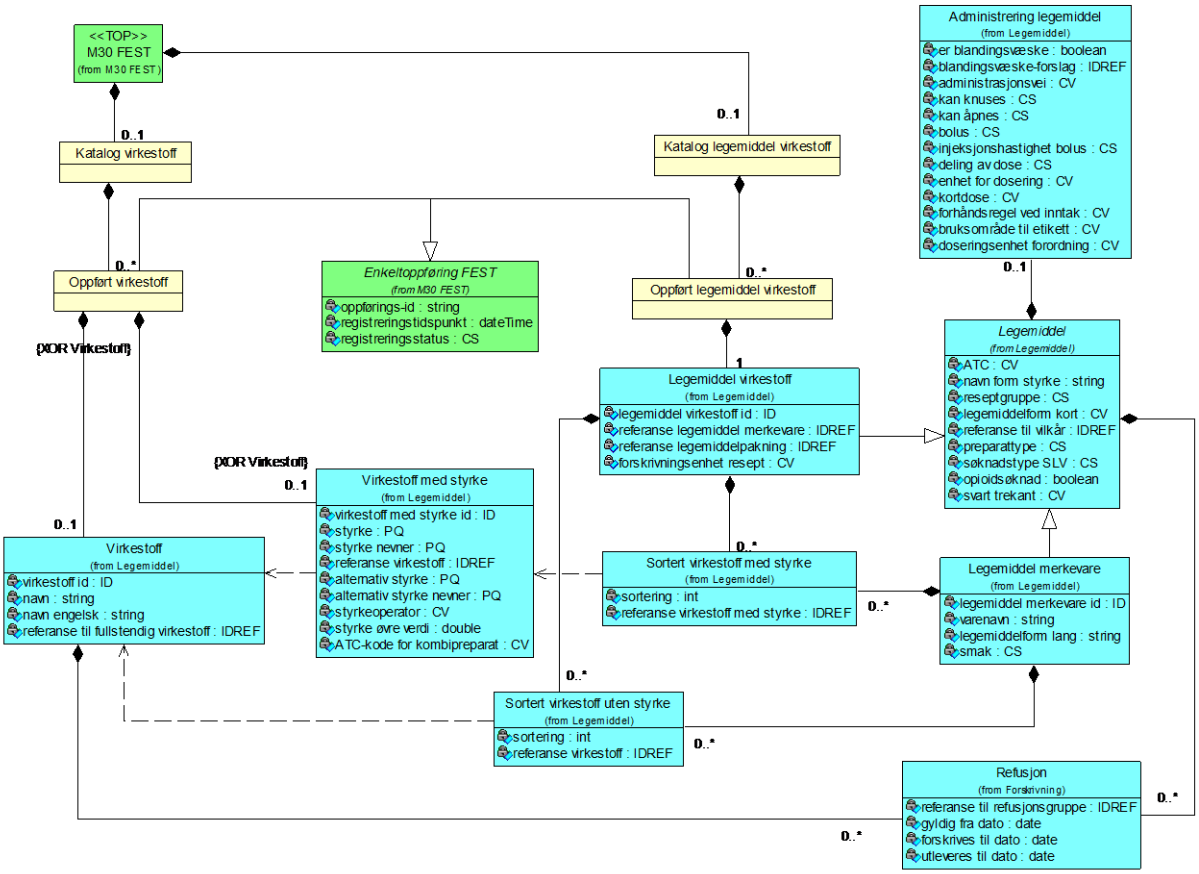

Figure 6 LegemiddelVirkestoff (MedicineActiveSubstance) (version 2.5.1)

3.2.2 *LegemiddelMerkevare (MedicineBrandedProduct)*

Prescription of a specific medicine without Package Size is based on the catalogue LegemiddelMerkevare (*MedicineBrandedProduct*). The figures below show the content of this catalogue, including what has been inherited from the general class Legemiddel (*Medicine*). Per 2024 it is no longer desirable that LegemiddelMerkevare is used for prescription.

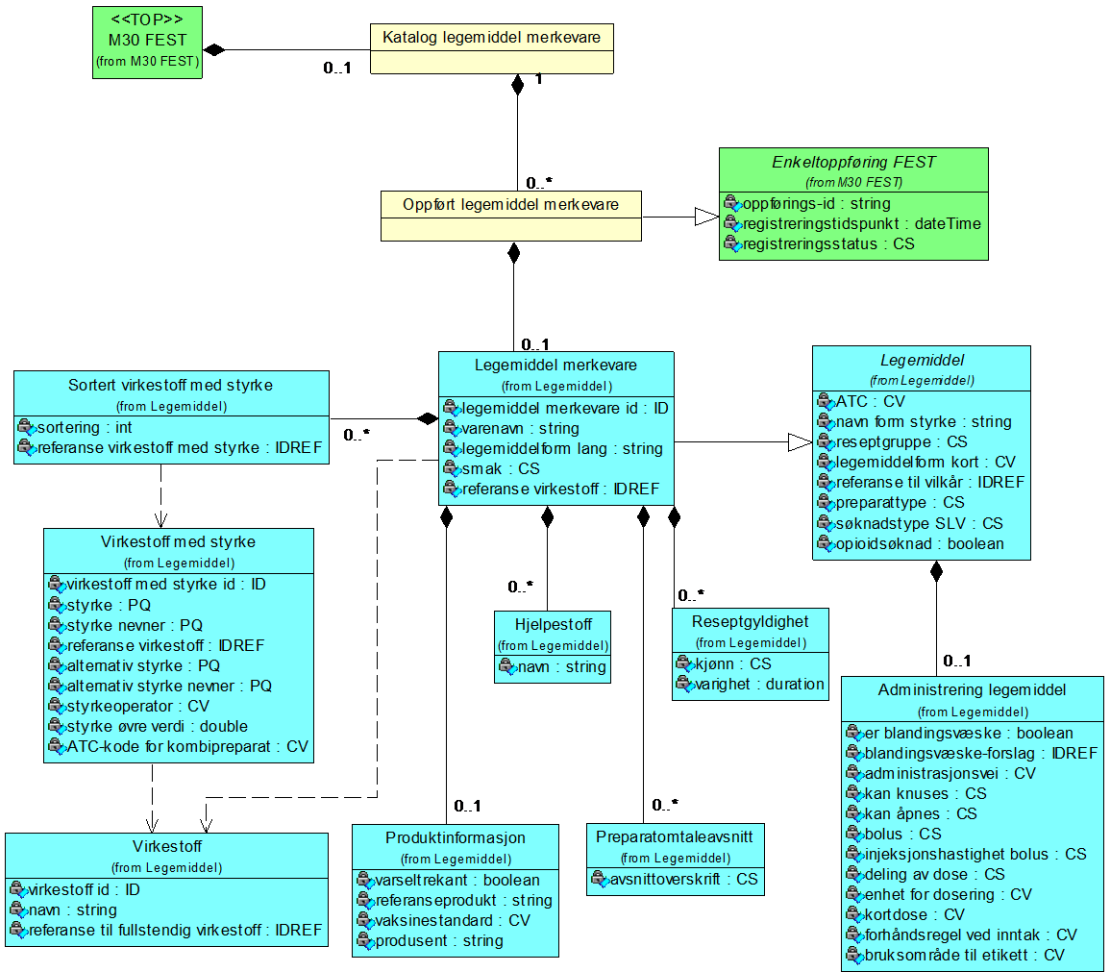

Figure 7 LegemiddelMerkevare (MedicineBrandedProduct) (version 2.5.0)

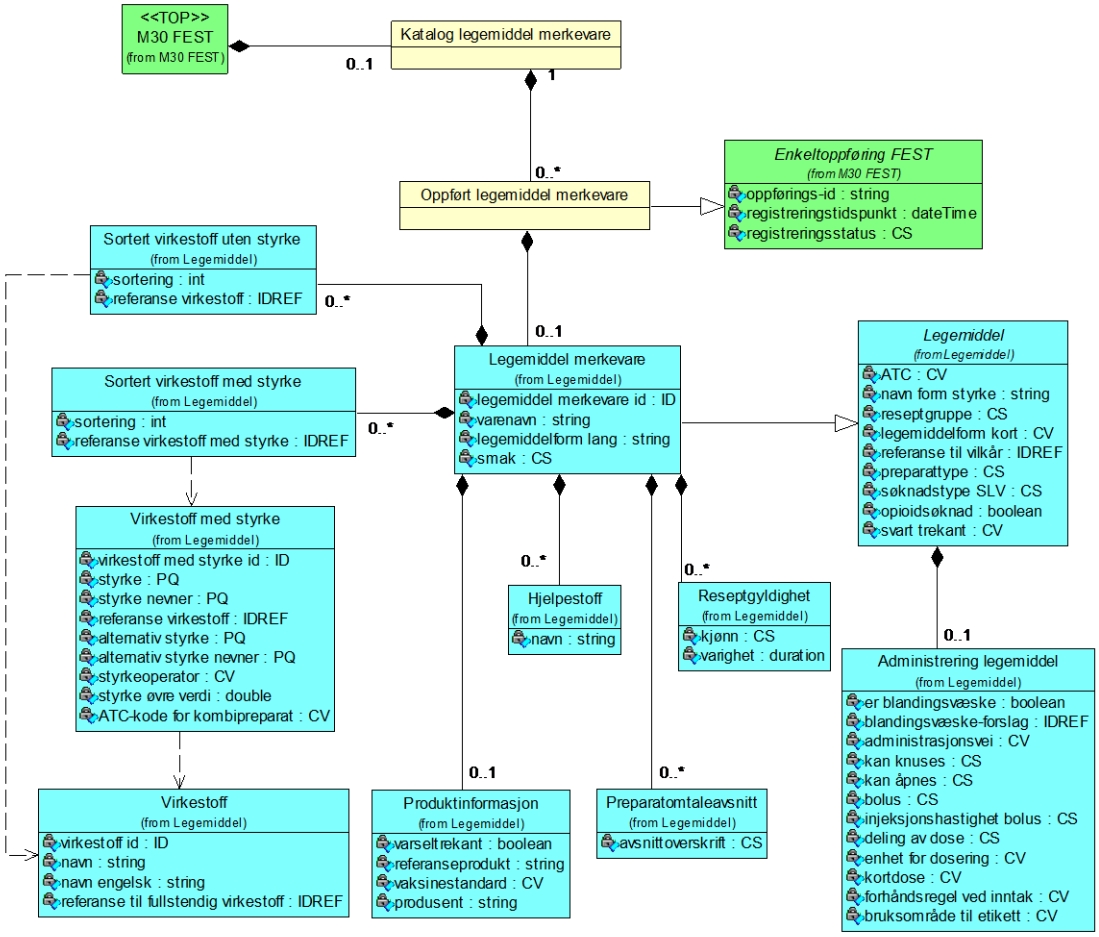

Figure 8 LegemiddelMerkevare (MedicineBrandedProduct) (version 2.5.1)

Special packaging

See Section 6.2.5 regarding how special packaging is entered.

3.2.3 *LegemiddelPakningMerkevare (MedicinePackageBrandedProduct)*

Prescription of packages is based on the catalogue LegemiddelPakningMerkevare (*MedicinePackageBrandedProduct*). Figure 9 and 10 show an extract of the content of this catalogue, including what has been inherited from the general class Legemiddel (*Medicine*).

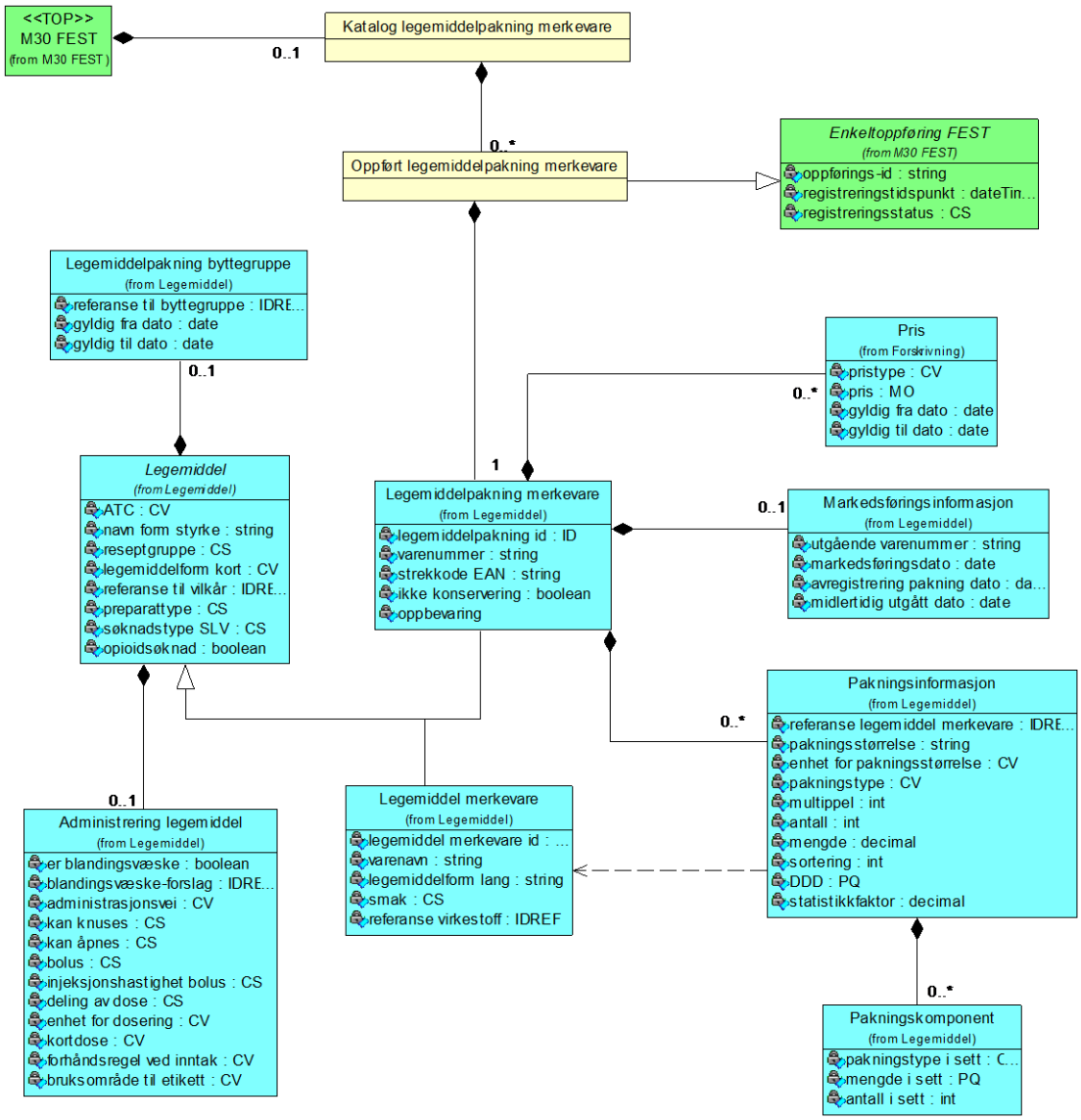

Figure 9 LegemiddelPakningMerkevare (MedicinePackageBrandedProduct) (version 2.5.0)

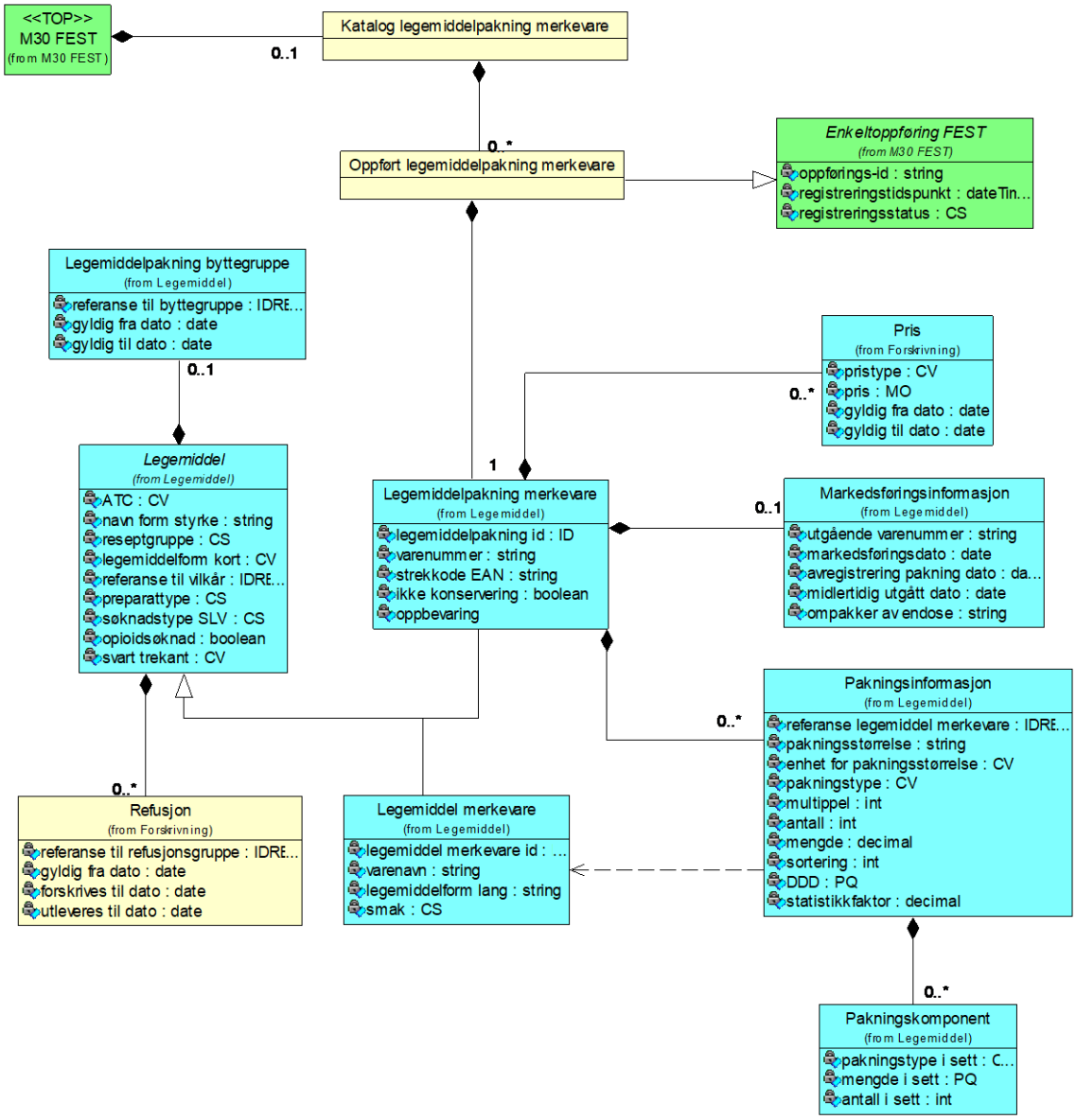

Figure 10 LegemiddelPakningMerkevare (MedicinePackageBrandedProduct) (version 2.5.1)

3.2.4 *LegemiddelDose (MedicineDose)*

Prescription of a certain medicine without a link to special packaging is based on the catalogue LegemiddelDose (*MedicineDose*). Figure 11 and Figure 12 below show the content of this catalogue, including what has been inherited from the general class Legemiddel (*Medicine*). Information in the catalogue LegemiddelDose (*MedicineDose*) facilitates prescription with dispensing to the patient at single dose level in hospitals.

For each of a medicine's branded products, the smallest unit contained in the package has been defined as a listing in the catalogue LegemiddelDose (*MedicineDose)*, for instance one tablet or one ampoule containing 5 ml. This means that all packages with the same NavnFormStyrke (*NameFormStrength*) will be linked

to the same LegemiddelDose (*MedicineDose)*. Each LegemiddelDose (*MedicineDose)* has its own unique ID (medicine dose ID) with its own LMR number.

The package type is only specified if there are two medications of the same quantity and unit of a branded product. This has been done as different packages may affect prescription and dispensing/administration. These are represented as two different LegemiddelDoser (*MedicineDoses*), each with its own LMR number.

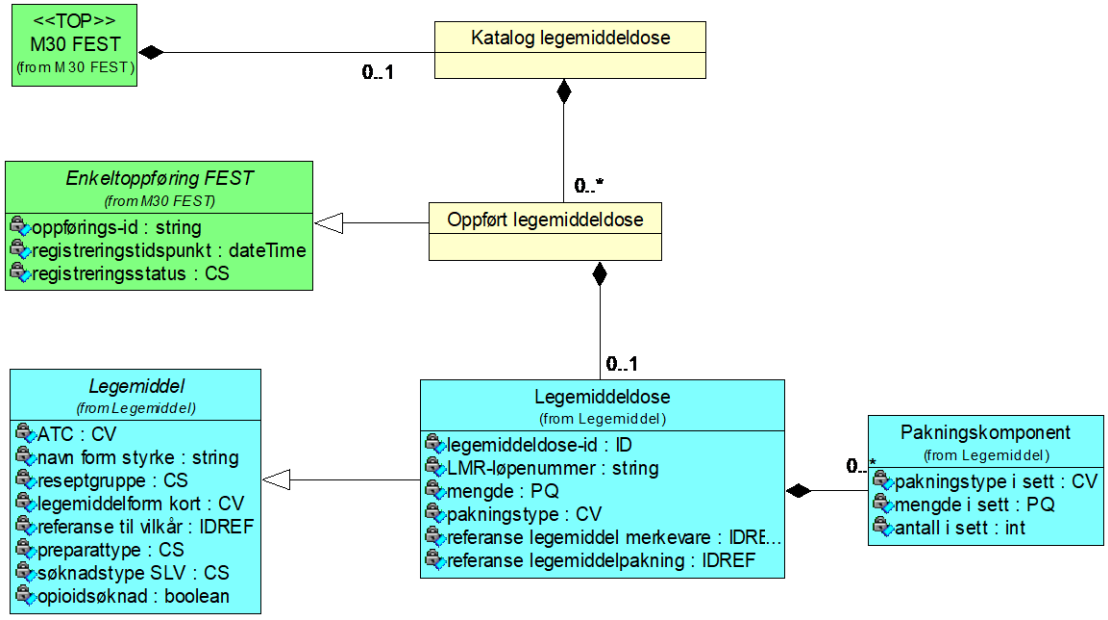

Figure 11 Different LegemiddelDose (MedicineDose) (version 2.5.0)

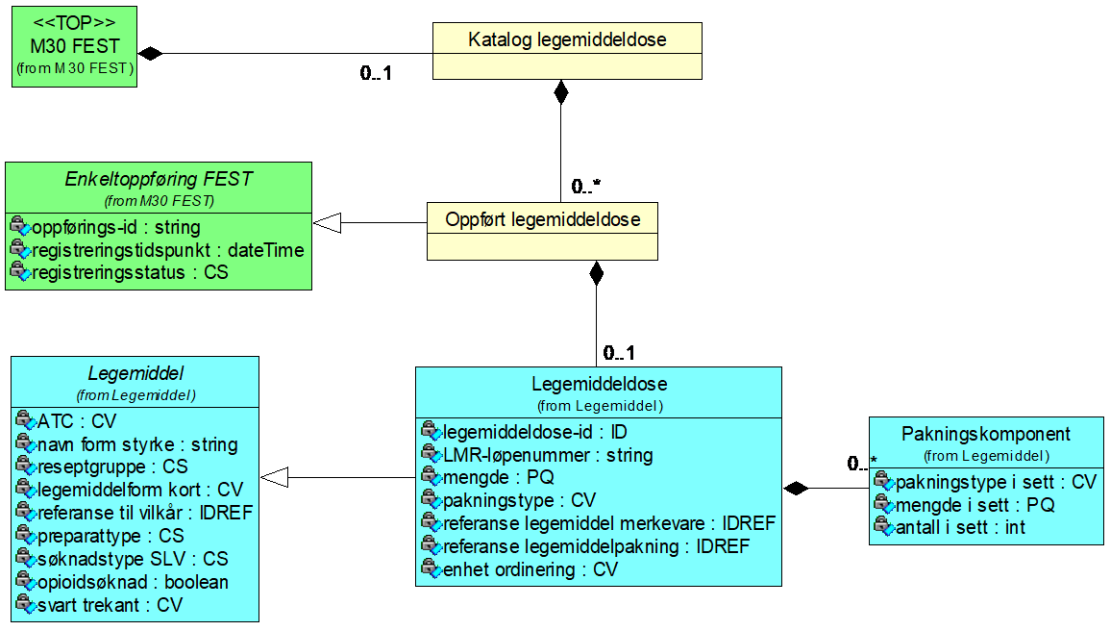

Figure 12 Different LegemiddelDose (MedicineDose) (version 2.5.1)

3.2.5 *Information content in shared categories linked to Legemiddel (Medicine)*

The information content in the various shared categories (cf. Figure 3 above) will be different depending on from which catalogue/level in FEST the information has been obtained. According to the Notification Description, there are some elements that should be available in all four catalogues. However, information has only been provided in some of the catalogues.

Table 2 shows which information is available in the shared categories linked to Legemiddel (*Medicine*) in the different catalogues.

Table 2 Information in shared categories linked to Legemiddel (Medicine)

Field from shared categories	LegemiddelPakningMerkevare (*MedicinePackageBrandedProduct*), Package	LegemiddelDose (*MedicineDose*), single dose	LegemiddelMerkevare (*MedicineBrandedProduct*, strength of branded product	LegemiddelVirkestoff (*MedicineActiveSubstance*), prescription of active substance
ATC	Normally level 5	As on the package	As on the package	As on the package
NavnForm Styrke (NameFormStrength)	String of branded product name, pharmaceutical form and strength	String of branded product name, pharmaceutical form and strength	String of branded product name, pharmaceutical form and strength	String of branded product name, pharmaceutical form and strength
Prescription group	Always completed	Always completed	Always completed	Always completed
Pharmaceutical form	Always completed	As on the package	As on the package, except for combination packages	As on the package
Reference to conditions	No information	No information	Dispensing regulations or other general conditions	Dispensing regulations or other general conditions
Type of medication	Always completed	As on the package	As on the package	As on the package
Application type SLV	Always completed	As on the package	As on the package	As on the package
Opioid application	Information only on packages requiring opioid application	As on the package	As on the package	As on the package
Reimbursement	Reference to reimbursement group on all packages with reimbursement §2, §3 or H-prescription	No information	No information	Reference to one or several reimbursement groups, that are a union of reimbursement relating to all packages with a

				common prescription of active substance
Medicine package substitution group	Reference to substitution group on all packages with generic substitution decision	No information	No information	No information
Medicine administration (indicated per field below)				
Mixing liquid	No information	No information	Indicated on medicine when relevant	Indicated on LegemiddelVirkestoff (*MedicineActiveSubstance*) if indicated on the associated LegemiddelMerkevare (*MedicineBrandedProduct*)
Mixing liquid proposal	No information	No information	Indicated on medicine when relevant	Indicated on LegemiddelVirkestoff (*MedicineActiveSubstance*) as the union of the values indicated on the associated LegemiddelMerkevare (*MedicineBrandedProduct*)
Route of administration	No information	No information	Indicated on all human medicines	Indicated on all LegemiddelVirkestoff (*MedicineActiveSubstance*), and identical with LegemiddelMerkevare (*MedicineBrandedProduct*)
Can be crushed	No information	No information		Indicated on LegemiddelVirkestoff (*MedicineActiveSubstance*), if indicated on the associated LegemiddelMerkevare (*MedicineBrandedProduct*)
Can be opened	No information	No information	Indicated on medicines where relevant	No information
Division of dose	No information	No information	Indicated on medicines where relevant	No information
Unit of dosage	No information	No information	Indicated with dosage unit. On all human pharmaceuticals	Indicated on LegemiddelVirkestoff (*MedicineActiveSubstance*) as the union of

			except radiopharmaceuticals	the values indicated on the associated LegemiddelMerkevare (*MedicineBrandedProduct*)
Short dose	No information	No information	One or several dosage proposals indicated on most human medicines	Indicated on LegemiddelVirkestoff (*MedicineActiveSubstance*) as the union of the values indicated on the associated LegemiddelMerkevare (*MedicineBrandedProduct*)
Ingestion precaution	No information	No information	Indicated with one or several precautions. On medicines when relevant	Indicated on LegemiddelVirkestoff (*MedicineActiveSubstance*) if it exists on the associated LegemiddelMerkevare (*MedicineBrandedProduct*)
Application	No information	No information	Indicated with one or several applications. On medicine where relevant	Indicated on LegemiddelVirkestoff (*MedicineActiveSubstance*) if it exists on the associated LegemiddelMerkevare (*MedicineBrandedProduct*)
Bolus	No information	No information	No information due to lack of source	No information due to lack of source
Injection rate bolus	No information	No information	No information due to lack of source	No information due to lack of source

3.3 Mapping between main pharmaceutical catalogues

Below follows a description of relevant mappings between main catalogues.

3.3.1 *Mapping LegemiddelVirkestoff (MedicineActiveSubstance → LegemiddelMerkevare (MedicineBrandedProduct)*

In version 2.5.0:

To map from the class LegemiddelVirkestoff (*MedicineActiveSubstance*) to the class LegemiddelMerkevare (*MedicineBrandedProduct*) one must go via the class SortertVirkestoffMedStyrke (*SortedActiveSubstanceWithStrength*), e.g. find the LegemiddelMerkevare (*MedicineBrandedProduct*) entries with a link to the same entry/entries of SortertVirkestoffMedStyrke (*SortedActiveSubstanceWithStrength*) as LegemiddelVirkestoff (*MedicineActiveSubstance*).

The following must be fulfilled in order for an incidence of the class LegemiddelMerkevare (*MedicineBrandedProduct*) to belong to a LegemiddelVirkestoff (MedicineActiveSubstance)

- All incidences of SortertVirkestoffMedStyrke (*SortedActiveSubstanceWithStrength*) referred on a LegemiddelMerkevare (MedicineBrandedProduct) must be the same as the corresponding incidences of SortertVirkestoffMedStyrke (*SortedActiveSubstanceWithStrength)* derived from LegemiddelVirkestoff (*MedicineActiveSubstance)*.
- The pharmaceutical form of the LegemiddelMerkevare (MedicineBrandedProduct) and the LegemiddelVirkestoff (*MedicineActiveSubstance*) must be the same.
- The ATC code for the LegemiddelMerkevare (MedicineBrandedProduct) and LegemiddelVirkestoff (MedicineActiveSubstance) must be the same.

The attribute Sortering (*Sorting)* in the class SortertVirkestoffMedStyrke (*SortedActiveSubstanceWithStrength)* indicates the order in which the active substances are displayed when there is more than one. Sorting can be ignored in this mapping, as it might start on different numbers.

In version 2.5.1:
There are direct references from LegemiddelVirkestoff (*MedicineActiveSubstance*) to the relevant entries in LegemiddelMerkevare (*MedicineBrandedProduct)* and LegemiddelPakningMerkevare (*MedicinePackageBrandedProduct*. To secure that the system returns correct branded product and branded packages that suites the prescription of active substance, the direct reference is to be used (IDref).

3.3.2 *Mapping LegemiddelMerkevare (MedicineBrandedProduct) → LegemiddelPakningMerkevare (MedicinePackageBrandedProduct)*

To map from LegemiddelMerkevare (*MedicineBrandedProduct*) to associated packages, one must go via IDref between LegemiddelPakningMerkevare (*MedicinePackageBrandedProduct)* and LegemiddelMerkevare (*MedicineBrandedProduct*). This is located in the class Pakningsinformasjon (*PackageInformation*) in the catalogue LegemiddelPakningMerkevare (*MedicinePackageBrandedProduct)*.

3.3.3 *Mapping LegemiddelMerkevare (MedicineBrandedProduct) → LegemiddelDose (MedicineDose)*

For each branded product of a medicine, the smallest unit contained in the package has been defined as a listing in the catalogue LegemiddelDose (*MedicineDose)*, for instance one tablet or one ampoule containing 5 ml. For each LegemiddelDose (*MedicineDose)* there is a direct reference (IDref) to LegemiddelMerkevare (*MedicineBrandedProduct)*.

3.3.4 *Mapping LegemiddelDose (MedicineDose) → LegemiddelPakningMerkevare (MedicinePackageBrandedProduct).*

To find the specific packages pertaining to an entry of LegemiddelDose (*MedicineDose*) a direct reference (IDref) to LegemiddelPakningMerkevare (*MedicinePackageBrandedProduct)* is used. This is located in the class LegemiddelDose (*MedicineDose*).

3.3.5 *Relevant scenarios*

This section describes some relevant scenarios where the mappings above must be used.

Active substance prescription:

All medicines suitable for prescription of active substance will be available as an entry in the catalogue LegemiddelVirkestoff (*MedicineActiveSubstance*). For prescription of active substances, the system used for preparation/distribution/dispensing must be able to find what packages/medicine doses are represented by the active substance prescription, e.g. what packages or single doses can be dispensed based on the indicated active substance, dosage form and strength. See also Chapter 4.

The Farmalogg-filter of FEST contains packages with both human- and veterinary ATC-codes linked to the same LegemiddelVirkestoff (*MedicineActiveSubstance*). We recommend that the user system separates human- and veterinary ATC-codes in LegemiddelVirkestoff so that only packages with human ATC-codes is shown in the pharmacy system when dispensing an active substance-based prescription.

To map from LegemiddelVirkestoff (*MedicineActiveSubstance*) to the individual LegemiddelPakningMerkevare (*MedicinePackageBrandedProduct)* entry, the following must be used:

- the navigation LegemiddelVirkestoff (*MedicineActiveSubstance*) ⇨LegemiddelMerkevare (*MedicineBrandedProduct)* as described in Chapter 3.3.1, and
- then the navigation LegemiddelMerkevare (*MedicineBrandedProduct*) to LegemiddelPakningMerkevare (*MedicinePackageBrandedProduct)* as described in Chapter 3.3.2.

Note; in version 2.5.1 it is possible to map directly from LegemiddelVirkestoff (*MedicineActiveSubstance*) to LegemiddelMerkevare (*MedicineBrandedProduct*) and LegemiddelMerkevarePakning (*MedicinePackageBrandedProduct)* via the IDref. Some information that will be displayed for active substance subscription must be navigated in from other catalogues. In such cases, navigation between catalogues is used as described above.

When the prescriber chooses an active substance in his own system, the amount of

prescribed medicine (e.g. 50 units (stk) of tablets or correct packaging), must be indicated, cf. Chapter 4.4. See also the Requisitioner requirements e-prescription [Norwegian]

- The quantity specifies the prescriber as a number.
- The lists of possible units which can be used in prescriptions, must be populated from the packages represented by the active subscription. This is done by retrieving all "LegemiddelPakningMerkevare.Pakningsinformasjon.enhet» (MedicinePackageBrandedProduct.Packageinformation.units) and aggregating them into the list of the prescriber's choice of unit.

Alternatively, the prescriber can be shown the available package sizes which are available for a given entry of LegemiddelVirkestoff (MedicineActiveSubstance). The navigation from LegemiddelVirkestoff (MedicineActiveSubstance) to LegemiddelPakningMerkevare (MedicinePackageBrandedProduct) (as described above) is then used, with the presentation of all package sizes to which the references refer. Examples of a package size are "Boks, 50 stk." (Box, 50 pcs.) and "Blisterpakning, 20 stk." (Blister pack, 20 pcs.).

Prescription validity aggregated to active substance prescription:
To find the prescription validity of an active substance prescription, it must be retrieved from LegemiddelMerkevare (MedicineBrandedProduct). It can be retrieved from any of the associated LegemiddleMerkevare.

This is because the prescription validity is always the same. As the ATC code is identical for all medicines which belong to the same active substance prescription, these will always have the same prescription validity. In theory, multiple strength- and combination packages are an exception, e.g. packages that refer to multiple entries of LegemiddelMerkevare (*MedicineBrandedProduct*). None of them has a prescription validity which deviates from the normal validity, i.e. one year.

Dispensing/administration of single doses:
When prescribing an active substance, mapping is required to show which LegemiddelDoser (*MedicineDoses*) can be dispensed based on the prescribed LegemiddelVirkestoff (*MedicineActiveSubstance*). In such cases, mapping 3.3.1 is used first, followed by mapping 3.3.3.

To obtain or sell a prescribed dose, it is a requirement that the package in question, from which the tablet originates, can be retrieved by searching on the same LegemiddelDose (*MedicineDose*). For this, mapping 3.3.4 is used.

Displaying information about a LegemiddelDose (*MedicineDose*):
To display information about a LegemiddelDose (*MedicineDose*) information has to be retrieved from other catalogues. Detailed information about strength must, for instance, be retrieved from SortertVirkestoffMedStyrke (SortedActiveSubstanceWithStrength) linked to LegemiddelMerkevare (*MedicineBrandedProduct*).

3.4 Cardinality more restricted than indicated in the data model

The data model allows more than is actually in use for FEST. The reason for this is that the data model must be suitable for use of other notifications in E-prescription. The categories in FEST are reused in other notifications. Two examples are shown below.

Table 3; Cardinality

Information element	Card. in data model	Card. in practice	Comment
Pharmaceutical package. Package information. Ref.LegemiddelMerkevare (*MedicineBrandedProduct*)	0..*	1..*	A package will always belong to at least one Merkevare (*BrandedProduct*) in FEST, usually only one, but more for multiple strength- and combination packages.
LegemiddelVirkestoff (*MedicineActiveSubstance*). SortertVirkestoffMedStyrke (*SortedActiveSubstanceWithStrength*).	0..*	1..*	A prescription of an active substance will always have at least one active substance with strength

Chapter 3.2.5 describes the four main catalogues/levels associated with prescription of medicines. The class Legemiddel (*Medicine*) is shared by all prescription categories.

4 Prescription of an active substance

4.1 Purpose of prescription of active substances

Prescription of active substances (generic prescription) is a prescription issued regardless of brand name. The purpose of prescription of active substances is mainly to promote awareness of the active substances and to ensure that the active substances are used in medical communication instead of the brand name. The active substances should be used as a basis for communication both internally in the health service and between the health service and the general public. This will help ensure that it is safer for patients to switch between equivalent medicines.

Meld. St. 28 (2014–2015) “White Paper on Medicinal Products - Correct use - better health” recommends that active substances are used for prescription/dispensing of medicines when possible.

4.2 Prescription of an active substance in FEST

An active substance prescription group is defined as medicines with an identical active substance, ATC code, pharmaceutical form, strength and prescription group.

In principle, all marketed medicines can be prescribed as an active substance. From 2019, information for active substance prescriptions (entries in the LegemiddelVirkestoff catalogue) will be supplied for pharmacy-produced and unregistered medicines in FEST.

In FEST, the following criteria imply that a medicine is unsuitable for prescription as an active substance:

- The medicine has more than three active substances
- The medicine has a strength indication unsuitable for prescription as an active substance.
- The medicine has no indication of strength
- The medicine has been assessed as being unsuitable for prescription based on active substance for medical or patient safety reasons.
- Technical limitations mean that the medicine is unsuitable for prescription based on active substance.

In these cases, no groups are available for active substance prescription (LegemiddelVirkestoff) in FEST.

4.3 Prescription of an active substance unregistered medicines

The TypeSoknadSLV field (TypeOfApplicationNorwegianMedicalProductsAgency) has been introduced in all entries of LegemiddelVirkestoff (MedicineActiveSubstance). In cases where LegemiddelVirkestoff only points to references to unregistered medicines, the field contains either "Apotek vurderer" (Pharmacy assesses) or "Må søkes» (Must be applied for).

This must be used by the prescription system in the same way as when managing the field for branded products/packages, i.e. to trigger a requirement for medical justification (through notification/«apotek vurderer») or an electronic application for approval exemption to NOMA («Må søkes»). The approval exemption solution does not work on such prescriptions today, groups with only unregistered drugs will not be delivered by NOMA.

More information is available from Norwegian Healthnet: Rekvirentspesifikasjon for e-resept - E-resept - dokumentasjon - Confluence (atlassian.net) [Norwegian]

4.4 Prescription of an active substance at the prescriber (generic prescription)

The prescriber should use prescription of active substance for medicines that are suitable for such prescription, both for the issuing of prescriptions and for internal dispensing in hospitals.

It shall be possible to search by active substance in the user system. The medicine will be selected based on active substance, form and type of medicine (Group of Active substances for prescription). Any associated reimbursements, notifications, interactions, etc. must be shown to the user (se chapter 9 for NOMA notifications and associations). The prescriber must write in the user system the desired amount of medicine, for instance 50 items.

In the user system, it should also be possible to search by brand name, and subsequently obtain hits on relevant active substance prescription groups. To stimulate the prescriber to use generic prescription, it is advised that all groups of active substances be listed alphabetically with the *active substance prescription groups first,* when a search is performed based on both Merkevare *(BrandedProducts)* and active substances.

To stimulate the use of active substance prescription (cf. the Medicinal Product Policy), the prescription system should have functionality which converts a prescription/dispensing based on brand to active substance. This should also apply to prescription renewals. See also https://www.nhn.no/tjenester/e-resept/dokumentasjon-for-e-resept [Norwegian]

If a medicine cannot be substituted by a generic for medical reasons, the physician

must prescribe a Pakning (*PackageBrandedProduct*) and not an active substance, and choose ‘prevent substitution’ in the usual manner.

The prescription system should specify relevant measuring units for the amount that is to be prescribed (e.g. ml), and suggest relevant package sizes in a dropdown list based on package references from LegemiddelVirkestoff (*MedicineActiveSubstance*) (e.g. bottle 5 ml).

For 2.5.0: Relevant amount units must be obtained from the attribute Enhet for pakningsstørrelse (*Unit for Package Size*) available in the class Pakningsinformasjon (*PackageInformation*) in the catalogue LegemiddelPakningMerkevare (*MedicinePackageBrandedProduct*). The mapping for this is described in Chapter 3.3. Relevant units for packages should be set by default, so that the prescriber only has to enter a number for the desired amount. Relevant package sizes are available via the same mapping.

For 2.5.1: The unit to specify the amount is submitted in the ForskrivningsenhetResept (PrescribingUnitPrescription) field in LegemiddelVirkestoff (MedicineActiveSubstance). Relevant package sizes are available via direct references to each individual package (RefPakning - *RefPackage*)

4.5 Dispensing medicines based on prescription of an active substance

The system used to dispense/issue a medicine must, based on a prescription of an active substance, be able to show which branded products, packages or single doses that can be dispensed. The mapping for this has been described in Chapter 3.3.

If the medication has a substitution group code, there will be instances where medications with a different LegemiddelVirkestoff (*MedicineActiveSubstance*) ((NavnFormStyrke (*NameFormStrength*)) can be selected, provided the medications have the same substitution group code. If the medication has a substitution group code, the pharmacy system must be linked to the substitution list and show which branded products can be used for substitution. The pharmacy system must always allow substitution with all products in the same substitution group, even if they do not have the same LegemiddelVirkestoff (*MedicineActiveSubstance*). This relates to, e.g., generic substitution of capsules and tablets. Cf. Chapter 6.5 for more information about substitution groups.

5 Information about medicines

This chapter describes what kind of information the recipient can expect to find in certain key fields in FEST.

5.1 Dosage form

The dosage form, as relevant for prescription, is available in the class Legemiddel (*Medicine*) as the attribute legemiddelform kort (*medicine short form*) (also referred to as kortform (*short form*). Legemiddelform kort (*Medicine short form*)/kortform (*short form*) refers to the coding system Legemiddelform (kort) (*Pharmaceutical form (short*)) available at www.volven.no (coding system 7448). The coding system also contains an abbreviated short form, e.g. the short form Tablett (*Tablet*) has been abbreviated to Tab.

The complete dosage form is only available in the catalogue LegemiddelMerkevare (*MedicineBrandedProduct*) as the attribute legemiddelform lang (*medicine long form*), and indicates the complete, approved pharmaceutical form pursuant to NLS (*Norwegian medicines standard*). An example is: «Injeksjonsvæske, oppløsning i ferdigfylt penn» (*Injection liquid, solution in prefilled pen*), with LegemiddelformKort (*MedicineShortForm*) «Inj væske».

In the FEST notification, the pharmaceutical forms are displayed as LegemiddelformKort (*MedicineShortForm*) and LegemiddelformLang (*MedicineLongForm*), cf. Figure 13 below.

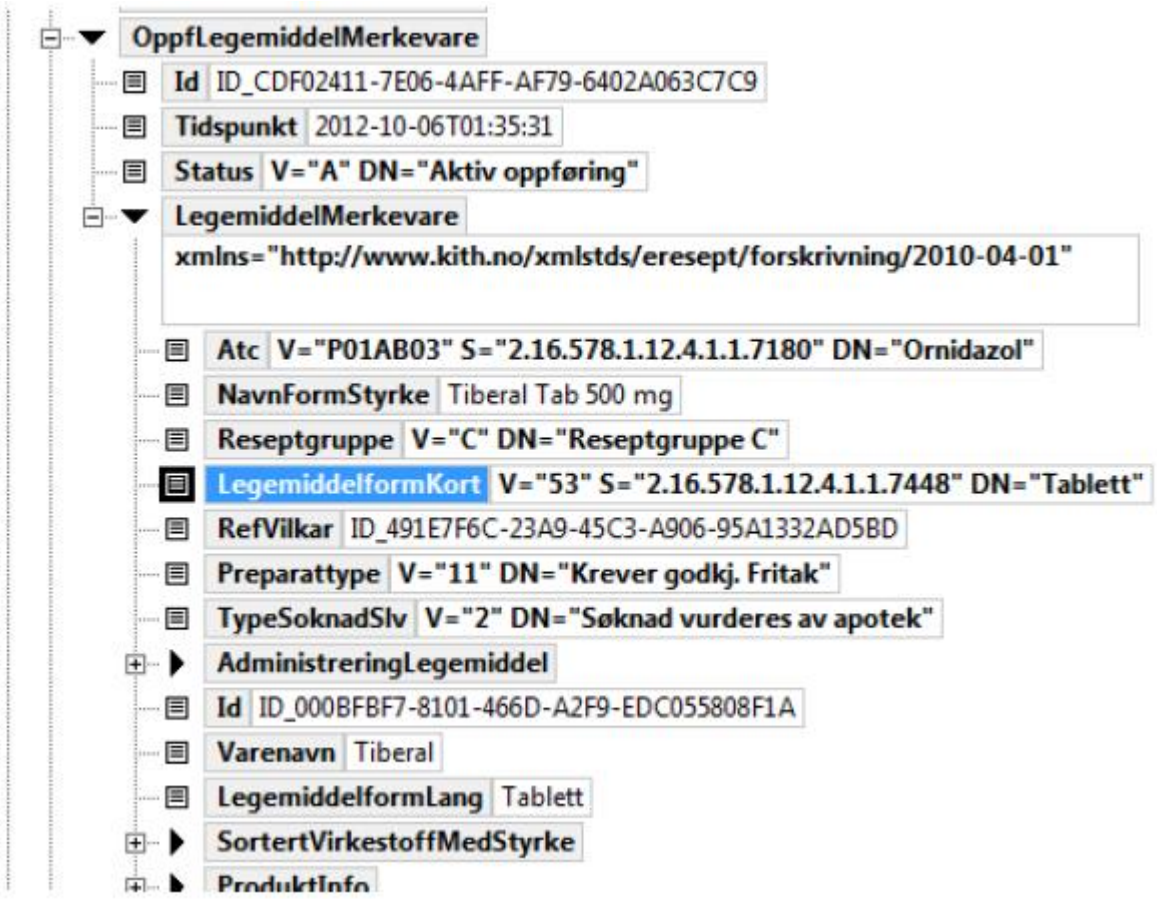

Figure 13 The coding systems LegemiddelformKort (MedicineShortForm) and LegemiddelformLang (MedicineLongForm) in FEST

5.2 Active substance with and without indication of strength

It is relevant to indicate the strength of most medicines. The strength is incorporated into the NavnFormStyrke (*NameFormStrength*) field, provided that the medicine contains no more than three active substances. If the medicine contains more than three active substances, the individual strength values will not be incorporated into the NavnFormStyrke (*NameFormStrength*) field, but may still be available in an entry of NavnFormStyrke (*NameFormStrength*) each.

The number of NavnFormStyrke entries (*NameFormStrength*) that can be linked to a LegemiddelMerkevare (*MedicineBrandedProduct*) is in principle infinite, i.e. they will all be included. Because of the limitation on field length in certain user systems, preparations with many ingredients will either be specified without a strength for an individual substance, or they will be collected together under joint designations. This applies for example to total parenteral nutrition.

For some medicines, there is no professional relevance in indicating the strength value in either NavnFormStyrke (*NameFormStrength*) or VirkestoffMedStyrke (*ActiveSubstanceWithStrength*). The reference from LegemiddelMerkevare (*MedicineBrandedProtect*) will then go directly to active substance (not via

VirkestoffMedStyrke – *ActiveSubstanceWithStrength).* There is also no associated entry in LegemiddelVirkestoff (*MedicineActiveSubstance*) for these medicines. This means that they cannot be generically prescribed.

5.3 Sorting of active substances without strength

In version 2.5.1, the sorting of active substances is given without strength according to the most potent drug first, but there are exceptions, e.g. certain old preparations.

5.4 Active substances in English

In version 2.5.1, the active substances names are also given in English, in addition to Norwegian.

5.5 Indication of strength

In the strength indication in the field NavnFormStyrke (*NameFormStrength*), there is a difference between a comma and a full stop. Comma is used to indicate thousand, whereas a full stop is used to indicate a decimal. In the class Virkestoff (*ActiveSubstance*), a comma is not used to indicate thousands, and a full stop is used as a decimal separator.

Up to four fields can be used to indicate a medicine's strength. This is to be able to calculate, for instance, the total dose of an active substance. See the examples in Table 4, and Figure 14 for the specification of Styrkeoperatør (*Strength operator*).

Table 4; Strength specified in different fields

Strength		Unit Strength numerator		Unit Strength denominator
1 mg/ml	1	mg	1	ml
5 mg/5 ml	5	mg	5	ml
>2.5 IE/dose See Figure 14	>2.5	IE	1	dose

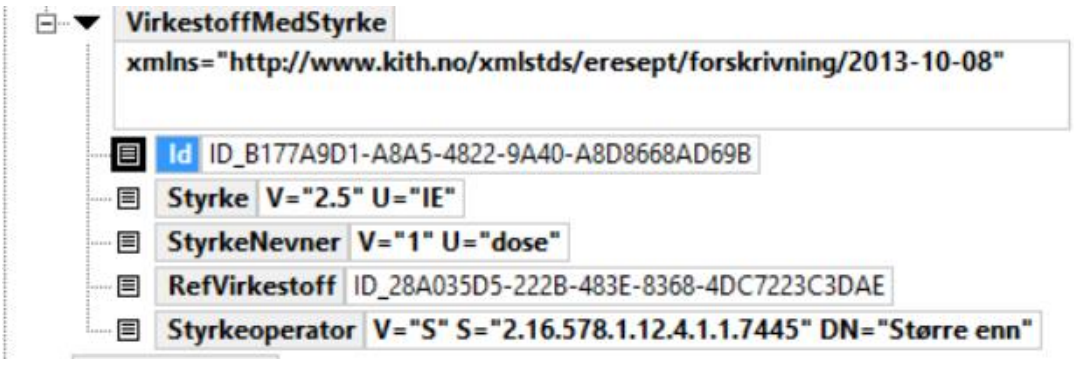

Figure 14 «Strength operator»

5.5.1 *Strength of liquid medication*

The strength of liquid medications is expressed as concentration, e.g. mg/ml. If the medicine unit is intended for consumption of the entire dose at once, the concentration will be expressed in amount per total volume, for instance 1 mg/0.5 ml in the case of prefilled dosing equipment.

5.5.2 *Strength of powder etc.*

The strength of a powder will be expressed as content of an active substance by weight, e.g. 2 mg. If the pharmaceutical form is Powder and solution, only the strength of the powder will be given. This will be the case even if the approved strength could deviate from this. The reason is that the way in which strength is specified in FEST means that it can be used for a solution with the desired volume of liquid.

5.5.3 *Alternative strength*

Alternative strength is an extra attribute for strength which is used in certain cases:

- If the strength of a medicine is expressed as a percentage, alternative strength will also be given in FEST, in addition to this strength. This will be expressed as weight/weight or weight/volume.
- If the medicine is eye drops, ear drops or for inhalation, strength per dose will be given as alternative strength unless the ordinary strength indication is given per dose.

5.6 Active substances for magistral prescription

Active substances for magistral prescription should be obtained from the class Virkestoff (*Active substance*) for use in magistral prescriptions. The catalogue LegemiddelVirkestoff (*MedicineActiveSubstance*) also contains active substances which are not referenced from any medicines/without a link to any medicines which can be used in connection with magistral prescription.

For reimbursement relating to magistral prescriptions, cf. Chapter 6.4.4.

5.7 Vilkår (Conditions)

Vilkår (*Conditions*) is a general class containing several types of conditions. What group of conditions a condition belongs to is defined through the attribute condition group. In other words, references to conditions are made from several categories, and must be used in different ways, depending on from where the reference originates.

- Vilkårsgruppe 1: Legemiddel (*Group of conditions 1 Medicine*): Withdrawn from use November 2017.
- Vilkårsgruppe 2 Handelsvare (*Group of conditions 2 Commodity):* References from the class Vare (*Product*) are conditions relating to commodities.

- Vilkårsgruppe 3 Refusjon (*Group of conditions 3 Reimbursement):* References from a reimbursement code in the class Refusjon (*Reimbursement*) are only used for reimbursements relating to medicines.
- Vilkårsgruppe 4 Utleveringsbestemmelse (*Group of conditions 4 Dispensing regulation*): Referances from the Legemiddel (*Medicine*) class, via the catalogue LegemiddelMerkevare (*MedicineBrandedProduct*) and LegemiddelVirkestoff (*MedicineActiveSubstance*), dispensing regulations apply. General conditions may for example apply to preparations without an MA and pharmacy-produced preparations.
- Vilkårsgruppe 5 Antibiotika (*Group of conditions 5 Antibiotics*): Referances from the Legemiddel (*Medicine*) class, via the catalogues LegemiddelMerkevare (*MedicineBrandedProduct*) and LegemiddelVirkestoff (*MedicineActiveSubstance*). Concerns conditions which apply to antibiotics.
- Vilkårsgruppe 6 Legemiddelgjennomgang (*Group of conditions 6 Medication review*): Referances from the Legemiddel (*Medicine*), via the catalogues LegemiddelMerkevare (*MedicineBrandedProduct*) and LegemiddelVirkestoff (*MedicineActiveSubstance*). Concerns conditions which are used as decision-making support for medication reviews.
- Vilkårsgruppe 7 Førerkort (*Group of conditions 7 Driving licence*): Referances from the Legemiddel (*Medicine*), via the catalogue LegemiddelMerkevare (*MedicineBrandedProduct*) and LegemiddelVirkestoff (*MedicineActiveSubstance*). Concerns conditions which are used for health requirements for driving licences (medicines).

For all groups of conditions, if a condition has a reference to LegemiddelVirkestoff (MedicineActiveSubstance), there will also be a reference from the condition to the condition for all associated LegemiddelMerkevare (MedicineBrandedProduct). More than one condition can apply to a LegemiddelMerkevare (Medicine Branded) product. They can belong to both different groups of conditions and the same group of conditions.

Figure 15 shows the class Vilkår (*Conditions*) and how it relates to the above-mentioned categories.

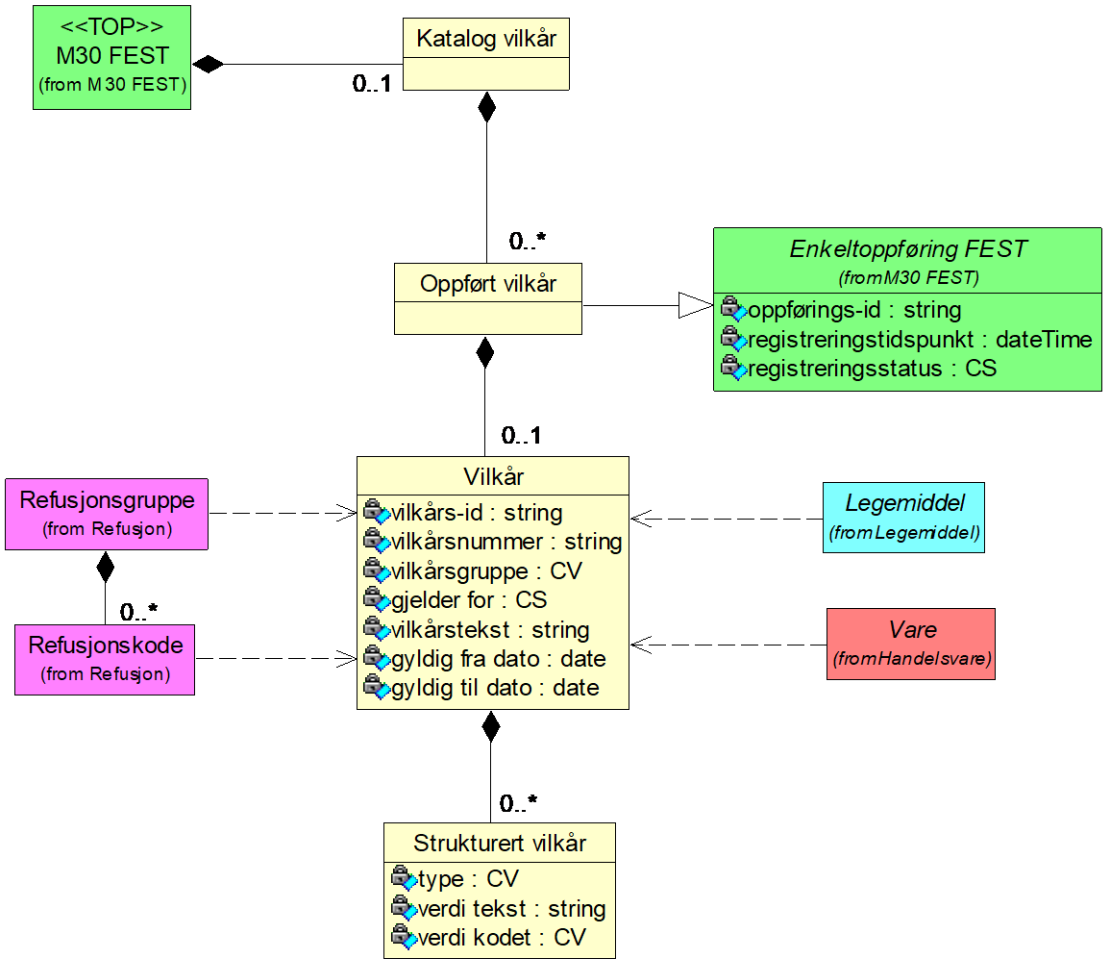

Figure 15 The catalogue Vilkår (Conditions)

5.8 Structured conditions

One or more structured conditions can be linked to a Vilkår (*Condition*). The text in a condition suitable for display will always be included. In addition, all or parts of the condition may be translated into structured (e.g. machine-readable) prerequisites (structured conditions). These codes can be used by the recipient system.

For instance, a notification may be triggered if the physician is not entitled to prescribe this medication: Example: “The treatment must be instituted by a specialist - Internal medicine, surgery, etc.” Or a notification may be given if a patient does not belong to an age group entitled to the medication on a “blåresept” (general § 2 reimbursement). Aerius, conditions for reimbursement: age – above six, age – below 12. Examples of conditions linked to structured conditions are provided below, in Table 5; Code values for structured conditions.

Example of reimbursement of a medicine, Figure 16:

Figure 16 Structured condition – reimbursement

Examples pertaining to a medicine (dispensing regulation), Figure 17:

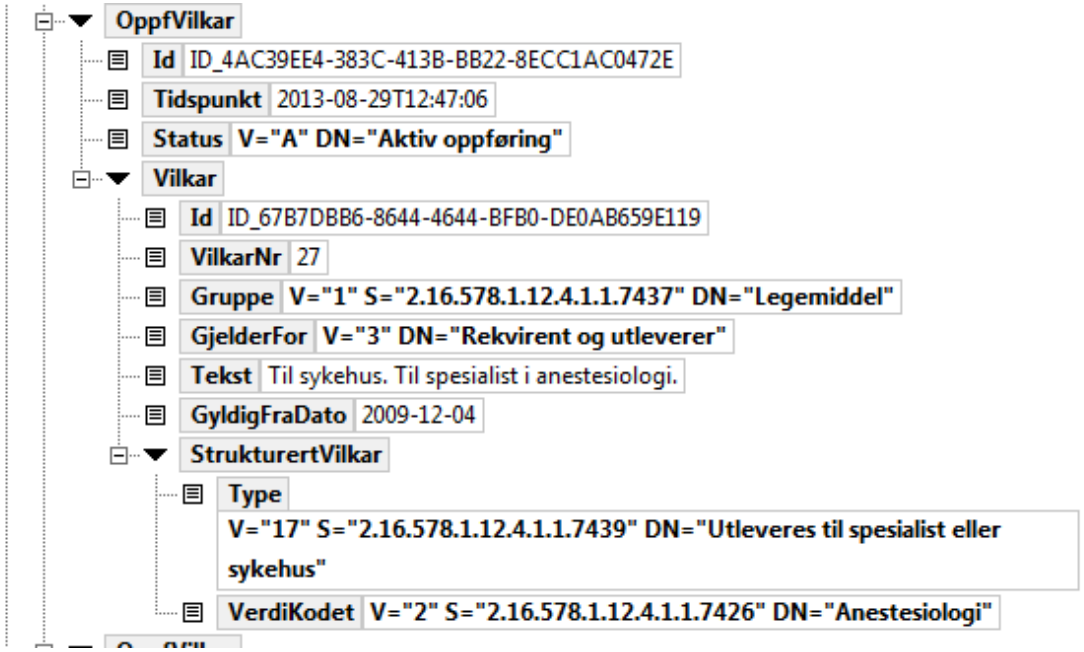

Figure 17 Structured condition – dispensing regulation

Example relating to reimbursement of a commodity, Figure 18:

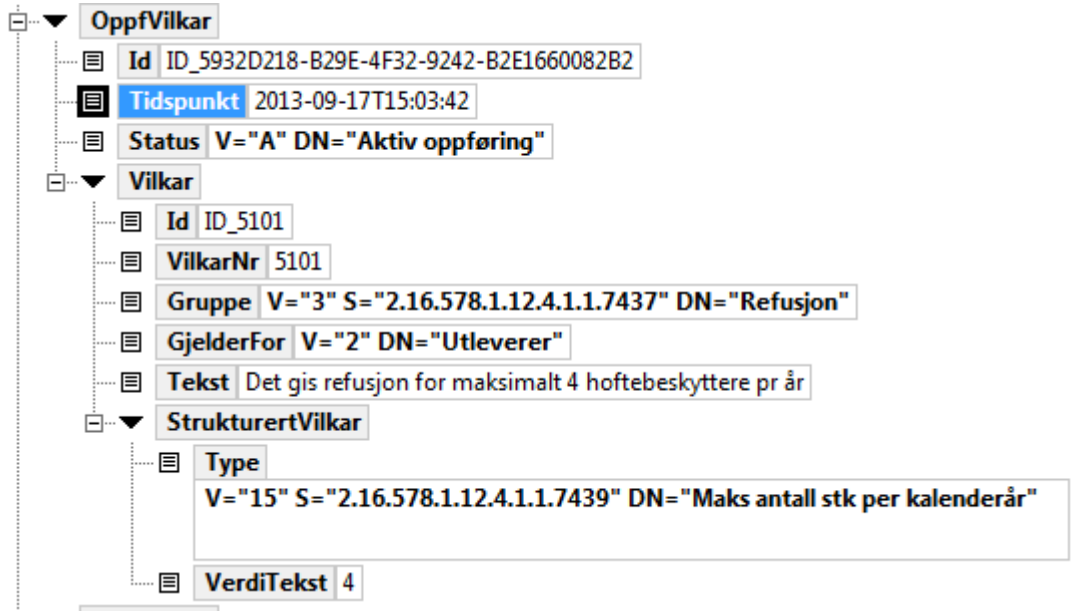

Figure 18 Structured condition – commodity

5.8.1 Overview of structured conditions

Reproduced in Table 5.

Table 5; Code values for structured conditions

Code	Verdi (No)	Value (EN)	Description	Usage
1	Alder lik eller større enn	Age equal to or above	The age of the patient must be equal to or above the number of years stated in the condition (value: integer)	Drugs and commodities
2	Alder mindre enn	Age below	The patient must be younger than the number of years stated in the condition (value: integer)	Drugs and commodities
3	Kjønn	Gender	Male or female (value: from coding system 8459)	Drugs
4	Instituert av spesialist	Instituted by a specialist	Requirement for medicinal treatment to be initiated by a physician with an identified speciality (value: from coding system 7426)	Drugs
5	Instituert på sykehus	Instituted at a hospital	Requirement for medicinal treatment to be initiated at a hospital (value: from coding system 1101 – yes/no)	Drugs
6	Instituert på navngitt sykehus	Instituted at a named hospital	Requirement for medicinal treatment to be initiated at a named hospital (value: from coding system 7428)	*Drugs – not in use*
7	Instituert av spesialist eller sykehus	Instituted by a specialist or hospital	Requirement for medicinal treatment to be initiated by a physician with an identified speciality or at the hospital (value: from coding system 7426)	Drugs
8	Forskrevet av spesialist	Prescribed by a specialist	Requirement for a prescription to be prescribed by a physician with an identified speciality (value: from coding system 7426)	Drugs

9	Forskrevet på sykehus	Prescribed at a hospital	Requirement for prescription to be issued at a hospital (value: from coding system 1101 – yes/no)	Drugs
10	Forskrevet av spesialist eller sykehus	Prescribed by a specialist or hospital	Requirement for prescription to be issued by a physician with an identified speciality or at a hospital (value: from coding system 7426)	Drugs and commodities
11	Forskrives på artikkelgruppe nivå	Prescribed at article group level	The article group must be specified on the prescription (value: from coding system 1101 – yes/no)	Commodities
12	Forskrives på varenummernivå	Prescribed at article number level	The article number must be specified on the prescription (value: from coding system 1101 – yes/no)	*Commodities – not in use*
13	Maks refusjonsperiode i dager	Max. reimbursement period (days)	Maximum number of days of consumption that can be prescribed on a blue (*general reimbursement*) prescription pursuant to paragraph 2 or 4 (value: integral)	*Drugs – not in use*
15	Maks antall stk. per kalenderår	Max. number of items per calendar year	Maximum number of items that can be prescribed to a patient per calendar year. The maximum number is in total for all items in an article group, not for each article.	Commodities
16	Maks antall stk. per ekspedisjon	Max. number of items per dispensing episode	Maximum number of items that can be dispensed to a patient at each dispensing episode. The maximum number is in total for all items in an article group, not for each article.	Commodities
17	Utleveres til spesialist eller sykehus	Dispensed to a specialist or hospital	Only dispensed to a physician with an identified speciality or to a hospital (value: from coding system 7426)	Drugs
18	Utleveres kun til sykehus	Dispensed to a hospital only	Only dispensed to a hospital (value: from coding system 1101 – yes/no)	Drugs
19	Maks utleveringsperiode i dager	Max. dispensing period in days	Maximum number of days of consumption that can be dispensed in total (value: integral)	Drugs
20	Forskrevet på navngitt sykehus	Prescribed at named hospital	Requirement for a prescription to be issued at a named hospital (value: from coding system 7428)	*Drugs – not in use*
21	~~Instituert av spesialist eller sykehus~~	~~Instituted by a specialist or hospital~~	~~Requirement for treatment to be initiated by a physician with an identified speciality or at a hospital (value: from coding system 1101 – yes/no)~~	Expired
22	Antall teststrimler til blodsukkermåling per døgn må oppgis	Number of test strips for blood sugar measuring per 24 hours must be stated	Requirement for prescription to state the number of test strips for blood sugar measuring per 24 hours (value: from coding system 1101 – yes/no)	Commodities
23	~~Kun til maskinell dosedispensering~~	~~Only for machine dose dispensing~~	~~Package is only approved to be used for machine dose dispensing (value: from coding system 1101 - yes/no)~~	Expired
25	Anbefalt diagnose	Recommended diagnose	The diagnoses recommended for the drug (Value: from coding system 7170)	*Drugs – not in use*

26	Ikke-anbefalt diagnose	Not - recommended diagnose	The diagnoses are not recommended for the drug. (Value: from coding system 7170)	*Drugs – not in use*
27	Diagnosekode påkrevet	Code for diagnose is required	It is required that the prescription contain a code for diagnose. (Value: from coding system 1101 – yes/no)	*Drugs – not in use*
28	Endret gyldighetstid på resept ved refusjon	Changed period of validity of prescription for refund	Possibility for expanded period of validity of prescription for refund, an example is: P1Y (1 year)	Drugs

5.8.2 *Details concerning how each structured condition is to be implemented.*

A requirement for «Instituert av» (*Instituted by*) means that the treatment must be started by a doctor with a given specialism or at a given hospital.

Age equal to or above (1)
Condition which is used where the patient's age must be equal to or greater than the number of years specified in the condition. The value that is given must be an integer.

Age below (2)
Condition which is used where the patient's age must be younger than the number of years specified in the condition. The value that is given must be an integer.

Gender (3)
Condition which is used where the patient must be of a specific gender, value male or female is used, and comes from coding system 8459.

Instituted by a specialist (4)
Condition where medicinal treatment must be initiated by a doctor with a specific specialism. The specialisms that can institute the treatment are given using values from coding system 7426.

Instituted at a hospital (5)
Condition where medicinal treatment must be initiated at a hospital. Value yes/no is given using a value from coding system 1101. 'Yes' will always be used. When there is no requirement for institution at a hospital, there will be no condition in FEST.

Instituted at a named hospital (6)
Condition where medicinal treatment must be initiated at a named hospital. The hospitals that can initiate the treatment are given by values from coding system 7428.

Instituted by a specialist or hospital (7)
Condition where medicinal treatment must be initiated by a doctor with a specific specialism or initiated at a hospital. The specialisms that can initiate the medicinal

treatment are given by values from coding system 7426.

Prescribed by a specialist (8)
Condition where the prescription must be issued by a doctor with a specific specialism. The specialisms that can initiate the medicinal treatment are given by values from coding system 7426.

Prescribed at a hospital (9)
Condition where the prescription must be issued at a hospital. Value yes/no is given by a value from coding system 1101. 'Yes' will always be used. Where there is no requirement for institution at a hospital. there will be no condition in FEST.

Prescribed by a specialist or hospital (10)
Condition where the prescription must be issued by a doctor with a specific specialism or issued at a hospital. The specialisms that can initiate the medicinal treatment are given by values from coding system 7426.

Prescribed at article group level (11)
Condition which is used for articles from the Handelsvare (*Commodities*) catalogue. The article group must be specified on the prescription (value: from coding system 1101 - yes/no).

Prescribed at article number level (12)
Condition which is used for articles from the Handelsvare (*Commodities*) catalogue. The article number must be specified on the prescription (value: from coding system 1101 - yes/no)

Max. reimbursement period (days) (13)
Condition where a medicine must be prescribed for a maximum number of days' consumption, specified as number of days' consumption. The value is given as an integer.

Max. number of items per calendar year (15)
Condition which is used for articles from the Handelsvare (*Commodities*) catalogue. Max. number of items which can be dispensed to a patient per calendar year. The max. number applies collectively for all articles in the article group, not to each individual article.

Max. number of items per dispensing episode (16)
Condition which is used for articles from the Handelsvare (*Commodities*) catalogue. Max. number of items which can be dispensed to a patient per dispensing episode. The max. number applies to all articles in the article group, not to each individual article.

Dispensed to a specialist or hospital (17)
Dispensed only to a doctor with an identified specialism or to a hospital, value: from coding system 7426.

Dispensed to a hospital only (18)
Dispensed only to a hospital, value: from coding system 1101 – yes/no.

Max. dispensing period in days (19)
Maximum number of days' consumption which can be dispensed in total, value: integer.

Prescribed at named hospital (20)
Condition where the prescription must be issued at a named hospital. The hospitals that can initiate the treatment are given by values from coding system 7428.

Only for machine dose dispensing (23)
Package is only approved for machine dose dispensing, value: from coding system 1101 – yes/no. Condition where the package cannot be sold ordinarily, but is only used for machine dose dispensing.

Recommended diagnosis (25)
The diagnoses that are recommended for the medicine, value: from coding system 7170. *Not in use. It has not been determined how these should be used.* They are intended as decision-making support regarding antibiotics, but linking diagnosis codes to the guidelines is not entirely «straightforward». Among other things, the diagnosis codes are not sufficiently precise, some active substances can be used in the treatment of many different conditions, and so on. The use of this requires EPI to require the doctor to specify diagnosis codes when prescribing.

Not recommended diagnosis (26)
The diagnoses are not recommended for the medicine, value: from coding system 7170, see also under recommended diagnosis.

Code for diagnosis is required (27)
Requirement for the prescription to have a diagnosis code, value: from coding system 1101 – yes/no. The field indicates whether it is a requirement that the requisitioner must specify a diagnosis code when prescribing. If the field (=yes), the requisitioner must specify a diagnosis code to conclude the prescription. In the first instance, this will concern certain antibiotics, in order to obtain statistics concerning the prescribing of antibiotics.

Changed period of validity of prescription for refund (28)

Option for extended period of validity for prescriptions with reimbursement, given as P1Y (1 year) for example. The field indicates the prescription validity that is to apply to the prescription if reimbursement is selected. In the first instance, this will be relevant for antibiotic prescriptions. Antibiotics have prescription validity of 10 days in FEST. Prescriptions with reimbursement have a validity of one year. This condition is intended to facilitate automation of this. The condition must be implemented so that when the requisitioner selects reimbursement in EPJ, the prescription validity will automatically be set to what is specified in the condition, one year, for antibiotics.

Note that the period of validity in StrukturertVilkår (*StructuredCondition*) is «string», but must be interpreted as XSD:duration according to ISO 8601. FEST uses codes which are defined in coding system 7443 - Duration.

5.9 Prescription validity

The maximum validity of a prescription for a medicine. Some medications have a different prescription validity, depending on gender. One example is Isotretinoin capsules, where the prescription is valid for seven days for fertile women, and one year for men or infertile women.

On 1 January 2018, the Requisitioning and Dispensing Regulations (*rekvirering- og utleveringsforskriften*) were amended so that prescriptions can have a validity period of less than one year. The change stems from the National action plan on antibiotic resistance, which includes an initiative to shorten the validity period for antibiotic prescriptions. Antibiotic prescriptions covered via the National Insurance scheme (Section 2, blue prescriptions and Section 4) shall have a normal prescription validity period of one year, and this is specified in FEST as a structured condition. The prescription system must automatically ensure that the requisitioner selects reimbursement under Section 2 (blue prescriptions) or Section 4; the prescription validity will then be set to one year. The prescription system must also have general provision to override the prescription validity to one year in cases where the requisitioner believes this is appropriate.

For information about mapping and prescription validity cf. Chapter 3.3.5.

5.10 Prescription groups

The prescription group can be indicated in an entry of LegemiddelPakningMerkevare (*MedicinePackageBrandedProduct*) as F (no prescription required), C (normal prescription), B (B medication), A (A medication) or K (food supplement).

For LegemiddelMerkevare (*MedicineBrandedProduct*) incidences (as well as for LegemiddelVirkestoff (*MedicineActiveSubstance*) and LegemiddelDose (*MedicineDose*), the prescription group CF may also be indicated. This means that

the medicine sometimes comes in packages with prescription group C and some with prescription group F.

5.11 Opioid applications

The information in this field is used in connection with applications to HELFO, i.e. it will state when a physician must submit an M2 notification (Individual application for reimbursement to HELFO). The field Opioidsøknad (*Opioid Application*) can be found in the class Legemiddel (*Medicine*). Chapter 3.2.5 specifies in which cases the field has been filled in.

The field Opioidsøknad (*Opioid Application*) is "true" for given ATC codes. NOMA receives information from HELFO about which ATC codes this applies to. If the field Opioidsøknad (*Opioid Application*) in the FEST notification is "true", the class Reseptklasse (*prescription class*) A or B must be completed in M2.

5.12 Link to summary of product characteristics (SPC)

According to the Notification Description, it is possible to add a link to the summary product description in a LegemiddelMerkevare (*MedicineBrandedProduct*) or LegemiddelPakningMerkevare (*MedicinePackageBrandedProduct*) incidence. Which incidence/catalogue the link is found in, depends on the procedure used for authorization of the medicine. No medicines have links in both places.

- Medicines which are authorized within a central procedure (CP) have the link in an incidence of LegemiddelPakningMerkevare (*MedicinePackageBrandedProduct*).
- Medicines which are authorized within another procedure, have the link in an incidence of LegemiddelMerkevare (*MedicineBrandedProduct*).
- Medicines that have been imported in parallel do not have a link to the summary of product characteristics.

The summary of product characteristics is a PDF file available at http://www.legemiddelsok.no or at the EMA web-pages: https://www.ema.europa.eu/en/medicines . Note that the SPC in the link at EMA, is a collection of all medicines in the product. It is a SPC containing different dosage forms and strengths in the same document.

5.13 Taste (Smak) and other additional information

Taste is registered as a specific field when it is not found linked to the dosage form or the product name in the SPC. In some instances the field for "smak" (taste) is used for other additional information. The field "smak" (taste) is placed in the catalog "Legemiddelmerkevare." Pharmaceutical form is one of the factors that determines if a product is available for prescription for active substance, and is to be independent of taste; see the separate field for "Smak" (*Taste*).

Taste is still included in the NavnFormStyrke (*NameFormStrength*) on Legemiddelpakning (*MedicinePackageBrandedProduct)*, LegemiddelMerkevare (*MedicineBrandedProduct)* and LegemiddelDose (*MedicineDose)*.

5.14 Animal species (Dyreart)

For veterinary medicinal products the animal species are registered in a coding system; see the separate field for “Dyreart” (Animal species).

Animal species is still included in the NavnFormStyrke (*NameFormStrength*) on Legemiddelpakning (*MedicinePackageBrandedProduct)*, LegemiddelMerkevare (*MedicineBrandedProduct)* and LegemiddelDose (*MedicineDose)*.

5.15 Medication review

Conditions with group of conditions 6 (medication review) must be used to offer decision-making support to the doctor during a medication review. The conditions are placed on specific LegemiddelMerkevare (*MedicineBrandedProducts*). In the event of a hit on these branded products in LIB, the condition text should be displayed to the doctor during a medication review (the design of this should be developed in collaboration with doctors and the EPJ supplier). Some conditions will be structured with criteria (e.g. Age equal to or greater than), and the condition text must only be displayed when the criteria are satisfied. The content of the conditions is limited to NOMA’s checklist for medication reviews, and this should be highlighted for the doctor. (https://www.dmp.no/globalassets/documents/bivirkninger-og-sikkerhet/rad-til-helsepersonell/legemiddelgjennomgang/sjekkliste-legemiddelgjennomgang-221121.pdf [Norwegian])

5.16 Driving licences

Conditions with group of conditions 7 (driving licences) must be used to offer decision-making support to the doctor linked to health requirements for driving licences and medicines (Directorate of Health). The conditions are placed on specific LegemiddelMerkevare (*MedicineBrandedProducts*). When these medicines are prescribed or renewed, the condition text should be displayed to the doctor in a side window, for example (the design of this should be developed in collaboration with doctors and the EPJ supplier). The condition text contains text and a direct link to the Directorate of Health’s provisions with specific designations of max. daily doses for different classes of driving licence.

The medicines/branded products which have conditions with group of conditions 7 linked to them are discussed in the Directorate of Health’s driving licence guidance: Legemidler (helsekrav til førerkort) (*Medicines (health requirements for driving licences)*).
(https://helsedirektoratet.no/retningslinjer/forerkortveilederen/seksjon?Tittel=legemidler-helsekrav-til-forerkort-10692 [Norwegian])

5.17 "Svart trekant"

Some medications have "svart trekant." These medications are monitored more closely regarding side effects. FEST displays "Svart trekant" for all three catalogues; "LegemiddelVirkestoff; LegemiddelMerkevare og Legemiddelpakning. For additional information about "svart trekant" see https://dmp.no/bivirkninger-og-sikkerhet/legemiddelovervaking/svart-trekant-hva-betyr-det [Norwegian]

6 Packages

6.1 Incoming/outgoing packages in FEST

Information about new and discontinued medicines is shown as dates in the class Markedsføringsinformasjon (*Marketing Information*). The three date fields below can be found in this class. Updates during loading of changes have been described in Chapter 13.

Functionality when renewing an old prescription: If the old prescription refers to an incidence of LegemiddelPakningMerkevare (*MedicinePackageBrandedProduct*) which is no longer available in FEST, the user will have to prescribe another article, or a changed entry of the same article. Using active substance prescription avoids problems linked to articles which are missing or discontinued.

The owner determines the packages that they wish to be marketed, withdrawn or temporarily discontinued at any one time.

6.1.1 *Marketing date*

The marketing date is the date when the package entered the market for the first time, i.e. the date it became available from the pharmacies. NOMA receives information from Farmalogg as routine imports. New packages have a marketing date ahead in time. The package cannot be purchased from a pharmacy before this date.

6.1.2 *Withdrawal date*

The withdrawal date is the date a package is withdrawn by NOMA. Most often, this takes place following an application from the market authorisation holder. The package may be sold for three months after the withdrawal date, to deplete stocks. After the three months, the package will be removed from FEST. The temporarily discontinued date will be removed from the notification if the package becomes available at pharmacies again.

6.1.3 *Temporarily discontinued date*

The temporarily discontinued date is the date a package is withdrawn from the market temporarily. Most often, this takes place following an application/notification from the marketing authorisation holder. A package may be taken off the market temporarily due to supply problems, but more often, it is withdrawn for commercial reasons, such as insufficient sales. The package may be sold for three months after the temporarily discontinued date, to deplete stocks. After the three months, the package will be removed from FEST. The temporarily discontinued date will be removed from the notification if it becomes available again at pharmacies.

6.2 Package information

6.2.1 *Package size*

The field Pakningsstr (*Package Size*) in FEST indicates the size of a package as a string field. Pakningsstr (*Package Size*) is detailed in separate fields to be used for calculation: Multiple, Number and Quantity. The field EnhetPakning (*UnitPackage*) must always be used together with Pakningsstr (*Package Size*), as it shows the unit for the field Mengde (*Quantity*).

The field Antall (*Number*) is only used if there are multiple receptacles in the same package, and reflects the number of receptacles. For instance, five ampoules with 1 ml solution (Number = 5). The field Multippel (*Multiple*) is only used if there are multiple packages pertaining to the same article number (multiple packages).

One example is Signifor injection solution. This medicine is available in ampoules of 1 ml. In one package size, there are six ampoules packed together, and there are 10 of these packages of six in one multiple package. Figure 19 shows how the package size is displayed for one of these packages.

Figure 19 Indication of package sizes in FEST

6.2.2 *Type of packaging*

The type of packaging is indicated on all packages. Several medicines with the same active substance, pharmaceutical form and strength may come in different packaging, such as vials and pre-filled syringes. It is therefore recommended that the type of packaging is available to the user.

6.2.3 *Bar code*

The information in the bar code field (EAN) has been imported from Farmalogg. The bar code is specified on the outside of the package, either as part of a 2D matrix or on older packages as a bar code. The bar code can have 12, 13 or 14 digits and be structured in accordance with GTIN (Global Trade Item Number) or NTIN (Nordic Trade Item Number). If a product changes article number (varenummer), FEST will deliver two bar codes for this article number. These bar codes are unstructured.

6.2.4 *Article number and discontinued article number (varenummer)*

A package in FEST always has an article number.

In some cases, a substitution article number in the article register will replace an article number. The package is the same in FEST, but the information linked to the package will be changed.

For instance, the name of a medicine may have changed from Simvastatin Sandoz to Simvastatin Novartis due to an intra-group sale of a marketing licence, whereas the manufacturing site remains the same.

- Such a package will remain the same, except for the name.
- The package will be displayed as one incidence in FEST under the new article number, whereas the old article number will be displayed as a discontinued article number.
- As long as both article numbers are for sale, the discontinued article number will be shown for the incidence.
- Once the wholesaler has sold all articles with the old article number (the Norwegian Medical Products Agency will be informed via Farmalogg), the discontinued article number will be removed for the incidence.

Other cases may involve substitution with an alternative article, where the changes made to the package are more substantial.

Example: A package of 100 tablets in a blister pack is replaced by a blister pack containing 98 tablets.

- There will be two different packages in FEST, each with its own article number.
- There will be no connection between them, other than that they belong to the same strength of medicine, i.e. there is a link to the same incidence in the catalogue LegemiddelMerkevare (*MedicineBrandedProduct*).

6.2.5 *Special packages*

Multiple strength packages and combination packages

A multiple strength package is a package containing a medicine in different strengths, for instance one tablet containing 12.5 mg and one tablet containing 25 mg

in the same package.

In FEST, they will occur with a reference from the catalogue LegemiddelPakningMerkevare (*MedicinePackageBrandedProduct*) to several LegemiddelMerkevare (*MedicineBrandedProduct*), one for each strength. Pakningstype/Pakningsstørrelse (*PackageType/PackageSize*) is also available along with the reference to each strength.

A combination package is a package containing a pharmaceutical in more than one dosage form. One example is Canesten, which has a 500 mg vaginal tablet and a 1% cream in the same package.

In FEST, they will occur with a reference from the catalogue LegemiddelPakningMerkevare (*MedicinePackageBrandedProduct*) to several LegemiddelMerkevare (*MedicineBrandedProduct*), one for each pharmaceutical form, with the associated strength. Pakningstype/Pakningsstørrelse (*PackageType/PackageSize*) is also available along with the reference to each LegemiddelMerkevare (*MedicineBrandedProduct*). Legemiddelform (*MedicineForm*) in the catalogue LegemiddelPakningMerkevare (*MedicinePackageBrandedProduct*) has been set at Kombinasjonspakning (*Combination Package*). NavnFormStyrke (*NameFormStrength*) contains both the medicine forms/several strengths.

NB: There are no entries in the catalogues LegemiddelVirkestoff (*MedicineActiveSubstance*) or LegemiddelDose (*MedicineDose*) for multiple strength- and combination packages.

There are specific LegemiddelMerkevare (MedicineBrandedProduct) entries for multiple strength- and combination packages. Example: Canesten (combination pack) has a reference to one LegemiddelMerkevare (MedicineBrandedProduct) which is cream 1%, and one LegemiddelMerkevare which is a vaginal tablet.

An ordinary package of Canesten is available which only contains cream 1%. It has a reference to a different entry of LegemiddelMerkevare than that which applies to cream 1% in the combination pack. There are therefore two identical LegemiddelMerkevare's in FEST for Canesten cream 1%, where the only difference is the LegemiddelMerkevare_ID (MedicineBrandedProduct_ID). This applies to a few articles where there is both a multiple strength/combination package and an ordinary package with the same content as one of the components in the multiple strength/combination package.

Kits

Kits are packages containing two or more components that must be mixed to produce a medicine that is ready for use. One example is a powder in a vial and a solution in a pre-filled syringe. In the catalogue LegemiddelPakningMerkevare

(*MedicinePackageBrandedProduct*) the number of kits will be given in the field Pakningsstr (*Package Size*), as well as in the field Mengde (*Quantity*). EnhetPakning *(Unit Package*) has been set as “sett” (*kit*).

Pakningstype (*Package Type*) has been set as “Sett” (*Kit*) and the details of the content in each of the components in the kit have been given in the class Pakningskomponent (*Package Component*). This means that this class contains information about each of the components in a kit. For all other medicines, the class will not contain any information. See Figure 20 and 21:

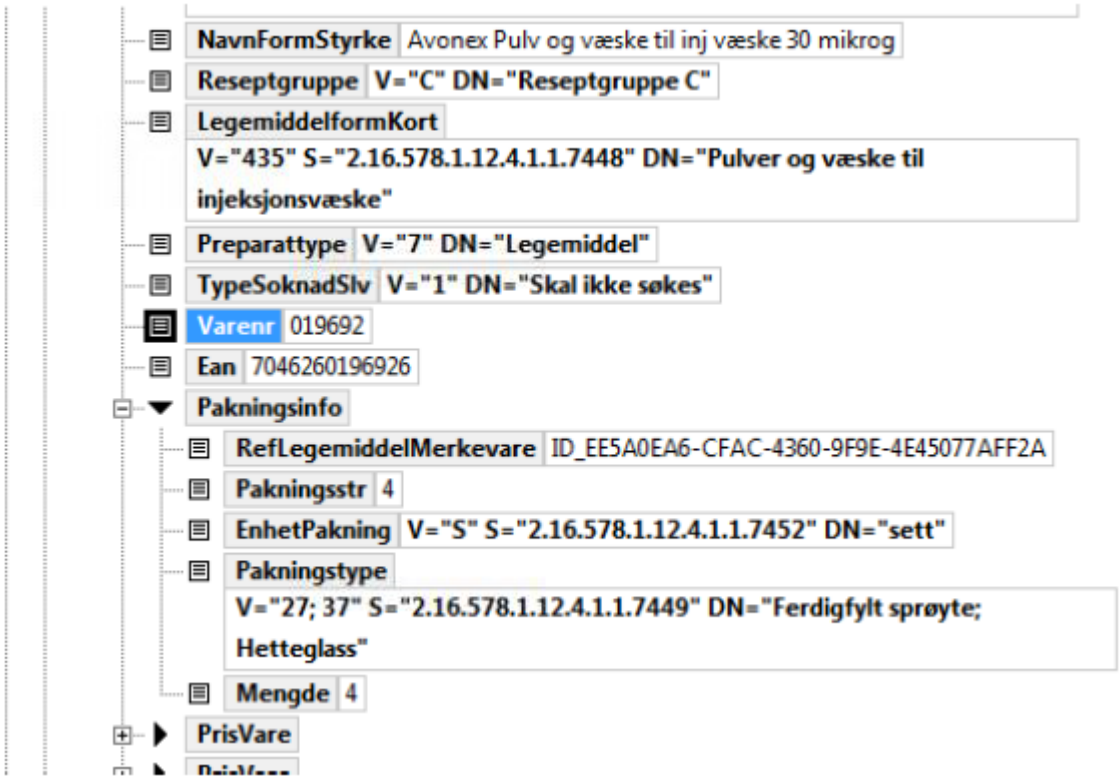

Figure 20 Example of incidence/entry of kits in FEST version 2.4

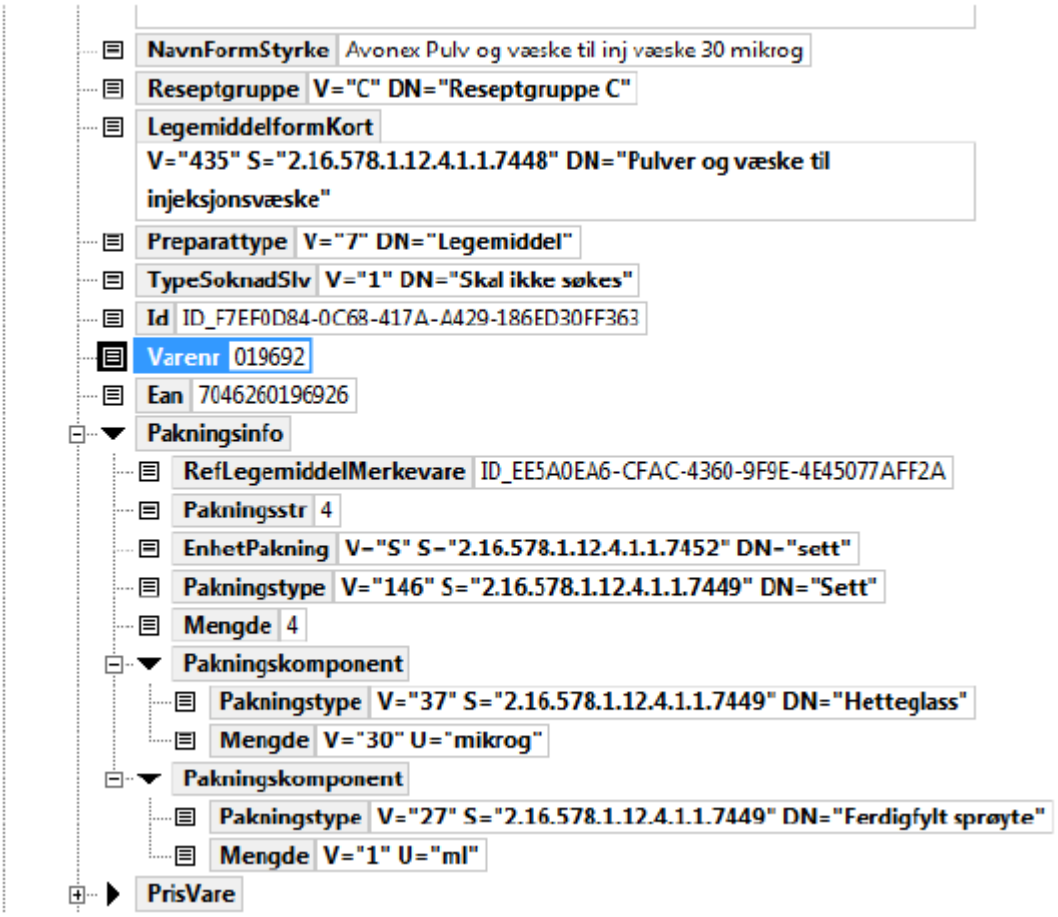

Figure 21 Example of incidence/entry of kits in FEST version 2.5

6.2.6 *Specific packages in FEST 2.5.1 for institutions*

In FEST version 2.5.1 for institutions, there are some packages that are not found in other versions, and they cannot be prescribed on a prescription.

These are *unit dose packages* which are repacked in pharmacies. They are marked with which Ompakker (pharmacy) that are responsible for the production of the unit doses, and a condition number 41: «Skal kun utleveres til sykehus eller pleie- og omsorgstjenesten.» This means that they are only to be delivered to hospitals and other institutions (PLO). The packages are linked to the same Legemiddeldose (*MedicineDose*) as the original package, see section 3.3.4.

The other type of packages are the *bulk packages,* that are authorized for marketing in Norway, but not yet marketed. They are according to regulations allowed to be sold for repacking, but not to retail. The packages are linked to the same Legemiddeldose (*MedicineDose)* as the original package, but they are listed as non-registered medicine. They are marked with the condition number 40: «Pakning er kun til bruk ved maskinell dosedispensering». This means, they only to be used in repackaging into unit doses.

These packages are available for Helfo version 2.5.1 as well, due to reimbursement in institutions others than hospitals (PLO).

6.3 Prices

Prices of medicines in FEST are as stipulated by NOMA, i.e. Maximum Pharmacy Purchase Price (AIP), Maximum Pharmacy Sales Price (AUP), stepped price and reimbursement price. The reimbursement price is pursuant to § 2 (general reimbursement). The same price applies for individual reimbursement pursuant to § 3. For the products that are covered by the H-prescription, there will be the maximum approved reimbursement price due to different companies. Approved AIP are the same for all. Only the versions for Farmalogg and Helfo have H-prescription maximum reimbursement price.

Actual pharmacy sales prices vary and are therefore not available in FEST.

6.3.1 *Validity dates*

Prices are displayed in FEST if there are fewer than three weeks until the GyldigFraDato (*ValidFromDate*). GyldigTilDato (*ValidUntilDate*) means valid until and indicates when the price is no longer valid and replaced by a new price. GyldigFraDato (ValidFromDate) means as of a certain date and indicates the date a price becomes valid.

6.4 Reimbursement

6.4.1 *Reimbursement validity*

GyldigTilDato (*ValidUntilDate*) means valid until and GyldigFraDato (*ValidFromDate*) means valid as of. There are different validity dates linked to the attributes in the class Refusjon (*Reimbursement*): valid from date, prescribe until date and dispersed until date.

Table 6 shows how attributes in the class Refusjonskode (*Reimbursement Code*) should be used.

Table 6; Information elements from the reimbursement code class

Attributes	Explanation
Refusjonskode/V (Reimbursement code/V)	The reimbursement code which must be saved along with the prescription and forwarded with the prescription to the pharmacy
Refusjonskode/DN (Reimbursement code/DN)	Description pertaining to the reimbursement code. This is displayed to the prescriber on the screen together with the reimbursement code if a sub-term has not been specified. When saved (in EPJ/on the prescription) DN is saved regardless of whether a sub-term has been specified for the preparation in FEST. Upon dispensing, only the code (V) will be displayed. The text (DN) must not be displayed to the prescriber in the system for privacy reasons
Underterm * (Sub-term)	Only for ICPC2 codes: When a sub-term has been specified it must replace the reimbursement code description when displayed to the prescriber. A

	sub-term is a limitation of the diagnosis represented by the reimbursement code
Referanse vilkår (Reference condition)	Reference used to find associated conditions
Gyldig fra dato (Valid from date)	Date from which the reimbursement is valid. For changes, this may be ahead in time. The reimbursement code must not be displayed as valid before the date has been reached
Forskrives til dato (Prescribe until date)	Prescribe until date is the date reimbursement ceases for a prescription. After this date the reimbursement code must not be displayed upon prescription
Utleveres til dato (Dispensed until date)	Dispensed until date is the date the reimbursement ceases for dispensing by a pharmacy. After this date, the reimbursement code must not be displayed upon dispensing. The dispensed until date can only be the same as or later than the Prescriber's "to date"

*Sub-term: This field and the special rules relating to what has been specified in the table only apply to codes from the CPC2 coding system. Anyone using ICD 10 codes does not have to pay attention to the sub-term field.

After the "prescribe to date" has passed, reimbursement information for the package or the reimbursement code will no longer be available in FEST.

In addition to reimbursement code validity linked to an instance of the class Refusjonsgruppe (*Reimbursement Group*), validity has been specified in a link from a LegemiddelPakningMerkevare (*MedicinePackageBrandedProduct*) or LegemiddelVirkestoff (*MedicineActiveSubstance*). This is presented in the class Refusjon (*Reimbursement*), linked from the shared class Legemiddel (*Medicine*).

Here, the "valid from date", "prescribed to date" and "dispense to date" are displayed. The dates have the same meaning as explained in the table above, but only apply to the relevant package. For a reimbursement to be valid, it must be valid both at the link to the class Refusjonskode/refusjonskode (*Reimbursement Code/Reimbursement Code*) and the link to LegemiddelPakningMerkevare (*MedicinePackageBrandedProduct*)/ LegemiddelVirkestoff (*MedicineActiveSubstance*).

Reimbursement conditions

The validity of reimbursement conditions linked to a reimbursement code is the same as the validity date for the reimbursement code. The attribute "valid from date" is also located in the class Vilkår (*Conditions*), which specifies when the condition was first established. Reimbursement conditions are explained in more detail in Chapter 5.5.

The reference from the class Refusjonsgruppe (*Reimbursement Group*) is only in use for reimbursement relating to commodities. Cf. Chapter 12.

6.4.2 *Preapproved reimbursement, Section 2 (blue prescription)*

All packages subject to preapproved reimbursement have a reference to the reimbursement group it belongs to and, furthermore, to the applicable reimbursement conditions. For prescribers, it is recommended that the valid reimbursement codes (including name) and conditions relating to the package appear on the prescription screen. This must also be shown when prescribing on active substances.

6.4.3 *Individual reimbursement, Section 3*

All reimbursement codes in the reimbursement list (Section 2) are valid for individual reimbursement pursuant to Section 3. For individual reimbursement pursuant to Section 3, all reimbursement codes in coding system 7435 (based on the ICD-10 coding system) are valid.

New following the changes to the Blue Prescription Regulation with effect from 1 January 2018. Section 3 is new and supersedes Sections 3a and 3b (individual reimbursement). Helfo no longer requires the reimbursement code to be specified in the application for individual reimbursement (M2). This applies both in connection with the use of new functionality for Section 3 and in connection with the use of the transitional scheme for Section 3a. There are reimbursement codes for Section 3 in FEST in the Kodeverk (*Coding system*) catalogue.

For use of the transitional scheme for Section 3a, FEST still contains information in the same way as before: All codes have been linked to a reimbursement group for individual reimbursement linked to Section 5-14, Section 3a. This reimbursement group has been given the name Individuell refusjon (*Individual Reimbursement*). In FEST, Gruppenr. (*Group No*.): V=Individual reimbursement and DN=IndRef.

6.4.4 *Magistral prescription reimbursement*

Magistral prescription means that a physician prescribes medication that will be prepared by a pharmacy prior to dispensing or administering it to a patient. This may, for instance, be morphine or nausea suppressants mixed with a saline solution prepared in a medication cassette for injection. In cases where reimbursement is granted for an active substance/medication in a mixture, reimbursement is made for the remaining content substances (medication/active substance or additives/solution substances). This also applies to content substances without reimbursement when dispensed separately.

Reimbursements relating to use of magistral prescription are available in FEST as reimbursement groups linked to an ATC code. This means that the reimbursement applies to all active substances that can be represented by the ATC code, cf. Chapter 11.3.1 Structure of the ATC coding system. Mapping between ATC codes and active substances has not been carried out in the Norwegian Medical Products Agency's master data. Until further notice, the prescriber systems must therefore handle this in order to find reimbursement on the ATC code for the active substances

that are prescribed magistrally. For general mapping between the different categories in FEST, cf. Chapter 0.

If there are any medications with a marketing authorisation that can be used, the packages will be linked to the reimbursement group/Refusjonsgruppe (*Reimbursement Group*) class to ensure that there is a reference from LegemiddelPakningMerkevare (*MedicinePackageBrandedProduct*) and LegemiddelVirkestoff (*MedicineActiveSubstance*) in the same way as for normal reimbursement pursuant to Section 2. For reimbursement groups without packages, the field KreverVarekobling (*Requires Product Link*) will be set at “false”. For reimbursement groups with packages this will be set at “true”.

6.4.5 *Reimbursement by H-prescription (H-resept)*

Health enterprise-financed medicines (H-resept legemidler) are medicines where responsibility for financing rests with the health enterprises. These medicinal products can only be requisitioned by a doctor in a health enterprise (helseforetak), or by practitioners within specific specialties.

Information about reimbursement by H-prescription can be found I FEST versions 2.5.0 and 2.5.1. All packages and/or groups of active substance prescription which have this kind of reimbursement will have a reference to the reimbursement group to which it belongs. Unlike pre-approved reimbursement under Section 2, reimbursement codes are not used, so the reference to the reimbursement condition will be found *directly* in the reimbursement group. The attribute KreverRefusjonskode (requires reimbursement code) is therefore set to “false”. There are also references to structured conditions.

6.5 Substitution group

A substitution group consists of packages of a similar size containing the same or equivalent medicine.

Packages in the same substitution group:

- contain the same **active substance** in equal quantities/same strength (different salts are acceptable).
- have the same **form group** (a form group can consist of several dosage forms, e.g. capsules and tablets)
- have been considered by the Norwegian Medical Products Agency and found to have equal **bioavailability**

Generic substitution means that a pharmacy can dispense a medicine other than the one prescribed. However, this is on the condition that substitutions take place only between packages in the same substitution group. NOMA decides which medicinal products that are suitable for substitution, and these are put on the substitution list (byttelisten). These will have the same substitution group reference in FEST.

6.5.1 *Substitution validity group*

GyldigTilDato (*ValidUntilDate*) means until a certain date and GyldigFraDato (*ValidFromDate*) means as of a certain date. The validity date for substitution is linked to each substitution group and each package in a substitution group (PakningByttegruppe (*PackageSubstitutionGroup)*).

The GyldigFraDato (*ValidFromDate)* is registered when a package is linked to a substitution group. When a package is deleted from a substitution group, the substitution reference is removed from the package. Consequently, the GyldigTilDato (*ValidUntilDate*) will never be filled in in FEST.

6.5.2 *Technical information about substitution groups*

There is a reference to the substitution group on the package, RefByttegruppe (*RefSubstitutionGroup*). All packages in the same substitution group have the same RefByttegruppe (*RefSubstitutionGroup*). From this, one can derive all packages belonging to the same substitution group.

6.5.3 *Remarks regarding substitution*

If a remark regarding substitution has been approved for the substitution group, a limitation will be specified regarding when generic substitution can be used.

- Limited substitution for all or part of the usage for an active substance. Limited substitution means that substitution is only possible on the first prescription for a patient.
- No substitution for part of a usage. This enables new substances to be included in the substitution list.

7 Administration

7.1 Administration information

Attributes in the class Administrering legemiddel (*Medicine Administration*) in the catalogues LegemiddelVirkestoff (*MedicineActiveSubstance*), LegemiddelMerkevare (*MedicineBrandedProduct*) and LegemiddelPakningMerkevare (*MedicinePackageBrandedProduct*) are completed with information retrieved from the summary product description. The information will be incomplete for unregistered medications.

- **Administrasjonsvei** (Route of administration): Has been specified for all medications
- **Blandingsvæske** (Admixing liquid): True has been entered for medications that can be used as a solution to dilute or resolve other medicines, e.g. solutions of sodium chloride and Ringer acetate.
- **Blandingsvæskeforslag** (Admixing liquid proposal): Has been stated for medications that should usually be diluted or resolved before administration, e.g. powder for injection, concentrate for infusion, etc.
- **Deling av dose** (Division of dose): Has been stated for tablets.
- **Enhet for dosering** (Dosage unit): States the medium which the medicine is administered as, e.g. tablet, ml, droplet. The dosage unit must be used together with the kortdose (*short dose*) text. Dosage units are available both in singular and plural in the coding system catalogue in FEST and are used as follows: <dose> is replaced by a unit in the singular, and <doser> (*doses*) by a plural number of the unit. For instance: Unit for dosage <tablett> (*tablet*) together with the short dose “2<doser>daglig” (*2 doses per day*) will give the dosage text “2 tabletter daglig” (*2 tablets per day*).
  Prefilled syringes will have Dosage unit <sprøyte> (<*syringe*>) when the entire content is given in a single dose.
- **Forholdsregel ved inntak** (Ingestion precaution): Any precautions that must be taken for administration of the medicine have been stated on the preparation. For instance: Swallow whole, to be taken with food.
- **Kortdose** (short dose): Indicates a dosage proposal adapted to the pharmacy label, linked to a certain strength and form of a medicine. Different generics may have different dosage proposals, as these are linked to a text from the Summary of ProductCharacteristics, SPC. Proposals have been made for medicines with uncomplicated dosage.
- **Bruksområde** To be used on the pharmacy labelling to the patient, and gives the usage of the drug.
- **Bolus/injeksjonshastighet** (Bolus/injection speed): Bolus may be added to injection medications, and may state whether the medication might be administered as bolus (the whole dose at once), as well as the administration speed (fast, slow, not specified).
- **Kan åpnes** (Can be opened): Specified for capsules.

- **Kan knuses** (Can be crushed): Specified for tablets and capsule content.

7.2 Structured dosage

The Norwegian Directorate of Health deliver and steward the information about structured dosage (strukturert dosering). The catalogue (*KatalogStrDosering*) is usually updated once a year. The catalogue is found in FEST version 2.5.0 and 2.5.1. It contains a structuring of the short doses (kortdoser) to support e.g multi-dosage prescription (multidose). Not all the short doses are structured.

7.2.1 *Short dose*

Not all the short doses are structured. More information on the data model and how structured dosing in M30 is intended to be used can be obtained from Norwegian Healthnet: https://www.nhn.no/tjenester/e-resept/dokumentasjon-for-e-resept [Norwegian]

7.2.2 *Medicine consumption*

Indicates the sequence of medicine consumption when the short dose consists of several medicine consumptions in sequence. Used to unambiguously present medicine consumption.

Most short doses have only one medicine consumption.

8 Interactions

Interactions in FEST will be used to provide health personnel with relevant information relating to unfortunate combinations of pharmaceuticals (interactions) for prescription, dispensing and distribution of pharmaceuticals. See also https://www.legemiddelsok.no/sider/Interaksjoner.aspx (*Interaction search – NOMA*)

8.1 Interactions in FEST

Interactions are entered as interaction pairs in FEST where there are two groups of substances interacting with each other.

An interaction contains maximum two substance groups.

8.1.1 Substance group

A substance group has been established in FEST to be able to gather all substance groups (ATC code and active substance) in the same interaction. Each substance group may consist of one or more active substances, with or without ATC codes. All substances with an ATC code will be entered with this code. Substances without an ATC code will have a reference to the attribute VirkestoffID (*ActiveSubstanceID*) in the class Virkestoff (*Active Substance*).

The ATC code may be at level 5 or levels 1-4. If the ATC code is at level 1-4, the substance group will also contain all underlying ATC codes. Read more about the ATC code hierarchy in Chapter 11.3. Active substances with several ATC codes: All relevant ATC codes are included in the substance group for the interaction (e.g. Efedrin: C01CA26, R03CA02).

If a substance group contains multiple elements, the name of the substance group will appear in the attribute group name in the class Substansgruppe (*Substance Group*). This name should appear in the interaction notification, e.g.: Substance group “Johannesurt” (*St. John's wort*) with the ATC code N06AX25 (prikkperikum (*hypericum perforatum*) and active substance perikum (*St. John's wort*) (without the ATC code).

Some substance group(s) contain fictional ATC-code with six levels. E.g. Smoking (Røyking) covered by the ATC-codes starting with ZV80AA. They are created like this so that there are no chance of confusion with accepted drugs at the WHOCC (in an agreement with them), but they have genuine interactions.

8.1.2 Information relating to the interaction

Relevance

Relevance says something about how serious an interaction might be. The interaction notification in the user systems should have a colour code according to the relevance of the interaction.

Relevace	Relevance	Colour code
Bør unngås	Should be avoided	Red
Forholdsregler bør tas	Precautions should be taken	Yellow/orange
Ingen tiltak nødvendig	No action necessary	Green (no colour)

Interactions with the relevance “No action necessary” should by default not trigger an interaction notification. These should only be displayed in potential interaction searches where all information is required.

Interactions with relevance “Should be avoided” and “Precautions should be taken”, should trigger a notification for all users. If fewer interaction notifications are required, this can be filtered by using display rule.

Display rule
Indicates to whom the interaction notification should be displayed: Pharmacy, hospital, specialist, general practitioner. This does not need to be displayed in the interaction notification itself.

Clinical consequence
Information about clinical risk relating to the interaction. This must be displayed in the interaction notification.

Situation criterion
If the interaction is dependent on fulfilment of certain criteria, it will be specified here. For instance: “Applies to daily amitriptyline doses of more than 75 mg.” Such information must be clearly indicated in the interaction notification.

Interaction mechanism
Description of the mechanism behind the interaction between the pharmaceuticals. This should be indicated in the interaction notification.

Handling
Text fields consisting of up to four paragraphs of information with the headlines: Dosetilpasning (*dose adjustment*); Justering av administrering (*administration adjustment*); Monitorering (*monitoring*); Legemiddelalternativer (*alternative medicines*). The information must be presented in the interaction notification in a clear and well-arranged manner, divided into paragraphs with headlines.

Source basis
Describes what type of sources the interaction information has been based on. A reference to background information about the interaction is available as a link. The source and the link should be displayed to the user.

8.2 Interaction notification

When prescribing a medicine, the EPJ/graph system should search in:

- Retrieved medicine.
- LiB (*medicines in use*) in the EPJ/graph system.
- Medicines in Kjernejournal (*Summary Care Record*).
- Medicines received as a dispensing notification from another prescriber and which are not represented in LiB.
- Medicines in the prescription database Reseptformidleren that are not represented in LiB.

If the combination of a prescribed medicine and any of these medicines is available as interaction pairs in FEST, this must appear from the interaction notification.

Medicines selected from the prescription should be checked in the pharmacy system for interaction with medicines which the patient has received from the pharmacy, for instance in the last year.

An interaction notification should contain the following information: Cf. Chapter 8.1.2 for details relating to the interaction.

8.3 Handling an interaction notification

If a physician or pharmacy would like to ignore an interaction notification, for instance if the interaction has already been taken into account and a dose has been reduced etc., it should be possible for the user to tick off that the interaction has been handled.

This should have the following results:

- The same interaction notification should not reappear for this patient.
- It should be possible for the physician/pharmacy to document how the interaction has been handled.

8.4 Interaction searches

Interactions in FEST can be used as basic data in applications or web pages where interaction searches are required. For free searches, it should be possible to search on all available interactions in FEST, regardless of display rule.

- If searching by a superior ATC code, interactions relating to this superior code should be displayed, as well as all interactions pertaining to the subordinate ATC codes, cf. Chapter 11.3. This also applies to substance groups.
- When searching by the name of a substance group, interaction for the substance group itself must appear in the search, as well as interactions pertaining to the individual ATC codes in the substance group, e.g. a search on contraceptives. The group contains the ATC codes G02BB01, G03AA, G03AB and G03HB, and subordinate ATC codes.

- By searching for contraceptives, interactions pertaining to contraceptives as a group should appear, as well as all interactions available for the individual ATC codes in the group, e.g. G03AB04 Norethisterone and oestrogen.

Interactions in the search result should be sorted by relevance, so that interactions with “should be avoided” appear at the top followed by “precautions should be taken”.

The result in the interaction search should display the same information as in an interaction notification. Cf. Chapter 8.1.2on information relating to the interaction. It is essential that the situation criterion is clearly displayed to the user.

8.5 Non-assessed interaction

FEST will contain an overview of ATC codes and active substances where it has not been assessed if a significant interaction exists or not. This applies to, e.g., new medicines on the market. It is possible to submit a notification stating that interactions have not been assessed for this medication, if a physician prescribes a medication with such an ATC code. After a professional assessment of whether the active substance has interactions or not, the ATC code notification will be removed.

It should be an objective to have as few ATC codes labelled InteraksjonIkkeVurdert (*InteractionNotAssessed*) as possible.

9 NOMA notifications

NOMA notifications provide the prescriber and dispenser with important information about medicines, also beyond the information in the summary product characteristics. The notifications will ensure that patients, pharmacies and health personnel have easy access to important information, for example notifications about shortage situations or new safety information about a medicine.

9.1 Notification types

When issuing a notification, it will be linked to a notification type. There are currently ten types of notifications in use:

- **Sikkerhetsinformasjon** (Safety information): Important safety updates and new serious adverse effects.
- **Leveringssvikt** (Supply interruption): In the event of long-term interruptions in the supply of important medicines, or in the event of withdrawal of commonly used medicines.
- **Salgsstopp og tilbakekalling** (Sales stop and recalls**):** Serious issues relating to a medication that may cause patient injury. This may prevent onward sales of individual batches or entire products.
- **Refusjon** (Reimbursement**):** New medicines on blue prescription (*general reimbursement*) or important changes in conditions.
- **Retningslinjer og råd** (Guidelines and advice**):** Recommendations and guidelines for prescribers and pharmacies relating to a single medication or group of medications.
- **Legemiddelanmeldelse** (Medicine review**):** Opportunity to link to reviews of selected medicines.
- **Generelle varsler** (General notifications**):** Intended to be used to provide information about, e.g., ongoing information campaigns, emergency preparedness measures, etc. Do not need to be linked to a specific medicine.
- **Indikasjonsendring** (Indication change**):** Information about when the indication of a medicine is either extended to include more diagnoses or restricted to contain fewer.
- **Doseringsendring** (Dosage change) Information when a dosage regime of a drug has been changed.
- **Tilbakeholdelsestid** (Period of withdrawal) Information about the period of withdrawal that is needed according to slaughter. Relevant for veterinarians.

9.2 Who should see the various notifications?

There are various types of notifications. However, not all notifications are relevant for all users. Consequently, each issued notification in FEST M30 is linked to a display rule which governs which groups will be able to see the notification. These display rules/groups are: Hospital, Pharmacy, General Practitioner, Specialist and Veterinary. Notifications in Five Star FEST (Femstjernes FEST) have no display rule, but the groups that the notification is to be visible to forms part of the data resources, "Tekst til forskriver" (Text for prescriber), "Tekst til apotek" (Text for pharmacies) and "Tekst til pasient" (Text for patient) instead. It has been decided that Five star FEST for notifications will not be continued in its existing format. No new users are being accepted.

9.3 Duration of a notification

The duration of a notification will vary according to the notification. It is natural for some notification types to be available in FEST for an extended period.

- A supply interruption notification, e.g., should be available as long as the interruption lasts.
- General notifications or guidelines will only be available in FEST for shorter periods, for instance 2 – 3 months.

A notification in FEST M30 has a "FraDato" (From date), but no "TilDato" (To date). When a notification is not valid any more, the ID-reference (entry ID) of the notification will come with the status "expired" in the FEST increment. It is important that expired notifications are not displayed in the user system after the period of validity. See Chapter 13 for technical guidance concerning expired entries.

9.4 Link to case on NOMa's web pages

There will usually be a link to NOMa's web pages in the notification or to other external web pages for more details about the content of the notification. Many notifications have a description together with the link. It is recommended that "The description" is shown as a clickable link in the user system instead of the actual URL-address (http:/www…etc).

9.5 Linking a notification to one of the main catalogues in FEST

If a notification is linked to an active substance prescription group (LegemiddelVirkestoff (*MedicineActiveSubstance*)), it will also be linked to all associated incidences in LegemiddelMerkevare (*MedicineBrandedProduct*) and all subordinate LegemiddelPakningMerkevare (*MedicinePackageBrandedProduct*) catalogues. If a notification is delivered like this, it is important that it show up when both prescribing on active substance and branded products/packages.

If a notification is linked to a LegemiddelMerkevare (*MedicineBrandedProduct*), it will also be linked to all subordinate LegemiddelPakningMerkevare (*MedicinePackageBrandedProduct)* catalogues*.* A notification linked like this, must

be shown to the prescriber on both Branded products and the packages. A notification can also be linked to only one or more (*MedicinePackageBrandedProduct*) and should only be shown to the physician on these specific packages.

9.6 Notifications can be used as follows:

- A notification consists of a headline and a text which should be shown to the user. The type of notification should also be shown to the user. The from date of a notification should be displayed to the user.
- Most notifications contain a reference to packages/branded products/active substances. It is possible to create a pop-up with information on the relevant medicine at the time of prescription/dispensing. It should be considered having pop-ups that can be ticked off once they have been read to prevent disturbances when dispensing frequently used medications.
- The various notification types can be applied as display rules according to where in the system the notification should be shown. The notification types Generelle varsler (*General Notifications*) and Råd og retningslinjer (*Advice and Guidelines*) will e.g. only be displayed as newsletters when the system is started up or in a person's inbox.
- A notification can be linked to patients who use the relevant medication so that lists of affected patients can be retrieved when necessary.
- Pop-up when looking up a patient who uses the relevant medication.
- Notification log, e.g. with from date and expiry date.
- It should be possible for the prescriber/dispenser to configure the desired functionality for displaying notifications.

10 Unregistered medicines

10.1 Unregistered medicines in FEST

The Norwegian Medical Products Agency has no documentation relating to unregistered medicines and can thus not vouch for the actual content. This applies to composition, manufacturing method and conditions, indication, etc.

An unregistered medicine in FEST will be removed if it is subsequently registered following a successful marketing authorisation application. There will be no link between a registered and unregistered medicine other than them containing the same active substance.

10.2 Labelling unregistered medicines in FEST

Unregistered medicines have a condition, number 34, linked to LegemiddelMerkevare (*MedicineBrandedProduct*) indicating that the physician has a special responsibility when prescribing a medicine that has not been registered/approved in Norway.

Condition 34: «Legemidlet du nå har valgt å forskrive er ikke vurdert av norske helsemyndigheter og har heller ikke markedsføringstillatelse i Norge. Når du velger å forskrive dette legemidlet, påtar du deg et særlig ansvar overfor pasienten og må utvise særlig aktsomhet med hensyn til legemidlets kvalitet, sikkerhet og effekt.»

Unregistered medicines have been labelled with Preparattype (*type of medication*): Krever godkj. Fritak (*requires approved exemption*) and has TypeSøknadSLV (*TypeApplicationNoMa*):

- Apotek vurderer (consideration by pharmacy)

The handling of the prescription at a pharmacy depends on which country the medicine has been procured from. If it has been imported from an EU country or another approved country, notification will be sufficient. This means that the medicine can be dispensed immediately and a notification be sent to the Norwegian Medical Products Agency afterwards.

- Må søkes (application must be submitted).

An application must be submitted to the Norwegian Medical Products Agency before the prescription can be processed.

10.3 For prescription systems using FEST

When the Preparattype (*type of medication*) is Krever godkj. Fritak (*requires approved exemption*), the system must request that the user fill in the necessary information for an exemption application. For more information, see document records available from Norwegian Healthnet. (In Norwegian)

11 Coding systems

All coding systems used in FEST are available at www.volven.no with information about who owns and manages the individual coding system. Details about each coding system, with a reference to the coding system number from Volven, are available in the Notification Description, linked to the field where the coding system is used. The coding systems used in FEST are also used in E-resept (*E-prescription*). More detailed information about how coding systems are managed in E-resept (*E-prescription*) is available from Norwegian Healthnet.

11.1 Coding systems in the coding system catalogue in FEST

The following coding system represents codes and code values made available in the FEST notification. The coding systems in the list below are from www.volven.no and are updated regularly (most frequently monthly).

- ATC (7180)
- Pharmaceutical form (short form) (7448)
- Measuring unit for package and strength denominator (7452)
- Vaccine standard (7447)
- Package type (7449)
- Measuring unit for strength (9090)
- Reimbursement statutory authority diagnosis Self-defined reimbursement codes (ICPC) (7434)
- Reimbursement statutory authority diagnosis Self-defined reimbursement codes (ICD) (7435)
- Ingestion precautions (7479)
- Administration route (7477)
- Dosage guidelines (short dose) (7478)
- Unit for dosage (7480)
- Product group (7403)
- Bruksområde (Product use) (7488)

The coding system Product group is for commodities, other coding systems for medicines.

11.2 Coding system for reimbursement codes

Reimbursement is mainly linked to the international diagnostic coding systems ICD-10 (coding system 7110 in Volven) and ICPC-2 (coding system 7170 in Volven). Coding systems 7434 and 7435 are the Norwegian Medical Products Agency's self-defined ICPC and ICD codes. The purpose of the self-defined codes is to cover diagnoses entitled to reimbursement, but where no suitable codes are available in the international diagnostic coding system. Coding system 7110 is no longer used in FEST. All relevant ICD type reimbursement codes have been entered in coding system 7435. This is because few codes at a suitable level are valid in the international coding system.

11.3 The ATC registry as coding system in FEST

The Anatomical Therapeutic Chemical (ATC) classification system, the ATC system, is updated and approved with English names by WHOCC. The English coding system is available on the WHOCC web pages, referred to at www.volven.no. The Norwegian Medical Products Agency is responsible for the Norwegian translation when in keeping with Norwegian orthography and approved active substance in the Norwegian Medicinal Standard.

The ATC coding system in FEST comprises codes used for medications or in interactions in FEST, as well as superior codes.

There exist non-approved ATC codes used in interactions within FEST. These codes are designed according to an agreement with WHOCC; Z80AAnn. For well-established and traditional plant-based as well as anthroposophic medicines, including homeopathic medicines, a shared ATC code named 'WITHOUT' has been created. This code is not part of the ATC system but has been established to prevent confusion with active substances

11.3.1 *Structure of the ATC coding system vs. active substance*

ATC is a hierarchical coding system with five levels. An ATC code at level five usually represents one active substance, but may also represent a combination of two or several active substances. The four superior levels represent groups of active substances.

Example:

Level 1:	C	Cardiovascular system
Level 2:	C01	Cardiac therapy
Level 3:	C01A	Cardiac glycosides
Level 4:	C01AB	Scilla glycosides
Level 5:	C01AB01	Proscillaridin

An active substance may be represented by more than one ATC code at level five as the active substance can be used in different ways or for different diagnoses located in separate parts of the coding system.

An ATC code with an associated Norwegian name can be found in the general class Legemiddel (*Medicine*). In addition to the ATC code specification relating to the medicines, the active substances in the medicines have also been specified. Active substances are specified in the class Virkestoff (*Active Substance*) and linked to the catalogue LegemiddelMerkevare (*MedicineBrandedProduct*) and the catalogue LegemiddelVirkestoff (*MedicineActiveSubstance*). Here, each active substance has been specified separately regardless of how many active substances the medicine contains.

There is no direct technical link between the active substance in the class Virkestoff (*ActiveSubstance*) and the name of the ATC code. They are normally identical as part of quality assurance. In the coding system catalogue, the ATC code exists with both the Norwegian and English name. This is also done for the veterinary medicines. For veterinary medicines, all names have been translated into Norwegian.

12 Commodities

12.1 Nutrients and Medical consumer products

The content in the categories Næringsmiddel (*Nutrients*) and Medisinsk forbruksmateriell (*Medical consumer products*) should be presented in a tree structure. **Feil! Fant ikke referansekilden.**Figure 22 gives a simple example.

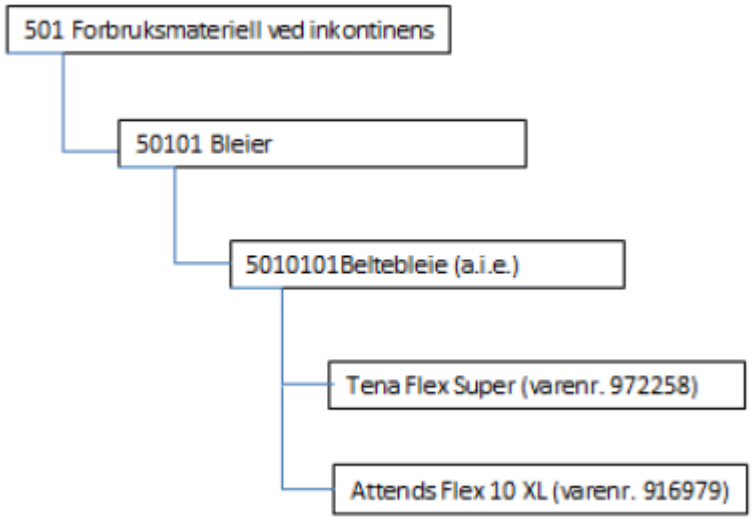

Figure 22 Tree structure for nutrients and medical consumer products

The content in the trees is not available in a single FEST catalogue, but must be created using coding system 7403 (from the Katalog Kodeverk (*Catalogue Coding System*) and Katalog Handelsvare (*Catalogue Commodity*).

The coding system Produktgruppe (*Product Group*) (7403) contains 1, 3, 5 and 7-digit codes with associated descriptions. The 7-digit codes from Produktgruppe (*Product Group*) are referred to from the group number attribute in the class Refusjonsgruppe (*Reimbursement Group*). The Refusjonsgruppe (*Reimbursement Group*) class is referred to in the class Refusjon (*Reimbursement*), which is a part of the abstract class Vare (Product). The categories Næringsmiddel (*Nutrients*) and Medisinsk forbruksmateriell (*Medical consumer products*) are both specialisations of the class Vare (*Product*).

The 1-digit code in Produktgruppe (*Product Group*) distinguishes between the main groups Næringsmiddler (*Nutrients*) (code “6”) and Medisinsk forbruksmateriell (*Medical consumer products*) (code “5”). The main groups have a different authority basis for reimbursement and their own trees. The tree in Figure 23 has been constructed as follows, cf. Table 7 below:

Table 7; Constructing a tree

Level of tree	Incidences	Description
1	3-digit code from 7403	Nutrients show a 3-digit code starting with “6” (for instance 601, 602). The 3-digit code for Medical consumer products starts with “5”. Note that the 3-digit level corresponds with the authority basis for reimbursement in code system 7427 (the codes at this level coincide with the authority codes in code system 7427).
2	5-digit code from 7403	Each 5-digit code has been grouped under the code at level 1 in the tree. The code 50101 falls under 501, code 50201 under 502, etc.
3	7-digit code from 7403	Each 7-digit code has been grouped under the code at level 2 in the tree. The code 5010101 falls under 50101, code 5020101 under 50201, etc.
4	Incidences of the categories Næringsmiddel (*Nutrients*) and Medisinsk forbruksmateriell (*Medical consumer products*)	Incidences of the categories Næringsmiddel (*Nutrients*) and Medisinsk forbruksmateriell (*Medical consumer products*) have been grouped under 7-digit codes in the coding system 7403 as follows: • Use the 7-digit code as a basis, e.g. “5010101” • Find all instances of the class Refusjonsgruppe (*Reimbursement Group*) referring to the coding system 7403 in the attribute group number. • Find all incidences of the categories Næringsmiddel (*Nutrients*) or Medisinsk forbruksmateriell (*Medical consumer products*) referring to one of the incidences in the class Refusjonsgruppe (*Reimbursement Group)*, cf. the bullet point above, via an aggregated incidence of the class Refusjon (*Reimbursement*).

12.2 How to populate what can be prescribed

The minimum requirement for prescription is that the physician is able to choose a product group at a 3-digit level, and a product group with seven digits with a structured condition that the group requires a separate prescription (structured condition type 11).

The tree structure may e.g. show product groups that cannot be prescribed in grey, and always display 7-digit product groups that can be prescribed (structured condition for separate prescription), i.e. as follows for 502, cf. Figure 23:

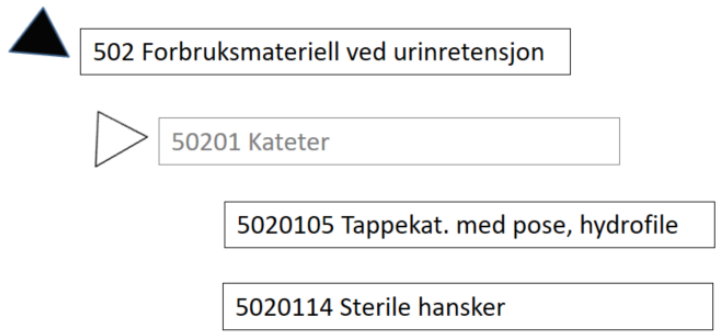

Figure 23 Product group 502

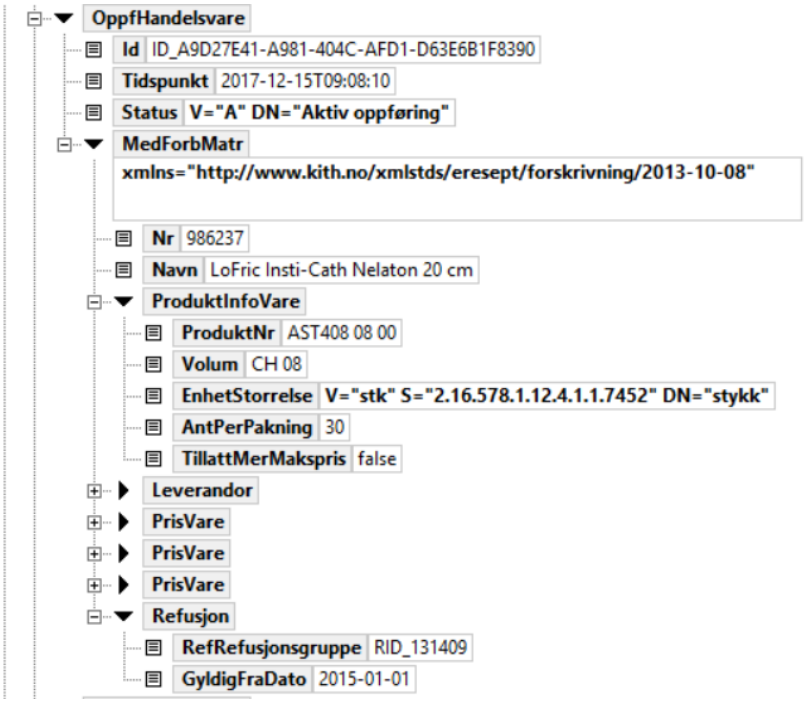

Figure 24 Entry of Commodity in FEST

Alternatively, only product groups that can be prescribed may be displayed, but with the option of clicking to retrieve the other product groups.

Such a compressed display may be misunderstood as one of the three subordinate product groups always have to be selected, instead of prescribing at the highest level, 502 Forbruksmateriell ved urinretensjon (*Consumer articles for urine retention*).

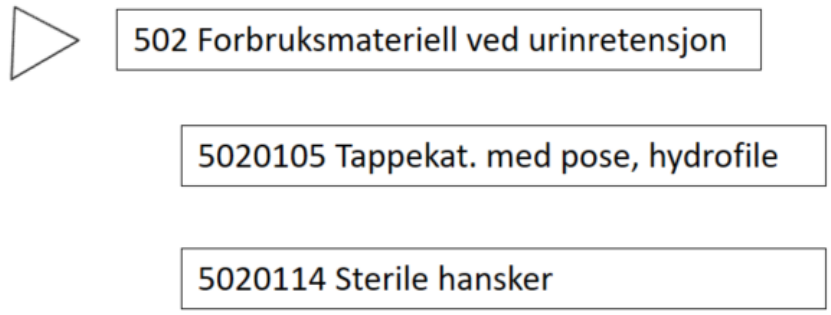

Figure 25 Opening screen, Product group 502

Prescribing at article number level is not recommended. It is better to display the articles in the 7-digit product group by selecting the product group without an option to select the articles for prescription.

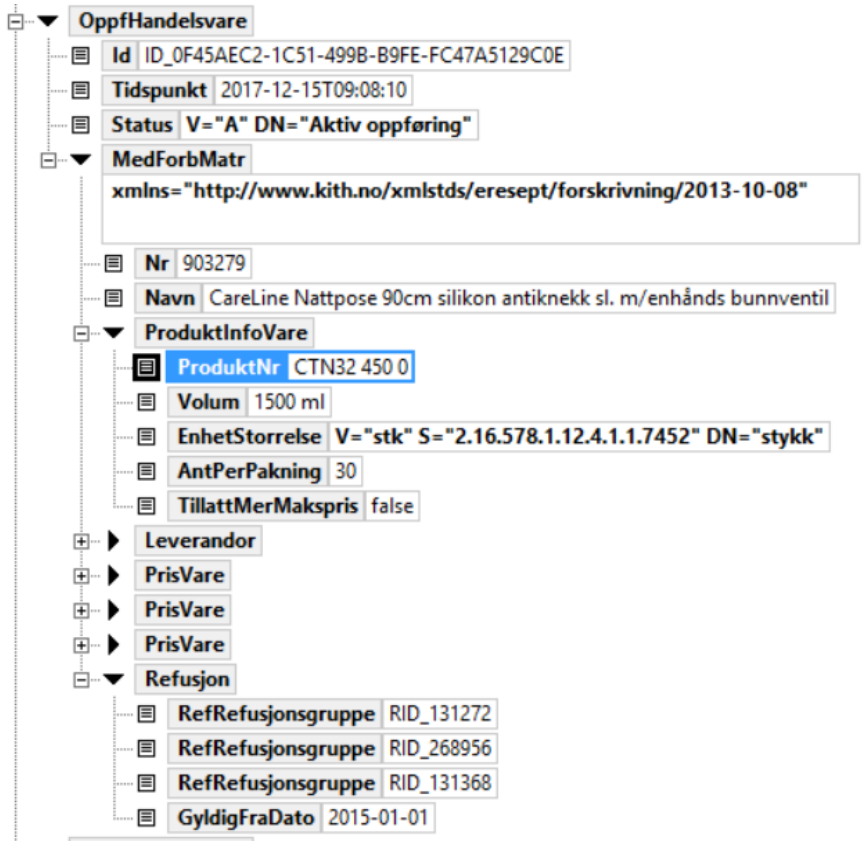

Figure 26 Commodity with Product No. in a different format

Commodities have certain structured conditions relating to a patient's age (structured condition types 1 and 2). It should not be possible to prescribe a product group if the age conditions are not met. Structured condition type 22 has been introduced for test strips for blood sugar measurement. The number of test strips per day must also be stated on the prescription.

Some product groups for commodities have a quantity limit (structured condition type 15). This specifies the maximum number of items which are covered by blue prescriptions per calendar year.

The reimbursement conditions applicable for a product group will be shown together with the product group.

The class Strukturert vilkår (*Structured Condition*) is part of the class Vilkår (*Conditions*), referred to in the class Refusjonsgruppe (*Reimbursement Group*). This means that it is not necessary to go the class Refusjonsgruppe (*Reimbursement Group*) to find the codes from coding system 7403 (via the group number attribute) and from there map to the class Vilkår (*Conditions*) to check for instances of the class Strukturert vilkår (*Structured Condition*) for the class Refusjonsgruppe (*Reimbursement Group*).

The class Breast Prosthesis must be ignored when issuing a prescription.

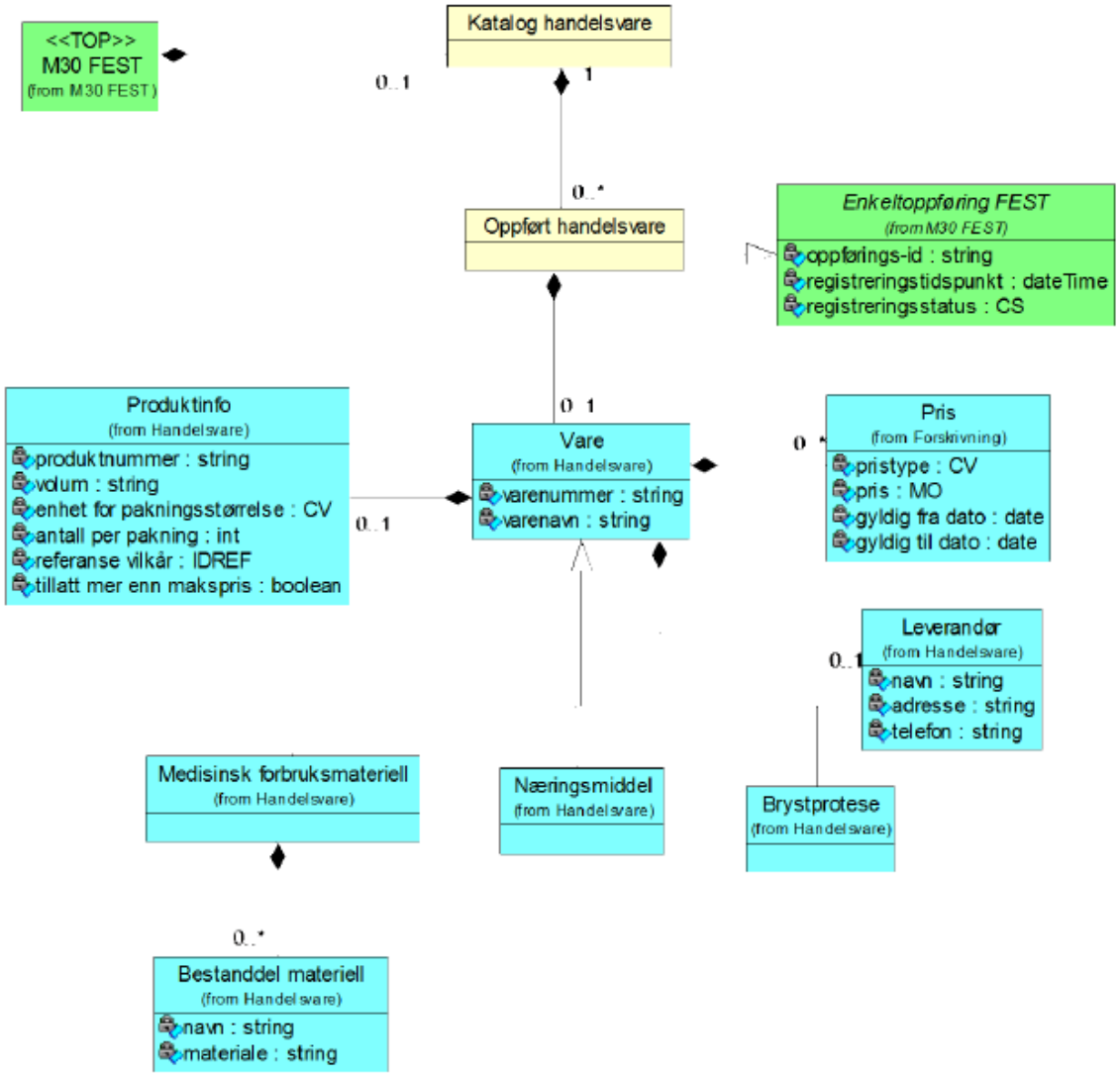

Figure 27 Katalog Handelsvare (Catalogue Commodity)

12.3 Nutrients, breast prostheses and consumer articles (M30N)

FEST is responsible for allocating all entry IDs in FEST. When an M30N from NAV is entered, each individual entry will be identified by an ID, which will always remain the same, typically via the product number or article number. When entering a new M30N, a field-by-field comparison will be made, and entries that have been changed since the previous update will receive a new entry ID. There is no history of data from the previous M30N in FEST. This means that only what is in the service at any given time will be available. The end systems themselves must build up a history based on individual entry IDs + registration status.

The articles have a reference to the condition that must be met to receive reimbursement for the product and what statutory authority applies for reimbursement.

13 Incremental downloads

13.1 Individual entry in FEST in M30 for incremental download

The class Enkeltoppføring (*Single Entry*) FEST has been entered in M30, which will help users retrieving the notification as an incremental download. This class consists of an entry ID, a registration time and a registration status.

An entry ID must be able to uniquely identify a version of an M30 entry. The registration time indicates when an entry received its current status and content in FEST. Registration status is always set at either active or expired. All changes in an entry, regardless of size, will ensure that a current entry is marked as expired and that a new active entry ID is created.

It is important to note that an Enkeltoppføring (*Single Entry*) in FEST must not be confused with other validity periods, etc. in the data recorded in an entry. It only indicates the following:

- New entry, and consequently a new entry ID
- Something has been changed, the previous entry ID will be discontinued and a new entry ID created
- Something is missing, the entry will be marked as expired.

It is optional to use the entry IDs when downloading full extracts.

- Expired entries will only be displayed via an incremental download from FEST. They will only have expired status and date, no other information.
- In the case of an expired entry of a LegemiddelPakning (*MedicinePackage*) due to a change, the new entry of the same LegemiddelPakning will have the new information, inc. information that has not been changed for this LegemiddelPakning.
- Most catalogues contain a unique ID in addition to an entry ID. For example, the catalogue LegemiddelPakning (*MedicinePackage*) contains a LegemiddelPakning-ID (*MedicinePackage-ID*). This ID will remain the same, even if information is altered and a new entry is constructed using a new entry-ID. This applies to catalogues generally.
- In the catalogue LegemiddelMerkevare (*MedicineBrandedProduct*) specifically, ID will not normally be changed, except when a number of different “Styrke i FEST” (*Strengths in FEST*) are created for a LegemiddelMerkevare (*MedicineBrandedProduct*). An example of this is if a LegemiddelMerkevare (*MedicineBrandedProduct*) has several different prefilled syringes, where each dose has a unique “Strength in FEST”.

Below follows an example of an entry in the catalogue LegemiddelMerkevare (*MedicineBrandedProduct*):

The entry ID is indicated in blue, and LegemiddelPakning-ID (MedicinePackage-ID)

in red. The example was retrieved from a file published on 26 June 2018. The expired entry for the same medicine package has been added below the active entry.

```
  <OppfLegemiddelpakning>
     <Id>ID_B61CEDD6-B346-4ED4-A30E-2B4F54476B63</Id>
     <Tidspunkt>2018-06-28T00:51:50</Tidspunkt>
     <Status V="A" DN="Aktiv oppføring" />
     <Legemiddelpakning
xmlns="http://www.kith.no/xmlstds/eresept/forskrivning/2014-12-01">
       <Atc V="C09DA03" S="2.16.578.1.12.4.1.1.7180" DN="Valsartan og diuretika"
/>
       <NavnFormStyrke>Corixil Tab 160 mg/12,5 mg</NavnFormStyrke>
       <Reseptgruppe V="C" DN="Reseptgruppe C" />
       <LegemiddelformKort V="53" S="2.16.578.1.12.4.1.1.7448" DN="Tablett" />
       <Preparattype V="7" DN="Legemiddel" />
       <TypeSoknadSlv V="1" DN="Skal ikke søkes" />
       <Refusjon>
         <RefRefusjonsgruppe>ID_5718DFE7-8B9A-46D0-BCCD-
B8FC529BC2CF</RefRefusjonsgruppe>
         <GyldigFraDato>2008-01-17</GyldigFraDato>
       </Refusjon>
       <PakningByttegruppe>
         <RefByttegruppe>ID_64466C62-A210-42EB-A849-
4FF56A170A9E</RefByttegruppe>
         <GyldigFraDato>2008-01-17</GyldigFraDato>
       </PakningByttegruppe>
       <Id>ID_00FB8D56-111B-4A82-8B68-9AD4B5422B0A</Id>
       <Varenr>108708</Varenr>

<!-- flere elementer... -->

         <Markedsforingsdato>2007-11-01</Markedsforingsdato>
       </Markedsforingsinfo>
     </Legemiddelpakning>
   </OppfLegemiddelpakning>
```

Utgått oppføring, som oppføringen over erstatter,

```
   <OppfLegemiddelpakning>
     <Id>ID_CBE3FD29-BAF7-44DC-AA80-23813EE09D9C</Id>
     <Tidspunkt>2018-06-28T00:51:50</Tidspunkt>
     <Status V="U" DN="Utgått oppføring" />
   </OppfLegemiddelpakning>
```

13.2 Incremental updates and Nutrients, Breast Prostheses and Medical consumer products (Commodities)

When importing a new M30N, all existing Handelsvarer (*Commodities*) will be replaced by all received articles with prices for a new three-month period. This means that FEST will not contain currently valid prices during the last two or three days before a new three-month period, only the future price.

13.3 Dates in connection with incremental extraction

<HentetDato> (*Retrieval Date*)

This is the first element to be retrieved in the M30 notification. However, the name is somewhat misleading. The field contains a time as well as a date. <HentetDato> (*Retrieval Date*) indicates the time the generation of the M30 notification started. It will normally take several days from the generation of a FEST notification until the quality-assured notification is published and available for downloading.

<SistOppdatert> (Last Updated)

The time of the last update can be specified in the M30 request (SistOppdatert (*Last Updated*)), which means a request for incremental extraction, including the changes that have taken place since the last update. However, this is inaccurate. SistOppdatert (*Last Updated*) must be set at the HentetDato (*Retrieval Date*) of the previously downloaded notification, i.e. the notification used for comparison. SistOppdatert (Last Updated) must be the time the downloaded notification was generated. This is available in the element HentetDato (*Retrieval Date).*

14 Glossary of terms

Table 8; Glossary of terms

English term	Norwegian term	Description
Active substance prescription	Virkestoffrekvirering	Cf. Chapter 0
Active substance prescription group	Virkestoffrekvireringsgruppe	Cf. Chapter 4.2
Administration	Administrering	Giving/taking a medicine
Aggregate	Aggregere	To collect in a mass
Application area	Bruksområde	A collective item saying something about what the medication is used for/against and/or where and how it should be used. Information has been obtained from SPC and/or Farmalogg and is intended for the pharmacy label.
ATC	ATC	Anatomical Therapeutic Chemical classification system, defined by the WHO collaboration centre
Attribute	Attributt	Field containing an information element
Bar code	Strekkode	Field in FEST containing the bar code imprinted on the package.
Bioavailability	Biotilgjengelighet	How a medicine is absorbed/distributed/metabolised in the body, i.e. how much of it has an effect.
Bolus/injection speed	Bolus/injeksjonshastighet	Injection of a medicine, “all-in-one”. The speed of the injection, i.e. if the plunger of the syringe is pressed down slowly or quickly.
Branded product	Merkevare	Article from a specific manufacturer, labelled with brand name.
Bulk package	Bulkpakning	The medicines are packed in a box, not individually. Often used for repacking at a hospital pharmacy or for multidose packaging. The package may then be bigger than what is dispensed directly to a patient.
Can be crushed	Kan knuses	Information relating to tablets, whether they can be crushed or not for easier administration to a patient.
Coding system	Kodeverk	A coding system defines what values can be used in a field.
Combination package/combination package	Kombinasjonspakning	Pharmaceutical package containing two different pharmaceutical forms in the same package for the patient to use together. E.g. a suppository and a cream.
Commodities	Handelsvarer	In FEST, this refers to medical consumer products and nutrients for medicinal use, as well as breast prostheses. These articles are reimbursable.
Dispensing	Utlevering	Sale of medicine to a customer at a pharmacy.

Dispensing regulation	Utleveringsbestemmelse	Condition from the Norwegian Medical Products Agency applying to dispensing of the pharmaceutical, cf. Chapter 5.5.
Division of dose/can be divided	Deling av dose/Kan deles	Cf. Chapter 7.1
Dosage unit	Enhet for dosering	Field in FEST in the class administration, cf. Chapter 7.1
Endringsforum	Endringsforum	Development forum at the Norwegian Directorate of Health
Generic substitution	Medisinbytte i apotek	Substitution of a medicine at a pharmacy in accordance with the substitution list. Cf. Chapter 6.5
Generics	Generika	Medicines that can be substituted by others in accordance with the substitution list, cf. generic substitution.
Generic prescription	Generisk forskrivning	See Active substance prescription
Inactive substances	Hjelpestoff	Substances in the medicine in addition to the active substance(s).
Indication (extension/restriction)	Indikasjon (utvidelse/innskrenkning)	What a medicine should be used for/against.
Individual reimbursement	Individuell refusjon	Cf. Chapter 6.4.3
Interaction(s)	Interaksjon(er)	When two medicines have an effect on each other when taken at the same time. Cf. Chapter 0
Kit	Sett	A medication consisting of two components that must be mixed before administration, e.g. a powder and a liquid.
LMR number	LMR-nummer	Number used to identify a single dose or the smallest unit that can be dispensed, for example one vial. Replaced the hospital pharmacies' Legemiddelregister (*medicine registry*).
Local articles	Lokale varer	Articles that have been entered in the pharmacy system, but that are not in the national register, Farmalogg or FEST.
Magistral prescription (extemporaneous prescription)	Magistrell forskrivning	Prescription of a medication that does not exist, but where the pharmacy must prepare it in accordance with the individual prescription for an individual patient.
Making ready (mixing at pharmacy)	Tilberedning (utblanding i apotek)	See preparation, used when a pharmacy makes a medication for a patient in hospital.
Mapping	Mapping	To use a connection/link between various categories to find relevant information, cf. Chapter 0
Maximum AIP price	Maks AIP pris	Maximum permitted purchase price for pharmacies
Maximum AUP price	Maks AUP pris	Maximum permitted sales price for pharmacies
Medicinal generic substitution	Medisinsk likeverdig bytte	Cf. generic substitution
Mixing liquid	Blandingsvæske	A liquid for dilution of a concentrate or powder.

NAF medications	NAF-preparater	Medications manufactured at pharmacies pursuant to regulations owned by the Norwegian Pharmacy Association. Following an exemption provision stipulated in the regulations, they do not need to be marketed in Norway to be sold there. NAF is the former name of the Norwegian Pharmacy Association.
NoMA Notification	Varsel fra SLV	Cf. Chapter 0
Notification description	Meldingsbeskrivelse	Information model for FEST
Opioid application	Opioidsøknad	Special application to HELFO for opioids.
Package size	Pakningsstørrelse	Describes how much is in a package, e.g. 100 tablets in a package or 100 g of cream in a tube.
Package type	Pakningstype	Describes the type of package, e.g. blister pack, tube, ampoule, vial
Medicine dose (cf. LMR number)	Legemiddeldose (jf. LMR-nummer)	Cf. Chapter 3.2.4
Medicine mixture	Legemiddelblanding	Multiple medicines that have been mixed together, for example in an infusion bag.
Medicines with marketing authorisation	Legemidler med markedsføringstillatelse	Medicines approved by the Norwegian Medical Products Agency granting the manufacturer the authorisation to market (=sell) the medicine in Norway. It does not mean it is available for sale. This depends on the choice of the manufacturer.
PO	PO	Medication description, also referred to as SPC, cf. SPC.
Populate	Populere	Fill in content in a field
Pre-approved reimbursement	Forhåndsgodkjent refusjon	Reimbursement for blue prescriptions (general reimbursement), cf. chapter 6.4.2
Preparation	Istandgjøring	Preparing a medicine for administration
Prescription	Rekvirering	The action of a physician issuing a prescription
Prescription	Ordinering	The process undertaken by a physician in hospital when he/she decides what pharmaceutical to issue for a patient and what dosage.
Product type	Preparattype	Field in FEST indicated the type of medication
Reimbursement codes	Refusjonskode	What diagnoses qualify for reimbursement are defined using reimbursement codes. The diagnosis coding system used as reimbursement codes.
Reimbursement price	Refusjonspris	The price HELFO pays to the pharmacy for a medicine eligible for pre-approved reimbursement.
Reimbursement validity	Refusjonsgyldighet	Indicates whether reimbursement is given for a medicine, i.e. if Helfo or the patient pays the pharmacy.
Route of administration	Administrasjonsvei	The path by which a drug is taken into the body, e.g. orally or intravenously.

Short dose	Kortdose	Field in FEST containing dosage suggestions. Cf. Chapter 7.1
Single dose	Endose	Package containing only one dose of a medicine, e.g. one tablet.
Single dose prescription	Endoseforskrivning	Prescription at KatalogLegemiddelDose (*CatalogueMedicineDose*) level
SPC	SPC	Summary product characteristics.
Multiple strength pack	Flerstyrkepakning	A package containing tablets of different strengths of the same medicine. For use at the start of a treatment when the dose is to be increased/reduced gradually.
Stepped price	Trinnpris	Price reduced in steps after a medicine has been on the market for a long time and is selling in large quantities. The stepped price is stipulated by the Norwegian Medical Products Agency.
Structured conditions	Strukturerte vilkår	Cf. Chapter 5.6
Structured dosage	Strukturert dosering	Catalogue in FEST, cf. Chapter 7.2
Substance	Substans	A drug, usually used about a substance which is an active ingredient
Substance groups	Substansgruppe	Field in FEST in the catalogue Interaksjon (*Interaction*) which groups together multiple substances. Cf. Chapter 8.1.1
Substitution group/substitution list	Byttegruppe/bytteliste	Cf. Chapter 6.5
Subterm	Underterm	Cf. Chapter 6.4.1
TPN	TPN	Total parenteral nutrition, a mixture where a patient's nutritional needs are covered by infusion.
Unregistered medicines	Uregistrerte legemidler	Medicines prescribed by a physician without having been authorised in Norway. An application for authorisation exemption is required from the physician. Unregistered medicines used in a certain quantity have been allocated a national article number where the wholesaler is responsible.

15 Preliminary missing content in FEST

Table 9; Missing content in FEST

Field missing in FEST - English	Felt som mangler i FEST	Comment
Diagnosis – the entire catalogue	Diagnose – hele katalogen	Content not available due to lack of source
Inactive substances	Hjelpestoffer	Content not available in FEST due to lack of quality assurance of information. This will be available by the end of 2015.
Infusion and injection	Infusjon og injeksjon	No source for administration data relating to infusion and injection. This applies to the fields Infusjonshastighet (*Infusion Speed*) and Gis som bolus (*Administered as bolus*)
Dosage unit for prescription. Prescription – the entire catalog	Doseringsenhet ved ordinering	Content is not available. The ISO 11240 standard might be used for the units.
Nutrients without reimbursement	Næringsmidler uten refusjon	Work is ongoing to find a solution
Pharmaceutical dose and special case: Kit	Legemiddeldose og spesialtilfelle: Sett	Single doses cannot currently be used for preparations with Pakningstype (*Package Type*): Kit