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Deliverable abstract

Norway Progress report on refactoring or new build of national IT systems, migration of national data, and data interfaces to EMA's SPOR.

This Progress report describes NoMA's progress in refactoring and/or developing new national IT-systems regarding Substances, Medicinal Products, Organisations and Referentials (SPOR) including EMA SPOR-interoperability and implementation of IDMP.

Norway will perform this implementation as a part of the DELE-project, which was established in the fall 2019. After a long procurement process, NoMA chose our new strategic IT-partner in October 2020, and is now planning the establishment of a new IT-platform upon which the new solutions and services will be developed.

NoMA has already started mapping and cleansing data between current databases and systems towards new IDMP-compliant services through the SAFEST-project, which will be merged with the DELE platform and project.

Keywords: NoMA, DELE, SAFEST, IDMP, SPOR, EMA, SNOMED, FHIR, ISO

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List of abbreviations

Abbreviation	Complete form
BoSS	Basis of Strength Substance
eAF	Electronic Application Form
EMA	European Medicines Agency
HMA	Heads of Medicines Agencies
IaaS	Infrastructure-as-a-Service
IDMP	Identification of Medicinal Products
ISO	International Organization for Standardization
NCA	National Competent Authority
NoMA	The Norwegian Medicines Agency
OMS	Organisation Management Services
PaaS	Platform-as-a-Service
PMS	Product Management Services
RMS	Referentials Management Services
SMS	Substance Management Services
SPOR	EMA's service delivering quality data management services for substances, products, organisations and referentials (SPOR) to power EU regulatory activities. The four SPOR data management services are: SMS, PMS. OMS, RMS
UPD	Union Product Database
WP	Work package

1   Executive summary

This Progress report describes NoMA's progress in refactoring and/or developing new national IT-systems regarding Substances, Medicinal Products, Organisations and Referentials (SPOR) including EMA SPOR-interoperability and implementation of IDMP.

Norway will perform this implementation as a part of the DELE-project, which was established in the fall 2019. After a long procurement process, NoMA chose the new strategic IT-partner in October 2020, and is now planning the establishment of a new IT-platform upon which the new solutions and services will be developed.

The one most important goal of the new DELE Platform is to fully optimize the effect of the common European initiatives including the SPOR data services and IDMP standards and fulfil our obligations and commitment to the European cooperation.

However, NoMA started already in February 2019 a project called SAFEST with a vision to offer prescription support and distribute structured data of high quality about all medicinal products to Norwegian hospitals. SAFEST is built up on the IDMP data model and FHIR is being used for data exchange.

During 2021 SAFEST shall be integrated with DELE and a plan for migrating the solution to the new platform will be worked out.

Together the DELE and the SAFEST projects will give NoMA the opportunity to fully deliver within the UNICOM scope and timeline as well as our national goals and objectives regarding offering high quality information to the Norwegian health sector and patients.

The next updates of this document are expected in month M26, M38 and M48.

2   The Norwegian Medicines Agency (NoMA)

The Mission of The Norwegian Medicines Agency (NOMA) is to evolve and safeguard public and animal health by ensuring the efficacy, quality and safety of medicines and to administer and enforce the medical devices regulation.

NOMA is an agency under the Ministry of Health and Care Services.

Figure 1. The Norwegian Medicines Agency, Oslo

Our goals

► Ensure that medicines are safe and effective.
► Ensure that the population has access to medicines regardless of ability to pay.
► Ensure the correct medicinal and economical use of medicines.
► Ensure the use of cost-effective medicines.
► Ensure that medical devices placed on the market and put into service in Norway meet the regulatory requirements

Our tasks

Assessment of medicines:

► Assess medicines and issue market authorisations.
► Assess clinical trials regarding medicines and medical devices
► Administration of the pharmaceutical distribution chain
► Authorise the manufacturing, import, sale and distribution of medicines.
► Classify products as medicines, narcotics or doping substances.
► Authorise the use of medicines that do not have market authorisation.
► Administer the narcotics and doping regulations and authorise the import and export of narcotics.

Pharmacoeconomics:

► Determine the price of prescription medicines.
► Determine medicines that should be included in the general reimbursement scheme.
► Evaluate cost effectiveness of medicines used in the specialist health service.
► Charge fees as regards revenues from sale of medicines, offer operational support and freight reimbursement to pharmacies in addition to preparing pharmacy statistics.

Supervision:

► Pharmacovigilance
► Supervise clinical trials
► Supervise manufacturers, blood banks, importers, wholesalers and pharmacies
► Supervise the marketing of medicines
► Handle safety deficiencies regarding medicines and medical devices

► Batch release
► Conduct laboratory analyses

Medical information:

► Provide information on correct medicinal and sound economical use of medicines to doctors and other prescribers.
► Provide information regarding regulations and procedures to MA holders, manufacturers, importers, wholesalers and pharmacies.
► Provide the general public with advice on the safe use of medicines.
► Medical devices:
► Administer, interpret and enforce the medical devices legislation
► Provide information and guidance regarding the medical devices regulations to manufacturers, importers, wholesalers and users
► Monitoring of the market and the actors involved

International cooperation:

► Represent Norway in EU scientific committees and working parties, and other international bodies such as the United Nations and EDQM.
► Participate in the European co-operation between Competent Authorities for medical devices, EU committees and working groups
► Make assessments of medicines on behalf of The European Medicines Agency.
► Take part in the development of European medicines and medical devices regulations.

2.1 Products of responsibility

NoMA is responsible for the following products:

► Medicines for humans
► Medicines for animals
► Medical devices
► Traditional plant-based medicines
► Homeopathics
► Narcotics
► E-Cigarettes

2.2 Core business

NoMA's core business is analysed and grouped into seven functional areas:

► Inspections of actors
► Permissions for actors
► Assessing and guiding clinical trials
► Marketing authorisation and product registration
► Pricing and financing
► Prescription support services and distribution of medical products data
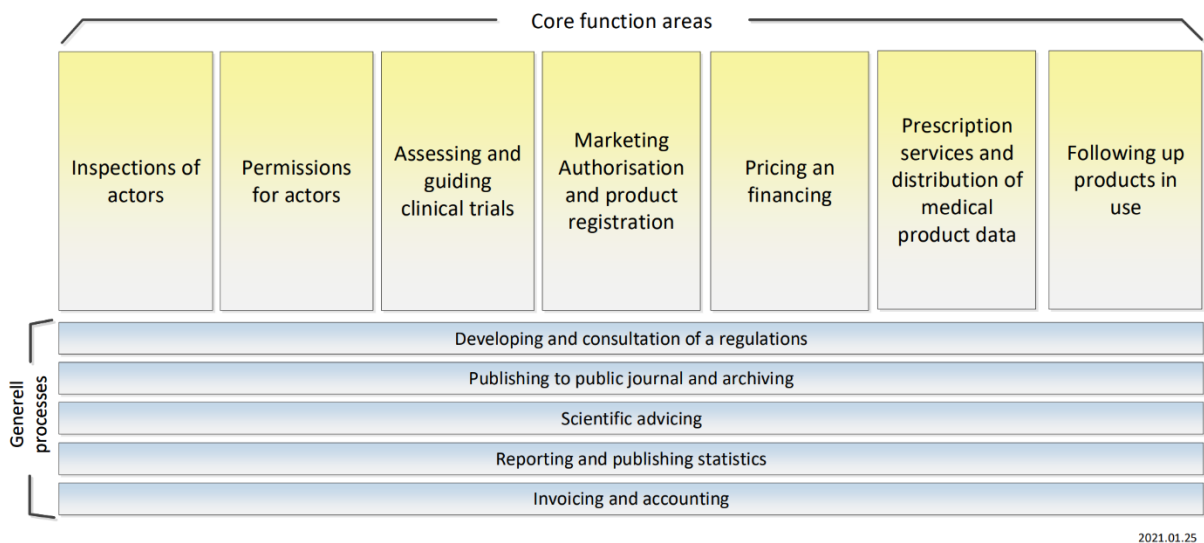► Following up products in use

Figure 2. NoMA's Core function areas

2.3 Key figures

► Number of Medicinal products
  ► 20 000 Licensed Marketing Authorisations in Norwegian National Registry, withdrawn approx. 45 000
► Number of Substances
  ► 6 900 (published) in Norwegian National Registry
► Number of Organisations
  ► Approx. 8 600 instances in our contact register, which includes pharmacies, whole sales, MA-holders, NCAs and more. Incudes both organisations and locations.
► Number of Referential Lists
  ► Main local system contains approx. 75 Referential Lists, 2 have RMS-mappings (Pharmaceutical dose form and Container)

2.4 IT at NoMA

A part of NoMA's IT strategy is «renting not owning», which means that both IT operations and development have been outsourced. Due to this, NoMA's IT unit is quite small, consisting of an IT manager, an enterprise architect, a test manager, a CISO, and five application managers.

3 IDMP implementation at NoMA

According to the commitments through participating in work package 4 (WP4), NoMA will realise use of IDMP through a project called DELE (Norwegian for "Sharing"). DELE was established as a project in the fall 2019 after a planning face from spring 2018 and consequential market dialogue thereafter.

However, NoMA started already in February 2019 a project called SAFEST with a vision to offer prescription support and distribute structured data of high quality about all medicinal products to Norwegian hospitals. The hospitals had a need of one source for such information, to reduce time consuming manual work, to heighten the quality of the data and to reduce risk for incorrect medication of the patients. SAFEST is built up on the IDMP data model and FHIR is being used for data exchange.

During 2021 SAFEST will be a subproject in DELE and a plan for migrating the solution to the new platform will be worked out.

3.1 SAFEST

SAFEST will give the Norwegian hospitals one source to medical product data. Data from our internal, legacy product register, Athene, is exported to the Integration component ITX. The same component is used for importing data from external data sources. In the Core component all data are compiled and transformed to IDMP. The Distribution component offers a regulatory FHIR-profile, which can be used by the hospitals in medication of patients.
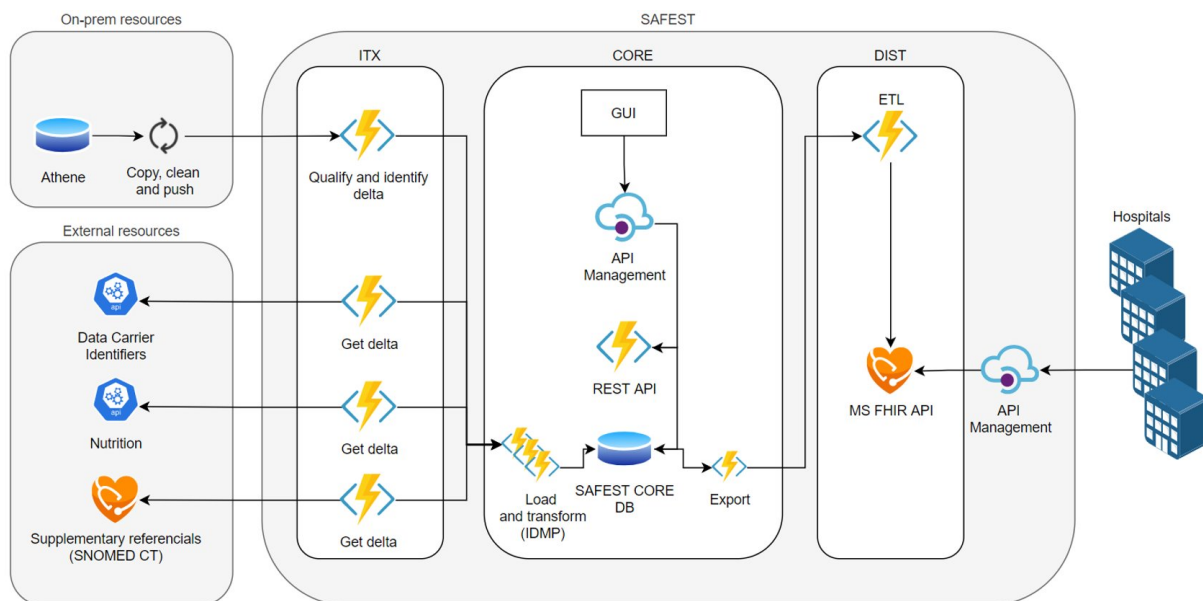
Figure 3. SAFEST - overall architecture

3.2 DELE-project

NoMA has through an extensive tender process established the DELE project. The main purpose of the DELE project is to modernize and further digitize NoMA's business processes using a new and flexible and configurable system platform.

An important part of the modernization is the transition from legacy data models and formats to solutions based on IDMP, FHIR, ATC, SNOMED-CT and other commonly used and agreed standards.

The DELE project will replace existing systems, as well as improving and extending system support for processes that currently do not have system support.

3.3 Vision and objectives

The vision for DELE-project is to establish er new coherent platform for sharing data, information, and knowledge so that we can:

- ► **Strengthen cooperation and collaboration with other European authorities**
  - o Integration with relevant external data sources (National sources, EMA, WHO, etc.) so that NoMA can operate on a common data foundation
  - o Integration with external collaboration and cooperation solutions in order to improve work flow and flow of data between external parties and NoMA
  - o Exchange of information based on structured data, in order to avoid manual data updates
  - o Emails and other messaging directly linked to cases instead of personal inboxes, in order to have communication documented on the case

- ► **Improve internal case handling**
  - o Move from a document centric to data centric way of working, in order to provide more time for high quality case handling work
  - o Automate in order to spend less time on routine work
  - o Improve processes to work more efficiently
  - o Resource allocation, in order for better resource usage
  - o Dynamic case handling tools that can accommodate process changes
  - o Data / information reuse – avoid manual moving of data
  - o Access to relevant information to support case handling
  - o Solutions based on international standards (e.g. IDMP / SPOR)
  - o Collaboration functionality for both internal and external collaboration, and data interchange

- ► **Make information / data more available to external consumers**
  - o Making information / data available, and provide guidance, in order to make it easier for external parties to create value for society from NoMA's data
  - o Accommodate requests and requirements from collaboration partners regarding new services and data
  - o Ensure that the data / information offering is consistent and of high quality
  - o Ensure that the data / information offering is well known and available, and experienced as a reliable and quality proven source

- ► **Have more predictable IT-costs**
  - o Lower maintenance cost through replacement of existing systems
  - o Lower development cost through platforms, configurability and flexibility

3.4 Principles

We have decided upon the following principles for the project and the DELE-platform:

- ► **Data centric**
  Data is our most valuable resource. We must secure high quality and integrity of our data both in the case handling process and by distribution of data for prescription and decision support. Data shall be stored once and be reused by different functions and processes. This means, we need to analyze functions and processes to identify which data is needed for the task.

- ► **Coherent process**
  To improve the internal case handling and prevent silos, NoMA's business shall be considered as a holistic and coherent process.
  This means, we need a "top down" approach to analyse the business.

► **Reuse of components**
To secure more predictable IT-costs, similar functionality shall be developed once and reused by different functions.
This means, we need to analyse and identify needs for common functionalities.

► **Use of standards and open application interfaces**
To strengthen the collaboration with other Norwegian and European actors, we will synchronise the data. Data shall not be copied or moved manually. This means integration must be automated and based on international standards and open application interfaces.

3.5 Standards

The SAFEST project establishes services for distributing data based on standard formats. The core of SAFEST is data based on IDMP, transformed from the existing legacy system Athene. SAFEST distributes data based on the FHIR standard.

A core part of the DELE project is implementing the IDMP standard as basis for NoMA's systems. The project will take advantage of the work already done in the SAFEST projects, both with regards to transformation from existing legacy systems and implementation of IDMP.

The DELE project will integrate with SPOR, and in compatibility with SPOR data models.

► The new Actor module will be compatible with OMS (IDMP)
► The new Referentials module will be compatible with RMS
► The new Medicines product module will be compatible with PMS and SMS (IDMP)

DELE will also accommodate standard referential data according to needs (I.e. SNOMED, ATC etc.)

3.6 Overall solution architecture for DELE

The overall architecture is designed to ensure flexibility and functionality to accommodate NoMA's architectural principles described above.
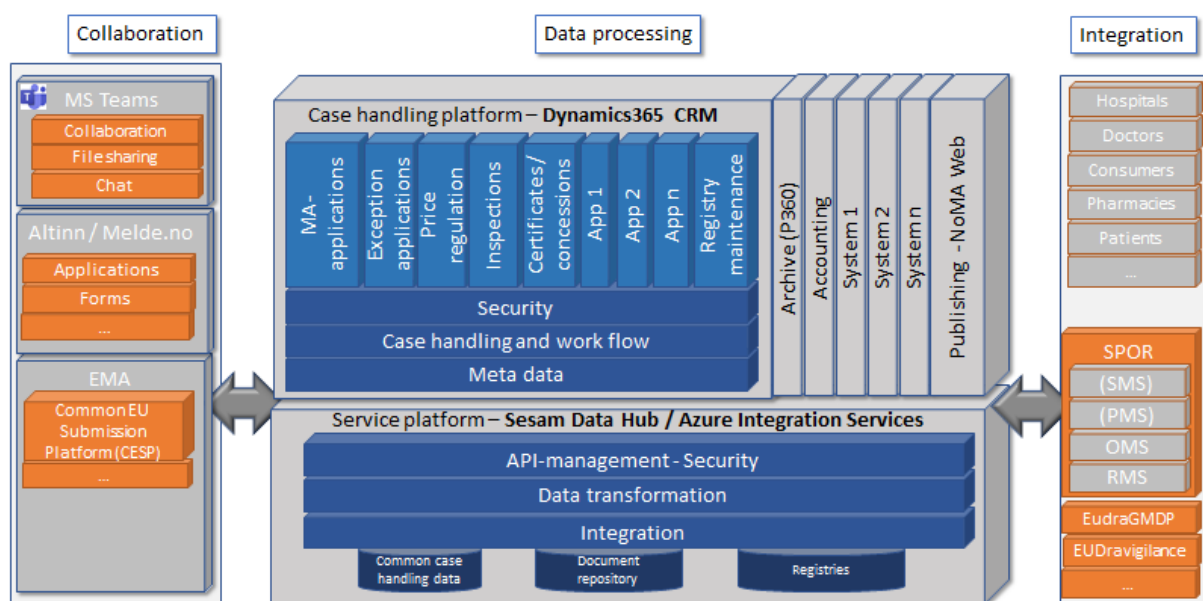

Figure 4. The overall architecture for the DELE platform

The main components of the architecture are:

► **Dynamics 365 CRM**
Dynamics 365 CRM provides functionality that covers many areas of basic functional needs for case handling, process support, task administration, document handling etc. The platform is highly configurable, and thus enables flexibility to accommodate new and changed needs. Tight integration with commonly used office products and collaboration solutions provides essential support for case handling work.

► **Sesam Data Hub**
In addition to providing a master data cache for internal systems, the Sesam Data Hub provides configurable functionality for handling the flow of data between NoMA and external data producers and consumers. Data from external sources can be merged with data from internal sources, transformed to standard formats (IDMP) and presented to both internal and external sources.

► **Azure Integration Services**
Azure Integration Services comprises the necessary functionality to handle integration both internally and externally. Core functionality comprises:
   o API Management, including security, traffic management and developer portal
   o Logic Apps for implementing integration applications for data processing and integration process support
   o Service Bus for message-based integrations and interactions
   o Event Grid for event-based integrations and interactions

3.7 Roadmap

The DELE roadmap is divided in two phases.

In the first phase we focus on developing solutions on the new system platform, that replaces existing systems. Included in this phase is the replacement of the existing solution for handling medicinal product data, with a new IDMP-based solution.

The second phase of DELE is aimed at extending the solutions to also cover functional areas and processes that do not have specific system support.

The details of the DELE roadmap are still to be decided.

4   Status

4.1 Status electronic application form

NOMA is participating in WP3 and will make necessary adjustments in internal systems to accommodate new data to be included in the electronic application forms (eAF). Data from the current eAFs are used to populate an existing system in a semi-automatic process. For other types of applications, data from a national register are used for automated processes.

4.2 Status Register of actors (NoMA's OMS)

A new, centralised register of actors will be established as part of the DELE-project.

Data about external actors/contacts, such as name and postal address, are maintained in several IT systems and Excel sheets today, with a considerable degree of manual registration. A preliminary analysis of current systems, data content and data flows have been completed, and the design phase for the new registry has started. Initially, the focus will be on core data for companies and organisations, not individual contact persons, but the scope will be expanded as the project develops. Integration with OMS and Norwegian national registers will be established for automatic updates in order to improve data quality and achieve more efficient work processes.

4.3 Status Referentials (NoMA's RMS)

There is a local system for management of Referentials. This includes both lists mapped to SPOR and local lists for national or internal use.

The plan is that updates in any List in Referentials we use, is to be automated in a new system. As of today, update is performed manually on a regular basis. When translation does not exist, there is a system of whom to involve and how to translate.

4.3.1 Pharmaceutical dose form

In Athene (NoMA's current medicinal product register) we have the approved Pharmaceutical dose form, as approved in point 1 in the SmPC. Hence the term list is a mix of Combined terms, Combined pharmaceutical dose forms and Pharmaceutical dose forms. We have implemented a change in Athene to mark which terms in the existing list that belongs to which of these three term lists from RMS/EDQM.

There are written rules/specifications to transform this one list to three separate lists. The resulting lists in SAFEST will then be harmonized with RMS. This will be implemented during 2021.

• Other Referentials

Several other lists are mapped to SPOR, e.g. Administration route and Units of measurement.

4.4 Status Substances (NoMA's SMS)

NoMA has had an expert in the SMS group for some years, and also the same person has been part of the EU-SRS POC project since the beginning, WP2 – Unicom.

This expert is the main responsible person for the approval of substances done according to the IDMP rules.

A local Substance database is in Athene as a separate module. The database has been cleansed internally over the past 2-3 years, this is of correct spelling and deprecating errors and duplicates. Any substance to be used in a product must be validated and approved before any MA is given. Editing a substance is done by documenting information in official databases if possible. IDMP categories are added, and so is also ID's that are found. The substances are put in a hierarchy if there is one.

The database was changed recently with the possibility to add different ID's, EUTCT code from SPOR, UNII code from US, and Snomed ID. Moreover, if the substance is a monograph in Ph.Eur, the Number has to be added along with Approved Ph.Eur.

The database is used for all kind of substances and it does not differ in human/veterinary, except for those from the Ph.Eur, which are defined as such.

There is an ongoing work for the future system and a new database for substances. The use of EU-SRS/SMS are vital for eAF and pharmacovigilance. There is a need for new entities to the different substances, e.g. synonyms and link to the ATC-codes only as examples from a long list.

4.5 Status Products (NoMA's PMS)

More than 40 medicinal products were modelled according to the IDMP standard. This work was done in coherence with the data pilot in the SPOR programme.

A comparison of the models and the data in our current system, Athene, was performed.

The following aspects were found that we had to address in order to transform the data to IDMP.

- Packaging hierarchy
- Reference strength
- Presentation/concentration strength
- Unit of presentation
- Pharmaceutical dose form

4.5.1 Packaging

To transform the data for packaging we made rules based on the way most packages was stored in our database. A lot of packages have been corrected to fit these rules. Ex. a package of "vial 3 units" is corrected to inform about the content in the vial, "vial 3*0,5 ml". By the end of 2020 most packages were transformed correctly into IDMP packaging hierarchy.

In the existing delivery to the Norwegian healthcare, we provide an ID for the smallest unit in a package. This may be a vial, a syringe or a tablet. The IDMP class Manufactured Item has been chosen to store this ID in our new delivery from the SAFEST project. Because tablets do not have an inner packaging for each tablet, we have chosen to store the number of tablets in a box/blister in the table between the Manufactured Item and the Packaged Medicinal Product. This was inspired from the work done in the SPOR data pilot.

4.5.2 Reference strength and basis of strength substance

We have the active substance as a hierarchy in our system but it lacks the reference strength and the basis of strength substance.

A new field for the BoSS (Basis of Strength Substance) was implemented in Athene and this information has been supplemented for most medicinal products. This was done as a preparation to transform the strength of the products to the new database where the reference strength will be stored according to IDMP format.

4.5.3 Strength pr concentration/presentation in Manufactured Item vs. Pharmaceutical product

The strength is stored in the way it is approved in the procedures. We have experienced a demand from the heath sector that they may need both the presentation strength and the concentration strength for most liquid preparations. For medicinal products with a transformation from the Manufactured Item to the Pharmaceutical product there is also different way to give the strength.

To transform the data from Athene to the correct place in IDMP we need a quite complex structure of rules. These rules are written but not yet implemented. This will be done throughout 2021.

The unit of presentation is data that we do not have in Athene. The rules for implementing the UoP is written, but not yet implemented.

4.6 Status UPD (NoMA's responsible tasks)

NoMA started in December 2020 a small project called "UPD/Database", where the scope is to identify how NoMA can find, structure and exchange data to the mandatory fields in UPD before 28.1.2022. NoMA's goal is to establish a system that is compatible with SPOR and IDMP standards in order to exchange data to mandatory fields to UPD. However, this UPD project has to be synchronized with the DELE project and there is a possibility that DELE regarding this issue is not finalised before the deadline of UPD 28.1.2022. Therefore, NoMA is simultaneously working with a solution to manually export required data to the UPD.

4.7 Challenges and risks

NoMA has experienced the following challenges and risks:

- It is uncertain how to handle terms for legacy products, ex pharmaceutical dose forms which are not listed in the standard terms and which do not follow the rules of today for standard terms

- FHIR resources used in regulatory work is different from FHIR resources used in clinical work and patient treatment.

- NoMA also wishes to address the problem of WHO-CC changing ATC-codes on a regular basis. Altered codes are supposed to be changed on the 1st January each year. The old codes are not to be found on WHO-CC Website after that.

    o The issue for January 2021 contains 81 alterations and this affects, in Norway alone, more than 700 MA's. This is an amount much more than usual and it is expected to be the same amount in 2022.
    o The alterations affect all SmPC's for the codes, and EU can reside in the situation that products with the same PhPID, is linked to different ATC codes until all of the MA holders has sent an application for change.
    This change involves all systems in EU NCAs.
    o This is an important matter also to Pharmacovigilance when linked to ATC codes.