Up-scaling the global univocal identification of medicines

AGES Best Practices
UNICOM WP4

Speakers: Georg Neuwirther (AGES), Noel Diamant (AGES)
Business Expert: Sonja Königshofer (AGES)

and many other experts from our agency who contributed to this success!

This project has received funding from the European Union's
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Disclaimer

The information provided represents the knowledge and status at the time of its preparation. It does not necessarily represent the view of the regulatory authority to which the presenter belongs. Do not use this information for decision making, but instead always refer to official documents, relevant regulations, regulatory guidelines and SPOR guidance material

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Agenda

- ***Georg Neuwirther***
  UNICOM WP3 Lead, Austrian Medicines and Medical Devices Agency
- ***Noel Diamant***
  Network Product Owner PLM Portal (eAF), Austrian Medicines and Medical Devices Agency

1. **Welcome**
   - *Georg Neuwirther*
2. **PHAROS - Implementation of ISO-IDMP Concepts**
   - *Georg Neuwirther*
3. **PHAROS - Importing eAF data based on the new FHIR format (Variation of CPs)**
   - *Noel Diamant*
4. **SPOR integration**
   - **OMS**
   - **RMS**
   - **SMS**
   - *Georg Neuwirther, Noel Diamant*
5. **Exporting Medicinal Product Data in FHIR 5.0 format – Outlook**
   - *Noel Diamant*
6. **Take Home Message**
   - *Georg Neuwirther*

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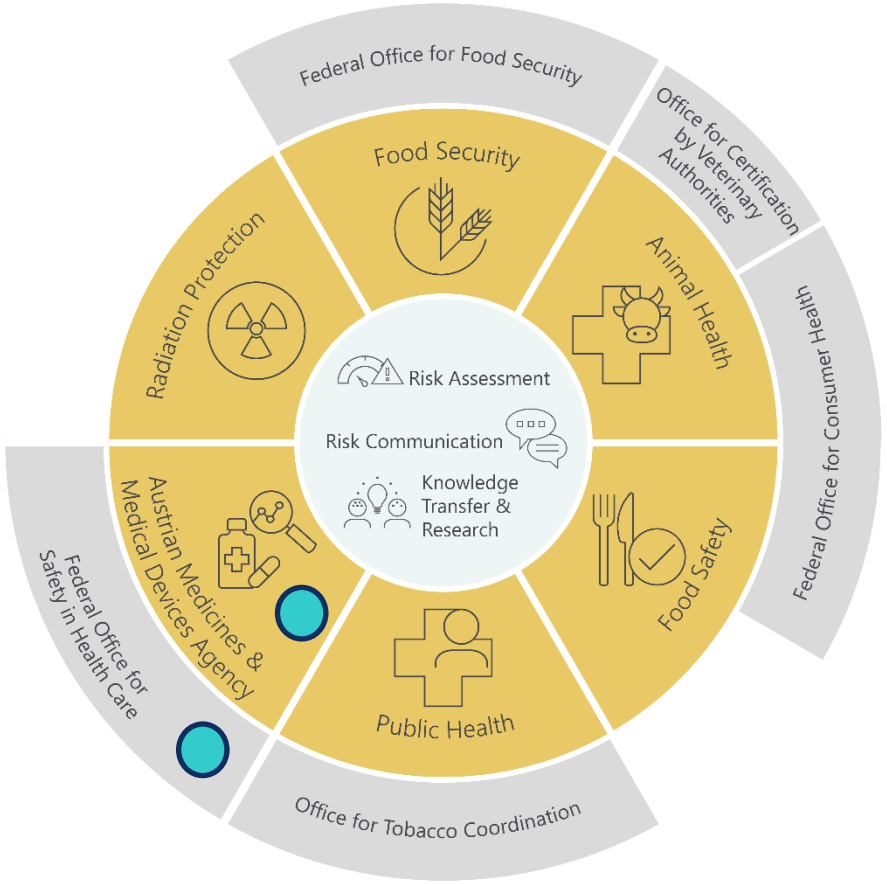
Austrian Medicines and Medical Devices Agency (AGES MEA)

- **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.
- 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**)



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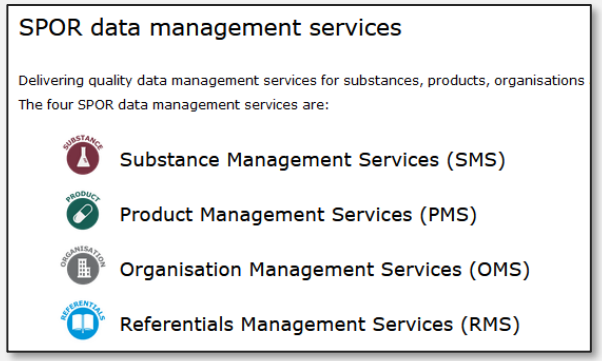
UNICOM deliverables covered in the presentation



eAF import based on FHIR XML

Mapping eAF-DES to FHIR

Implementation based on EU IDMP Guidelines

PHAROS

ORGANISATIONSOPTIMIERUNGS- UND IT-PROJEKT DER AGES Medizinmarktaufsicht

Refactoring, Extending
the national core IT-System **PHAROS**

- User-Interface
- Business Logic
- Database Model

Updating SOPs, training material

Extending exising data exports for usage in eHealth use case to support **cross-border-prescription** according to eHDSI

Prototyping an **FHIR 5.0** compliant data export

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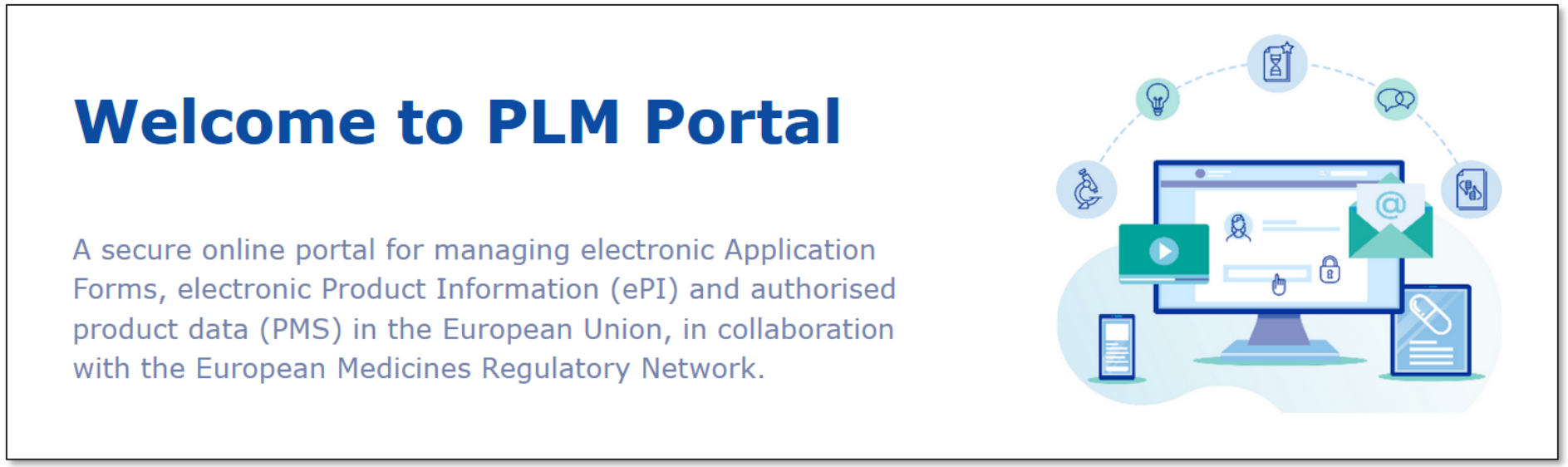
AGES contribution in European initiatives



AGES (Noel Diamant) is acting as **Network Product Owner**
for the implementation of the new eAF-creation tool and message exchange format
→ see UNICOM WP3

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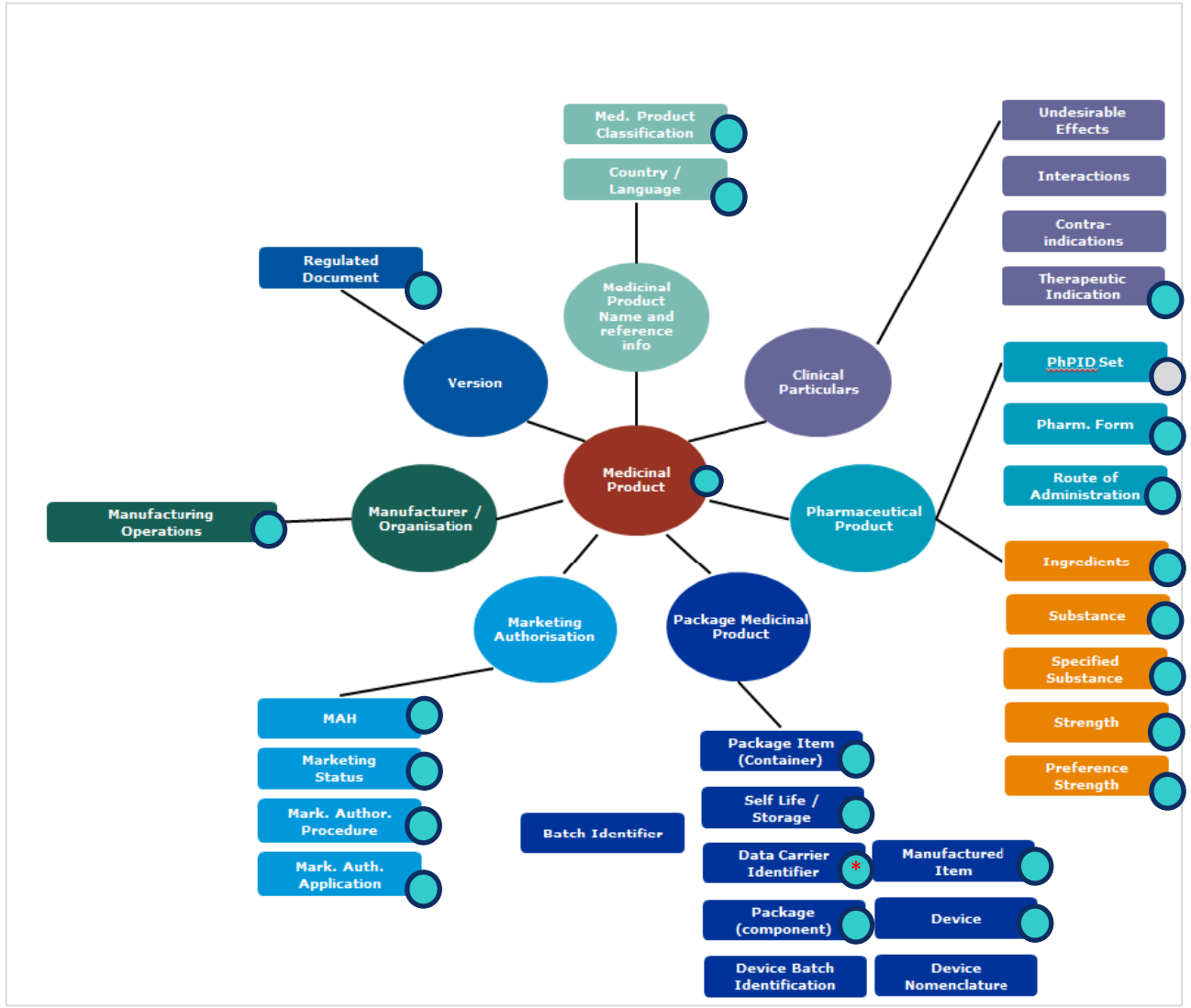
PHAROS - Implementation of ISO-IDMP concepts

Georg Neuwirther

Status of implementation in PHAROS



Source: EMA – Introduction to ISO Identification of MedicinalProducts, SPOR programme

Reviewed/Implemented/Refactored/ within UNICOM project timeframe

Pending due to missing EU IG

Reviewed/Implemented/Refactored/ within UNICOM project timeframe considering national specifics

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Key Changes in PHAROS

- **Implementing *Administrable Product* (Pharmaceutical Product)**
  - Based on existing concepts of the former database concept “RDM v3”
- **Detailing *Package* structure**
- **Implementing *Indication* Elements**
- **Detailing *Manufacturer* Details**
- **Implementing *Part Names***
- **Implementing *Additional Monitoring Attribute***
  - Additional attribute can be stored according to 1.8. Additional monitoring indicator from EU IG chapter 2
- **Migration legacy data into IDMP-compliant database model**

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Implementing Administrable Product (AP)
(Pharmaceutical Product - PhP)

- AP-concept had to be added to the PHAROS-world
  - Before: the Manufactured Item (MI) was the leading class

- Following principles were applied while refactoring:
  - Find synergies with business rules for legacy data migration
  - Ensure compatibility for eAF data import
  - Usage of RMS dictionaries is mandatory
  - Minimise administrative effort for data lifecycle management
  - Find a good balance in enriching the user interface
    - ✓ (complexity vs. usability)

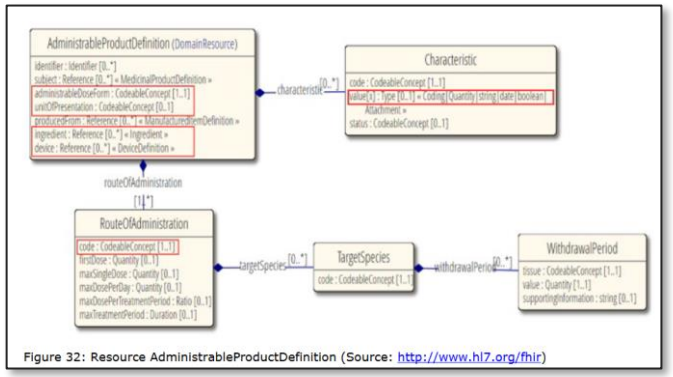

Figure 32: Resource AdministrableProductDefinition (Source: http://www.hl7.org/fhir)

Source: EAM EU IG ch.2

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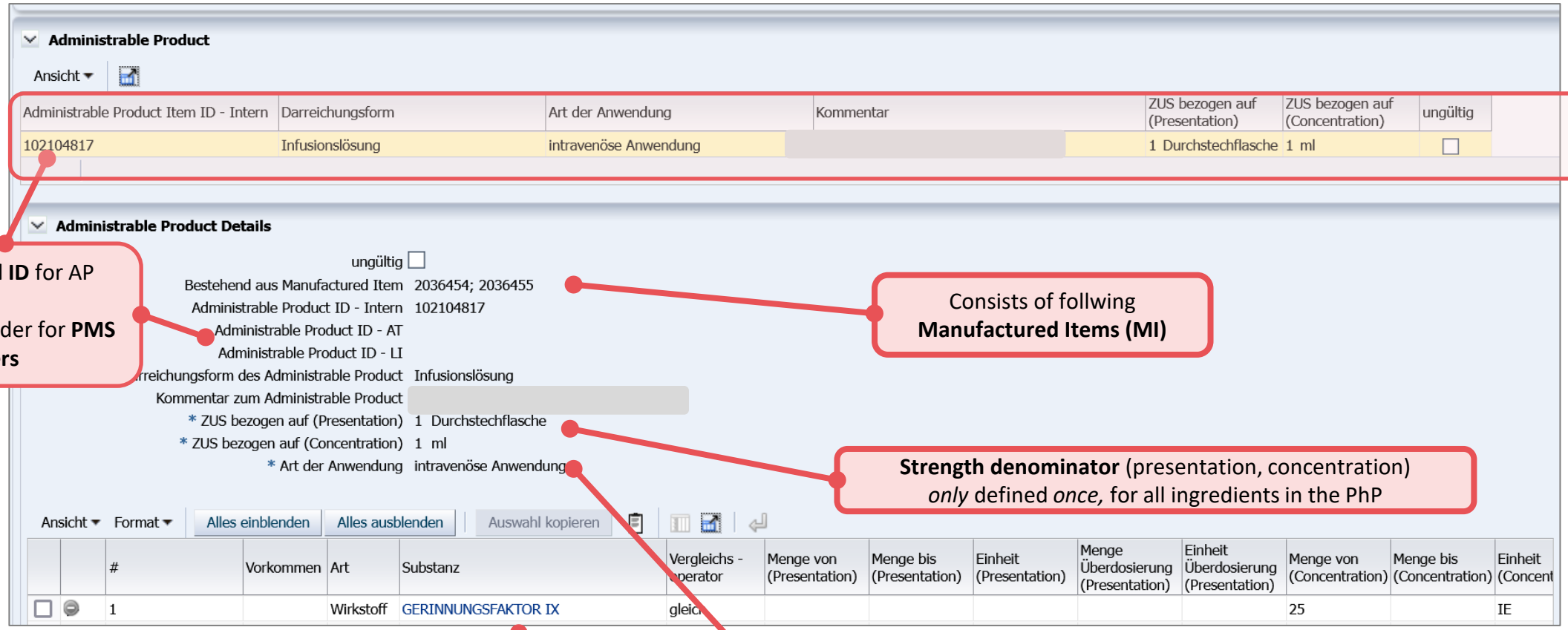
Implementation of Administrable Product (AP)



- **National ID** for AP
- Placeholder for **PMS identifiers**

Consists of follwing **Manufactured Items (MI)**

Strength denominator (presentation, concentration) *only* defined *once,* for all ingredients in the PhP

List of **ingredients** of the AP

Route of Administration of AP

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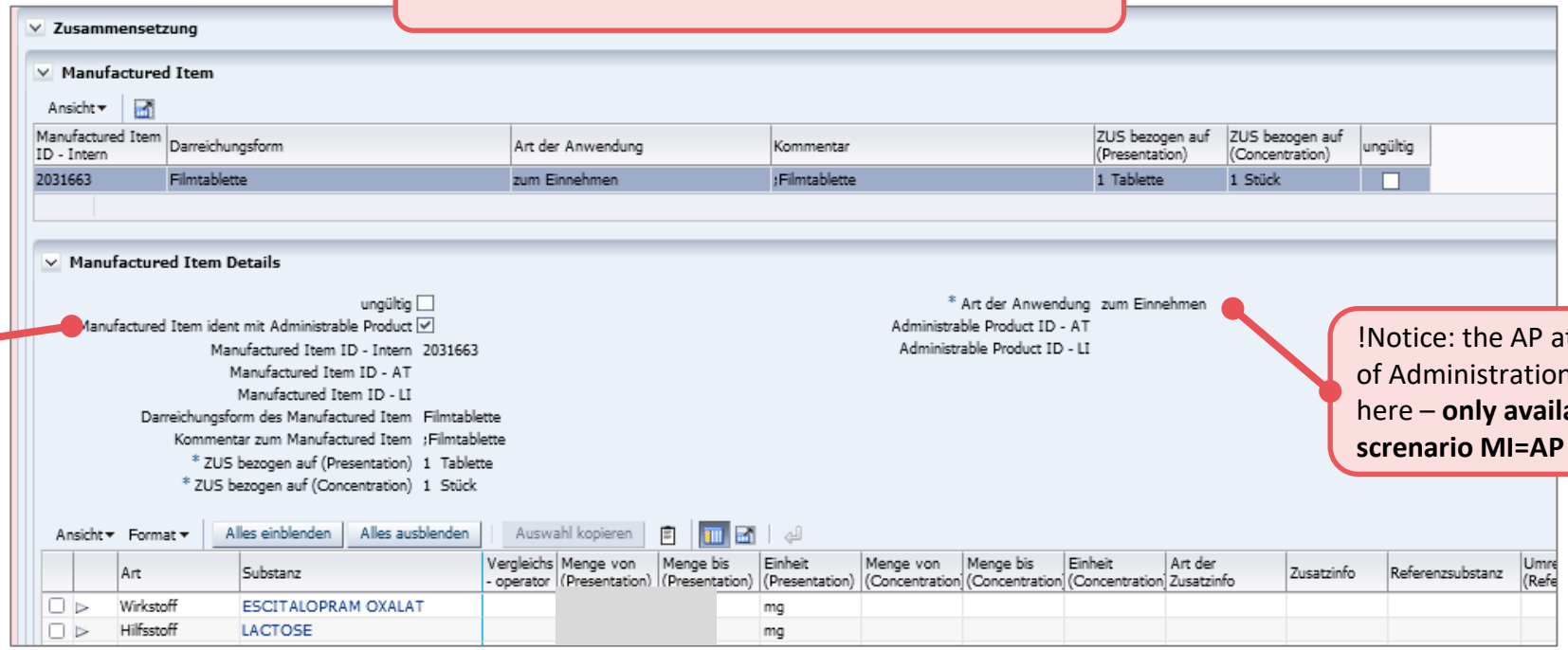
Implementation of Manufactured Item (MI)

This screenshot demonstrates the following scenario:
The Administrable Product is also the Manufactured Item
(applicable for all tablet presentations and any product without reconstitution)
Goal: minimizing administrative effort and error reduction

Concepts from AP were duplicated – see slide before

Flag to mark that MI = AP



!Notice: the AP attribute „Route of Administration“ can be entered here – **only available for the screnario MI=AP**

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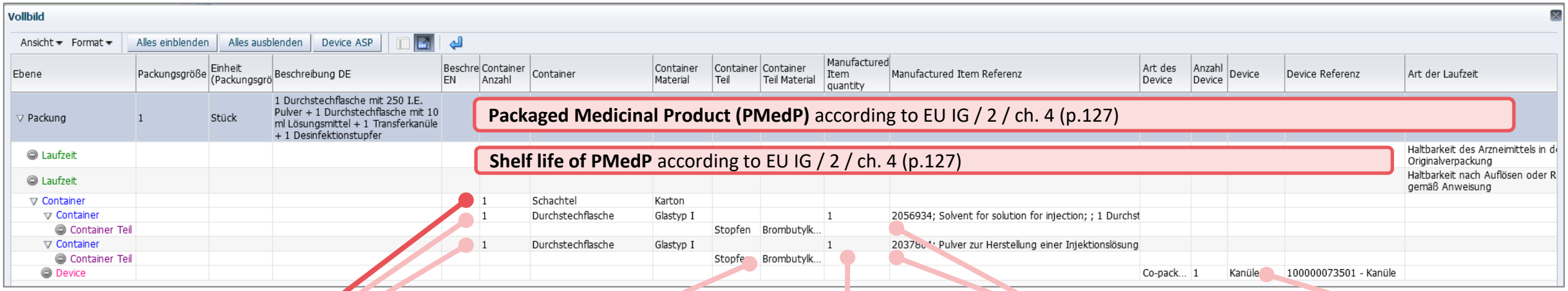
Implementation of Package



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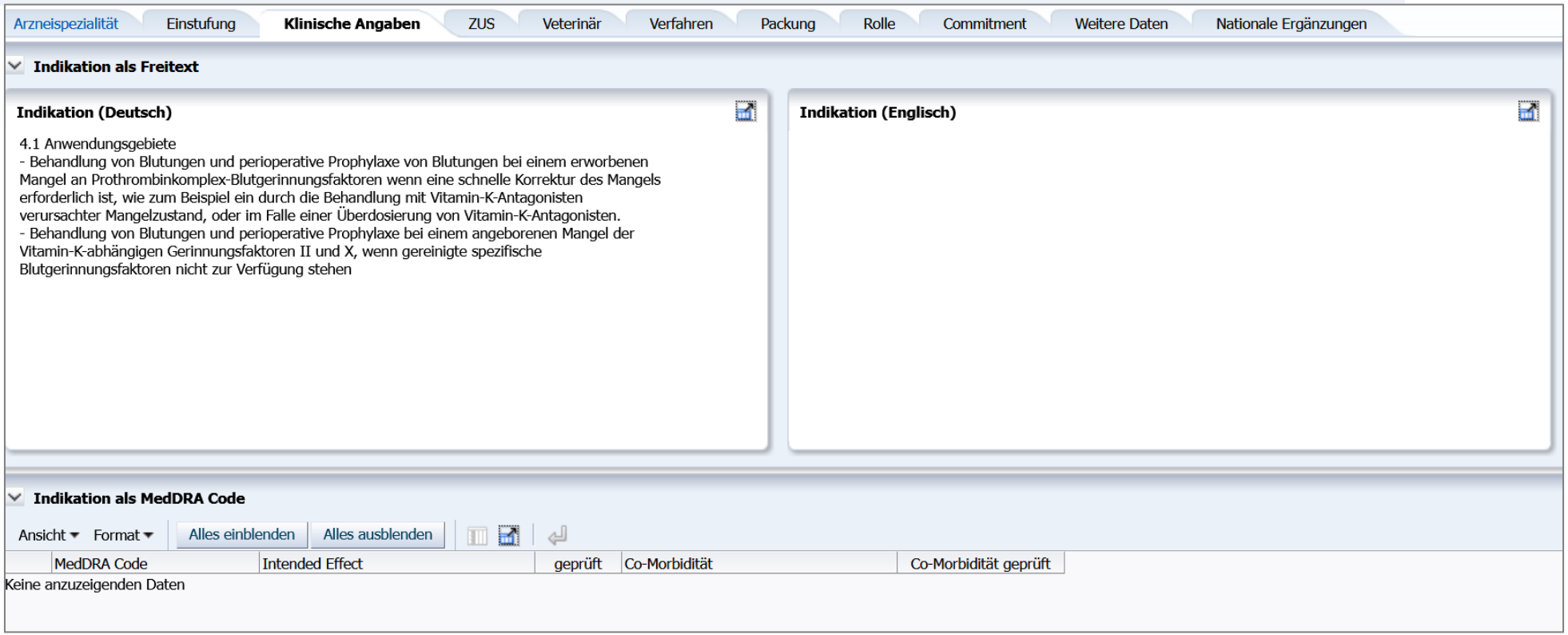
Implementing Indications



- Indication information is now **automatically** imported from SMPC (section 4.1)
- Coded indication elements are prepared for future consumption from SPOR PMS

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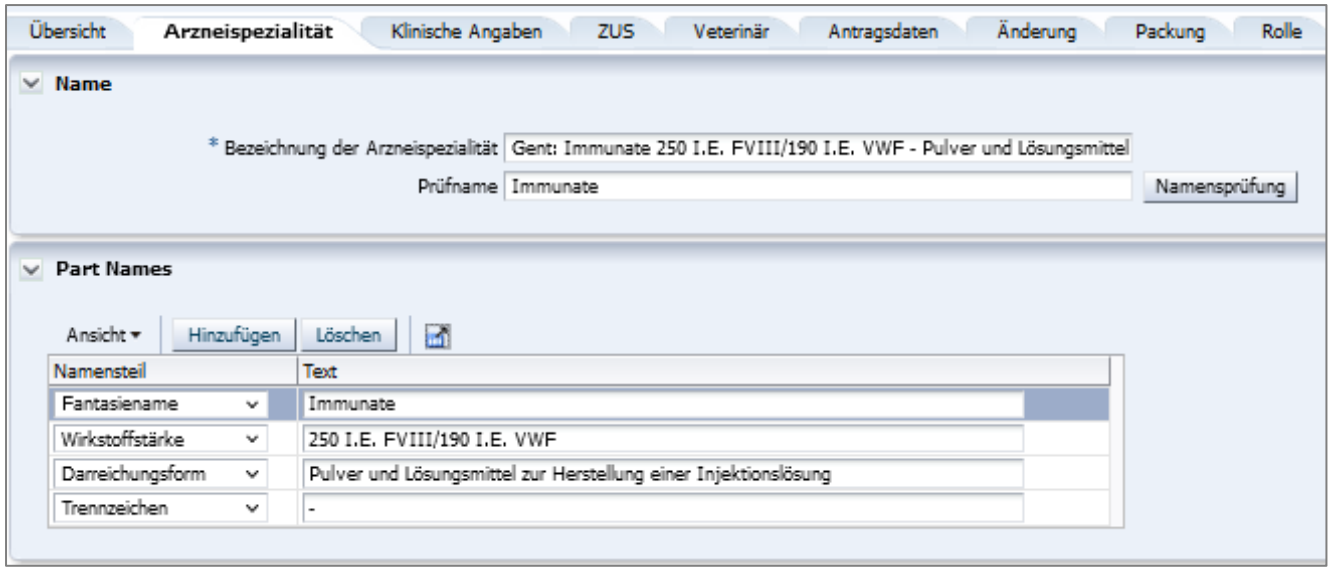
Implementing *Name Parts*



Katalogwert	Beispiel
Fantasiename	nicht INN
Wissenschaftlicher Name	INN
Marke/Firma	MAH Name
Formulierung	forte
Wirkstoffstärke	50 mg
Darreichungsform	Injektionslösung
Container/Verpackung	in einer Fertigspritze
Medizinprodukt	Handihaler
Zeit/Zeitraum	24h
Geschmack	Orangengeschmack
Zielgruppe	für Kinder
Zieltierart	für Hunde und Katzen
Verwendungszweck	zur Diagnose
Trennzeichen	-
Historischer Name	alter Name wie in Bezeichnung der ASP bei Namensänderung

- Part Names are now prepared for future data import from eAF (FHIR)

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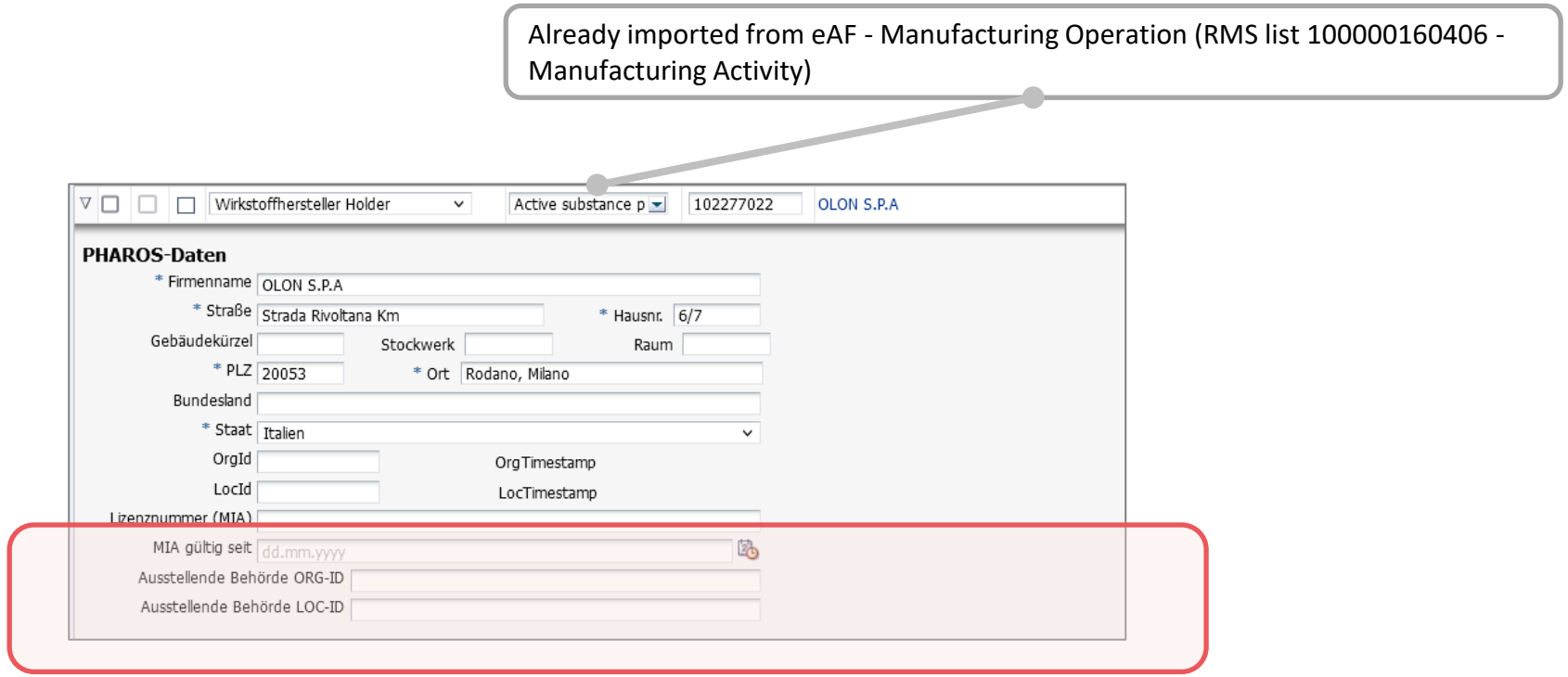
Detailing *Manufacturer* information



- **Prepared for future data import from the new eAF (FHIR)**

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Migration into IDMP-compliant database model

- Stepwise migration of legacy data – bottom-up
  - Started with MI enrichment
  - Created *APs composed of MIs*
  - Finalised with *Package* layers including links to *MIs*

- Manual preparing legacy data was needed for:
  - a limited number of “old” products
  - manufactured items to enrich “unit of presentation”
    - ✓ existing package information was helpful

- Packages could be brought into the layered structured **automatically**
  - Manual work was needed to correct “*manufactured item quantity*” information

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SPOR Integration - OMS

Georg Neuwirther

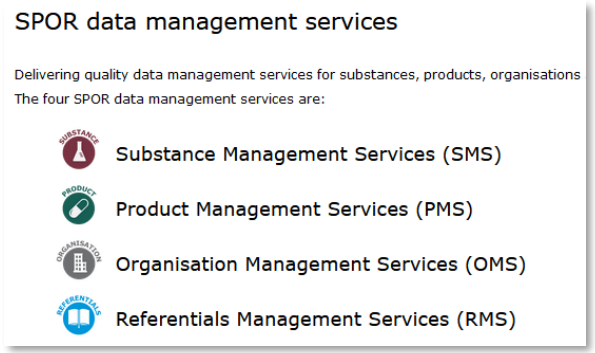
UNICOM

OMS integration - concept

1. Initial Import of Organisation and address data from eAF MAA, Variation, Renewals

PHAROS
ORGANISATIONSOPTIMIERUNGS- UND IT-PROJEKT DER AGES Medizinmarktaufsicht

2. Regular OMS syncs to keep PHAROS data aligned with SPOR OMS



- **New organisation records will be taken ONLY from e.g.,**
  - eAF, CTs , other applications, ..
- **For official letters PHAROS data is used – might deviate from OMS data (see challenges in next slides)**
- **All relevant organisation records in PHAROS are linked to an OMS-ID/LOC-ID reference**

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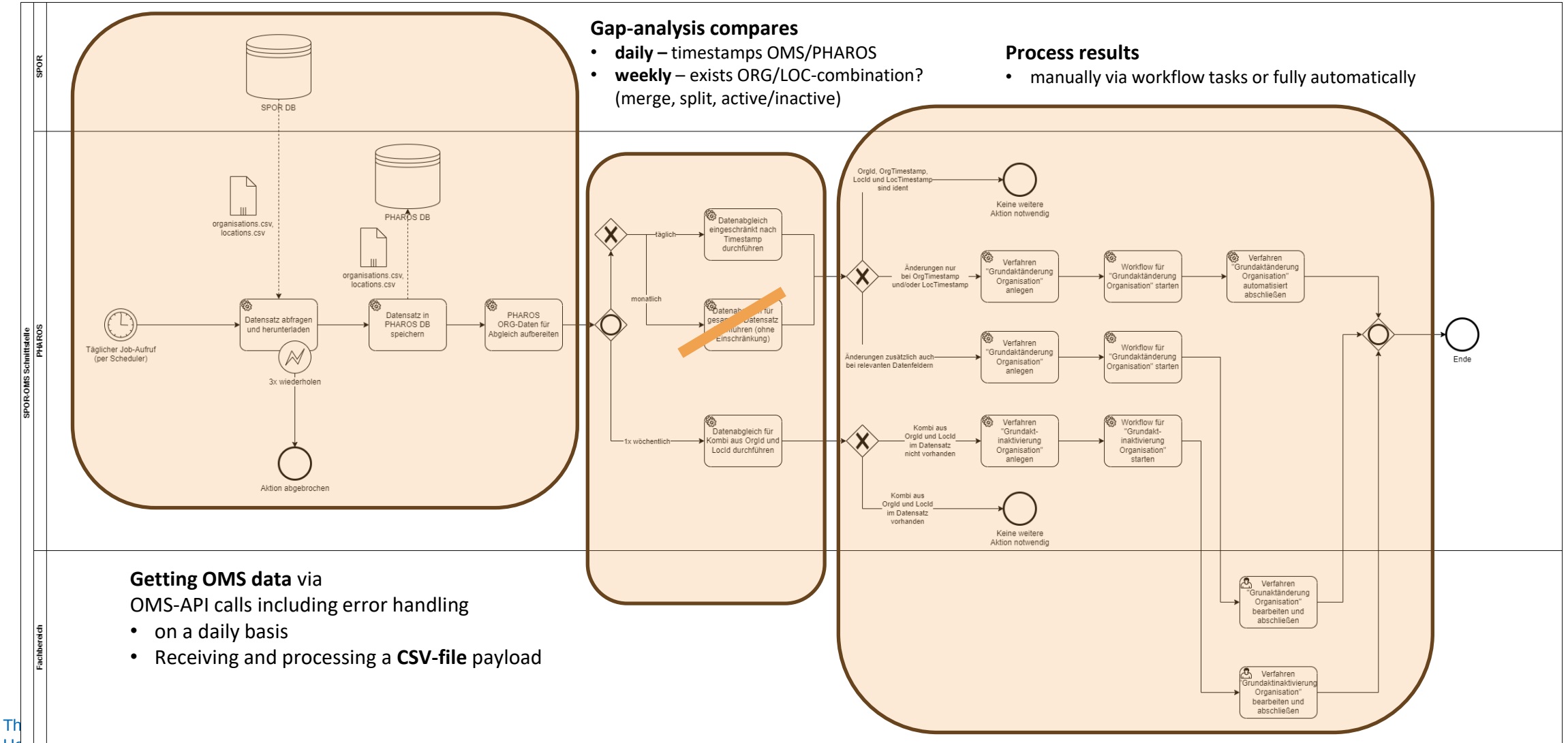
Synchronisation: OMS --> PHAROS



Gap-analysis compares

- **daily –** timestamps OMS/PHAROS
- **weekly** – exists ORG/LOC-combination? (merge, split, active/inactive)

Process results

- manually via workflow tasks or fully automatically

Getting OMS data via
OMS-API calls including error handling

- on a daily basis
- Receiving and processing a **CSV-file** payload

Th
Horizon 2020 research and innovation programme under grant agreement No 873299

Findings and challenges

- Processing the CSV payload is not optimal but more stable than separate OMS-calls
  - Open service ticket that CSV data is different from OMS UI data
- High administrative manual effort when handling OMS data quality topics
  - e.g. Active/inactive, lost IDs
  - e.g. rejected OMS requests for new entries or updates
- Umlauts in names and addresses [Ö/Ü/Ä -> OE/UE/AE]
  - ß in addresses [Straße; ß -> Strasse; ss]
- Semantics in address lines do not match PHAROS address structure
- “Districts” are included in address lines which creates manual effort to delete it again
  - Otherwise districts would be included in PHAROS street elements
- Differences between DE and EN names and addresses

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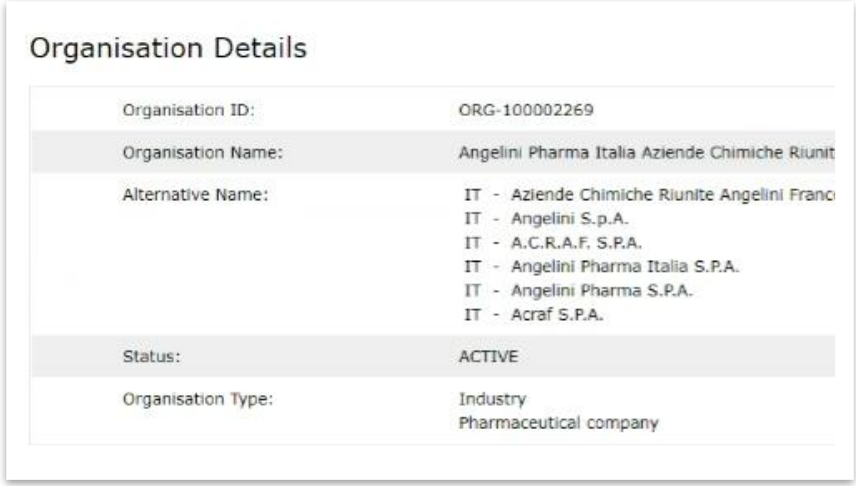
Findings and challenges

- Business logic to deal with names and alternative names
  - eAF story exists in PLM backlog



Organisation Details

Organisation ID:	ORG-100002269
Organisation Name:	Angelini Pharma Italia Aziende Chimiche Riunit
Alternative Name:	IT - Aziende Chimiche Riunite Angelini Franc IT - Angelini S.p.A. IT - A.C.R.A.F. S.P.A. IT - Angelini Pharma Italia S.P.A. IT - Angelini Pharma S.P.A. IT - Acraf S.P.A.
Status:	ACTIVE
Organisation Type:	Industry Pharmaceutical company

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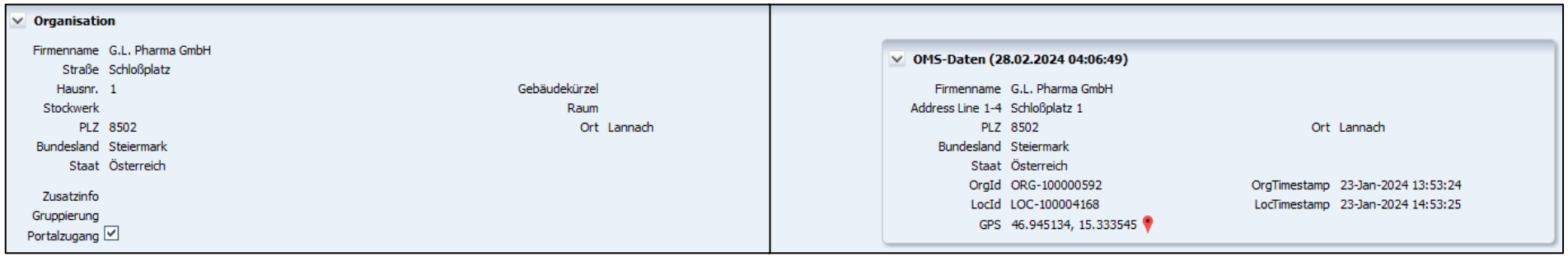
We now have OMS data in PHAROS ☺



- **OMS attributes**
- **LOC address lines**
- **GPS-coordinates**

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PHAROS - Importing eAF data based on the new FHIR format (Variation of CPs)

Noel Diamant

UNICOM

Motivation

Data availability in regulator systems (HMA/EMA) is essential for multiples use cases and of strategic importance

The eAF is a vessel to provide that data

Source: EMA - High-quality data to empowerdata-drivenmedicines regulation in the European Union | European Medicines Agency (europa.eu)

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eAF-import of Medicinal Products Data into PHAROS

Product Lifecycle Management Portal

Applicants

PDF-based forms including a PDF- DES: proprietary Data Exchange Format

Since 2015: DES-format

Initial Applications

Lifecycle Management

Regulators

EUROPEAN MEDICINES AGENCY
SPOR

eCTD
module 1 → eAF

FHIR

Regulatory IT-Systems

Since 2023: DES + FHIR format

WP 3

WP 4

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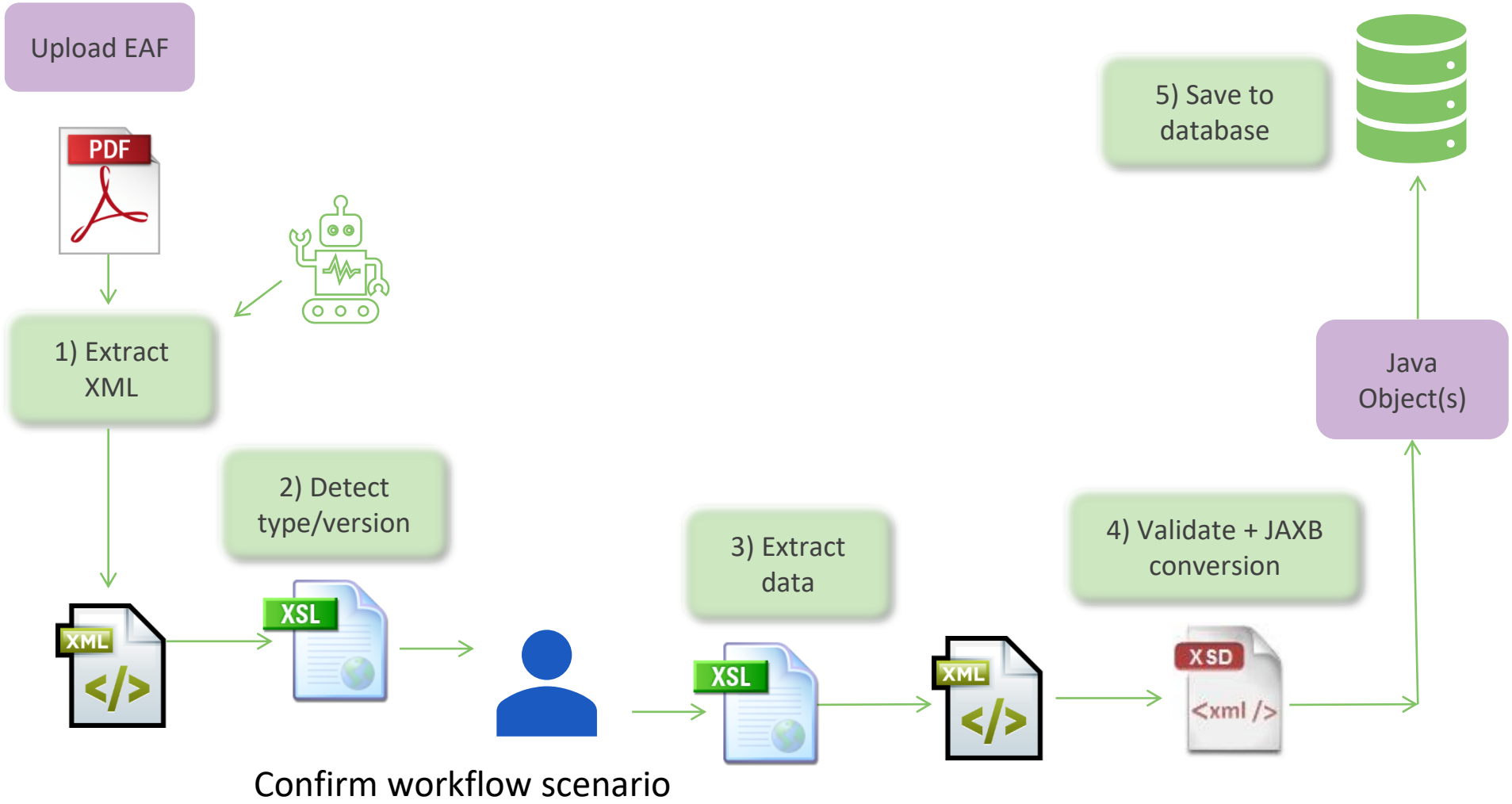
Technical Flow



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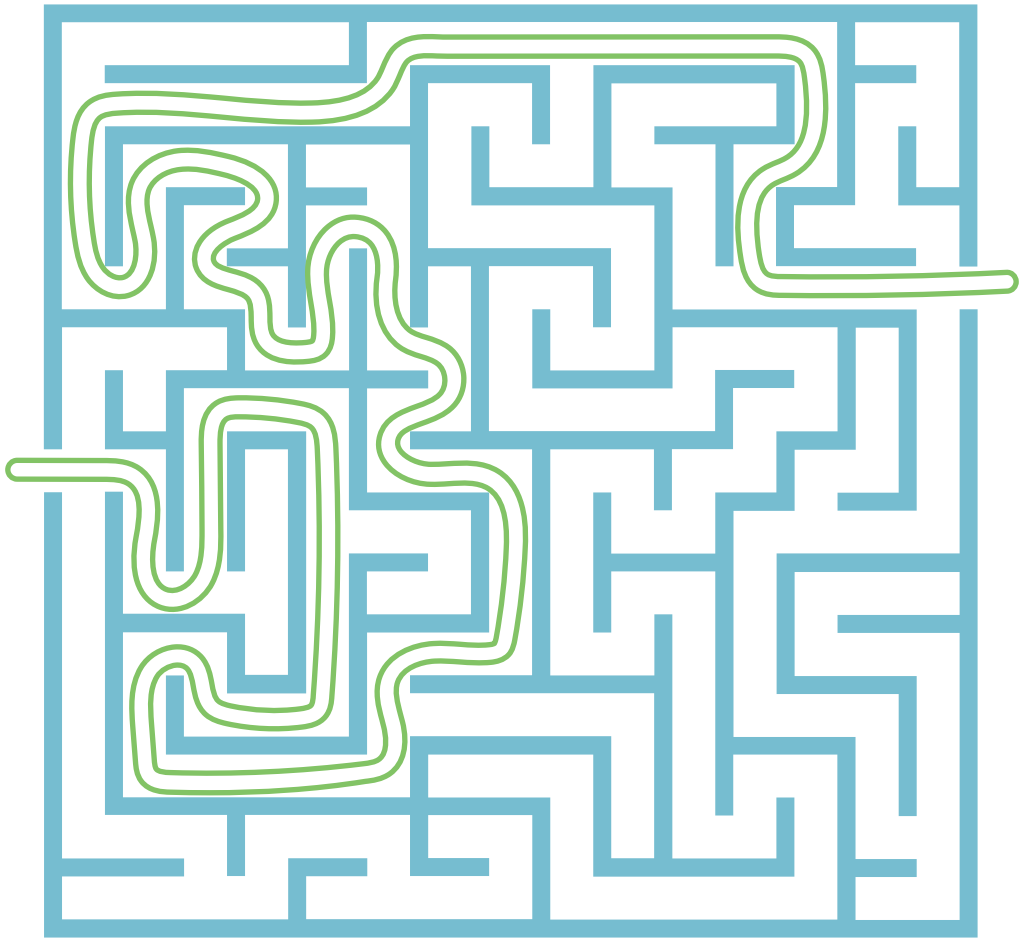
Links

FHIR 4.6

The FHIR variation message attached to the eAF has been developed in FHIR version 4.6.0 is being released in 5.0.0 in Q2 this year.

This is the best time to start thinking about an automated import to be ready for the MRP / DCP / national variations from the PLM portal.



FHIR 5.0

Latest release notes on the eAF FHIR XML:
Bookmark this Link!

In the release notes you will find extensive examples (here)

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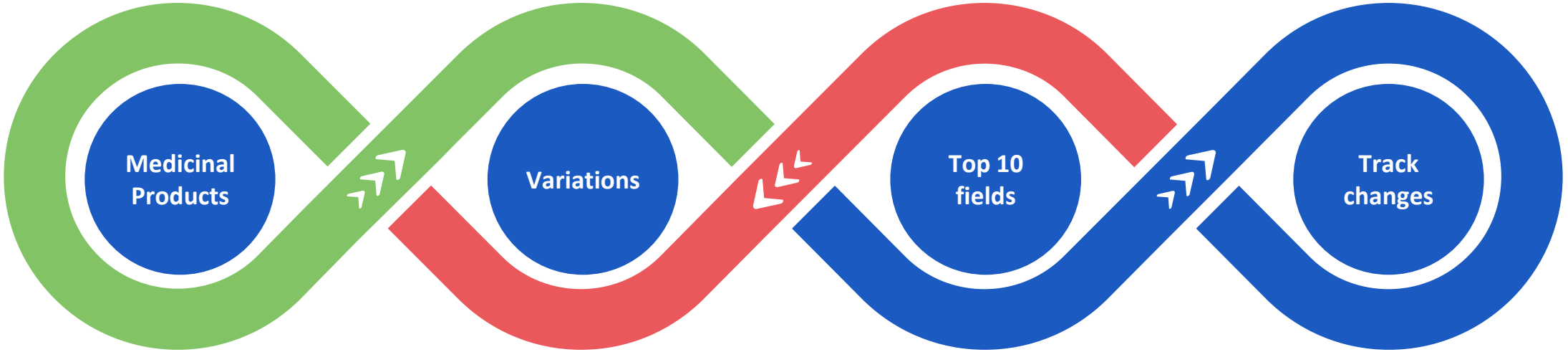
FHIR Trainings for NCAs provided by AGES & AEMPS



Get an overview of the medicinal product

The basics of the medicinal product and its references

--> (recording) <--

The procedure envelop

Get an overview of the variation message:

--> (recording) <--

What to start importing

Top 10 most wanted IDMP fields

--> (recording) <--

What has changed in a variation?

How to track changes on a medicinal product using FHIR provenances

--> (recording) <--

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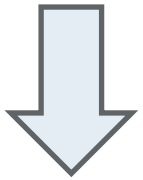
Demo on Variation (CP)



Verfahren zu bestehenden Grundakt/en anlegen

Antragsformblatt (xml/pdf) example eAF for PHAROS (FHIR ... Aktualisieren...

Betrachtungsobjekt Hinzufügen Löschen Von Suche übernehmen

DEMO

Grundzahl	Typ	Name des Betrachtungsobjekts	MP/DC/CP Nummer	Status	Zulassungsnummer	PMS-ID
13763447	Arzneispezialität	Ultomiris 1.100 m...	EMEA/H/C/004954	GA - zugelassen	EU/1/19/1371/003	
13763443	Arzneispezialität	Ultomiris 300 mg/...	EMEA/H/C/004954	GA - zugelassen	EU/1/19/1371/002	

Verfahrenstyp Zentrale Variation human

Referenzierte Verfahrensnummer

Anlegen Abbrechen

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Extracted from eAF (currently, more to come)

MA Number(s) *	Product -> RegulatedAuthorization.identifier
Member State *	Product -> RegulatedAuthorization.region
Scope(s)	Task.contained.Task[partOf.reference=#].code.coding[system=scopeType].code
Procedure type(s)	Task.contained.Task[partOf.reference=#][code.coding[system=scopeType]].input[type=procedureType].valueCoding.code
Implementation Date	Task.contained.Task[partOf.reference=#].code.coding[system=scopeType].executionPeriod
Domain	Task.input[type=Domain].valueCoding
Type of authorisation	RegulatedAuthorisation[MedicinalProductDefinition(type=marketingAuthorisation].case.type
Variation procedure Numbers	Task.identifier type=ProcedureNr
Type of application	Task.Input[type=grouping].valuestring
Including a line extension	Task.Input[type=lineExtension].valueBoolean
Worksharing	Task.input[type=worksharing].valueBoolean? Task.input[type.coding.code="100000155556"].valueBoolean=true/false
IG / Supergrouping - grouping of type IA variations	Task.Input[type=IG].valueBoolean
Procedure type	Task.input[type=Procedure Type].valueCoding -> There can be multiple task inputs here Task.code & RegulatedAuthorisation[MedicinalProductDefinition(type=marketingAuthorisation].case.application.type (both: only the highest type IA < IB < type II)
MA Holder	Task.for->Organisation
Member State **	Task.requestor->PractionerRole->Location.address.country
E-mail	Task.requestor->PractionerRole.telecom[system=email].value
Company	Task.requestor->PractionerRole->Organization
Precise scope for change	Task.input[precisescope].valueString
Summary of product characteristics (Annex I)	Task.input[type=ProductCharacteristics].valueReference->DocumentReference
Labelling (Annex IIIA)	Task.input[type=labelling].valueReference->DocumentReference
Package leaflet (Annex IIIB)	Task.input[type=PIL].valueReference->DocumentReference

* Used for Identification of products

** Only if AT

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RMS - Integration of EMA SPOR services

Noel Diamant

UNICOM

Fact Sheet

01

Sporify API

In order to avoid the RMS throttling of 50 requests per minute as well as recent unexpected downtimes SPORIFY was chosen as an API “Proxy”

02

National Extensions

Even though we want to use RMS lists, we need national values and extensions for many lists that require its own database and UI (developed in Oracle APEX)

03

Synchronise changes

A method was chosen to only request changes since the last synchronisation: “`v1/lists/search-terms?modified-after=$date`”

A Detail algorithm can be found in the next slide

04

Validate every change

New terms, updated names / descriptions in german or changes in status need to be validated.
Terms can be blacklisted if they should never be overwritten.

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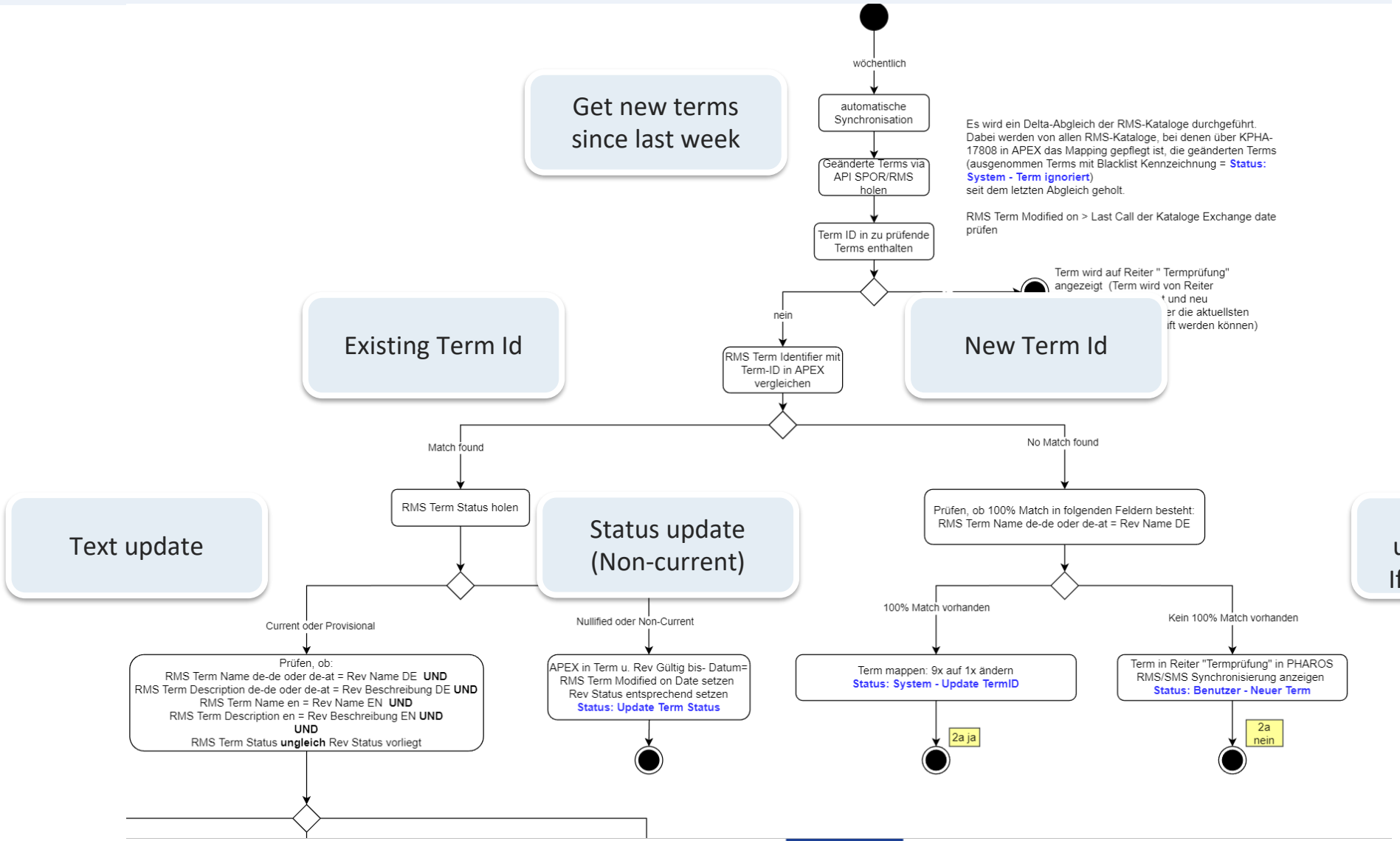
RMS / SMS syncing rules I



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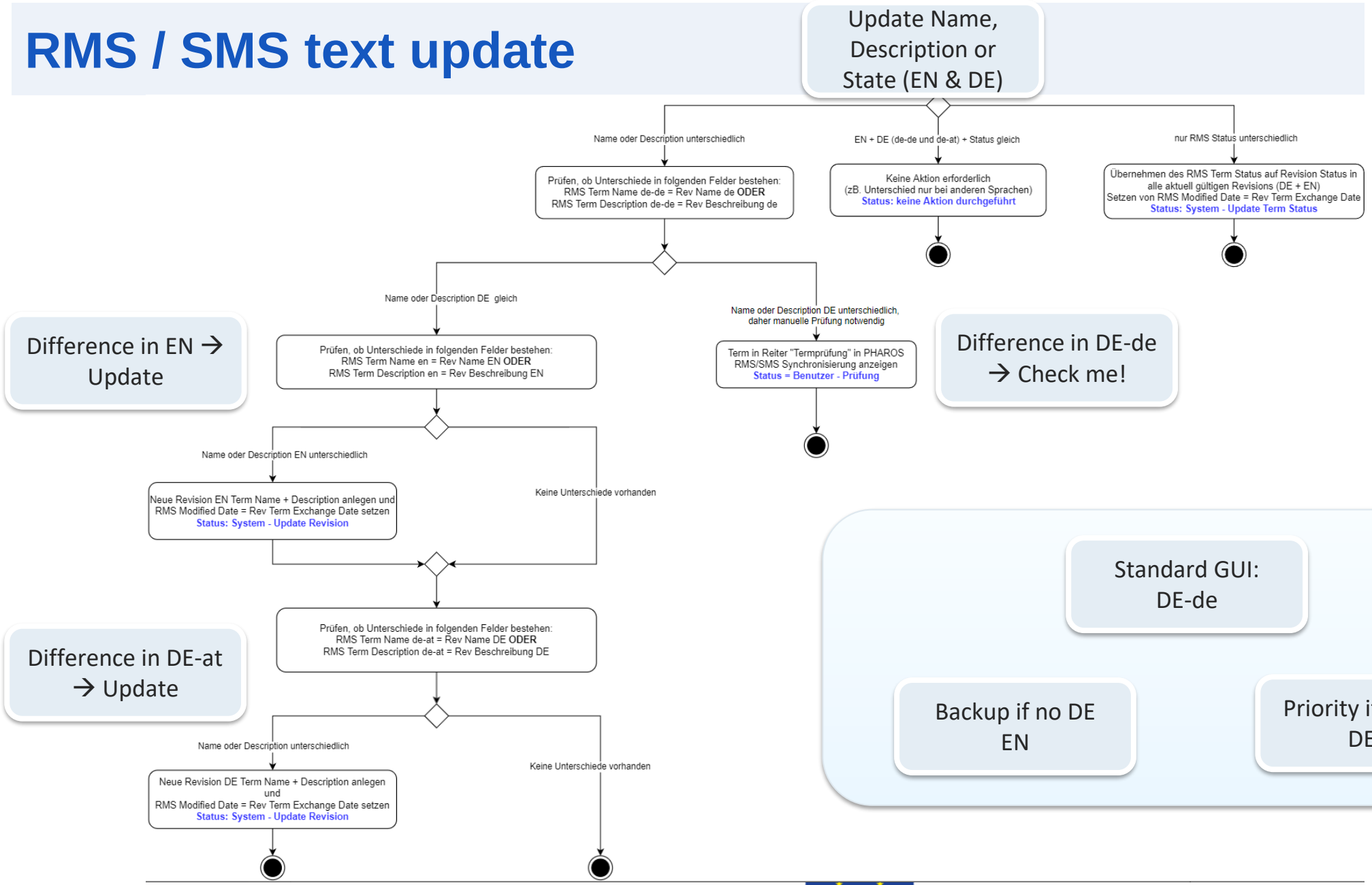
RMS / SMS text update



Difference in EN → Update

Difference in DE-de → Check me!

Difference in DE-at → Update

Standard GUI: DE-de

Backup if no DE EN

Priority if it exists: DE-at

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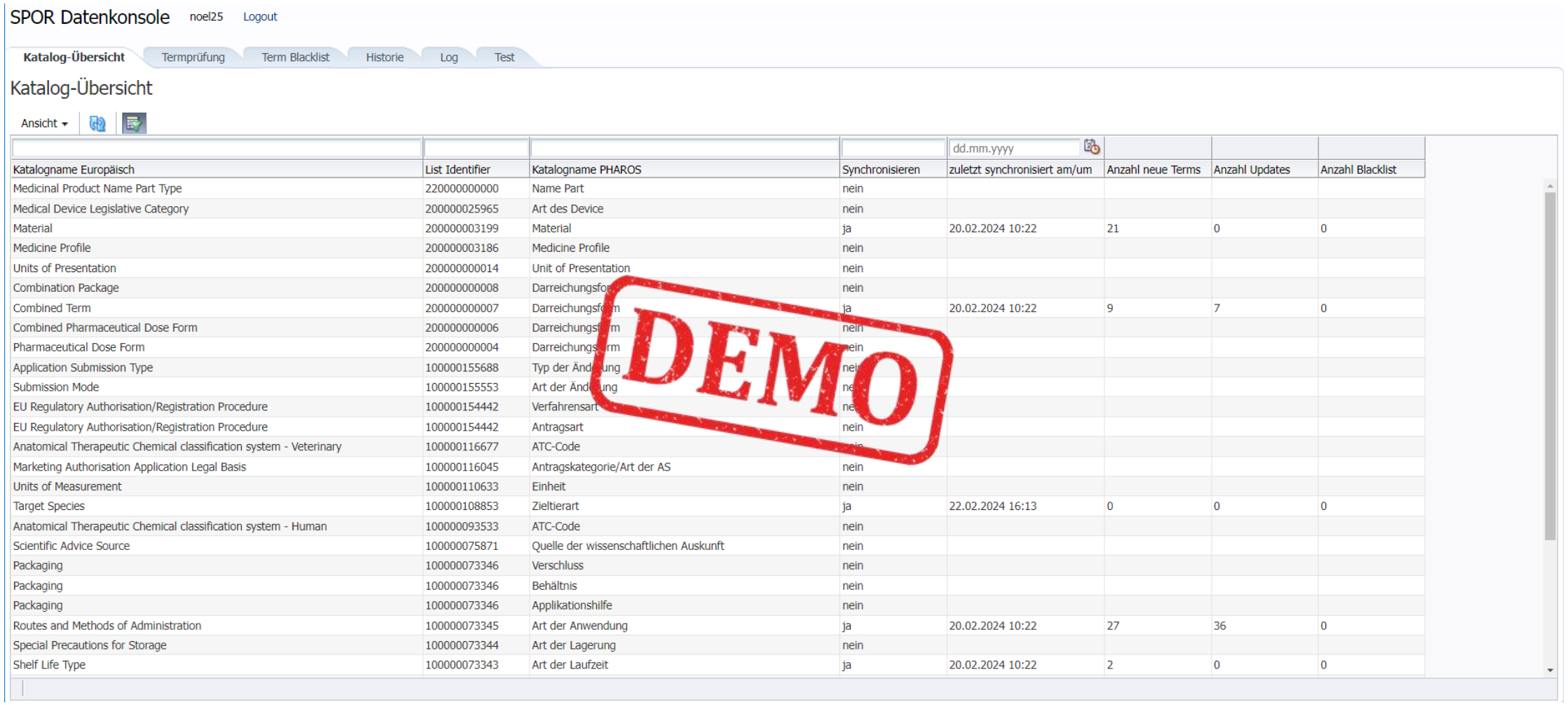
Demo



Katalogname Europäisch	List Identifier	Katalogname PHAROS	Synchronisieren	zuletzt synchronisiert am/um	Anzahl neue Terms	Anzahl Updates	Anzahl Blacklist
Medicinal Product Name Part Type	220000000000	Name Part	nein				
Medical Device Legislative Category	200000025965	Art des Device	nein				
Material	200000003199	Material	ja	20.02.2024 10:22	21	0	0
Medicine Profile	200000003186	Medicine Profile	nein				
Units of Presentation	200000000014	Unit of Presentation	nein				
Combination Package	200000000008	Darreichungsfo	nein				
Combined Term	200000000007	Darreichungsf m	ja	20.02.2024 10:22	9	7	0
Combined Pharmaceutical Dose Form	200000000006	Darreichungsf m	nein				
Pharmaceutical Dose Form	200000000004	Darreichungs rm	nein				
Application Submission Type	100000155688	Typ der Änd ung	nei				
Submission Mode	100000155553	Art der Änd ung	ne				
EU Regulatory Authorisation/Registration Procedure	100000154442	Verfahrensart	ne				
EU Regulatory Authorisation/Registration Procedure	100000154442	Antragsart	nein				
Anatomical Therapeutic Chemical classification system - Veterinary	100000116677	ATC-Code					
Marketing Authorisation Application Legal Basis	100000116045	Antragskategorie/Art der AS	nein				
Units of Measurement	100000110633	Einheit	nein				
Target Species	100000108853	Zieltierart	ja	22.02.2024 16:13	0	0	0
Anatomical Therapeutic Chemical classification system - Human	100000093533	ATC-Code	nein				
Scientific Advice Source	100000075871	Quelle der wissenschaftlichen Auskunft	nein				
Packaging	100000073346	Verschluss	nein				
Packaging	100000073346	Behältnis	nein				
Packaging	100000073346	Applikationshilfe	nein				
Routes and Methods of Administration	100000073345	Art der Anwendung	ja	20.02.2024 10:22	27	36	0
Special Precautions for Storage	100000073344	Art der Lagerung	nein				
Shelf Life Type	100000073343	Art der Laufzeit	ja	20.02.2024 10:22	2	0	0

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SMS - Integration of EMA SPOR services

Noel Diamant

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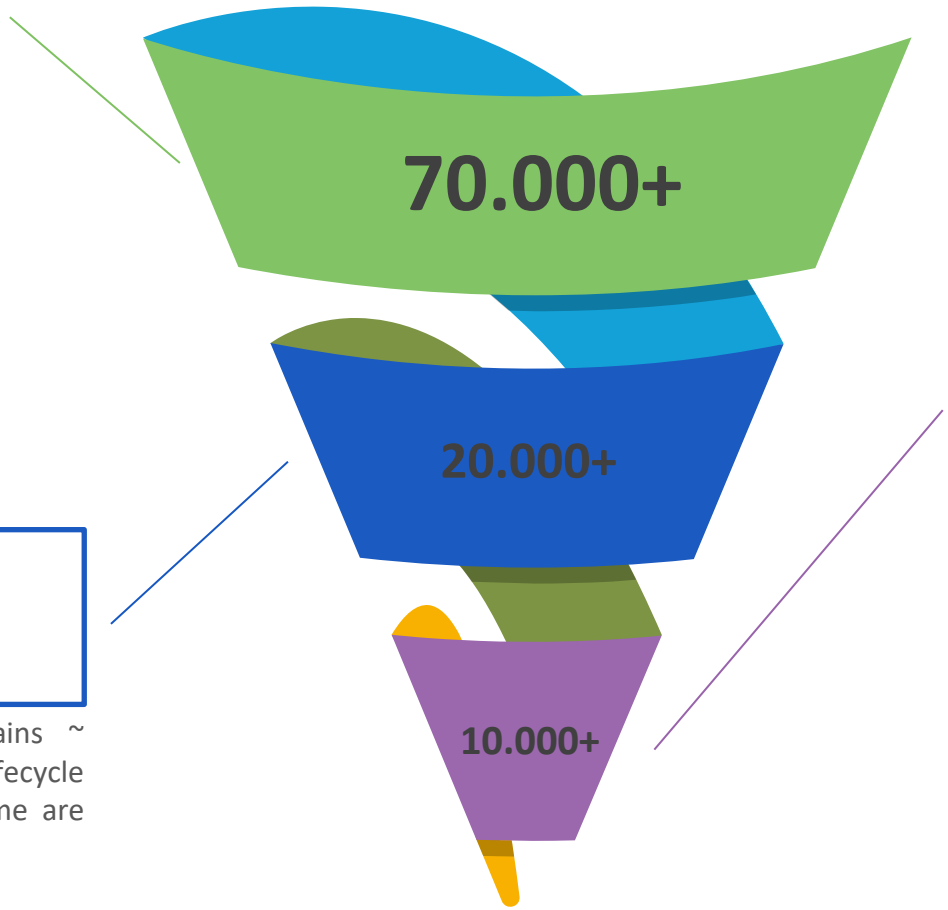
Figures on Substances

SMS: Substance List

EMA's SPOR SMS List contains over 70.000 Substances

Positive: A complete List, stable IDs, mappings

Challenges: A lot of duplicates exist, that are constantly being merged



PHAROS: CTL Substance

Our national database Pharos contains ~ 20.000 Substances. Some are used in Lifecycle management, some in Inspections, some are not used

PHAROS: Substance Master Folder

Substances used in the lifecycle of a medicinal product have a "Master Folder". These are enriched with Information on:

Synonyms, Doping, Narcotics, Psychotropics, drug interactions, PHV Issues, IDs, type, base substance calculations and documentations

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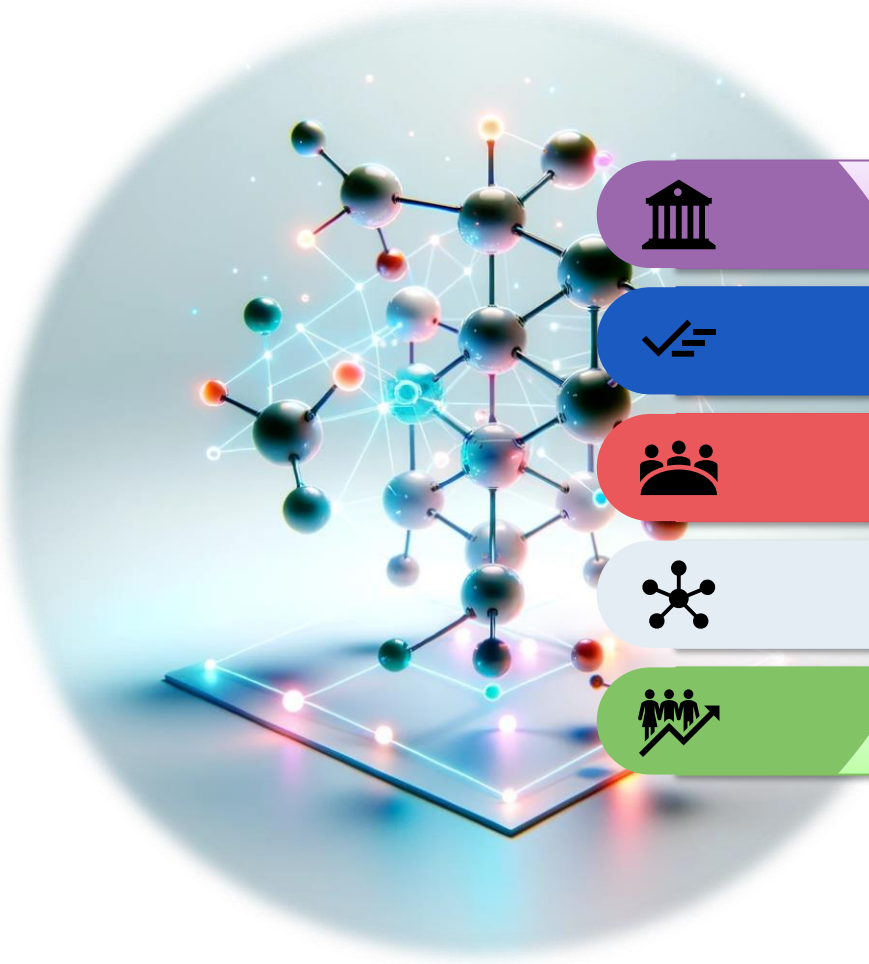
SMS-Sync: Principles



- We handle SMS like any other RMS list (with some additional attributes)
- We only synchronise substances on-demand (keep it clean)
- We use the “Comment” field from SMS to understand merges of non-current substances
- Substance Name source, Type, Weight and Formular will be synced if available.
- The sync checks if the updated substance is used to facilitate necessary master folder updates

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Substance Structure - WMUOPVGLPLDJIX-UHFFFAOYSA-N

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How to find a substance in Pubchem using the structure from SMS:

https://pubchem.ncbi.nlm.nih.gov/compound/WMUOPVGLPLDJIX-UHFFFAOYSA-N#section=3D-Conformer&embed=true

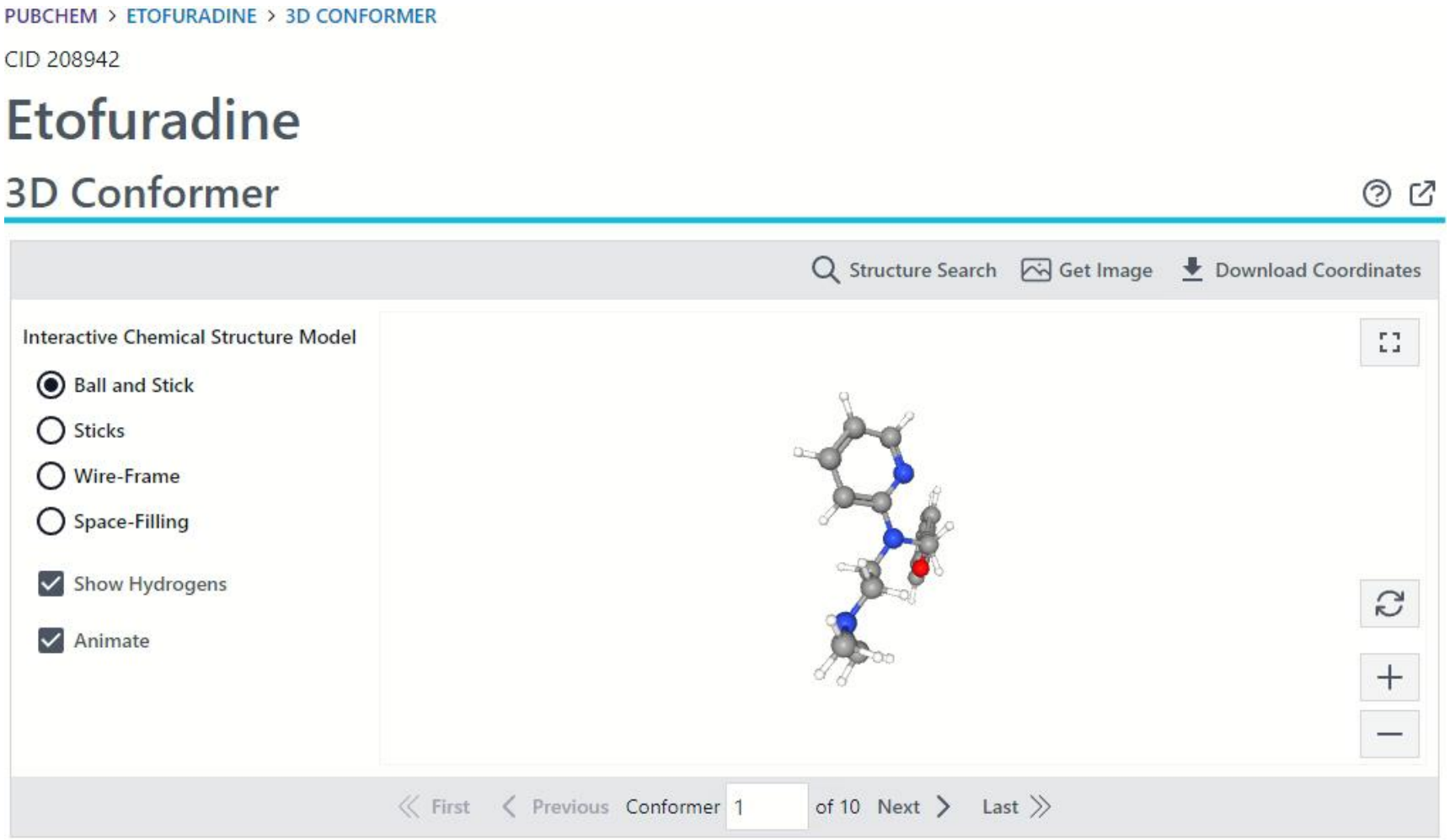
https://pubchem.ncbi.nlm.nih.gov/compound/WMUOPVGLPLDJIX-UHFFFAOYSA-N#section=2D-Structure&embed=true

How add into an existing web application:

<iframe class="pubchem-widget" src="https://pubchem.ncbi.nlm.nih.gov/compound/aspirin#section=3D-Conformer&embed=true" style="width: 600px; max-width: 100%; height: 900px;">

How to get only the image via REST:

https://pubchem.ncbi.nlm.nih.gov/docs/pug-rest-tutorial#section=How-PUG-REST-Works



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Exporting Medicinal Product Data in FHIR 5.0 format – Outlook

Noel Diamant

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How to start your own FHIR export

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HL7 FHIR
http://hl7.org/fhir/

FHIR version 5.0 has been released and is stable

1. We start with *„2024 01 30 AF Data Requirements.xlsx“*
   - https://esubmission.ema.europa.eu/cessp/PLM%20Portal%20eAF%20FHIR%20XML%20-%20package.zip
2. Chose the fields we want to use:

Product Data	Header	1	m
Name of the medicinal product	Header	n	m
Country	Select	n	m
Language	Select	n	m
Full Product Name	Text	1	R/O
Name Parts	Header	n	d
Name Part	Text	1	m
Name Part Type	Select	1	m
For applications submitted in accordance with Art. 8(3) or Art. 10a of Directive 2001/83/EC	Header	1	d

3. Use the FHIR paths in the documentation
4. Add national requirements (E.g. PZN Nr for every package)
5. Coordinate with national HL7 FHIR Austria for the extension names
   - E.g. MedicinalProductDefinition.identifier.system=https://www.datacare.at/
   - RegulatedAuthorization.status.extension[url=https://www.ages.at/fhir/extension/positiveAuthStatus]
6. Create the the xml or JSON message using HAPI FHIR in case of JAVA

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Current export format

- Currently medicinal product data will be provided to eHealth-organisations in a proprietary data format („ClaML“):

```
<Class code="0012581">
    <Rubric kind="preferred">
        <Label xml:lang="de" xml:space="default">CONTRACTUBEX GEL</Label>
    </Rubric>
    <Meta name="Bezeichnung_Arzneispezialitaet_Zulassung" value="Contractubex - Gel"/>
    <Meta name="ZulassungsNummer" value="1.2.40.0.34.4.17:13883"/>
    <Meta name="ELGA_Gültigkeit" value="true"/>
    <Meta name="ELGA_MedikationPackungsstatusLieferbar" value="true"/>
    <Meta name="GroesseGewicht" value="50"/>
    <Meta name="ELGA_MedikationMengenart_code" value="2.16.840.1.113883.6.8:g"/>
    <Meta name="ELGA_MedikationMengenart_text" value="Gramm"/>
    <Meta name="ELGA_MedikationRezeptpflichtStatus_code" value="1.2.40.0.10.1.4.3.4.3.7:100000072076"/>
    <Meta name="ELGA_MedikationRezeptpflichtStatus_text" value="Arzneimittel zur Abgabe ohne aerztliche Verschreibung"/>
    <Meta name="ELGA_whoATC_01_code" value="2.16.840.1.113883.6.73:D03AX"/>
    <Meta name="ELGA_whoATC_01_text" value="Andere Wundbehandlungsmittel"/>
    <Meta name="ELGA_MedikationArtAnwendung_01_code" value="1.2.40.0.10.1.4.3.4.3.4:100000073566"/>
    <Meta name="ELGA_MedikationArtAnwendung_01_text" value="Anwendung auf der Haut"/>
    <Meta name="ELGA_Substanz_01_code" value="1.2.40.0.34.5.156:1712596"/>
    <Meta name="ELGA_Substanz_01_text" value="ALLII CEPAE BULBUS (AUSZUG) "/>
    <Meta name="ELGA_Substanz_02_code" value="1.2.40.0.34.5.156:1705858"/>
    <Meta name="ELGA_Substanz_02_text" value="ALLANTOIN"/>
    <Meta name="ELGA_Substanz_03_code" value="1.2.40.0.34.5.156:1708475"/>
    <Meta name="ELGA_Substanz_03_text" value="HEPARIN NATRIUM"/>
    <Meta name="ELGA_MedikationDarreichungsform_01_code" value="1.2.40.0.10.1.4.3.4.3.5:100000073726"/>
    <Meta name="ELGA_MedikationDarreichungsform_01_text" value="Gel"/>
    <Meta name="ELGA_MedikationWechselwirkungsRelevant" value="false"/>
    <Meta name="Domaene" value="human"/>
</Class>
```

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New opportunity: FHIR messaging

- With EMA's decision to use FHIR as a messaging format and the ongoing establishment of FHIR in the eHealth domain, FHIR is gaining in importance for the exchange of Medicinal Product Data.

- In a prototyp we will export master data from PHAROS in FHIRv5 format
- The result will be discussed with eHealth-organisations to discuss the benefit und plan next steps:

  - **The object oriented structure of FHIR allows for more complex datasets**
  - **- not always needed for eHealth-scenarios!**

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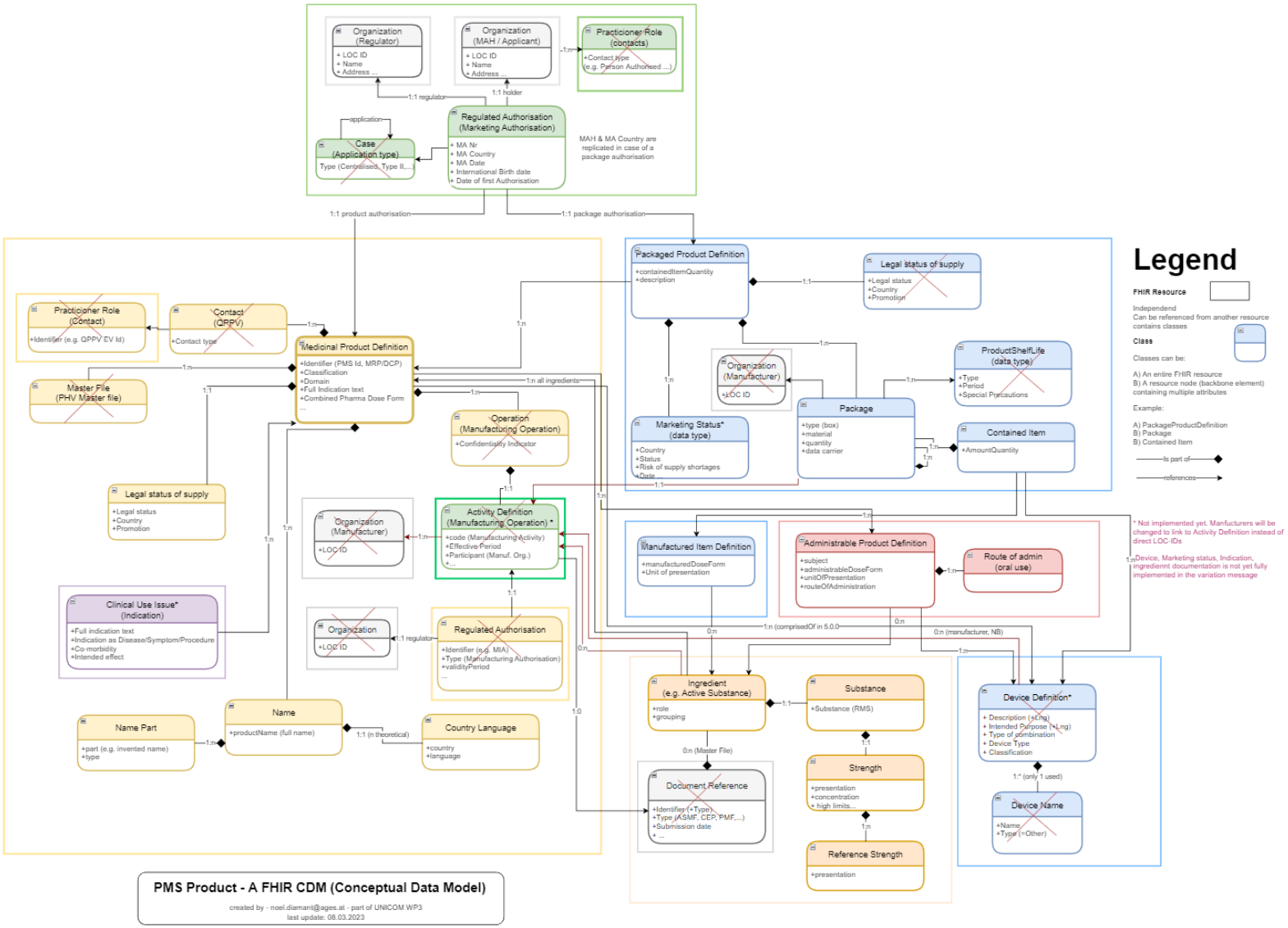
MVP approach for eHealth exports



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Conclusions

Take Home Message

- **Implementing ISO-IDMP has not been a sprint, but a marathon and we expect additional effort over the next years, for e.g.**
  - Upcoming EMA‘s IDMP Guidelines
  - Upcoming FHIR versions
  - UX-improvements
  - Data enrichment, e.g. importing data from the new eAFs and synchronisation
  - Sync data with SPOR PMS
  - OMS improvements
  - Mapping national terms to SPOR (e.g. for remaining SMS terms)

- **PHAROS is now structurally IDMP-ready to store data according to EU IGs**
  - We will use data from the “MAA and Variation eAF” (FHIR) via an automatised data import
  - We are evaluating the use of the PMS-API to download CPs

- **IDMP-concepts are complex, perhaps too complex for some data consumers**
  - We are evaluating this together with national eHealth organisations

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Thanks for your attention!