Common factors in the Fast Healthcare Interoperability Resources (FHIR) data standard for Art57(2) and eAF

25 January 2022, 10:30–12:00 Central European Time (CET)
Webinar: WebEx

Presenting for SPOR: Veronica Lipucci Di Paola
Product Co-Owner for PMS, EMA

Presenting for DADI: Noel Diamant
Product Co-Owner for DADI, UNICOM

*Please note that **this session is being recorded** and **will be made available** through the **EMA Corporate Website***

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Agenda

1	**Welcome** 10:30 – 10:35	***Kristiina Puusaari*** *Product Co-Owner for DADI, EMA*
2	**Introduction to the Variation FHIR Message** 10:35 – 11:15	***Noel Diamant*** *Product Co-Owner for DADI, UNICOM** ***Veronica Lipucci Di Paola*** *Product Co-Owner for PMS, EMA* ***Marcos Fernandez Gomez*** *Product Co-Owner for PMS, EMA*
3	**Mapping & examples** 11:15 – 11:25	***Noel Diamant*** *Product Co-Owner for DADI, UNICOM**
4	**Q&A Session** 11:25 – 11:55	***Moderator:*** ***Cristina Pepato*** *DADI Change Manager*
5	**Closing** 11:55 – 12:00	***Kristiina Puusaari*** *Product Co-Owner for DADI, EMA*

*The UNICOM Innovation Action has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 875299.

Introducing DADI

DADI is a **Network project** led by the **European Medicines Agency (EMA)** which will support both **centrally authorised product (CAP)** applications and **nationally authorised product (NAP)** applications.

Network

The project will replace forms used for **key EU procedures**, including:

- *centralised procedures managed by **EMA**,*
- *non-centralised procedures managed by **NCAs**.*

Both EMA and NCAs are involved to ensure that results can fulfil current and upcoming requirements.

Product Owners

Product ownership of the web-forms is shared between **EMA and NCAs**. An EMA representative acts as product owner in collaboration with a **Network product owner funded by UNICOM*.**

SME Group

The DADI project has established a **group** representing **subject matter experts from EMA, NCAs and Industry.**

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Introduction to the Variation FHIR Message

***Noel Diamant**, Product Co-Owner for DADI, UNICOM**

***Veronica Lipucci Di Paola**, Product Co-Owner for PMS, EMA*

***Marcos Fernandez Gomez**, Product Co-Owner for PMS, EMA*

*The UNICOM Innovation Action has received funding from the European Union's Horizon 2020 research and innovationprogramme under grant agreement No. 875299.

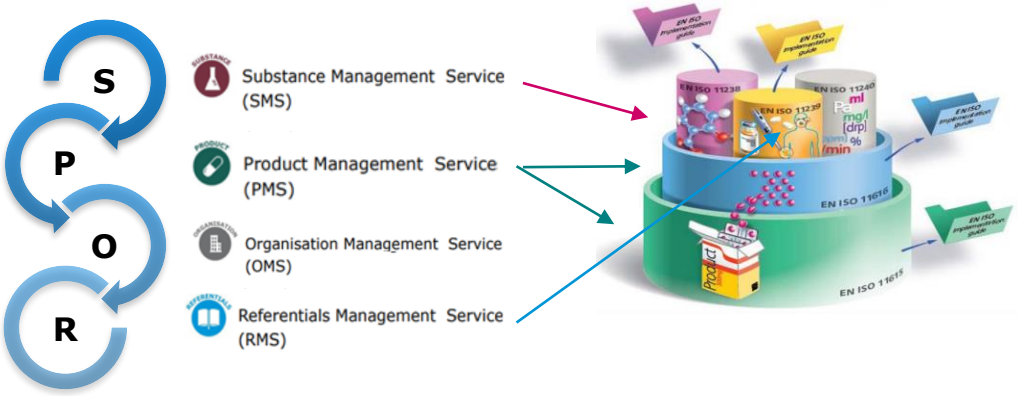
Objectives of the Webinar

Provide to the **technical experts from Industry and National Competent Authorities'** (NCA):

- An introduction of the SPOR programme
- An introduction of the variation FHIR format
- Further clarification on the PMS data model and how it links to the eAF
- Clarifying the origin of migrated data (i.e. SIAMED, xEVMDP)
- Displaying the mapping from eAF variation & MAA medicinal product to FHIR and PMS IG 2.1

SPOR Services

- **European Medicines Agency** is implementing the standards developed by the International Organization for Standardization (**ISO**) for the identification of medicinal products (**IDMP**)
- To comply with Commission Implementing **Regulation (EU) No 520/2012** (articles 25 and 26)
- ISO IDMP implementation in the EU in a step wise approach
- Four domains of master data used in pharmaceutical regulatory processes: **Substance**, **Product**, **Organisation** and **Referential** (SPOR) data



ISO IDMP	Description
ISO 11238	Data elements and structures for unique identification and exchange of regulated information on Substances
ISO 11239	Data elements and structures for unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging
ISO 11240	Data elements and structures for unique identification and exchange of units of measurement
ISO 11616	Data elements and structures for unique identification and exchange of regulated pharmaceutical Product information
ISO 11615	Data elements and structures for unique identification and exchange of regulated medicinal Product information

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Product Management Service – role, scope, benefits

- Standardization of the definition of **product** data
- Increase **data quality** and **process efficiency**
- Improvement of **Data Integrity** enabling:
  - **Reliability** of data
  - **Re-usability** of data
  - **Avoidance of duplication** of data and services
- Optimisation and simplification of data operating model and data management practices reducing silos and improving **interoperability** and **exchange of data across EU systems**
- **Streamline, optimise and simplify regulatory processes** to fulfil regulatory requirements more efficiently
- **Speed up decision-making** and improve communication with our stakeholders through easily accessible and highly reliable data

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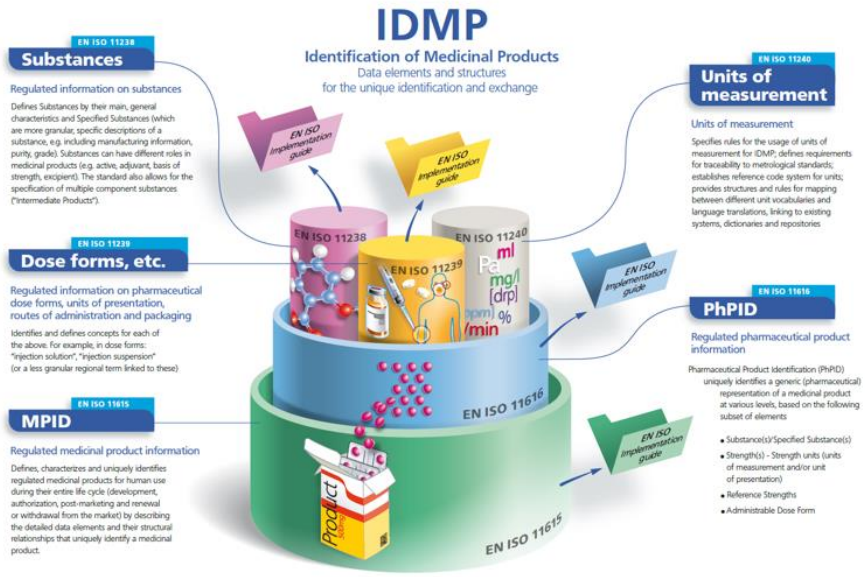
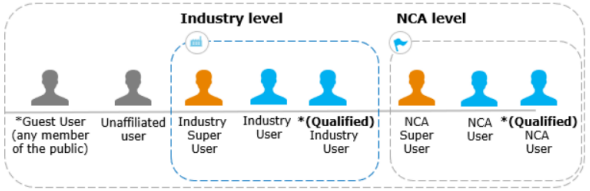
Product Management Service – role, scope, benefits

- PMS **EU IDMP Implementation Guide**
- **PMS** is **ISO IDMP compliant** and contains a subset of IDMP product information & **EU specific extensions**
- PMS Data model contains ~**160 data fields** vs ~50 xEVMPD
- **Messaging based on HL7 (FHIR) standards**
- PMS is **supported by RMS, SMS and OMS** and uses standardized SPOR master data to populate the PMS data elements
- PMS contain **Authorised Medicinal Product** (AMP) data
- Supports the implementation of the **target operating model (TOM)** for managing medicinal product data





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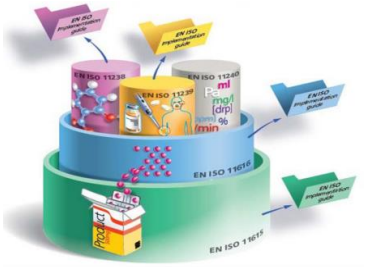
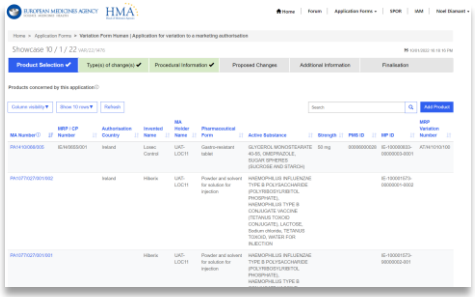
How PMS data links to eAF

PMS



eAF



Key concepts

- The use of PMS data will be enabled within **variation procedures**
  - PMS is queried to select affected medicinal products and show all structured data elements that can be changed in scope of the variation classification
- PMS and eAF data structures adhere to the **ISO IDMP** (for human CAPs and non-CAPs); Veterinary products will follow in a similar fashion (UPD)
- Not all PMS data elements are in scope of **MAA / variation / MA Renewal** forms
  - Data/Process **Out of scope**: MA transfer, Update of QPPV, PSMF location, PhV contacts, marketing status and authorisation status
- The DADI project does not define the new business processes, but is focusing on providing the basis for data to be exchanged: A common FHIR message format for medicinal products
- Processes that can be built based on the same FHIR message are for example:
  - Feeding approved data **back to PMS**
  - The submission of **Art 57(2)** data elements
  - as well as **data cleansing/enrichment**

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Overview: eAF FHIR messages including the PMS products

Task = The (Variation) Application

- *Overarching element of the application*
- Procedural Information:
  Procedure type summary, Type of Authorisation, Procedure numbers, Grouping, Worksharing, Background & Details, etc...
- Annexed Documents, Declaration, Proof of Payment, Signatories
- List of medicinal products, list of changes (provenances)

Medicinal Products (copy from PMS)

- Product as selected from PMS, changed by the eAF application
- Has the same data structure as the PMS product, as described in the EU IG
- Is an independent element referenced by the task to be reused in other activities (e.g. Art 57 (2)
- Contains Authorisations like:
  Marketing Authorisation, Manufacturer Authorisations,…

Subtask = 1 Scope of the variation classification
Provenance = „Present / Proposed" content

- Contains Scope & Procedure type
- Contains current value, proposed value (link to a product resource & attribute or free text)
- Conditions, Documentations
- List of affected medicinal products & packaged medicinal products (presentations)

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The FHIR „Task" Resource represents an eAF Application (focus on variations)

Task

- Procedural Information
- Annexed Documents
- Declaration
- Proof of payment
- Signatories
- List of products
- List of changes

Regulated Authorisations

- Additional Information

Procedural Information

- Domain, Type of Authorisation
- Variation procedure numbers; RMS / CMS
- Type of application (single, grouping, worksharing, line extension)
- Procedure type (Distinct list of all procedure types within the provenances)
- Changes concerns
- Lead MAH & contact persons (Other MAH info is in the product marketing authorisation)
- Precise scope & background (free text)

Scopes (variation classification) and the „Present /Proposed" section are not found in the Task, but in the Subtask and Provenance

Annexed Documents

- Tickboxes of which documents are attached with the submission

Declaration

- Declaration checkboxes
- Submission of the same type II in other Member States
- Information on harmonisation of Product Information

Proof of payment

Signatories

Additional Information

- Request to change for: Orphan Designation, Paediatric, Market exclusivity
- These authorisations are references to a medicinal product, but not part of PMS

List of products (medicinal products from PMS)

List of changes (provenances)

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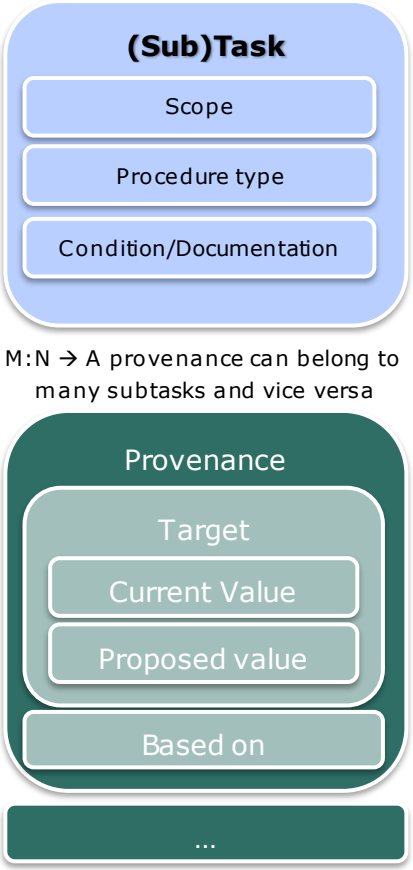
Task (Variation Procedure)



Scope and procedure type

- Each scope according to the variation classification and the procedure type pair have their own subtask;
- Each subtask can have many provenances (changes) and every provenance can belong to multiple subtasks
- Implementations dates / comments for IA variations

Conditions and Documentations

- Conditions and Documentations are shared within a subtask and apply to all provenances that are linked. Each provenance can depict one data field or resource change.

Target

- Which resources and elements are affected by the change. A list of links to the lowest point of the changed content. A link can always be followed to identify which medicinal product or packaged medicinal product is being changed.

Current Value

- Value and Type of the „old" data

Proposed Value

- A value and type or a link to a resource and an attribute within the product area

Based on

- The link to (Sub)Task showing that a specific change can belong to many variation classifications

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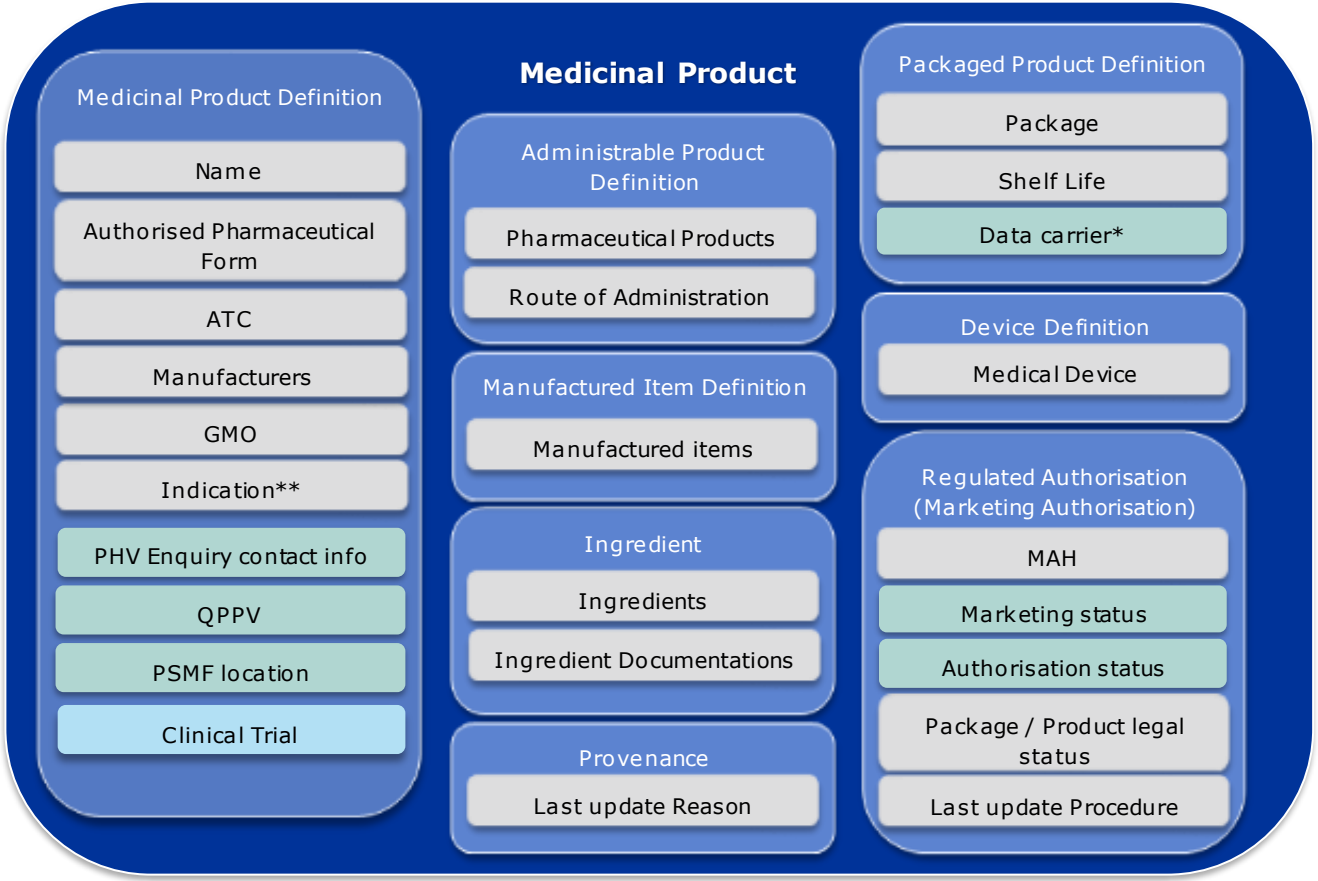
Medicinal Product FHIR message elements (human)

Where do PMS elements come from?



Legend

FHIR Resource

A Product area split according to variation classification

data provided by:

Common eAF & PMS product areas

PMS only areas

eAF only areas

* More details on coming slides

** Under development

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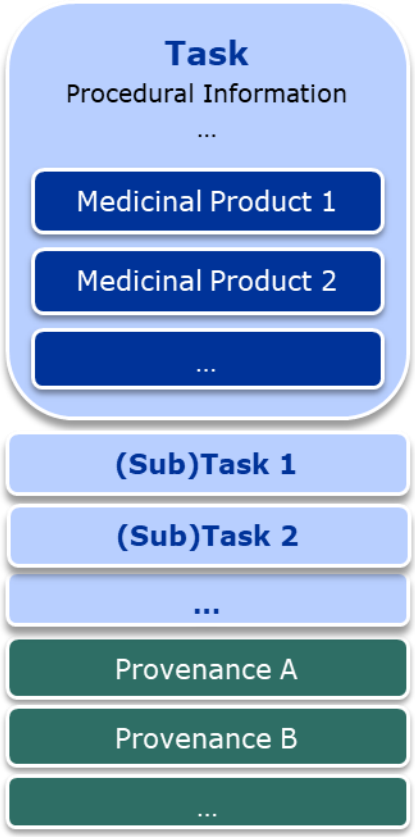
How PMS data links to DADI

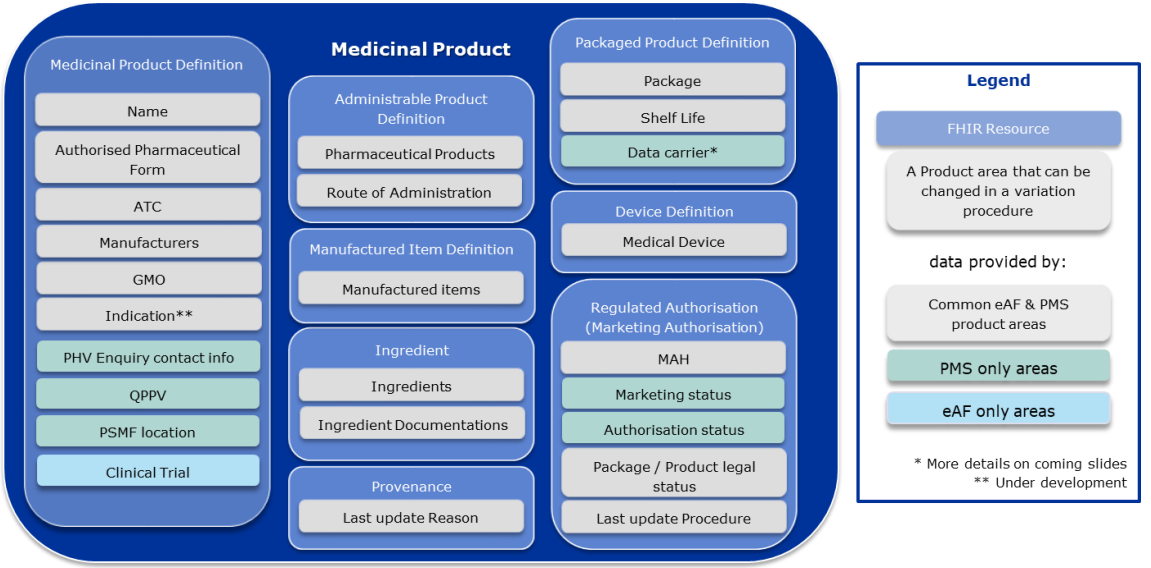
Overview of the eAF FHIR messages including the PMS product data



Medicinal Products (As known from PMS)

- Can be submitted separately for the Art 57 (2) process
- Core Data (as described in the EU IG)
- Authorisations (Marketing Authorisations, Manufacturer Authorisations,…)

Medicinal Product FHIR message elements (human) from PMS



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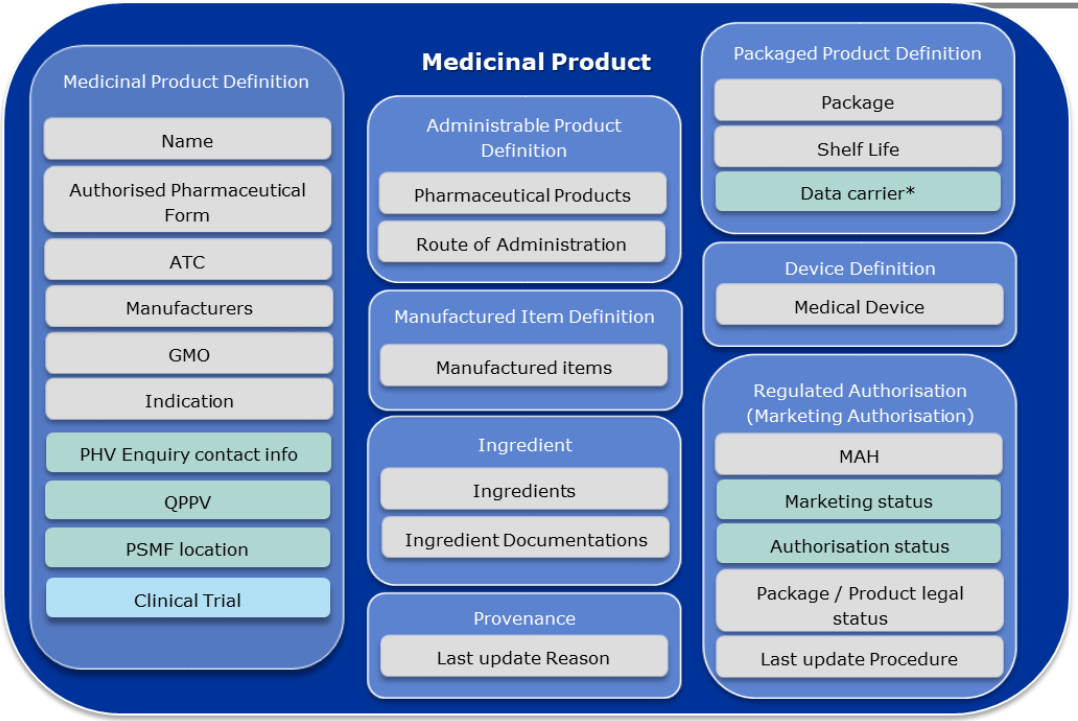
How PMS data links to DADI



PMS data in scope of eAF

- Data in grey boxes are retrieved from PMS
- ISO IDMP class/FHIR resources and relevant paths apply
- Authorised data from eAF ➡ PMS at the end of RA procedure
- Initial data load from SIAMED/XEVMPD

⬇

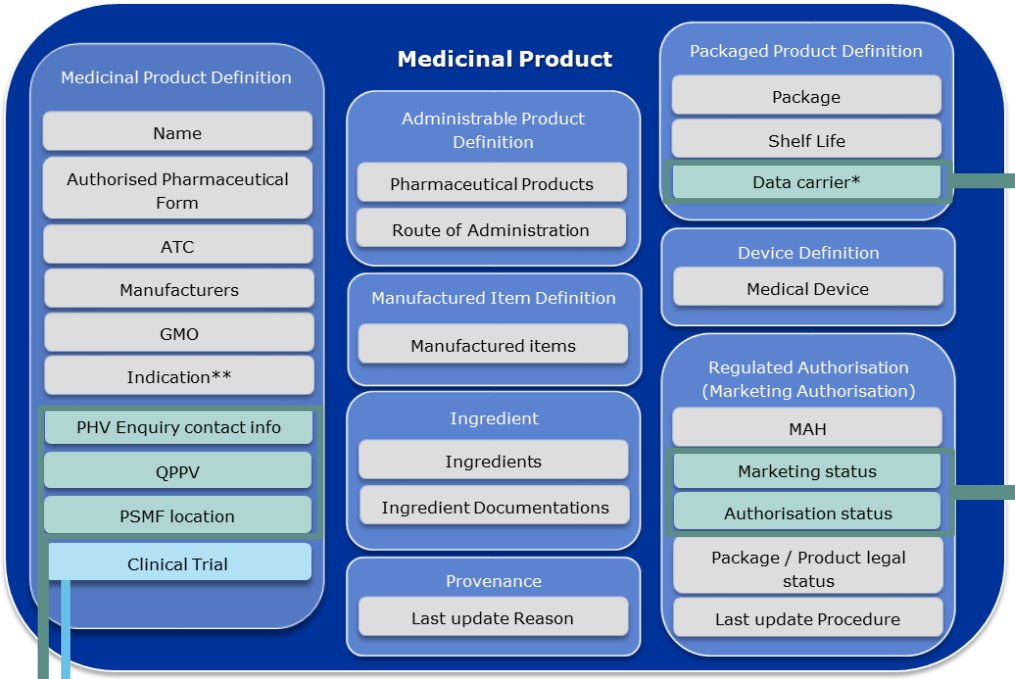
Partial lack of medicinal product data

⬇

Data enrichment/correction in PMS.**

*Refer to diagram in slide 18 for product data fields without migrated information or with partial data available after the data migration, requiring data enrichment.

How PMS data links to DADI



- Data submitted ONLY directly into PMS
- Information **NOT in scope** of eAF

- Data submitted directly in IRIS -> PMS (CAP only); *Data submission for non-CAP products under discussion.*
- Information **NOT in scope** of eAF

- Data submitted ONLY via eAF Var. form
- Information in scope of eAF

- Data submitted into XEVMPD -> PMS
- Information **NOT in scope** of eAF Var. (QPPV in scope of MAA)

Grey boxes:
- Data submission directly from eAF -> PMS
- Information in scope of eAF

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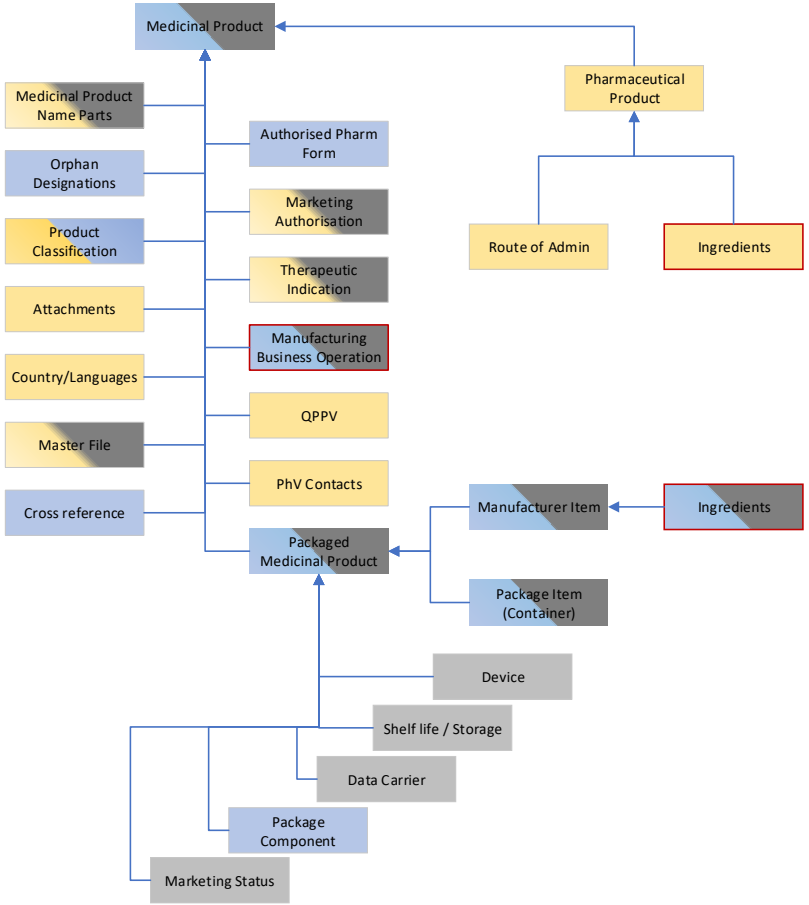
Origin of existing product data in PMS

Legend:

- Fields coming from Art. 57
- Fields coming from SIAMED
- Fields without migrated info
- Fields coming from Art. 57 but missing data
- Fields coming from SIAMED but missing data
- Fields to be checked with highest priority



- **CAP**: data sourced from SIAMED and XEVMPD
- **Non-CAP**: limited data sourced only from XEVMPD
- Despite the initial data load from SIAMED and XEVMPD some PMS definitions & resources **may be missing or inconsistent** (e.g. non-CAP MBO, data carrier, device etc.)
- **Data correction** and **enrichment/completion** is needed in PMS (process & data flow under discussion)

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PMS elements requiring data enrichment/completion

Data Enrichment

Centrally authorised products (CAP):

- Elements of Manufacturer / Manufacturer Business Operation

CAP & non-CAP

- Device
- Marketing Status
- Shelf-life / Storage
- Data Carrier
- Master File (except PSMF)
- Elements of:
  - Medicinal Product Name Parts
  - Therapeutic Indication
  - Package Item (Container)
  - Pharmaceutical Product

Non-Centrally authorised products (non-CAP):

- Manufacturers / Manufacturer Business Operation
- Legal Status of Supply
- Package Item (Component)
- Elements:
  - Manufactured Item
  - Manfactutured Item Ingredient
  - Product Classification
  - Marketing Authorisation (Product level)

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PMS elements likely to require data correction

Data Correction

Centrally authorised products (CAP):

- Manufacturer / Manufacturer Business Operation
- Composition of Pharmacetutical Product (Ingredients) vs Manufactured Item (Ingredients)

CAP & non-CAP

Full PMS data set:

- Authorised Pharmaceutical Form
- Manufactured item
- Pharmaceutical product

etc

Non-Centrally authorised products (non-CAP):

- Ingredients in Medicinal Product without Active Substance
- All authorised Packaged Medicinal Product(s) migrated

- Industry is responsible to check the correctness of product data used in applications (and previously migrated into PMS)
- The resource(s) and attributes highlighted in the boxes are those more likely to require correction
- Migrated product data are expected to be aligned with the PMS EU IG business rules and reflect the data as authorised data

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Mapping & examples

***Noel Diamant**, Product Co-Owner for DADI, UNICOM**

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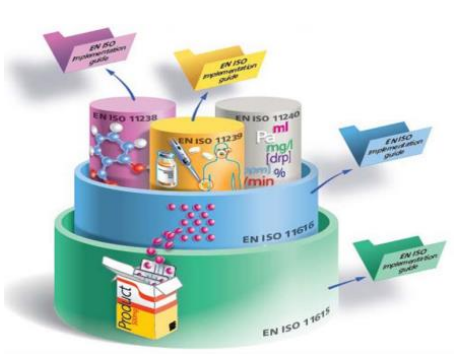
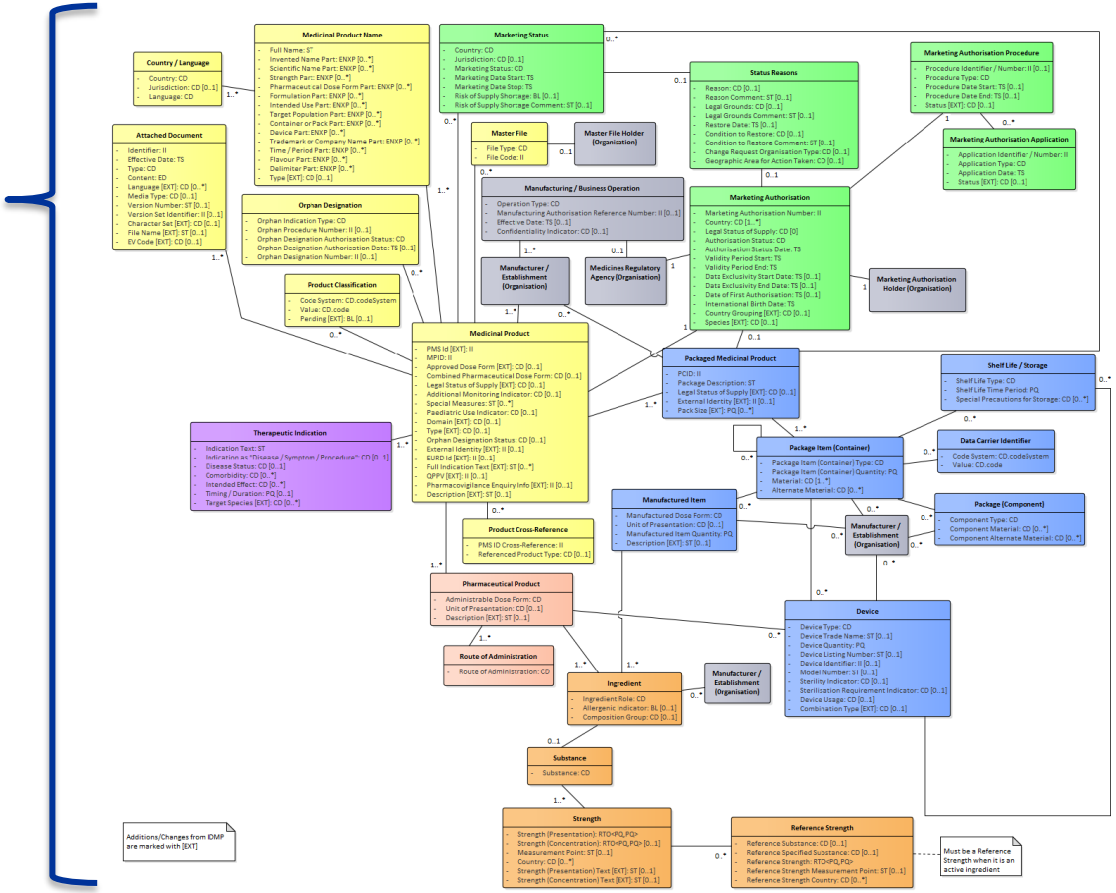
PMS Data Model



Colour legend

- Medicinal Product definition
- Regulated Authorisation (Marketing Authorisation)
- Manufacturer / Organization definition
- Therapeutic indication
- Packaged Medicinal Product Definition
- Pharmaceutical Product
- Ingredient



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References

- All product fields are described in detail in EU IG Chapter 2 (*Data elements for the electronic submission of information on medicinal products for human use*) on EMA S&PMS webpage
- A list of all fields required for Variation with the new IDMP structure as well as the FHIR mapping (draft version)
  - Published AF Requirements (work in progress)

Examples of **FHIR messages**

- Main Example: Losec Control; Other examples are provided to become familiar with the provenance structure for grouping and worksharing

FHIR links

- DADI is using FHIR in the version 4.6: https://hl7.org/fhir/2021May/medicinalproductdefinition.html
- PMS / EU IG will update to 4.6 but is still on 4.2 / 4.4: http://hl7.org/fhir/directory.html
  - The update to 4.6 mainly includes approved elements that were extensions in previous versions. Business rules should not be changed

Q&A session

*Moderator: **Cristina Pepato**, DADI Change Manager*

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Closing

Kristiina Puusaari, *Product Co-Owner for DADI, EMA*

Further information

http://esubmission.ema.europa.eu/cessp/cessp.htm

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