UNICOM WP4

- MPA knowledge exchange webinar
2022-10-13

Jonas Bern
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

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<th>Trading pharmaceuticals</th>
<th>Treatment and prescription</th>
<th>About the Swedish Medical Products Agency</th>
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<td>Advisory</td>
<td>Pharmacy</td>
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<td>Clinical trials</td>
<td>Retail sale of OTC medicines</td>
<td>Substitutable drugs</td>
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<td>Manufacturing authorisation</td>
<td>Distance and online sales</td>
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<td>After the approval</td>
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<td>Control</td>
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<td>Medicinal products for animals</td>
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<td>Laws and regulations</td>
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<td>Swedish Code of Statutes (SFS)</td>
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We act for public and animal health
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
  o How to break down the deliverables and compose them in a way that is independent and don’t disturb ongoing use of legacy systems?
  o How to define what IDMP-adaptations that is necessary and to what extent, and when to execute the adaptations?
  o How to create an efficient way of working and not lose sight of the most important objectives in a 5-year project?

• Lessons learned
  o Create an information layer so we can get more independent of the database structure
  o Not let the major undertaking of IDMP-adaptations keep us back from developing new IT-systems and replace the legacy ones
  o Utilise the efficiency of DevOps and agile way of working
  o 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
  o Legacy (1990s era) IT-system for referentials
  o Legacy information and database structure
  o Simple information structure

• To-be
  o New IT-system utilising new technology
  o New information layer which is aligned to RMS
  o A developed product and information management organisation with abilities
  o Abilities to map and synchronize to RMS

• Status
  o IT-system RALF for referentials
  o A lot of ongoing work with mapping of lists and terms, and translations
Alignment and use of RMS

• Main issues
  o Probably the same issues as several of the agencies have encountered
  o National terms not supported by RMS
  o Translations

• Lessons learned
  o Allocate enough time - mapping ”always” more complex than initially estimated
  o 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
  o Legacy (1990s era) IT-system for organisations
  o Legacy information and database structure
  o A true national information structure

• To-be
  o New IT-system utilising new technology
  o New information layer which is aligned to OMS
  o A developed product and information management organisation with abilities
  o Abilities to map and synchronize to OMS

• Status
  o IT-system IOR for organisations
  o For now read-only → launch of MVP and datamigration from legacy in 1st quarter 2023
  o A lot of ongoing work with cleansing, mapping and structuring data, when switching to a new information structure
  o Use of SPORIFY is a major advantage
Alignment and use of OMS

• Main issues
  o 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?
  o Organisations and units, different rules and way of working with addresses
  o Major data quality issues (duplicates, incompleteness, incorrectness, outdated)
  o 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
  o Allocate enough time – cleansing and mapping ”always” more complex than initially estimated, marging, duplicates
  o Identify the competencies needed, in this case team work between subject matter experts and business/information/solution/software architect
  o Identify external dependencies early (in our case eHealth Agency), address them and work in collaboration to solve issues
  o 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
  o Locked into legacy database structure
  o Locked into existing business behaviour that does not include the use of IDMP

• To-be
  o Properly adapted, for the correct items with appropriate ambitions
  o Interoperable within the regulatory community
  o MPA business that benefits from IDMP and have the resources and competencies to digest and manage the information
  o 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
  o Legacy is now taken care of – we are ready for next step
  o Continuing to contribute to UNICOM
  o Starting building relations nationally
  o 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:
  o Gap analysis of current data model against the IDMP implementation guide
  o Assessment of interoperabilities requirements within EU and nationally
  o Assessment of benefits and efficiency gains using automations
  o Identify needed changes
  o Design the phase II data model
  o Plan implementation and data migration
  o Implementation of the phase II version of the medicines register
  o Data migration
  o Cleansing of the legacy data
IMDP implementation thermometer

SE-MPA,
Johan Aulin
To what extent does the MPA product database support IDMP?
- Structure
- Terminology
- Data
<table>
<thead>
<tr>
<th><strong>Structure</strong> – to what extent is the current database structured similar to IDMP?</th>
<th>Structure different from IDMP with redesign needed</th>
<th>Structure similar to IDMP but adjustment needed</th>
<th>Structure close enough to IDMP</th>
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<td><strong>Terminology</strong> – to what extent is the current database and/or API terminology similar to IDMP?</td>
<td>Terminology different from IDMP with redesign needed</td>
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</tr>
<tr>
<td><strong>Data</strong> – to what extent does the current database hold the data IDMP covers?</td>
<td>Data isn’t available</td>
<td>Some data is available and/or not always up-to-date</td>
<td>Data is available and kept up-to-date</td>
</tr>
</tbody>
</table>
IDMP implementation at SE-MPA

Status may 2022

- Structure
- Terminology
- Data

Clinical Particulars

Medicinal Product Name

Header

Ingredient

Pharmaceutical Product

Medicinal Product

Manufacturer / Establishment (Organisation)

Manuf.item

Packaged Medicinal Product

Marketing Authorisation

Läkemedelsverket

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IDMP implementation at SE-MPA

Goal

Used in UPD and asked for by UNICOM-PPL.

Clinical Particulars
- Structure
- Terminology
- Data

Medicinal Product Name
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- Structure
- Terminology
- Data