

Last changed: 2022-10-13

UNICOM WP4

- MPA knowledge exchange webinar
2022-10-13

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Agenda

- About MPA
- Strategy, project management and development of IT-systems
- Alignment and use of RMS
- Alignment and use of OMS
- Adaptation of IDMP – a stepwise approach

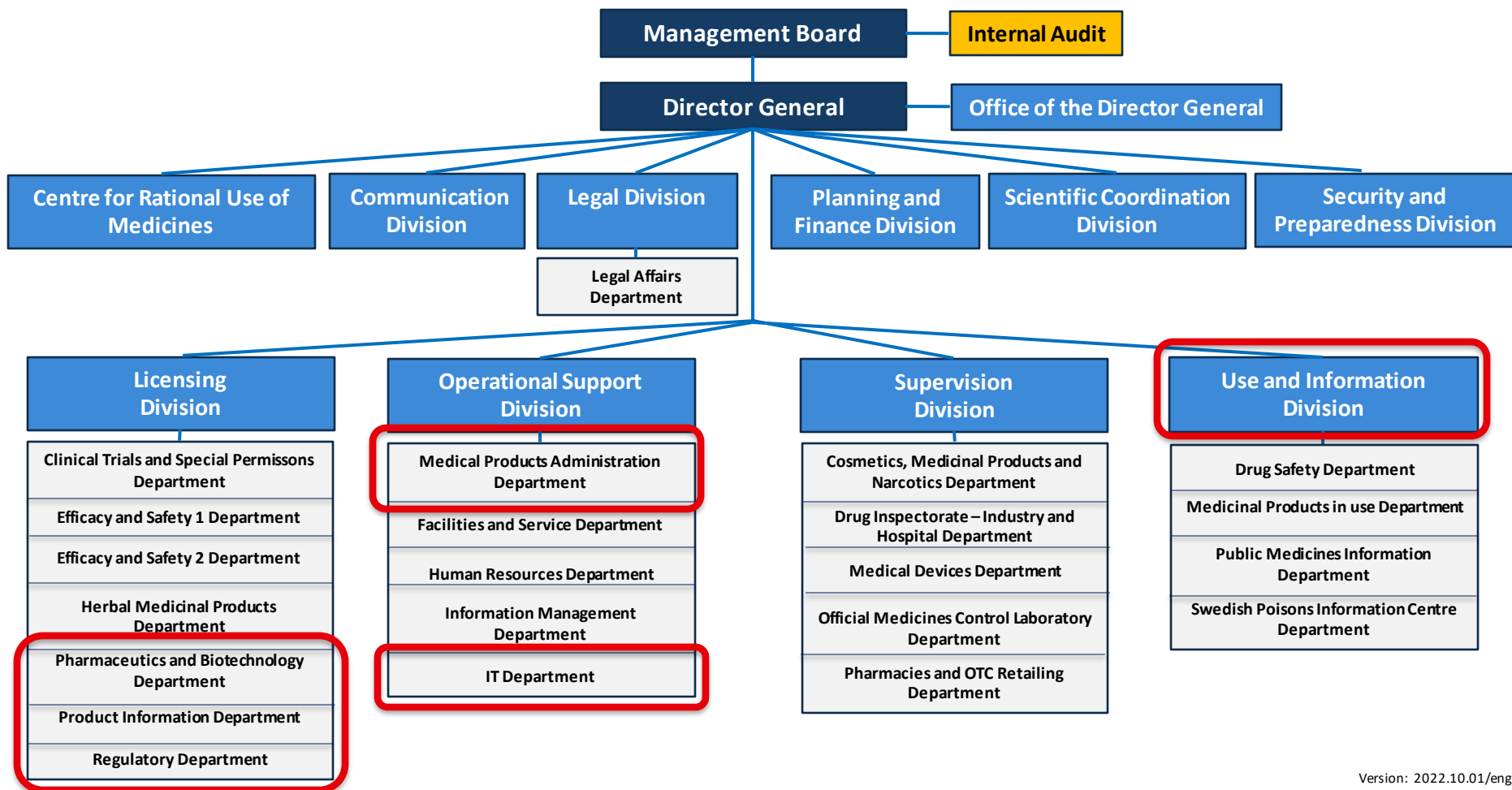
About MPA

- Covers a broad area around medicines, CTs, MDs
- 900+ employees with approx 90+ IT (whole spectra with own hosting), major collaborations within EU and nationally
- National information provider via different channels where eHealth Agency is a major one
- Continuously building abilities within civil defence, medicine availability/shortages, new legislations



We act for public and animal health

| | | |
|---|--|---|
| Permission, approval and control Advisory Clinical trials Manufacturing authorisation Marketing authorisation After the approval Control | Trading pharmaceuticals Pharmacy Retail sale of OTC medicines Distance and online sales Wholesale trade Export certificate List of online retailers | Treatment and prescription Prescription Substitutable drugs Buy, use and handle medicines |
| Medical devices Medicinal products for animals Cosmetics Tattoo inks Narcotic drugs | Laws and regulations Codes of Statutes Swedish Code of Statutes (SFS) | About the Swedish Medical Products Agency Contact us Press office |



Strategy, project management and development of IT-systems

- As-it-was 2019
 - Legacy (1990s era) IT-systems for medicinal product management, organisations and referentials
 - Embedded in the surrounding IT-environment
 - Legacy information and database structure
- To-be
 - New IT-systems utilising new technology
 - Agile and efficient way of working through DevOps
 - Replaced legacy systems without interfering the surroundings
 - New information layer with basic IDMP-adaptation
 - Alignment and utilising RMS and OMS
- Status
 - Mostly done, additional set of MVPs early 2023
 - IT-system EIRA for medicinal products, packaging and compositions, substitution, search
 - IT-system RALF for referentials
 - IT-system IOR for organisations
 - IT-system LVIN for invoicing abilities
 - New information layer MPA-IDMP for abilities to adapt to IDMP in a stepwise approach
 - Use of .NET and REST-services in an agile framework using DevOps

Strategy, project management and development of IT-systems

- Main issues

- How to break down the deliverables and compose them in a way that is independent and don't disturb on-going use of legacy systems?
- How to define what IDMP-adaptations that is necessary and to what extent, and when to execute the adaptations?
- How to create an efficient way of working and not loose sight of the most important objectives in a 5-year project?

- Lessons learned

- Create an information layer so we can get more independent of the database structure
- Not let the major undertaking of IDMP-adaptations keep us back from developing new IT-systems and replace the legacy ones
- Utilise the efficiency of DevOps and agile way of working
- Divide the project into 2 phases and be clear of the main objective for the first phase; MVPs

Alignment and use of RMS

- As-it-was 2019
 - Legacy (1990s era) IT-system for referentials
 - Legacy information and database structure
 - Simple information structure
- To-be
 - New IT-system utilising new technology
 - New information layer which is aligned to RMS
 - A developed product and information management organisation with abilities
 - Abilities to map and synchronize to RMS
- Status
 - IT-system RALF for referentials
 - A lot of ongoing work with mapping of lists and terms, and translations

Alignment and use of RMS

- Main issues
 - Probably the same issues as several of the agencies have encountered
 - National terms not supported by RMS
 - Translations
- Lessons learned
 - Allocate enough time - mapping "always" more complex than initially estimated
 - Identify the competencies needed, sometimes a team work between subject matter experts and business/information architect

Alignment and use of OMS

- As-it-was 2019
 - Legacy (1990s era) IT-system for organisations
 - Legacy information and database structure
 - A true national information structure
- To-be
 - New IT-system utilising new technology
 - New information layer which is aligned to OMS
 - A developed product and information management organisation with abilities
 - Abilities to map and synchronize to OMS
- Status
 - IT-system IOR for organisations
 - For now read-only → launch of MVP and datamigration from legacy in 1st quarter 2023
 - A lot of ongoing work with cleansing, mapping and structuring data, when switching to a new information structure
 - Use of SPORIFY is a major advantage

Alignment and use of OMS

- Main issues

- How to go from a true national information model to a structure that is aligned with OMS? And what will it mean for the business?
- Organisations and units, different rules and way of working with addresses
- Major data quality issues (duplicates, incompleteness, incorrectness, outdated)
- SMPA is information provider to eHealth Agency who uses the organisation information but they are firmly dependent on technicals in the information structure → headaches and long time for changes

- Lessons learned

- Allocate enough time – cleansing and mapping "always" more complex than initially estimated, margining, duplicates
- Identify the competencies needed, in this case team work between subject matter experts and business/information/solution/software architect
- Identify external dependencies early (in our case eHealth Agency), address them and work in collaboration to solve issues
- Assess the level of information quality in OMS early → we can not really trust and use OMS. We are prepared and are using OMS in full regarding CTs, but not for medicines

Adaptation to IDMP – a stepwise approach

- **As-is**
 - Locked into legacy database structure
 - Locked into existing business behaviour that does not include the use of IDMP
- **To-be**
 - Properly adapted, for the correct items with appropriate ambitions
 - Interoperable within the regulatory community
 - MPA business that benefits from IDMP and have the resources and competencies to digest and manage the information
 - Nationally interoperable, especially with eHealth Agency
- **Strategy**
 1. Get rid of the legacy and open up for possible adaptations
 2. Interoperability is not one persons business, it comes within a community → UNICOM, rest of the regulatory community, eHealth Agency
 3. Identify competencies and persons, and assign "the enablers" a mission
- **Status**
 - Legacy is now taken care of – we are ready for next step
 - Continuing to contribute to UNICOM
 - Starting building relations nationally
 - Waiting for DADI and eAF as input

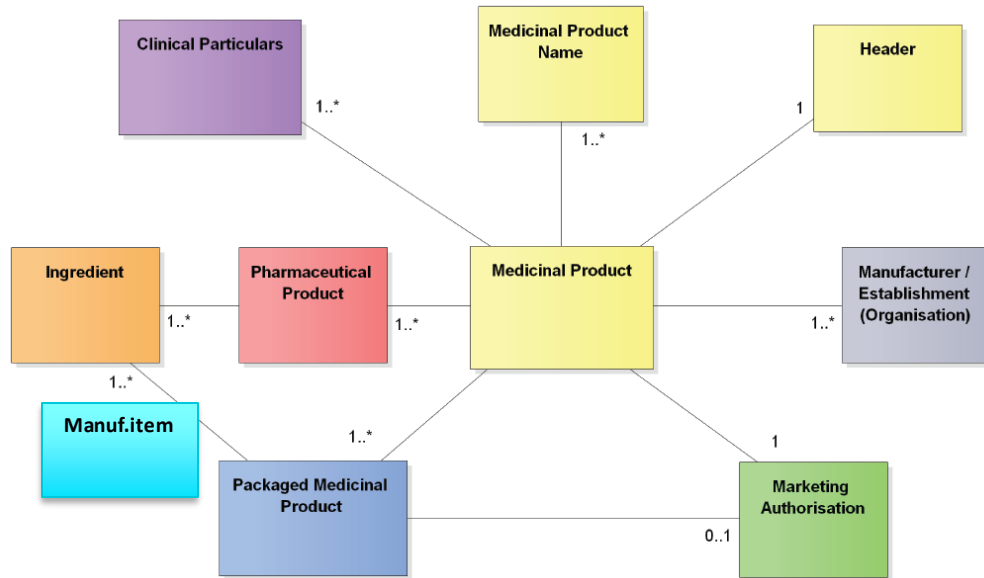
Adaptation to IDMP – a stepwise approach

- In 2023 we plan for the first part of larger adaptation to specific IDMP-attributes
- The tasks include the following:
 - Gap analysis of current data model against the IDMP implementation guide
 - Assessment of interoperabilities requirements within EU and nationally
 - Assessment of benefits and efficiency gains using automations
 - Identify needed changes
 - Design the phase II data model
 - Plan implementation and data migration
 - Implementation of the phase II version of the medicines register
 - Data migration
 - Cleansing of the legacy data

IMDP implementation thermometer

SE-MPA,
Johan Aulin

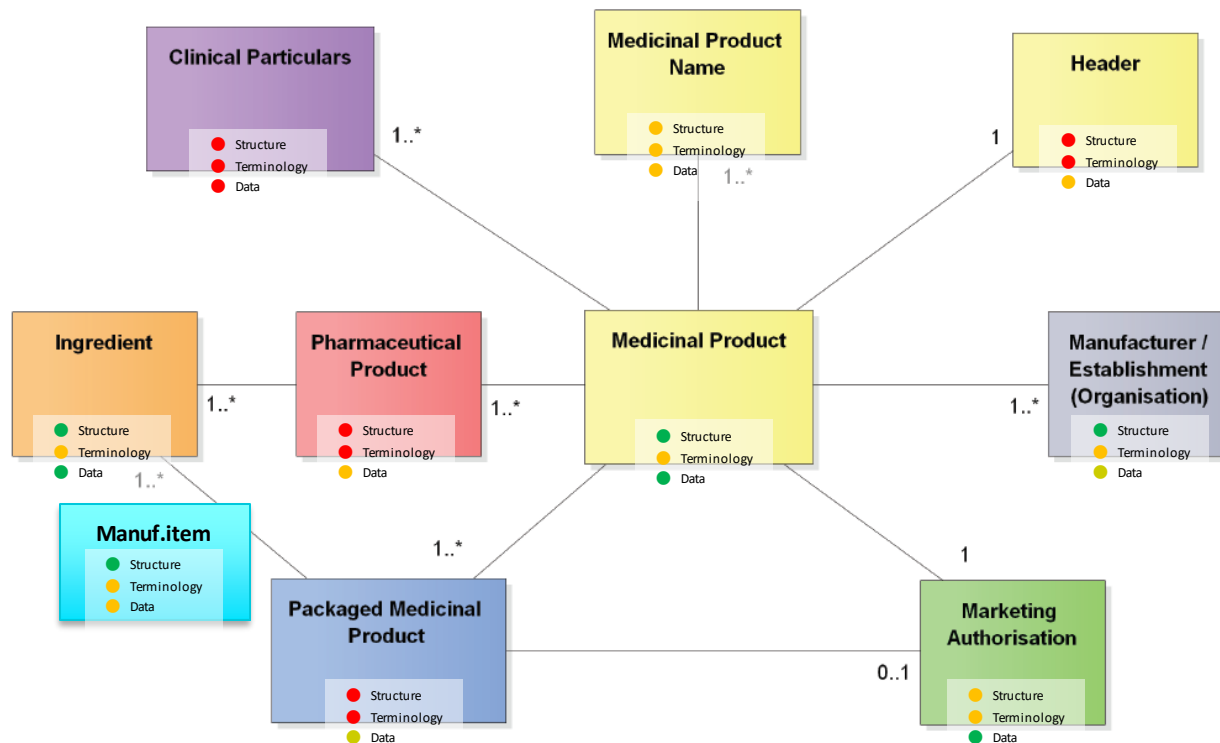
IDMP implementation at SE-MPA



To what extent does the MPA product database support IDMP?

- Structure
- Terminology
- Data

| Structure – to what extent is the current database structured similar to IDMP? | Structure different from IDMP with redesign needed | Structure similar to IDMP but adjustment needed | Structure close enough to IDMP |
|---|--|---|---------------------------------------|
| Terminology – to what extent is the current database and/or API terminology similar to IDMP? | Terminology different from IDMP with redesign needed | Terminology similar to IDMP but adjustment needed | Terminology close enough to IDMP |
| Data – to what extent does the current database hold the data IDMP covers? | Data isn't available | Some data is available and/or not always up-to-date | Data is available and kept up-to-date |



IDMP implementation at SE-MPA

Goal

