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<tr>
<td>19 Sept. 2013</td>
<td>Document version 0.1 prepared</td>
</tr>
<tr>
<td>22 Oct. 2013</td>
<td>Document version 0.2, much of the content in place, ready for review at general meeting</td>
</tr>
<tr>
<td>1 Nov. 2013</td>
<td>Document version 0.3 reviewed internally. Amendment proposals and several comments.</td>
</tr>
<tr>
<td>4 Nov. 2013</td>
<td>Document version 0.4, proposals from version 0.3 approved.</td>
</tr>
<tr>
<td>20 Nov. 2013</td>
<td>Document version 0.5 reviewed after discussion</td>
</tr>
<tr>
<td>27 Nov. 2013</td>
<td>Document version 0.6 reviewed study of version 0.5.</td>
</tr>
<tr>
<td>9 Dec. 2012</td>
<td>Document 1.0 final version</td>
</tr>
<tr>
<td>6 Nov. 2014</td>
<td>English translation final version</td>
</tr>
<tr>
<td>24 August 2015</td>
<td>Document 1.3, QA to ensure changes in Norwegian version 1.3, with linked references.</td>
</tr>
<tr>
<td>08 October 2015</td>
<td>Document 1.4 reviewed and translated from Norwegian version 1.4.</td>
</tr>
<tr>
<td>29 October 2015</td>
<td>Document 2.0 final</td>
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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, pharmacies and manufactures of surgical appliances receive updated information about all articles available for prescription/dispensing in Norway from one single source.

Basic data provided by the Norwegian Medicines Agency 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 Norwegian Medicines Agency’s web pages: [https://legemiddelverket.no/andre-temaer/fest](https://legemiddelverket.no/andre-temaer/fest).

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 the Norwegian Medicines Agency’s web pages: [Informasjonsmodell og XML-meldingsbeskrivelse (v. 2.5.0)](https://www.legemiddelverket.no/medicinsk-ferdigheter/innforsel-og-ekstern-tilgang/innforsel-melding-til-fest/download) / [Informasjonsmodell og XML-meldingsbeskrivelse (v. 2.5.1)](https) [Norwegian] (Information Model and XML notification description - hereinafter referred to as the Notification Description).

The Norwegian Medicines Agency 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.
2 The purpose of FEST

To promote safe and effective use of pharmaceuticals, the Norwegian Medicines Agency 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. The Norwegian Medicines Agency 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 the Norwegian Medicines Agency, the Norwegian Medical Association, the Norwegian Pharmacy Association, Bandagistenes næringspolitiskes 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.

The Norwegian Directorate of Health’s E-prescription document records contain the required documentation for suppliers who want to prepare their systems for E-prescription. [https://ehelse.no/Sider/Dokumentasjon-for-e-resept.aspx](https://ehelse.no/Sider/Dokumentasjon-for-e-resept.aspx)

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.

- Pharmaceuticals with marketing authorisation in Norway
- Pharmaceuticals produced by hospital pharmacists
  - Prerequisite: has been allocated a national article number
• NAF medications
• Unregistered pharmaceuticals
  o Prerequisite: has been allocated a national article number
• Nutrition supplements sold by pharmacies
• Commodities with reimbursement:
  o Medical consumables
  o Nutrients
  o 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 gathered in one 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:
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:
As shown in the figure above, there are five main catalogues for prescription. The four top ones are main catalogues for prescription of pharmaceuticals, whereas the last one is the main catalogue for prescription of medical consumer products:

- The catalogue LegemiddelVirkestoff (MedicineActiveSubstance): prescription of active pharmaceutical ingredients
- The catalogue LegemiddelMerkevare (MedicineBrandedProduct): prescription of a strength and form of a specific branded product
- 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.
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 Handelsvare (Commodity): commodities entitled for reimbursement, e.g. medical consumables, nutrients and breast prostheses.

The content in the four top catalogues is linked to pharmaceuticals and has been described in more detail in Chapters 0, 0, 0 and 0. The content in the catalogue Handelsvare (Commodity) has been described in Chapter 13. The other categories contain information about pharmaceuticals and commodities.

2.4 Quality in FEST

2.4.1 Data quality and ownership

The Norwegian Medicines Agency 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. Non-conformance procedures have also been prepared.

Most of the information about pharmaceuticals has been obtained from the Norwegian Medicines Agency’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.

**External data sources**

In addition to information from the Norwegian Medicines 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>
<thead>
<tr>
<th>Content</th>
<th>Owner</th>
<th>Update frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>ATC coding system</td>
<td>The WHO collaborating centre</td>
<td>Annually</td>
</tr>
<tr>
<td>Commodities, with reimbursement and conditions, as well as product group coding system</td>
<td>HELFO</td>
<td>Every quarter, with option for extraordinary updates every month.</td>
</tr>
</tbody>
</table>
The Norwegian Medicines Agency

<table>
<thead>
<tr>
<th>Interactions</th>
<th>The Norwegian Medicines Agency</th>
<th>As required by the 1st and 15th of each month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceuticals manufactured by hospital pharmacies</td>
<td>Hospital pharmacies’ administration</td>
<td>By the 1st and 15th of each month</td>
</tr>
<tr>
<td>Unregistered pharmaceuticals</td>
<td>Farmalogg</td>
<td>By the 1st and 15th of each month</td>
</tr>
<tr>
<td>Food supplements</td>
<td>Farmalogg</td>
<td>By the 1st and 15th of each month</td>
</tr>
<tr>
<td>Structured dosage</td>
<td>The Norwegian Directorate of Health</td>
<td>Each year</td>
</tr>
<tr>
<td>NoMA notifications</td>
<td>The Norwegian Medicines Agency</td>
<td>As required by the 1st and 15th of each month in M30. When NoMA notifications is available Five star FEST (open data), it will be pushed on a daily basis.</td>
</tr>
</tbody>
</table>

Table 1; Catalogue structure in FEST

2.4.2 Enquiries

Enquiries relating to FEST can be sent to: fest@legemiddelverket.no
This email is staffed by employees of the FEST section, Monday–Friday during regular working hours.

The FEST section receives and processes enquiries relating to FEST, such as change requests, needs, non-conformance, FEST notification errors, questions about the service, etc.

If any errors or non-conformities in FEST notifications are reported, the FEST section will be responsible for error correction. Errors/non-conformities are registered in our non-conformance system. In the event of serious errors/non-conformities, the FEST section will issue an operation notification to the users, including consequences and error correction status. Requests for changes and reported needs relating to development of the service will be processed as input to the section’s development work. Other queries will be dealt with as they are received.

More information about FEST and the FEST section’s work is available on the Norwegian Medicines Agency’s web pages: https://legemiddelverket.no/andre-temaer/fest.

Subscribing to operation notifications is recommended. To subscribe, please send an e-mail containing your contact information to fest@legemiddelverket.no.
2.4.3 Updates

Ordinary updates take place every second week. The dates for updates are available here: https://legemiddelverket.no/andre-temaer/fest/nedlasting-av-fest.

Extraordinary updates may also take place. Automatic updates should therefore be set to install every three days.
3 Medicine

3.1 The «Legemiddel» class

The class Legemiddel (Medicine) 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)
3.2 Main catalogues for prescribing medicines

The four main catalogues represent the four different approaches for prescribing medicines. Each of the four catalogues; LegemiddelVirkstoff (MedicineActiveSubstance), LegemiddelMerkevare (MedicineBrandedProduct), LegemiddelPakningMerkevare (MedicinePackageBrandedProduct) and LegemiddelDose (MedicineDose) 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 catalogue, cf. 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 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 0 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 0.
FEST implementation guidelines

Figure 5; LegemiddelVirkstoff (MedicineActiveSubstance) (version 2.5.0)

Figure 6; LegemiddelVirkstoff (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 shows the content of this catalogue, including what has been inherited from the general class Legemiddel (Medicine).

![Diagram of LegemiddelMerkevare (MedicineBrandedProduct)](image)

Figure 7: LegemiddelMerkevare (MedicineBrandedProduct) (version 2.5.0)
Figure 8: LegemiddelMerkevare (MedicineBrandedProduct) (version 2.5.1)
3.2.3 LegemiddelPakningMerkevare (MedicinePackageBrandedProduct)

Prescription of packages is based on the catalogue LegemiddelPakningMerkevare (MedicinePackageBrandedProduct). Figure 99 and 10 shows the content of this catalogue, including what has been inherited from the general class Legemiddel (Medicine).
3.2.4 LegemiddelDose (MedicineDose)

Prescription of a dose of a certain medicine is based on the catalogue LegemiddelDose (MedicineDose). The figure below shows the content of this catalogue, including what has been inherited from the general class Legemiddel (Medicine). Information in the catalogue LegemiddelDose (MedicineDose) facilitates prescription 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, administered by the Norwegian Medicines Agency. This has been transferred from the Norwegian prescription database (LMR) which used to belong to the hospital pharmacy enterprise HF.

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.

![Diagram](image1.png)

**Figure 11:** Different LegemiddelDose (MedicineDose) (version 2.5.0)

![Diagram](image2.png)

**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>
<thead>
<tr>
<th>Fields from general categories</th>
<th>LegemiddelPakning (MedicinePackageB randedProduct), Package</th>
<th>LegemiddelDose (MedicineDose), single dose</th>
<th>LegemiddelMerkevare (MedicineBrandedPro duct, strength of branded product)</th>
<th>LegemiddelVirkestoff (MedicineActiveSubstance), prescription of active substance</th>
</tr>
</thead>
<tbody>
<tr>
<td>ATC</td>
<td>Normally level 5</td>
<td>As on the package</td>
<td>As on the package</td>
<td>As on the package</td>
</tr>
<tr>
<td>NavnFormStyrke (NameFormStren gth)</td>
<td>String of branded product name, pharmaceutical form and strength</td>
<td>String of branded product name, pharmaceutical form and strength</td>
<td>String of branded product name, pharmaceutical form and strength</td>
<td>String of branded product name, pharmaceutical form and strength</td>
</tr>
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<td>Prescription group</td>
<td>Always completed</td>
<td>Always completed</td>
<td>Always completed</td>
<td>Always completed</td>
</tr>
<tr>
<td>Pharmaceutical form</td>
<td>Always completed</td>
<td>As on the package, except for combination packages</td>
<td>As on the package</td>
<td>As on the package</td>
</tr>
<tr>
<td>Reference to conditions</td>
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<td>No information</td>
<td>Dispensing regulations or other general conditions</td>
<td>Dispensing regulations or other general conditions</td>
</tr>
<tr>
<td>Type of medication</td>
<td>Always completed</td>
<td>As on the package</td>
<td>As on the package</td>
<td>As on the package</td>
</tr>
<tr>
<td>Application type SLV</td>
<td>Always completed</td>
<td>As on the package</td>
<td>As on the package</td>
<td>As on the package</td>
</tr>
<tr>
<td>Opioid application</td>
<td>Information only on packages requiring opioid application</td>
<td>As on the package</td>
<td>As on the package</td>
<td>As on the package</td>
</tr>
<tr>
<td>Reimbursement</td>
<td>Reference to reimbursement group on all packages with reimbursement §2, § 4a (not in v 2.4) or H-prescription (not in v 2.4)</td>
<td>No information</td>
<td>No information</td>
<td>Reference to one or several reimbursement groups, that are a union of reimbursement relating to all packages with a common prescription of active substance</td>
</tr>
<tr>
<td>Medicine package substitution group</td>
<td>Reference to substitution group on all packages with generic substitution decision</td>
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<td>No information</td>
<td>No information</td>
</tr>
<tr>
<td>Medicine administration (indicated per field below)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Mixing liquid</td>
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<td>No information</td>
<td>Indicated on medicine when relevant</td>
<td>Indicated on LegemiddelVirkestoff (MedicineActiveSubstance) if indicated on the associated LegemiddelMerkevare (MedicineBrandedProduct)</td>
</tr>
<tr>
<td>Mixing liquid proposal</td>
<td>No information</td>
<td>No information</td>
<td>Indicated on medicine when relevant</td>
<td>Indicated on LegemiddelVirkestoff</td>
</tr>
<tr>
<td><strong>Route of administration</strong></td>
<td>No information</td>
<td>No information</td>
<td>Indicated on all medicines</td>
<td>Indicated on all LegemiddelVirkestoff (MedicineActiveSubstance), and identical with LegemiddelMerkevare (MedicineBrandedProduct)</td>
</tr>
<tr>
<td>----------------------------</td>
<td>----------------</td>
<td>----------------</td>
<td>---------------------------</td>
<td>--------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Can be crushed</strong></td>
<td>No information</td>
<td>No information</td>
<td>Indicated on LegemiddelVirkestoff (MedicineActiveSubstance), if indicated on the associated LegemiddelMerkevare (MedicineBrandedProduct)</td>
<td>No information</td>
</tr>
<tr>
<td><strong>Can be opened</strong></td>
<td>No information</td>
<td>No information</td>
<td>Indicated on medicines where relevant</td>
<td>No information</td>
</tr>
<tr>
<td><strong>Division of dose</strong></td>
<td>No information</td>
<td>No information</td>
<td>Indicated on medicines where relevant</td>
<td>No information</td>
</tr>
<tr>
<td><strong>Unit of dosage</strong></td>
<td>No information</td>
<td>No information</td>
<td>Indicated with dosage unit. On all pharmaceuticals except radiopharmaceuticals</td>
<td>Indicated on LegemiddelVirkestoff (MedicineActiveSubstance) as the union of the values indicated on the associated LegemiddelMerkevare (MedicineBrandedProduct)</td>
</tr>
<tr>
<td><strong>Short dose</strong></td>
<td>No information</td>
<td>No information</td>
<td>One or several dosage proposals indicated. For medicines with uncomplicated dosage</td>
<td>Indicated on LegemiddelVirkestoff (MedicineActiveSubstance) as the union of the values indicated on the associated LegemiddelMerkevare (MedicineBrandedProduct)</td>
</tr>
<tr>
<td><strong>Ingestion precaution</strong></td>
<td>No information</td>
<td>No information</td>
<td>Indicated with one or several precautions. On medicines when relevant</td>
<td>Indicated on LegemiddelVirkestoff (MedicineActiveSubstance) if it exist on the associated LegemiddelMerkevare (MedicineBrandedProduct)</td>
</tr>
<tr>
<td><strong>Application</strong></td>
<td>No information</td>
<td>No information</td>
<td>Indicated with one or several applications. On medicine where relevant (submission of information not completed, see status on Legemiddelverket.no/F EST)</td>
<td>Indicated on LegemiddelVirkestoff (MedicineActiveSubstance) if it exist on the associated LegemiddelMerkevare (MedicineBrandedProduct)</td>
</tr>
<tr>
<td><strong>Bolus</strong></td>
<td>No information</td>
<td>No information</td>
<td>No information due to lack of source</td>
<td>No information due to lack of source</td>
</tr>
<tr>
<td><strong>Injection rate bolus</strong></td>
<td>No information</td>
<td>No information</td>
<td>No information due to lack of source</td>
<td>No information due to lack of source</td>
</tr>
</tbody>
</table>

*Table 2: Information in general categories relating to Legemiddel (Medicine)*
3.3 Mapping between main pharmaceutical catalogues

Below follows a description of relevant mappings between main catalogues. This chapter has been written mainly for technical resources.

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*).

If an incidence of the class LegemiddelMerkevare (*MedicineBrandedProduct*) has several incidences of SortertVirkestoffMedStyrke (*SortedActiveSubstanceWithStrength*) all incidences of SortertVirkestoffMedStyrke (*SortedActiveSubstanceWithStrength*) must be the same as the corresponding incidences of SortertVirkestoffMedStyrke (*SortedActiveSubstanceWithStrength*) derived from LegemiddelVirkestoff (*MedicineActiveSubstance*). In addition, the pharmaceutical form and ATC code must be the same in LegemiddelVirkestoff (*MedicineActiveSubstance*) and in the associated LegemiddelMerkevare (*MedicineBrandedProduct*). 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.

To map from LegemiddelVirkestoff (MedicineActiveSubstance) to the individual LegemiddelPakningMerkevare (MedicinePackageBrandedProduct) entry, one must first use 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, i.e. 50 units (stk) of tablets, must be indicated, cf. Chapter 4.3.
populate the lists of potential units for prescription, one must for each of the packages represented by the active substance prescription retrieve all LegemiddelPakningMerkevare.Pakningsinformasjon.enhet (MedicinePackageBrandedProduct.PackageInformation.units) and aggregate them into the list of the prescriber’s choice of unit (i.e. unit/stk). The prescriber should indicate the amount as a figure, i.e. 50.

Prescription validity aggregated to active substance prescription:
The prescription validity is available in connection with LegemiddelMerkevare (MedicineBrandedProduct). The prescription validity is always the same, provided the ATC code is the same. As the ATC code is identical in all LegemiddelVirkestoff (MedicineActiveSubstance) entries, these will also always have the same prescription validity. In theory, start 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 single 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, also in E-prescription, where the categories in FEST are reused in other notifications.

<table>
<thead>
<tr>
<th>Information element</th>
<th>Card. in data model</th>
<th>Card. in practice</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceutical package. Package information. Ref. LegemiddelMerkevare (MedicineBrandedProduct)</td>
<td>0..*</td>
<td>1..*</td>
<td>A package will always belong to at least one Merkevare</td>
</tr>
</tbody>
</table>
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.

Table: Cardinality

<table>
<thead>
<tr>
<th>Class Name</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>LegemiddelVirkestoff (MedicineActiveSubstance)</td>
<td>0..*</td>
<td>1..*</td>
<td>A prescription of an active substance will always have at least one active substance with strength</td>
</tr>
<tr>
<td>SortertVirkestoffMedStyrke (SortedActiveSubstanceWithStrength)</td>
<td></td>
<td></td>
<td>(BrandedProduct) in FEST, usually only one, but more for start and combination packages.</td>
</tr>
</tbody>
</table>
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. Report No. 28 (2014-2015) to the Storting (the Medicinal Product Policy, Legemiddelmeldingen) 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.

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

- Medicine which is a gene-modified organism
- The medicine has more than three active substances
- The medicine has no marketing authorisation as unregistered medication (Preparattype: Krever godkj. Fritak (medication type: requires approved exemption)) or pharmacy-prepared medication (Preparattype: sykehuspreparat eller NAF-preparat (medication type: special formulation for use in hospitals or for one patient))
- The medicine has a strength indication unsuitable for prescription as an active substance.
- The medicine has no indication of strength
- The medicines with the same active substance have been classified as non-replaceable

4.3 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 internal ordination in hospitals and for issuing prescriptions.
It should be possible to search by active substance in the user system. The medicine will then be selected based on active substance, form and type of medicine (Group of Active substances for prescription). Any associated reimbursements, notifications, etc. must be shown to the user (see 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 active substance prescription groups where this branded name belong. To stimulate the prescriber to use generic prescription, it is advised that all groups of active substances are listed alphabetically before Merkevarer (BrandedProducts), when there is made a search on both Merkevare (BrandedProducts) and active substances.

If a medicine cannot be substituted by a generic for medical reasons, the physician must prescribe a Merkevare (BrandedProduct) 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. This 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 has been described in Chapter 0. Relevant units should be default so that the prescriber only have to enter a number for the desired amount.

4.4 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 0.

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). One such example is: Tablett, filmdrasjert (Tablet, film coated).

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](image)
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.

For some medicines, there is no professional relevance in indicating the strength value in either NavnFormStyrke (NameFormStrength) or VirkestoffMedStyrke (ActiveSubstanceWithStrength), nor is there an associated entry in LegemiddelVirkestoff (MedicineActiveSubstance) for these medicines. This means that they cannot be generic prescribed.

5.3 Sorting of active substances without strength

In version 2.5.1 the sorting of active substances are given without strength according to the most potent drug.

5.4 Active substances in English

In version 2.5.1 the active substances names are given also in English.

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) comma is not used to indicate thousand.

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. One example of this is: 1 mg/ml will be divided into the fields: 1, mg, 1, ml. The standard for strength is “equal”. However, it is possible to indicate the strength by using greater than/less than or an interval.

For medicines with more than three active substances, strength will not be indicated in the field NavnFormStyrke (NameFormStrength). Here, strength will be indicated for the various active substances in the class VirkestoffMedStyrke (ActiveSubstanceWithStrength).
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.

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.

5.5.3 Alternative strength

If the strength of a medicine is expressed in a percentage, an alternative strength will also be indicated in FEST. This will be expressed as weight/weight or weight/volume.

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, and not from the catalogue LegemiddelVirkestoff (MedicineActiveSubstance).

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): Reference from the class Legemiddel (Medicine) and LegemiddelVirkestoff, only via the catalogue LegemiddelMerkevare (MedicineBrandedProduct), applies to dispensing regulations and other general conditions for a medicine. General conditions can i.e be associated to drugs without MT and drugs produced in pharmacies. If a condition has a reference to LegemiddelVirkestoff, there will also be a reference from the condition to all LegemiddelMerkevare associated.

- 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.

Figure 14 shows the class Vilkår (Conditions) and how it relates to the above-mentioned categories.

Figure 14; 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 4.

Example of reimbursement of a medicine, Figure 415:

![Structure of reimbursement](image)

*Figure 4; Structured condition – reimbursement*

Examples pertaining to a medicine (dispensing regulation), Figure 6:
Example relating to reimbursement of a commodity, Figure 57:

An overview of structured conditions is available at www.volven.no, coding system 7439. This is also summarised in Table 4.
<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Alder mindre enn</td>
<td>Age below</td>
</tr>
<tr>
<td></td>
<td>The patient must be younger than the number of years stated in the condition (value: integer)</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Kjønn</td>
<td>Gender</td>
</tr>
<tr>
<td></td>
<td>Male or female (value: from coding system 8459)</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Instituert av spesialist</td>
<td>Instituted by a specialist</td>
</tr>
<tr>
<td></td>
<td>Requirement for medicinal treatment to be initiated by a physician with an identified speciality (value: from coding system 7426)</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Instituert på sykehus</td>
<td>Instituted at a hospital</td>
</tr>
<tr>
<td></td>
<td>Requirement for medicinal treatment to be initiated at a hospital (value: from coding system 1101 – yes/no)</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Instituert på navngitt sykehus</td>
<td>Instituted at a named hospital</td>
</tr>
<tr>
<td></td>
<td>Requirement for medicinal treatment to be initiated at a named hospital (value: from coding system 7428)</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Instituert av spesialist eller sykehus</td>
<td>Instituted by a specialist or hospital</td>
</tr>
<tr>
<td></td>
<td>Requirement for medicinal treatment to be initiated by a physician with an identified speciality or at the hospital (value: from coding system 7426)</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Forskrevet av spesialist</td>
<td>Prescribed by a specialist</td>
</tr>
<tr>
<td></td>
<td>Requirement for a prescription to be prescribed by a physician with an identified speciality (value: from coding system 7426)</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Forskrevet på sykehus</td>
<td>Prescribed at a hospital</td>
</tr>
<tr>
<td></td>
<td>Requirement for prescription to be issued at a hospital (value: from coding system 1101 – yes/no)</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Forskrevet av spesialist eller sykehus</td>
<td>Prescribed by a specialist or hospital</td>
</tr>
<tr>
<td></td>
<td>Requirement for prescription to be issued by a physician with an identified speciality or at a hospital (value: from coding system 7426)</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Forskriveres på artikkelgruppenivå</td>
<td>Prescribed at article group level</td>
</tr>
<tr>
<td></td>
<td>The article group must be specified on the prescription (value: from coding system 1101 – yes/no)</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Forskriveres på varenummernivå</td>
<td>Prescribed at article number level</td>
</tr>
<tr>
<td></td>
<td>The article number must be specified on the prescription (value: from coding system 1101 – yes/no)</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Maks refusjonsperiode i dager</td>
<td>Max. reimbursement period (days)</td>
</tr>
<tr>
<td></td>
<td>Maximum number of days of consumption that can be prescribed on a blue (general reimbursement) prescription</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td><strong>14</strong></td>
<td>Maks antall stk. per kalenderår</td>
<td>Max. number of items per calendar year</td>
</tr>
<tr>
<td><strong>15</strong></td>
<td>Maks antall stk. per ekspedisjon</td>
<td>Max. number of items per dispensing episode</td>
</tr>
<tr>
<td><strong>16</strong></td>
<td>Utleveres til spesialist eller sykehus</td>
<td>Dispensed to a specialist or hospital</td>
</tr>
<tr>
<td><strong>17</strong></td>
<td>Utleveres kun til sykehus</td>
<td>Dispensed to a hospital only</td>
</tr>
<tr>
<td><strong>18</strong></td>
<td>Maks utleveringsperiode i dager</td>
<td>Max. dispensing period in days</td>
</tr>
<tr>
<td><strong>19</strong></td>
<td>Forskrevet på navngitt sykehus</td>
<td>Prescribed at named hospital</td>
</tr>
<tr>
<td><strong>20</strong></td>
<td>Instituert av spesialist eller sykehus</td>
<td>Instituted by a specialist or hospital</td>
</tr>
<tr>
<td><strong>21</strong></td>
<td>Antall teststrimler til blodsukkermåling per døgn må oppgis</td>
<td>Number of test strips for blood sugar measuring per 24 hours must be stated</td>
</tr>
</tbody>
</table>

Table 4: Code values for structured conditions

The “instituted by” requirement means that a treatment must be initiated by a physician who is specialised in a certain field or at a certain, specified hospital.

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.
The Norwegian Medicines Agency

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 LegemiddelVirkstoff (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. The Norwegian Medicines Agency 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 www.legemiddelverket.no, or at the EMA web-pages: http://www.ema.europa.eu/ema/. 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)
Taste is registered as a specific field when it is not found linked to the dosage form or the product name in the SPC. This means not in an approved product name and pharmaceutical form.
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.
Taste is still included in the NavnFormStyrke (NameFormStrength) on Legemiddelpakning (MedicinePackageBrandedProduct), LegemiddelMerkevare (MedicineBrandedProduct) and LegemiddelDose (MedicineDose).
When taste is not part of the pharmaceutical form, it is part of a specific field Smak.

5.14 Animal species (Dyreart)
For veterinary medicinal products the animal species are registered in a coding system. They are no longer associated to the pharmaceutical form.
Animal species is still included in the NavnFormStyrke (NameFormStrength) on Legemiddelpakning (MedicinePackageBrandedProduct), LegemiddelMerkevare (MedicineBrandedProduct) and LegemiddelDose (MedicineDose).
When animal species is not part of the dosage form, it is part of a specific field Dyreart.
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.

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. The Norwegian Medicines Agency 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 the Norwegian Medicines Agency. 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.

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 (Unit Package) 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 68 shows how the package size is displayed for one of these packages.
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, and is the bar code indicated on the outside of the package. The bar code consists of 13 digits. The bar code is non-mandatory.

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. This may be the case when changing to an alternative article, for example if a package of 100 tablets in a blister pack is replaced by a blister pack containing 98 tablets. In such a case, 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).

In other cases, the article number will be changed and the package remains the same. 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. In such a case, a package containing 100 tablets of the pharmaceutical 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 Medicines Agency will be informed via Farmalogg), the discontinued article number will be removed for the incidence.

6.2.5 Special packages

Starter packs
A starter pack 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.

**Combination packs**

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).

There are no entries in the catalogues LegemiddelVirkestoff (MedicineActiveSubstance) or LegemiddelDose (MedicineDose) for starter and combination packages.

**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). In version 2.4, the individual elements in the package have been included in the field Pakningstype (Package Type), separated by a semicolon.

In version 2.5, 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. Cf. Figure 9 and Figure 20: Examples of incidence(entry of kits in FEST version 2.5 below for examples from FEST versions 2.4 and 2.5.
Figure 19; Example of incidence/entry of kits in FEST version 2.4

Figure 20; 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.

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 utleieres 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 pkt 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 as well, due to reimbursement in institutions others than hospitals (PLO).

6.3 Prices

Prices of medicines in FEST are as stipulated by the Norwegian Medicines Agency, 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 and for reimbursement relating to contagious diseases that may endanger public health pursuant to § 4.

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.

Note; information about the reimbursement by § 4 and H-prescription is only available in version 2.5.0 and 2.5.1.

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 5 shows how attributes in the class Refusjonskode (Reimbursement Code) should be used.

<table>
<thead>
<tr>
<th>Attributes</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refusjonskode/V (Reimbursement code/V)</td>
<td>The reimbursement code which must be saved along with the prescription and forwarded with the prescription to the pharmacy</td>
</tr>
<tr>
<td>Refusjonskode/DN (Reimbursement code/DN)</td>
<td>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</td>
</tr>
<tr>
<td>Underterm * (Sub-term)</td>
<td>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</td>
</tr>
<tr>
<td>Referanse vilkår (Reference condition)</td>
<td>Reference used to find associated conditions</td>
</tr>
<tr>
<td>Gyldig fra dato (Valid from date)</td>
<td>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</td>
</tr>
<tr>
<td>Forskrives til dato (Prescribe until date)</td>
<td>Prescribe until date is the date reimbursement ceases for a prescription. After this date the reimbursement code must not be displayed upon prescription</td>
</tr>
<tr>
<td>Utleveres til dato (Dispensed until date)</td>
<td>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”</td>
</tr>
</tbody>
</table>

*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 13.

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, Sections 3a and 3b

All reimbursement codes in the reimbursement list (Section 2) are valid for individual reimbursement pursuant to Section 3a. In addition, there are some reimbursement codes (ICD-10) that are only used under Section 3a. 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.

Reimbursement codes are not relevant for individual reimbursement pursuant to Section 3b.

6.4.4 Magistral prescription reimbursement

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Translation from Norwegian
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 12.3.1 Structure of the ATC coding system. 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 in cases of MRSA pursuant to Section 4

A reimbursement code has been established with associated conditions for medicines reimbursed pursuant to Section 4 of the Blue Prescription Regulations for treatment and prevention of transmission of methicillin-resistant yellow staphylococcus aureus (MRSA). These codes have been labelled with statutory authority Section 5-14, Section 4. A separate reimbursement code has been established for this; “-04” “Allmennfarlige smittsomme sykdommer” (communicable diseases with a risk to public health). Other illnesses where a patient is entitled to reimbursement pursuant to Section 4 have not yet been included in FEST.

This has generated problems for some pharmacies. Consequently, reimbursement pursuant to Section 4 has been removed from FEST until all relevant ATC codes have been labelled. This is pt.t only relevant for the version 2.4.

6.4.6 Reimbursement by section 4a and H-prescription (H-resept)

For medicinal products used in treatment of hepatitis C-infection it is given economical support after § 4a in the regulations of reimbursement (blâreseptforskriften). These medicinal products demands that the patient has a resolution (individual application) with two exceptions: medicinal products containing the active substances ribavirin or
peginterferon. These medicinal products can be prescribed without a resolution. Therefore it exists two pursuant codes: 401 (with a resolution) and 402 (without a resolution).

Medicinal products included in H-prescription (H-resept) are some medicinal products used in treatment of dermatological diseases, gastrointestinal diseases, rheumatological disease, multiple sclerosis and cancer. 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 § 4a and H-prescription will be found in FEST version 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 a reimbursement group. It is not use reimbursement codes for § 4a and H-prescription, so the reference to the reimbursement condition will be found direct in the reimbursement group. The attribute Krever refusjonskode (require code of reimbursement) is therefore set to “false”. In addition it is references to structured conditions defining which specialties that can claim the reimbursement.

A package or/and a active substance prescription group may have reimbursement after both § 2 and § 4a. Therefore, a system must be able to handle a scenario with multiple reimbursement listings connected to one package and/or group of active substance prescription. A system must also be able to show both the pursuant of the reimbursement and the condition in the screen of prescription. This must also be catered when using generic prescription.
6.5 Substitution group

A substitution group consists of packages of a similar size containing the same or equivalent medicine. Packages with a reference to the same substitution group are interchangeable. 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 Medicines 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.
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).
- **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 Product Characteristics, 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 multi-dosage prescription (multidose), but not all the short doses are structured. More information about the data model and how structured dosage is to be used in M1 can be found here: https://ehelse.no/Sider/Dokumentasjon-for-e-resept.aspx
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. 

http://legemiddelverket.no/Legemiddelsoek/Sider/Interaksjoner.aspx (Interaction search – Norwegian Medicines Agency)

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).
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.

<table>
<thead>
<tr>
<th>Relevance</th>
<th>Relevance</th>
<th>Colour code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bør unngås</td>
<td>Should be avoided</td>
<td>Red</td>
</tr>
<tr>
<td>Forholdsregler bør tas</td>
<td>Precautions should be taken</td>
<td>Yellow/orange</td>
</tr>
<tr>
<td>Ingen tiltak nødvendig</td>
<td>No action necessary</td>
<td>Green (no colour)</td>
</tr>
</tbody>
</table>

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 0 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:
1. The same interaction notification should not reappear for this patient.
2. 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 00n 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.
- **Doseringendring** (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 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 relevant for
The Norwegian Medicines Agency

Pharmacies and patients (also prescriber) will in the future be published as Five Star FEST (Femstjernes FEST) as Linked, open data. This solution is being developed during the spring of 2016. The notifications in Five Star FEST has no rule of display, but there will be published three different texts were it is relevant, “Text for prescriber”, “Text for pharmacy” and “Text for patient”.

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”, but no “TilDato”, which means it contains only the date it was first published. 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 (see Cp. 13). It is important that expired notifications don’t show up in the user system.

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 has a description together with the link. It is recommended that the physician is shown as a clickable link in the user system instead of the actual URL-address (http/...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:

- 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 have headline and a text which should be shown to the used. The type of notification should also be shown, e.g. safety information. The date from which the notification is valid should also be shown.

- Most notifications contain a referance 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.

- A notification can be connected 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.

- It should be possible for the prescriber/dispenser to configure the desired functionality for displaying notifications.
11 Unregistered medicines

11.1 Unregistered medicines in FEST

The Norwegian Medicines 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.

11.2 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) or Må søkes (application must be submitted). 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 Medicines Agency afterwards.

11.3 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, cf. the Norwegian Directorate of Health’s dokumentarkiv (document records) for E-prescription and the documents “Detaljert funksjonell spesifikasjon e-resept” (DFS) and “eResept_arkitektur” (ark.dok).

12 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-prescription (E-prescription). More detailed information about how coding systems are managed in E-preszept (E-prescription) is available in the Norwegian Directorate of Health’s dokumentarkiv (document records) (the document “Kodeverk Eresept”).

12.1 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).

- 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)

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

12.2 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 Medicines 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.

12.3 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 Medicines 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.

12.3.1 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 LegemiddelMerkerve (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.

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 the use in the interaction database, there are existing substance group(s) containing 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 ATC-codes from the WHOCC (in an agreement with them).
13 Commodities

13.1 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. Figure 21 gives a simple example.

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 has been constructed as follows, cf. Table 1 below:

<table>
<thead>
<tr>
<th>Level of tree</th>
<th>Incidences</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>3-digit code from 7403</td>
<td>Nutrients show a 3-digit code starting with “6” (for instance 601, 602). The 3-digit code for</td>
</tr>
</tbody>
</table>
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).

<table>
<thead>
<tr>
<th></th>
<th>5-digit code from 7403</th>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.</td>
<td>7-digit code from 7403</td>
<td>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.</td>
</tr>
</tbody>
</table>

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).

**Table 6: Constructing a tree**

### 13.2 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 22:
Alternatively, only product groups that can be prescribed may be displayed, but with the option of clicking to retrieve the other product groups. The opening screen will then look as follows for 502, cf. Figure 23:

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).

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.

Commodities have certain structured conditions relating to a patient’s age. It should not be possible to prescribe a product group if the age conditions have not been met.
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 can be ignored when issuing a prescription.

13.3 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.
14 Incremental downloads

14.1 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 the 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 and the expired registration will only be displayed via an incremental download from FEST. The same ID, for instance LegemiddelMerkevare (MedicineBrandedProduct), will not be entered twice in the notification. Expired entries of a given LegemiddelMerkevare (MedicineBrandedProduct) will only have expired status and date, no other information. The new entry of the same LegemiddelMerkevare (MedicineBrandedProduct) will have the new information, incl. information that has not been changed for this LegemiddelMerkevare (MedicineBrandedProduct). In the catalogue LegemiddelMerkevare (MedicineBrandedProduct), The LegemiddelMerkevare (MedicineBrandedProduct) ID will never be changed for the same medicine. The corresponding ID, which will remain the same, will be available in all catalogues. Below follows an example of an entry in the catalogue LegemiddelMerkevare (MedicineBrandedProduct): Download from FEST 5 July 2008. This element, “RID_11B40768-...” is copied into the EPJ system:

```xml
<LegemiddelMerkevare>
  <Id RID="11B40768-D493-49A0-B793-F3E4AC22085F" />
  <Tidspunkt>2008-07-05</Tidspunkt>
  <Status V="A" DN="Aktiv oppføring" />
  <LegemiddelMerkevare>
    <Id ID="11B40768-D493-49A0-B793-F3E4AC22085F" />
    <Legemiddelform V="70" S="2.16.578.1.12.4.1.1.9077" DN="Tablett" />
    <Vareavn ZESTRIL</Vareavn>
    <Vareavn</Vareavn>
    <Vareavn</Vareavn>
  </LegemiddelMerkevare>
</LegemiddelMerkevare>
```
Between 5 July 2008 and 5 September 2008, the relevant LegemiddelMerkevare (MedicineBrandedProduct) was updated twice in FEST. When downloading FEST on 5 September 2008 (i.e. two months later), it will contain three OppfLegemiddelMerkevare (EntryMedicineBrandedProduct) elements relating to the relevant LegemiddelMerkevare (MedicineBrandedProduct). The first two will be marked Ugyldig (Invalid), whereas the third will be the current, valid element.

The element “RID_11B40768-...” indicates that the previous registration in the EPJ system must be set as the status “expired, replaced by a new version”.

The element RID_AF800386-...” is of no interest to the EPJ system and may be omitted.

The element “RID_66E72270-...” is the new valid element and copied into the EPJ system.

Two changes have taken place in LegemiddelMerkevare (MedicineBrandedProduct): pharmaceutical form and article name:

```
<OppfLegemiddelMerkevare>
    <Id RID="11B40768-D493-49A0-B793-F3E4AC22085F"/>
    <Tidspunkt>2008-08-27</Tidspunkt>
    <Status V="U" DN="Utgått oppføring"/>
</OppfLegemiddelMerkevare>

<OppfLegemiddelMerkevare>
    <Id RID="AF800386-45C6-4913-8DDE-0FEB03CDF5E6"/>
    <Tidspunkt>2008-09-02</Tidspunkt>
    <Status V="U" DN="Utgått oppføring"/>
</OppfLegemiddelMerkevare>

<OppfLegemiddelMerkevare>
    <Id RID="66E72270-D10F-4CAC-8504-BF1AC42D9613"/>
    <Tidspunkt>2008-09-02</Tidspunkt>
    <Status V="A" DN="Aktiv oppføring"/>
    <LegemiddelMerkevare>
        <Id RID="A8811112-2583-4452-89FE-4C73CE20FFFF"/>
        <Legemiddelform V="73" S="2.10.578.1.12.4.1.1.9078" DN="Tyggekapsel"/>
        <Varenavn>ZESTRILENDRETNAVN</Varenavn>
        <!-- flere elementer -->
    </LegemiddelMerkevare>
</OppfLegemiddelMerkevare>
```

Please note that the ID element located under an entry in the catalogue LegemiddelMerkevare (MedicineBrandedProduct) remains the same both before and after the update. It is this field that is referred to in the entry RefLegemiddelMerkevare (RefMedicineBrandedProduct) under Pakningsinfo (Package Info) in LegemiddelPakningMerkevare (MedicinePackageBrandedProduct).
14.2 Incremental updates and Nutrients, Breast Prostheses and Medical consumer products (Commodities)

When entering a new M30N, all existing Handelsvarer (Commodities) will be replaced by all received articles with prices for a new three-month period.

<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. From this time, it may take a couple of hours before the new notification is available to be downloaded. In the meantime, the previous notification will be available.

<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).
## 15 Glossary of terms

<table>
<thead>
<tr>
<th>English term</th>
<th>Norwegian term</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active substance prescription</td>
<td>Virkestofforskrivning</td>
<td>Cf. Chapter 0</td>
</tr>
<tr>
<td>Active substance prescription group</td>
<td>Virkestofforskrivningsgruppe</td>
<td>Cf. Chapter 4.2</td>
</tr>
<tr>
<td>Administration</td>
<td>Administreringsgruppe</td>
<td>Giving/taking a medicine</td>
</tr>
<tr>
<td>Aggregate</td>
<td>Aggregere</td>
<td>To collect in a mass</td>
</tr>
<tr>
<td>Application area</td>
<td>Bruksområde</td>
<td>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.</td>
</tr>
<tr>
<td>ATC</td>
<td>ATC</td>
<td>Anatomical Therapeutic Chemical classification system, defined by the WHO collaboration center</td>
</tr>
<tr>
<td>Attribute</td>
<td>Attributt</td>
<td>Field containing an information element</td>
</tr>
<tr>
<td>Bar code</td>
<td>Strekkode</td>
<td>Field in FEST containing the bar code imprinted on the package.</td>
</tr>
<tr>
<td>Bioavailability</td>
<td>Biotilgjengelighet</td>
<td>How a medicine is absorbed/distributed/metabolised in the body, i.e. how much of it has an effect.</td>
</tr>
<tr>
<td>Bolus/injection speed</td>
<td>Bolus/injeksjonshastighet</td>
<td>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.</td>
</tr>
<tr>
<td>Branded product</td>
<td>Merkevare</td>
<td>Article from a specific manufacturer, labelled with brand name.</td>
</tr>
<tr>
<td>Bulk package</td>
<td>Bulkpakning</td>
<td>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.</td>
</tr>
<tr>
<td>Can be crushed</td>
<td>Kan knuses</td>
<td>Information relating to tablets, whether they can be crushed or not for easier administration to a patient.</td>
</tr>
<tr>
<td>Coding system</td>
<td>Kodeverk</td>
<td>A coding system defines what values can be used in a field.</td>
</tr>
<tr>
<td>---------------</td>
<td>----------</td>
<td>---------------------------------------------------------------</td>
</tr>
<tr>
<td>Combination package/combination package</td>
<td>Kombinasjonspakning</td>
<td>Pharmaceutical package containing two different pharmaceutical forms in the same package for the patient to use together. E.g. a suppository and a cream.</td>
</tr>
<tr>
<td>Commodities</td>
<td>Handelsvarer</td>
<td>In FEST, this refers to medical consumer products and nutrients for medicinal use, as well as breast prostheses. These articles are reimbursable.</td>
</tr>
<tr>
<td>Dispensing</td>
<td>Utlevering</td>
<td>Sale of medicine to a customer at a pharmacy.</td>
</tr>
<tr>
<td>Dispensing regulation</td>
<td>Utleveringsbestemmelse</td>
<td>Condition from the Norwegian Medicines Agency applying to dispensing of the pharmaceutical, cf. Chapter 5.5.</td>
</tr>
<tr>
<td>Division of dose/can be divided</td>
<td>Deling av dose/Kan deles</td>
<td>Cf. Chapter 7.1</td>
</tr>
<tr>
<td>Dosage unit</td>
<td>Enhet for dosering</td>
<td>Field in FEST in the class administration, cf. Chapter 7.1</td>
</tr>
<tr>
<td>Endringsforum</td>
<td>Endringsforum</td>
<td>Development forum at the Norwegian Directorate of Health</td>
</tr>
<tr>
<td>Generic substitution</td>
<td>Generisk bytte</td>
<td>Substitution of a medicine at a pharmacy in accordance with the substitution list. Cf. Chapter 6.5</td>
</tr>
<tr>
<td>Generics</td>
<td>Generika</td>
<td>Medicines that can be substituted by others in accordance with the substitution list, cf. generic substitution.</td>
</tr>
<tr>
<td>Generic prescription</td>
<td>Generisk forskrivning</td>
<td>See Active substance prescription</td>
</tr>
<tr>
<td>Inactive substances</td>
<td>Hjelpestoff</td>
<td>Substances in the medicine in addition to the active substance(s).</td>
</tr>
<tr>
<td>Indication (extension/restriction)</td>
<td>Indikasjon (utvidelse/innskrenkning)</td>
<td>What a medicine should be used for/against.</td>
</tr>
<tr>
<td>Individual reimbursement</td>
<td>Individuell refusjon</td>
<td>Cf. Chapter 6.4.3</td>
</tr>
<tr>
<td>Interaction(s)</td>
<td>Interaksjon(er)</td>
<td>When two medicines have an effect on each other when taken at the same time. Cf. Chapter 0</td>
</tr>
<tr>
<td>Kit</td>
<td>Sett</td>
<td>A medication consisting of two components that must be mixed</td>
</tr>
<tr>
<td>Term</td>
<td>Norwegian</td>
<td>Description</td>
</tr>
<tr>
<td>------</td>
<td>-----------</td>
<td>-------------</td>
</tr>
<tr>
<td>LMR number</td>
<td>LMR-nummer</td>
<td>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).</td>
</tr>
<tr>
<td>Local articles</td>
<td>Lokale varer</td>
<td>Articles that have been entered in the pharmacy system, but that are not in the national register, Farmalogg or FEST.</td>
</tr>
<tr>
<td>Magistral prescription (extemporaneous prescription)</td>
<td>Magistrell forskrivning</td>
<td>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.</td>
</tr>
<tr>
<td>Making ready (mixing at pharmacy)</td>
<td>Tilberedning (utblanding i apotek)</td>
<td>See preparation, used when a pharmacy makes a medication for a patient in hospital.</td>
</tr>
<tr>
<td>Mapping</td>
<td>Mapping</td>
<td>To use a connection/link between various categories to find relevant information, cf. Chapter 0</td>
</tr>
<tr>
<td>Maximum AIP price</td>
<td>Maks AIP pris</td>
<td>Maximum permitted purchase price for pharmacies</td>
</tr>
<tr>
<td>Maximum AUP price</td>
<td>Maks AUP pris</td>
<td>Maximum permitted sales price for pharmacies</td>
</tr>
<tr>
<td>Medicinal generic substitution</td>
<td>Medisinsk likeverdig bytte</td>
<td>Cf. generic substitution</td>
</tr>
<tr>
<td>Mixing liquid</td>
<td>Blandingsvæske</td>
<td>A liquid for dilution of a concentrate or powder.</td>
</tr>
<tr>
<td>NAF medications</td>
<td>NAF-preparater</td>
<td>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.</td>
</tr>
<tr>
<td>NoMA Notification</td>
<td>Varsel fra SLV</td>
<td>Cf. Chapter 0</td>
</tr>
<tr>
<td>Notification description</td>
<td>Meldingsbeskrivelse</td>
<td>Information model for FEST</td>
</tr>
<tr>
<td>Opioid application</td>
<td>Opioidsøknad</td>
<td>Special application to HELFO for opioids.</td>
</tr>
<tr>
<td><strong>Package size</strong></td>
<td><strong>Pakningsstørrelse</strong></td>
<td>Describes how much is in a package, e.g. 100 tablets in a package or 100 g of cream in a tube.</td>
</tr>
<tr>
<td>------------------</td>
<td>----------------------</td>
<td>------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Package type</strong></td>
<td><strong>Pakningstype</strong></td>
<td>Describes the type of package, e.g. blister pack, tube, ampoule, vial.</td>
</tr>
<tr>
<td><strong>Medicine dose (cf. LMR number)</strong></td>
<td><strong>Legemiddeldose (jf. LMR-nummer)</strong></td>
<td>Cf. Chapter 3.2.4</td>
</tr>
<tr>
<td><strong>Medicine mixture</strong></td>
<td><strong>Legemiddelblanding</strong></td>
<td>Multiple medicines that have been mixed together, for example in an infusion bag.</td>
</tr>
<tr>
<td><strong>Medicines with marketing authorisation</strong></td>
<td><strong>Legemidler med markedsføringstillatelse</strong></td>
<td>Medicines approved by the Norwegian Medicines 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.</td>
</tr>
<tr>
<td><strong>PO</strong></td>
<td><strong>PO</strong></td>
<td>Medication description, also referred to as SPC, cf. SPC.</td>
</tr>
<tr>
<td><strong>Populate</strong></td>
<td><strong>Populere</strong></td>
<td>Fill in content in a field</td>
</tr>
<tr>
<td><strong>Pre-approved reimbursement</strong></td>
<td><strong>Forhåndsgodkjent refusjon</strong></td>
<td>Reimbursement for blue prescriptions (general reimbursement), cf. chapter 6.4.2</td>
</tr>
<tr>
<td><strong>Preparation</strong></td>
<td><strong>Istandgjøring</strong></td>
<td>Preparing a medicine for administration</td>
</tr>
<tr>
<td><strong>Prescription</strong></td>
<td><strong>Forskrivning</strong></td>
<td>The action of a physician issuing a prescription</td>
</tr>
<tr>
<td><strong>Prescription</strong></td>
<td><strong>Ordinering</strong></td>
<td>The process undertaken by a physician in hospital when he/she decides what pharmaceutical to issue for a patient and what dosage.</td>
</tr>
<tr>
<td><strong>Product type</strong></td>
<td><strong>Preparattype</strong></td>
<td>Field in FEST indicated the type of medication</td>
</tr>
<tr>
<td><strong>Reimbursement codes</strong></td>
<td><strong>Refusjonskode</strong></td>
<td>What diagnoses qualify for reimbursement are defined using reimbursement codes. The diagnosis coding system used as reimbursement codes.</td>
</tr>
<tr>
<td><strong>Reimbursement price</strong></td>
<td><strong>Refusjonspris</strong></td>
<td>The price HELFO pays to the pharmacy for a medicine eligible for pre-approved reimbursement.</td>
</tr>
<tr>
<td>Reimbursement validity</td>
<td>Refusjonsgyldighet</td>
<td>Indicates whether reimbursement is given for a medicine, i.e. if Helfo or the patient pays the pharmacy.</td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>--------------------</td>
<td>----------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Route of administration</td>
<td>Administrasjonsvei</td>
<td>The path by which a drug is taken into the body, e.g. orally or intravenously.</td>
</tr>
<tr>
<td>Short dose</td>
<td>Kortdose</td>
<td>Field in FEST containing dosage suggestions. Cf. Chapter 7.1</td>
</tr>
<tr>
<td>Single dose</td>
<td>Endose</td>
<td>Package containing only one dose of a medicine, e.g. one tablet.</td>
</tr>
<tr>
<td>Single dose prescription</td>
<td>Endoseforskrivning</td>
<td>Prescription at KatalogLegemiddelDose (CatalogueMedicineDose) level</td>
</tr>
<tr>
<td>SPC</td>
<td>SPC</td>
<td>Summary product characteristics.</td>
</tr>
<tr>
<td>Starter pack</td>
<td>Startpakning</td>
<td>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.</td>
</tr>
<tr>
<td>Stepped price</td>
<td>Trinnpris</td>
<td>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 Medicines Agency.</td>
</tr>
<tr>
<td>Structured conditions</td>
<td>Strukturerte vilkår</td>
<td>Cf. Chapter 5.6</td>
</tr>
<tr>
<td>Structured dosage</td>
<td>Strukturert dosering</td>
<td>Catalogue in FEST, cf. Chapter 7.2</td>
</tr>
<tr>
<td>Substance</td>
<td>Substans</td>
<td>A drug, usually used about a substance which is an active ingredient.</td>
</tr>
<tr>
<td>Substance groups</td>
<td>Substansgruppe</td>
<td>Field in FEST in the catalogue Interaksjon (Interaction) which groups together multiple substances. Cf. Chapter 8.1.1</td>
</tr>
<tr>
<td>Substitution group/substitution list</td>
<td>Byttegruppe/bytteliste</td>
<td>Cf. Chapter 6.5</td>
</tr>
<tr>
<td>Subterm</td>
<td>Underterm</td>
<td>Cf. Chapter 6.4.1</td>
</tr>
<tr>
<td>TPN</td>
<td>TPN</td>
<td>Total parenteral nutrition, a mixture where a patient’s nutritional needs are covered by infusion.</td>
</tr>
<tr>
<td>Unregistered medicines</td>
<td>Uregistrerte legemidler</td>
<td>Medicines prescribed by a physician without having been authorised in Norway. An application for authorisation exemption is required from the</td>
</tr>
</tbody>
</table>
physician. Unregistered medicines used in a certain quantity have been allocated a national article number where the wholesaler is responsible.

### 16 Preliminary missing content in FEST

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

*Table 7: Glossary of terms*

*Table 8: Missing content in FEST*