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WP4 IDMP implementation at National Drug Agencies

D4.1: Austria: Progress report on implementation

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[1] Dissemination level: PU: Public; CO: Confidential, only for members of the consortium (including the Commission Services); EU-RES: Classified Information: RESTREINT UE (Commission Decision 2005/444/EC); EU-CON: Classified Information: CONFIDENTIEL UE (Commission Decision 2005/444/EC); EU-SEC Classified Information: SECRET UE (Commission Decision 2005/444/EC)

[2] Type of the deliverable: R: Document, report; DEM: Demonstrator, pilot, prototype; DEC: Websites, patent fillings, videos, etc.; OTHER; ETHICS: Ethics requirement; ORDP: Open Research Data Pilot

Revision history

Version	Date	Changes made	Author(s)
0.1	01.12.2020	Initial draft	HL, ND, SK
0.2	04.01.2021	Deliverable abstract, executive summary	GN, HL
0.3	04.01.2021	Work package management	HL
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0.5	07.01.2021	Internal review	GN, HL
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Statement of originality

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Deliverable abstract

Task 4.2 foresees the refactoring of the core IT system (PHAROS) towards ISO IDMP and SPOR at the Austrian Agency for Health and Food Safety (AGES).

The task includes work on the following topics:

- European-wide guidance how to standardise legacy data according towards IDMP and best-practices for other national competent authorities (NCAs) are drafted
- Essential tasks to provide ISO IDMP-compatible IT-systems are progressed based on national implementation plans
- Legacy data migration is progressed towards ISO IDMP based on national migration plans
- Essential tasks on data connectivity to EMA's SPOR services are progressed based on national implementation plans
- Prototype of an ISO IDMP compatible data feed to national eHealth providers will be presented according to national plans
- Increase knowledge and share best practices of how to implement ISO IDMP at NCA level

This report represents deliverable D4.1 and describes the status of the report period December 2019 to December 2020.

Keywords: AGES, ISO IDMP, SPOR, REFACTORING

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List of abbreviations

Abbreviation	Complete form
AGES	Austrian Agency for Food and Health Safety
API	Application Programming Interface
BASG	Federal Office for Safety in Health Care (German: Bundesamt für Sicherheit im Gesundheitswesen)
CTS	Communication and Tracking System
DCP	Decentralised Procedure
eAF	Electronic Application Form
EMA	European Medicines Agency
FHIR	Fast Healthcare Interoperability Resources
IDMP	Identification of Medicinal Products
IG	Implementation Guide
ISO	International Organization for Standardization
MEA	AGES Medicines & Medical Devices business segment (German: Medizinmarktaufsicht)
MP	Medicinal Product
MRP	Mutual Recognition Procedure
NCA	National Competent Authority
OMS	Organisation Management Services
PHAROS	Pharmaceutical Organisation System at AGES
PM	Project Manager
PMS	Product Management Services
RDM	Relational Data Model designed by EMA for medicinal products (depreciated)
RMS	Reference Member State
RMS	Referentials Management Services
SMS	Substance Management Services
SPOR	EMA service delivering quality data management services for substances, products, organisations and referentials (SPOR) to power EU regulatory activities.
WP	Work package

Table 1. List of abbreviations

1 Executive summary

Task 4.2 foresees the refactoring of the core IT system (PHAROS) towards ISO IDMP and SPOR at the Austrian Agency for Health and Food Safety (AGES). This report represents deliverable D4.1 of the underlying Grand Agreement.

Chapter 2 describes the authorship and responsibilities for this report.

Chapter 3 contains a short description of the beneficiary AGES and provides the key figures of the concerned medicinal products and organisations.

Chapter 4 describes the status of the topics which are in scope of this task. This includes general information about the project. The setup of the project started on November 2019 and is now in the phase of implementing the first requirements.

Chapter 5 describes the status of evaluation tasks and is structured into sub-chapter as follows:

Sub-chapter 5.1 provides the status of the interoperability between PHAROS and EMA's SPOR. This will enhance the data exchange between RMS, OMS, SMS and PHAROS. Currently a tool supporting data mapping and optional permanent data synchronisation is under evaluation.

Sub-chapter 5.2 gives an overview of the status of the refactoring of the AGES core IT system PHAROS. This work is in the analysis and requirements phase with the focus on the evaluation of the PHAROS database model in relation to ISO IDMP Standards and the EU Implementation Guide and HL7 FHIR models. A first evaluation identified that major refactoring has to be done for the ISO IDMP/HL7 FHIR artefacts "ingredient", "manufactured item", "pharmaceutical product" and "package". Planning for the necessary data migration is in progress and supporting tools have been identified.

Sub-chapter 5.3 describes the status of the evaluation about the future PHAROS data content taking into consideration of utilizing a potential SPOR PMS repository.

Sub-chapter 5.4 describes the status of the contribution to the definition of common rules how to standardise medicinal product data according to ISO IDMP. This work has started with reviewing EMA's EU Implementation Guide in July 2020 followed by a first best practise workshop together with WP 4 partners. AGES also attended WP 1 sessions about IDMP standards.

Chapter 6 provides the status of a prototype of an IDMP compatible data feed to national eHealth provider ELGA GmbH. A first planning was performed and prototyping will be done in 2023.

2 Authorship and responsibilities Authorship and responsibilities

The Project Coordinator is responsible of submitting the deliverables in accordance with the timing and conditions set out in the DoA.

The leader of the Work Package to which the deliverable is assigned is responsible of reporting to the Project Coordinator about the progress and completion of the output and the document, and ensure that it has the required quality.

The lead beneficiary of each deliverable, as identified in the Description of the Action (DoA), is responsible of editing the document. For that purpose he or she may count with the contribution of other partners. All authors that have made significant contributions to the deliverable shall be listed in the table contained in the second page of the template.

3 AGES, Austrian Agency for Food and Health Safety

- AGES MEA is a division of the Austrian Agency for Health and Food Safety (AGES), which is the leading expert organisation for risk minimisation in the fields of health, food safety and consumer protection.
- 350 FTEs are working at AGES MEA.
- AGES is wholly owned by the Republic of Austria.
- The AGES MEA business unit is the service provider for the Federal Office for Safety in Health Care (BASG).

Key figures – Medicinal product Authorisations, Registrations, Parallel Traded

HUMAN		VETERINARY (for information and comparison purposes)	
Total:	13.643	Total:	1.544
MRP/DCP:	5.575	MRP/DCP:	1.046
National:	8.068	National	498
Total:	**15.187**		

Table 2. Key figures by November 2020 – Medicinal product Authorisations, Registrations, Parallel Traded

Key figures - Organisations

HUMAN		VETERINARY (for information and comparison purposes)	
Organisations total:	8.117	Organisations total:	1.477
With OMS-IDs:	1.375	With OMS-IDs:	305
Holder's Organisations:	1.989	Holder's Organisations:	245
With OMS-IDs:	564 (28%)	With OMS-IDs:	79 (32%)

Table 3. Key figures by November 2020 - Organisations

4 Workpackage Management

4.1 Project Organisation

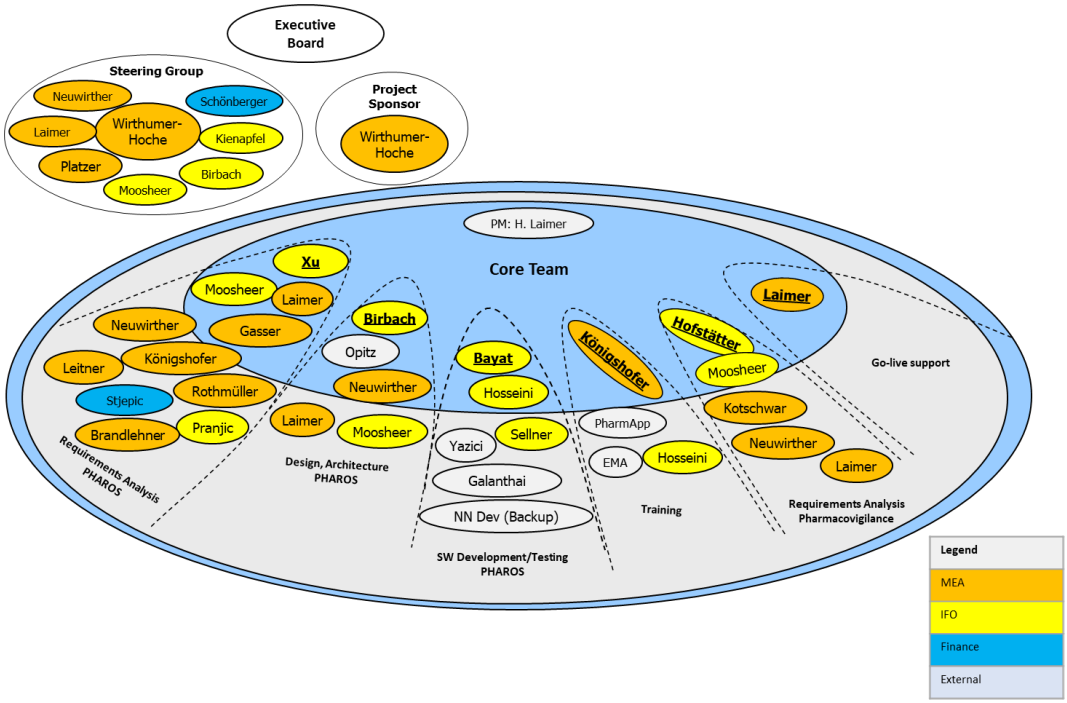

Figure 1. Project Organisation as of December 2020

4.2 Preliminary Milestones

#	Description of the milestone	Due to
M2.2	Decision whether in-house developed tool or Sporify should be used for RMS/SMS mapping	Feb 28, 2021
M2.3	PHAROS conceptual data model created	Mar 30, 2021
M2.4	Data cleansing RMS started	Apr 1, 2021
M2.5	Data cleansing SMS started	Apr 1, 2021
M2.6	PHAROS logical data model adapted and matched with IDMP SPOR fields	Apr 30, 2021
M2.7	Functional requirements of PHAROS/APEX extensions and big picture created	Apr 30, 2021
M2.8	Use cases and user stories created based on functional requirements and big picture	Aug 31, 2021
M2.9	Initial backlog prioritised and initial release plan created	Aug 31, 2021
M2.10	Data cleansing RMS finished	Sept 30, 2021
M2.11	1. sprint for PHAROS adaptions started based on the backlog	Oct 1, 2021
M2.12	Contribute in the definition of common rules how to standardise data according to IDMP	Nov 31, 2021
M2.13	Go-live synchronisation with RMS (using RMS Mapper and/or Sporify)	Dec 31, 2021

M2.14	Go-Live synchronisation with SMS (using SMS Mapper and/or Sporify)	Mar 31, 2022
M2.15	Data cleansing OMS started	Apr 1, 2022
M2.16	Adaption of the logical data model according to version 3 of the EU IG finished	Sept 28, 2022
M2.17	Data cleansing PMS started	Dec 1, 2022
M2.18	Data cleansing OMS finished	Apr 1, 2023
M2.19	Data cleansing SMS finished	Jul 31, 2023
M2.20	Last sprint for PHAROS adaptions based on backlog finished	Nov 31, 2023
M2.21	Prototype for ASP-List for eMedication in FHIR created	Nov 31, 2023
M2.22	Adaptions eAF import done	Dec 31, 2023
M2.23	Data cleansing PMS finished	Dec 31, 2023
M2.24	Project closure	Mar 31, 2024

Table 4. Preliminary Milestones

4.3 Risks

#	Description of risk	Proposed risk-mitigation measures	Risk by Dec 2020 (L/M/H acc. GA)
1	Low availability of IDMP and NCA/EMA experts.	Intensive collaboration with consortium partners and, if needed, with external experts to clarify relevant topics.	H
2	Data migration towards IDMP delayed or scope must be reduced.	Adapt the scope of IDMP data migration to a minimum which is defined by the needs of the data consumers.	M
3	Due to national prioritisations and internal dependencies implementation of national tasks slows down or benefits from more financial resources.	Contribution monitoring of progress and consumption at NCA level. Possible reallocation of funding between tasks (NCA's) to mitigate risk and enhance progress where possible.	H
4	The high number of beneficiaries increases cross-WP communication efforts and alignment needs between the partners.	Shift resources from technical tasks to WP coordination. Optimise links and cross-fertilisation between WPs.	M
5	ISO IDMP identifiers needed for the univocal identification of medicinal products that depend on EMA publication and maintenance are not available.	Find replacement for these identifiers through direct collaboration with Drug NCAs of countries involved; substitute with MP data of repository piloted in WP9.	H
6	Different work packages are not aligned or progress at different paces thus affecting the outcome of WP4.	Increase alignment efforts between work packages. Regular - monthly - review meetings of timetable and progress.	M
7	Low availability of IT-Resources at NCA.	Acquire external resources, prioritize the project over other measures in the implementation period.	H
8	Low availability of subject matter experts at NCA due to the daily business.	Prioritization of tasks, broaden knowledge within the core team / key users	H
9	The complexity of the task was underestimated.	Apply agile approach to implementation, present interim results early and obtain feedback on an ongoing basis, willingness to reduce complexity through alternative solutions and/or appropriate prioritization in the backlog	M
10	Short-term changes in the scope of the project.	Trade off requirements, bring in additional resources	M
11	Important decisions are not made by the EU (SPOR API, EU IG v2...) or influence the project negatively.	Bringing this aspect to European working groups and boards.	H
12	Covid-19 measures, subject matter expert illness, lockdown.	Promote home office. Spread expertise, involve multiple developers	H

Table 5. Risks

5 Status of evaluation tasks

5.1 Interoperability between PHAROS and EMA's SPOR

5.1.1 Experience with EMA's SPOR PMS

- We are currently testing the SPOR API v2 for PMS
  - There is a test system for SPOR available for all NCAs with self registration:
    - https://spor-uat.portal.azure-api.net/signin
    - The test system url changed from https://spor-uat.ema.europa.eu/v1/ to https://spor-uat.azure-api.net/pms/api/v2/
  - Documentation provided:
    - FHIR: http://build.fhir.org/
      - The current FHIR version used is R5 preview 2 and an upgrade to preview 3 is on the way
    - PMS: EMA VMP-Reg knowledge base: https://knowledgebase.ema.europa.eu/confluence/display/VL/UPD+Production+Release+Notes+for+1.0.0+September+2020
      - This documentation is helpful but is lacking examples for complex scenarios:

- Lessons learnt from SPOR API v2 (PMS)
  - There are many possibilities how the FHIR API can be interpreted e.g.
    - A "reference" can be a value or a link to another resource
      - e.g., document reference can be a link to a document or a document number
    - A codable concept can be any list and guidance needs to be clear which one it is
      - Behind the codable concept "pharmaceutical dose form" can be any of 4 catalogues
  - Creation of a product is asynchronous and the status of the creation has to be checked for errors
  - SPOR API v2 does not provide validation feedback at the moment. According to EMA this should be introduced into the next upgrade of the upgrade for the veterinary domain. We assume that this extension can also be used for the human domain.
  - Creating a valid API resource bundle for medicinal product is challenging.
  - Downloads can be done incrementally by date of last change:
    - $date = Get-Date - date $(get-date).AddDays(-10) - Format s
    - $url = https://spor-uat.azure-api.net/pms/api/v2/locations?pagesize=200&page=200&sortby=org-name&loc-modified-after=$date&summary=false
  - There is a more performant "download all" option (currently in OMS/RMS) using pagesize=0
    - https://spor-uat.azure-api.net/pms/api/v2/locations?pagesize=0

5.1.2 Experience with EMA's SPOR RMS

- We are currently testing the SPOR v1 for RMS.
- RDM Terminology data structures keep entries for different languages, versions and status of terms
  - PHAROS is already based on a catalogue service.
  - We want to synchronise from SPOR to PHAROS automatically, and if necessary, manually in the other direction.
- Approach
  - "One off" mappings using mapping tools
    - The tool "Sporify" is in evaluation
  - "Continuous" maintenance process using a self-made RMS sync tool or also the tool "Sporify".
    Major challenges in this synchronisation process:
    - Term in local language has changed
    - Term in a different language has changed
    - A completely irrelevant change has triggered a new version
    - The term status was changed (e.g. non-current)
    - In special cases national terms might have priority
- Documentation provided:
  - RMS: https://spor.ema.europa.eu/rmswi/#/viewDocuments

5.1.3 Experience with EMA's SPOR SMS

- Currently the SPOR API for SMS contains very little data for test purposes. Until SMS is further developed EUTCT is being used.
- PHAROS currently uses a purist master data record of all substances containing:
  - Substance name & synonyms
  - EUTCT Id
  - Links to substance documentation in relation to products
  - Links to manufacturers in relation to products
  - National specifics (e.g. doping relevant)
- Approach (similar to RMS):
  - "One off" mappings using mapping tools
    - The tool "Sporify" is in evaluation
    - Substances not known by SMS will be re-evaluated and if need be submitted to SMS
    - The SMS term id will be stored in PHAROS to enable the maintenance process
  - "Continuous" maintenance process using a self-made RMS sync tool or also the tool "Sporify".

5.1.4 Experience with EMA's SPOR OMS

- We are currently testing the SPOR API v1 for OMS but we are not planning to use this API as for RMS and SMS.
- Approach:
  - Organisations from OMS that are submitted via the eAF during regulatory activities are matched against the locally stored Organisations in PHAROS.
  - If the OMS information is not in PHAROS, the relevant OMS identifiers are automatically added to the organisation record in PHAROS.

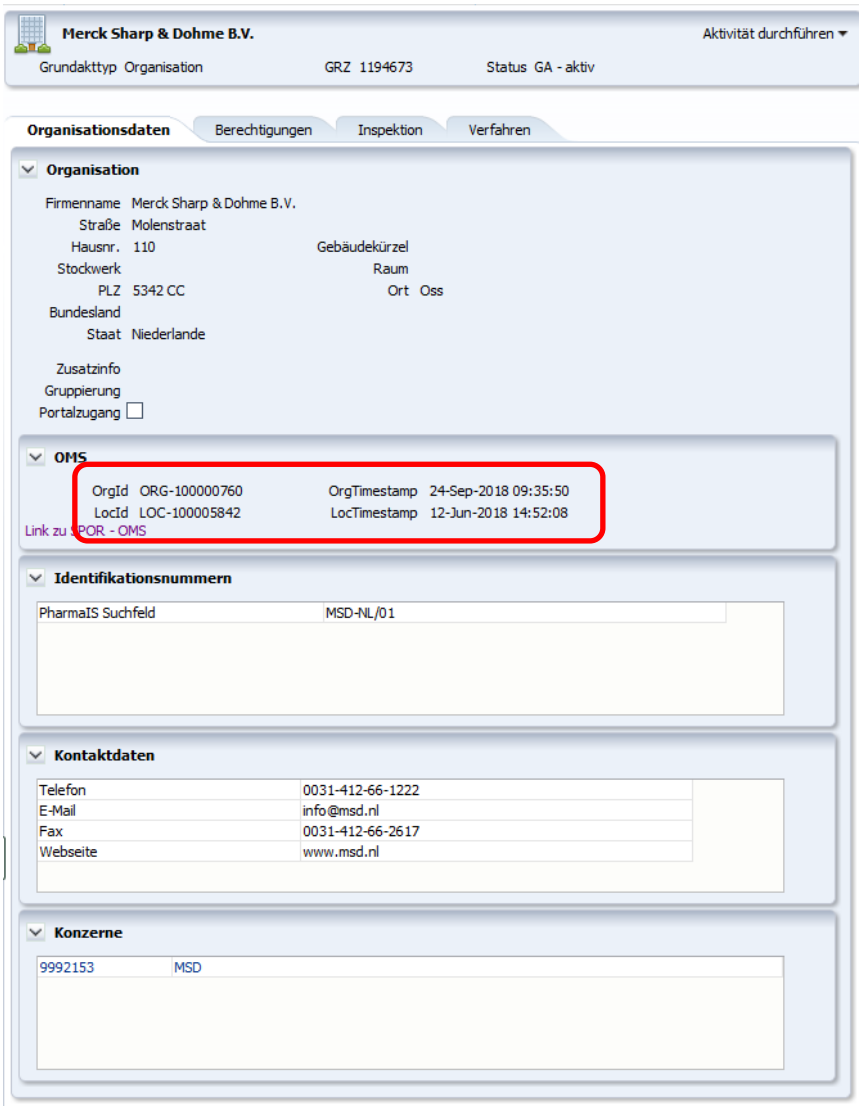

Figure 2. Organisations in PHAROS including SPOR OMS identifiers

5.2 Transition Strategy

5.2.1 Database Model

- The current PHAROS database model was built on RDM model published by EMA. This model anticipated some of the ISO IDMP concepts (e.g. multilingual terminology, manufactured item, ingredients, organisation roles, etc...)
- Approach:
  - The database transition will focus on elements which are described in the EU IG v2 and data elements included in the eAF.
    - Notice: EMA announced plans to publish an EU IG v3. Further investigation is necessary to analyse impacts on the database model transition.
  - Identify all attributes to be exchanged by examining the EU-IGv2/3
    - Gaps of information in PHAROS
    - Transformation needed in PHAROS
    - Data standardization/enrichment needed in PHAROS
  - Mapping the identified attributes between their FHIR location and the PHAROS name
  - Use the gained information to decide
    - What part of the local database is changed?
    - When is a transformation to a message more efficient?
  - Implement the changes
    - We are planning
      - to extend and restructure the PHAROS database and
      - for special purposes we plan to transform and provide data using web services.
  - Extend catalogue terms:
    - Extension of RMS list units of presentation for the pharmaceutical product, e.g mL for solutions

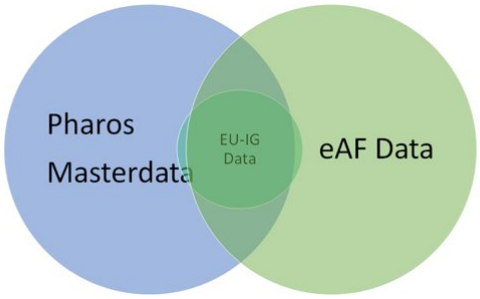

Figure 3. Data overview

5.2.2 User Interface

Displaying medicinal product data in an ISO IDMP/HL7/EU IG compatible style will have major impacts on the existing PHAROS UI. Outcome of the relevant analysis can be grouped into the following refactoring topics:

- Name representation (e.g. Splitting into parts)

- Packages representation (e.g. Reordering Container & Package information)
- Composition representation (e.g. Split of Manufactured item & Pharmaceutical item)
  - Concentration strength
  - Reference strength
- Ingredient representation (e.g. multiple usage)
- Displaying SPOR identifiers

5.2.3 Examples of relevant adaptions in the topic group „Composition“

Example AT/H/0154/003_ Immunate 1000 IU FVIII/750 IU VWF powder and solvent for solution for injection

Current Solution

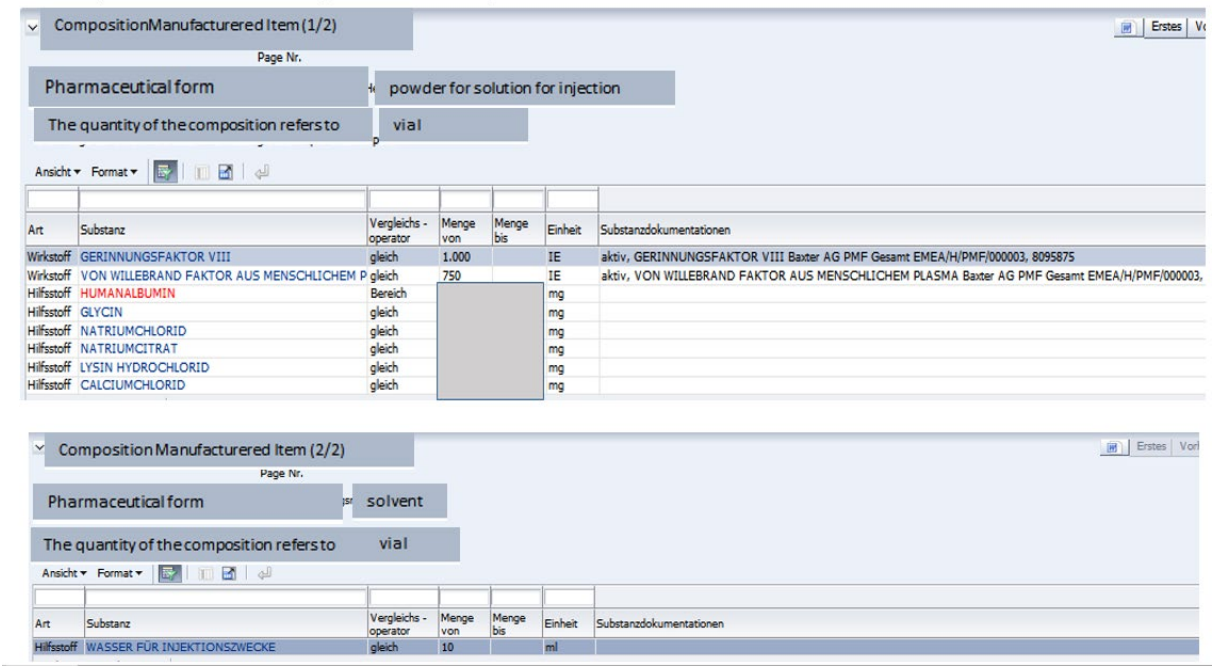

Figure 4. Composition as today, one table per manufactured item

Proposed Solution

¶
Immunate· 1000¶U· FVIII/750¶U· VWF· contains· approximately· 100¶U/ml· of· human· coagulation·factor·VIII·and·75¶U/ml·human·von·Willebrand·factor·after·reconstitution.¶
¶

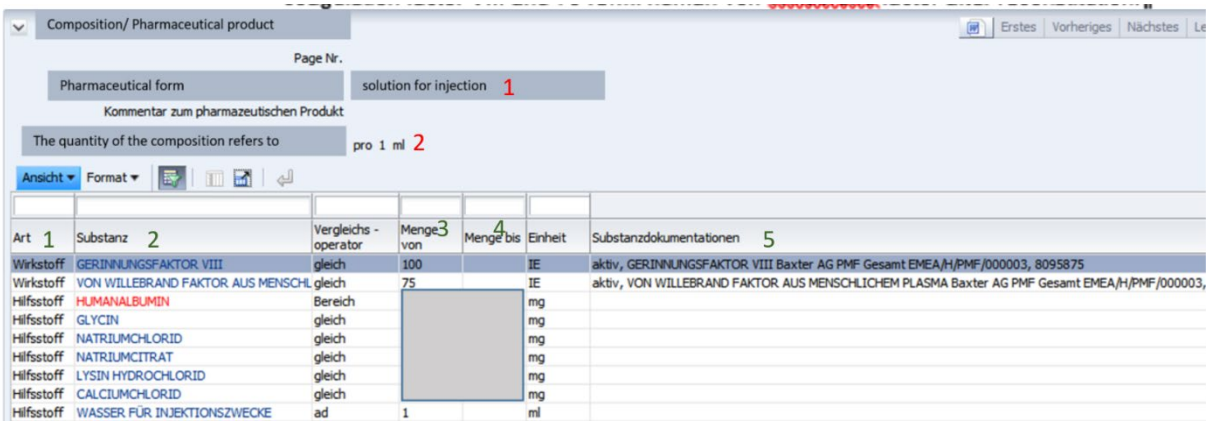

Figure 5. Proposal for pharmaceutical product

Mapping to FHIR ressources

- FHIR resource: AdministrableProductDefinition / ManufacturedItemDefinition
    1. AdministrableProductDefinition/ManufacturedItemDefinition.unitOfPresentation
    2. AdministrableProductDefinition.administrableDoseForm / ManufacturedItemDefinition.manufacturedDoseForm
    3. AdministrableProductDefinition/ManufacturedItemDefinition.ingredient

1. Ingredient.role
2. Ingredient.substance
3. Ingredient.substance.strength.presentation
4. Ingredient.substance.strength.presentationHighLimit (in case of range)
5. Ingredient.manufacturer

5.2.4 Examples of relevant adaptions in the topic group „Packages”

Example: Seroquel 25 mg Filmtabletten, NL/H/0156/001

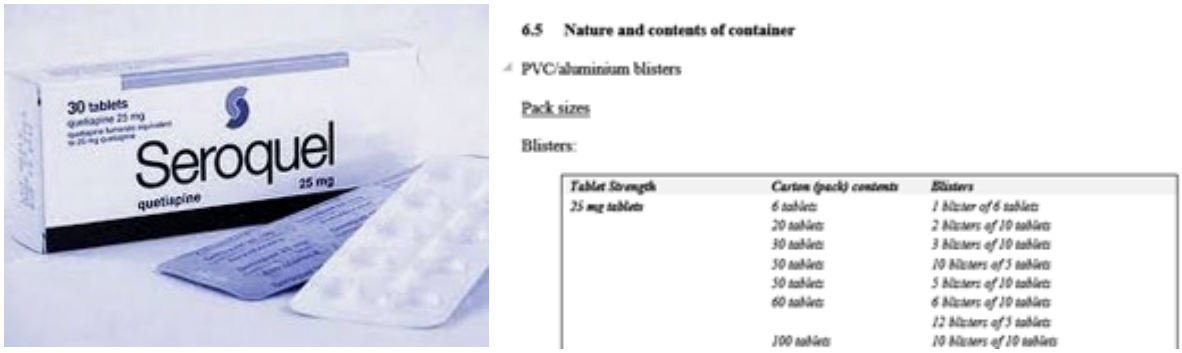

Figure 6. FHIR PackagedProductDefinition

Current Solution

Packungsgröße	Einheit (Packungsgröß	Container	Beschreibung	Pharmazentraln	Dosier- und Verabreichung	F
6	Stück	Blisterpackung	6 Stück (1 Blister mit 6 Filmtabletten)	1300313		
20	Stück	Blisterpackung	20 Stück (2 Blister mit 10 Filmtabletten)			
30	Stück	Blisterpackung	30 Stück (3 Blister mit 10 Filmtabletten)			
50	Stück	Blisterpackung	50 Stück (10 Blister mit 5 Filmtabletten)			
50	Stück	Blisterpackung	50 Stück (5 Blister mit 10 Filmtabletten)			
60	Stück	Blisterpackung	60 Stück (6 Blister zu 10 Filmtabletten)	2427435		
100	Stück	Blisterpackung	100 Stück (10 Blister mit 10 Filmtabletten)			

Figure 7. Packages (today)

Proposed Solution

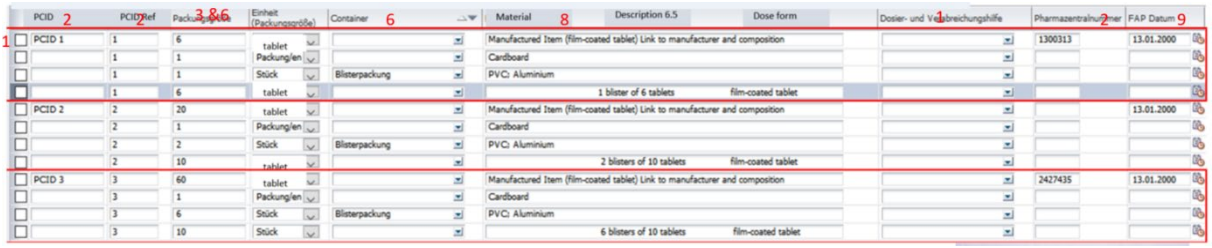

Figure 8. Packages (proposed solution)

Mapping to FHIR ressources

- PackagedProductDefinition
  1. PackagedProductDefinition.package.containedItem.item (Package or Manufactured item, or Device)
  2. PackagedProductDefinition.identifier (PCID and PCN)
  3. PackagedProductDefinition.type
  4. PackagedProductDefinition.package.quantity (total amount)
  5. PackagedProductDefinition.package.containedItem.amount (package size)
  6. PackagedProductDefinition.package.type
  7. PackagedProductDefinition.package.material
  8. PackagedProductDefinition.description (or name to be confirmed)
  9. PackagedProductDefinition.statusDate
  10. PackagedProductDefinition.legalStatusOfSupply
  11. PackagedProductDefinition.package.shelfLifeStorage

5.3 Data Content

- The PHAROS database already stores all relevant data elements of medicinal products.
- As an outcome of the data content evaluation it was identified that nearly all ISO IDMP/EU IG elements are already contained in the PHAROS data landscape apart from elements of clinical particulars.

Approach:

- Once clinical particulars (e.g. indications) will be available in a structured way (e.g. via a dataset) we will further evaluate if we will extend the data content in PHAROS.
- EMA is planning to introduce a central repository for medicinal products (SPOR PMS). This will support potential opportunities in sharing data:
  - e.g. automatic downloads of centralized product information
  - e.g. automatic downloads of reference products
- At the time of creation of this report no stable implementation plan about SPOR PMS was published. When available a further planning how to utilize this opportunity will be done.

5.4 Contribution to the definition of common rules how to standardise data according to IDMP

- Reviewing and commenting EMA's EU Implementation Guide in July 2020
- First best practise workshop together with WP 4 partners
- AGES attended WP 1 sessions about IDMP standards
- Reviewing of Estonia's and Finland's "Progress report on implementation"
- Attending informal meetings on the SPOR API with EMA

6 Prototype of an IDMP compatible data feed

According to our milestone plan work on this topic will start 2023. Initial discussions with our implementation partner, ELGA GmbH, have already taken place.