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Medicinal product reporting

EU implementation of ISO IDMP: from XEVMPD to PMS

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Outline

- Background: ISO IDMP and pharmacovigilance use case
- Implementation of ISO IDMP
- Transition: from XEVMPD (EudraVigilance Medicinal Product Dictionary) to PMS (Product Master Service)
- Take home messages

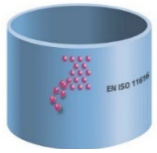
ISO standards for IDentification of Medicinal Products: IDMP

- The set of ISO IDMP standards establishes *definitions and concepts, common vocabularies* and describes *data elements and their structural relationships* that are required for the unique identification of medicines. Developed to ensure worldwide **interoperability** across regulatory and healthcare communities.

Substances (Substance ID/Specified Substance ID) - ISO 11238

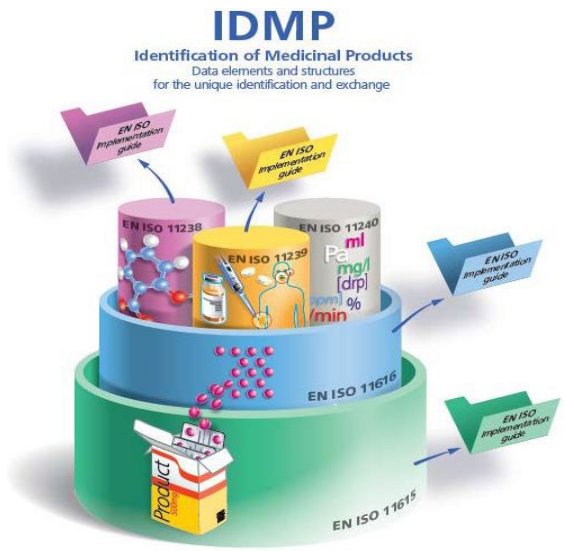
Pharmaceutical dose forms, units of presentation, routes of administration and packaging - ISO 11239

Units of measurement - ISO 11240



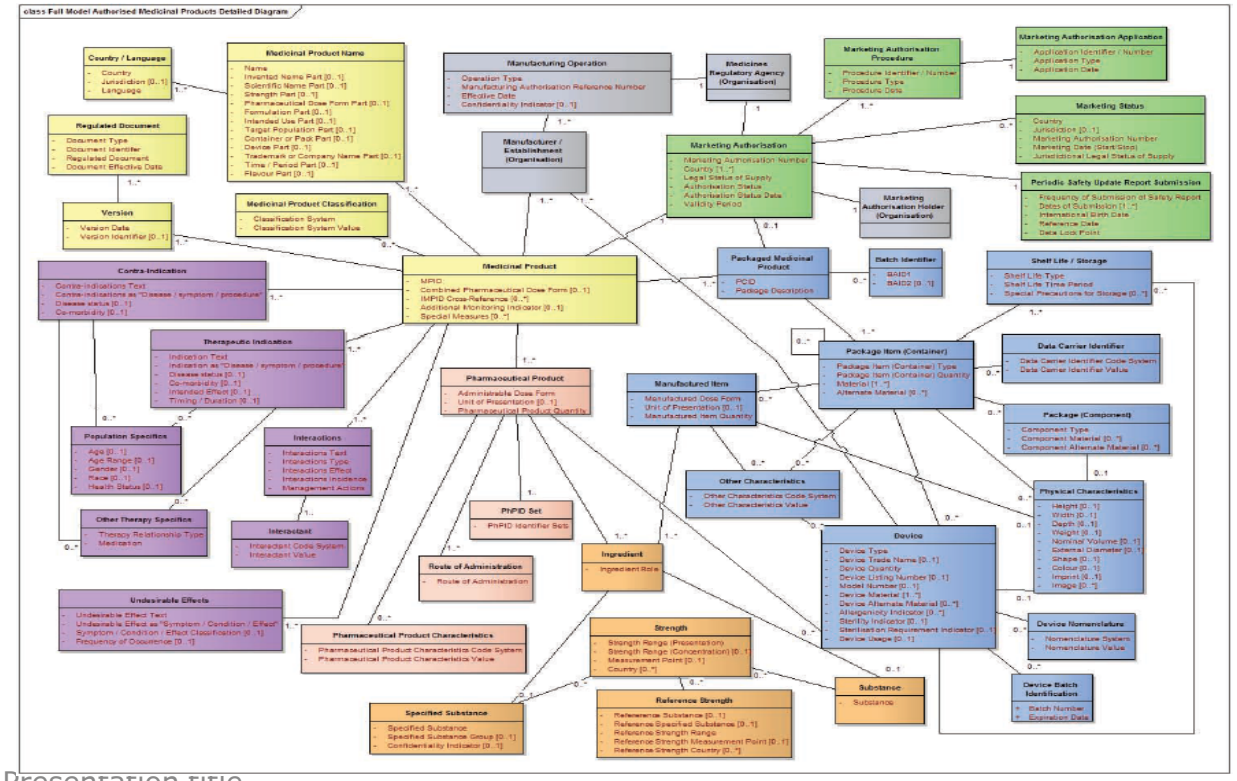
Pharmaceutical product (PhPID) - ISO 11616

Medicinal product (MPID/PCID) - ISO 11615



IDMP: from data models and terminologies to identifiers

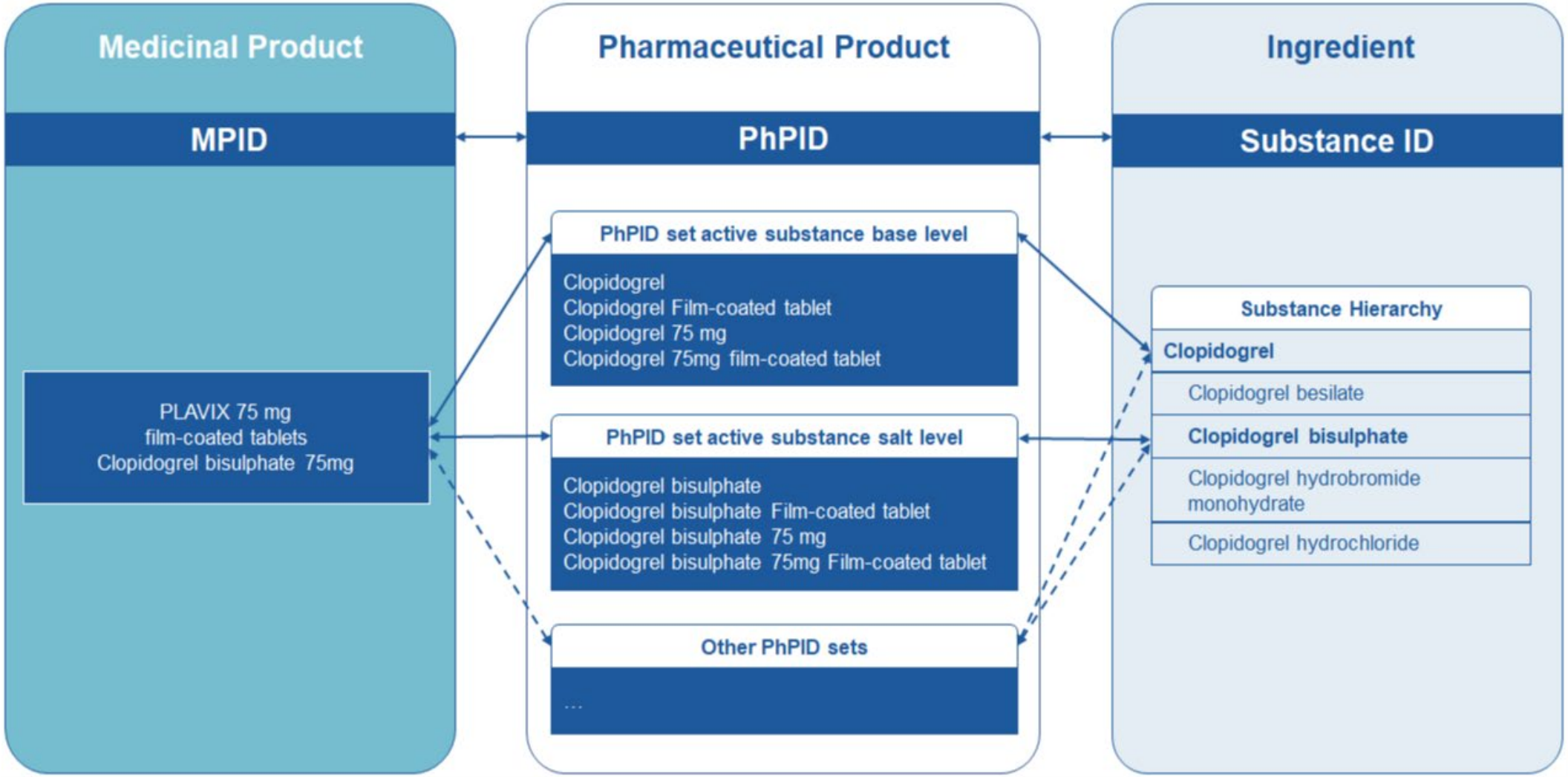
ISO Standards containing
~250 data attributes



Unique Product Identifiers

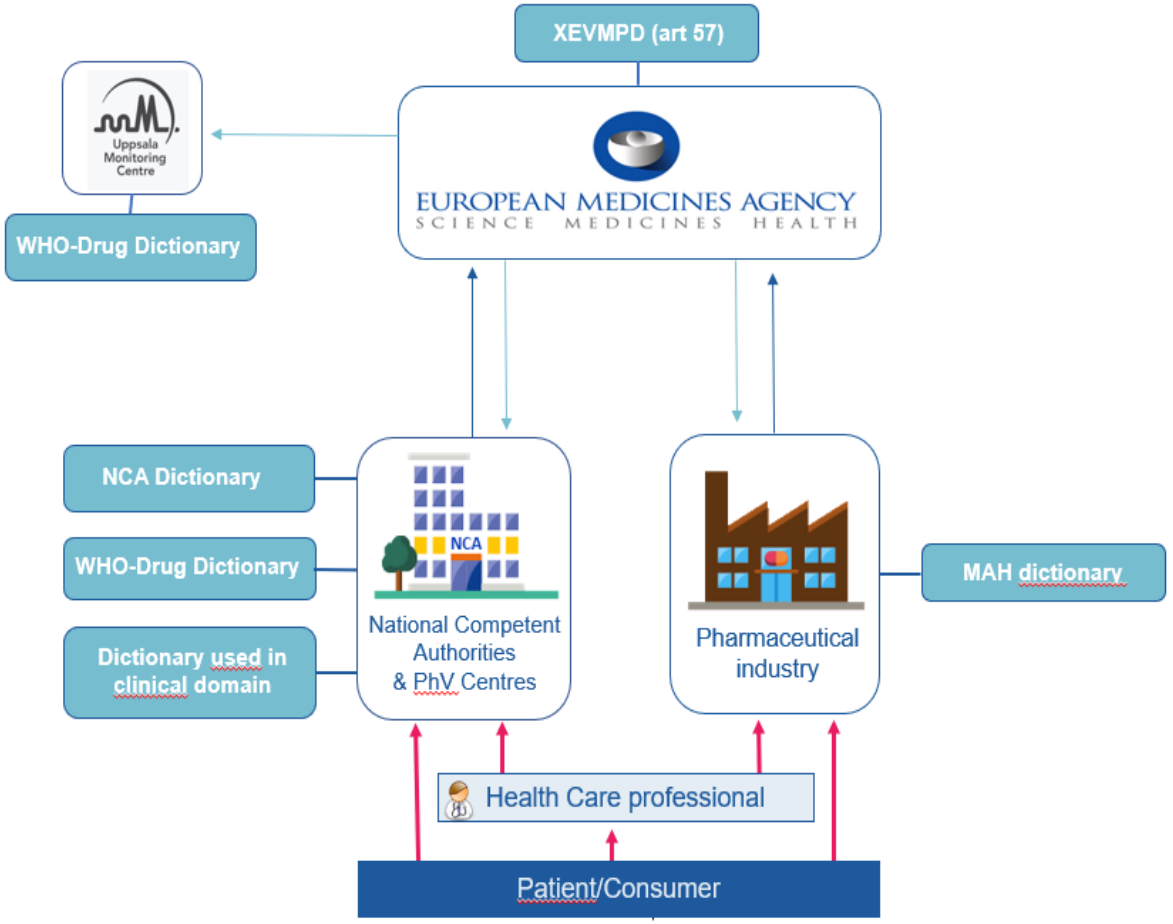
PHPID	Pharmaceutical Product ID
MPID	Medicinal Product ID
SID	Substance ID
PCID	Medicinal Product Package ID

IDMP identifiers - relationships



EU structured medicinal product data – ISO IDMP vision

- International exchange of Individual Case Safety Reports (ICSRs) was initial driver for developing IDMP standards
- Drug information is exchanged as free text, requiring classification against the drug dictionary implemented in the pharmacovigilance database
- Replacing free text drug information with IDMP identifiers is expected to:
  - Improve efficiency of ICSR processing
  - Improve accuracy of data analysis of ICSRs
  - Improve collation of data globally facilitating earlier signal detection



Light and dark blue arrows indicate exchange in ICSR format.

ISO IDMP in ICSRs

- The ISO ICSR standard in ICH E2B(R3) format became mandatory in EU in June 2022
- E2B(R3) format already uses 2 IDMP standards
- E2B(R3) format contains data-elements for transmitting IDMP identifiers MPID, PhPID, (Specified) Substance ID
  - EU Individual Case Safety Report (ICSR)1 Implementation Guide explains that free text is used until such identifiers are implemented
  - Different levels can be used within the ICSR – depending upon what information on medicine is available

ISO IDMP	Description	EU ICSR
11238	Data elements and structures for unique identification of regulated information on **Substances**	⏳
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**	✓
11240	Data elements and structures for unique identification of **units of measurements**	✓
11615	Data elements and structures for unique identification and exchange of regulated **Medicinal product information**	⏳
11616	Data elements and structures for unique identification and exchange of regulated **Pharmaceutical product information**	⏳

ISO IDMP groups

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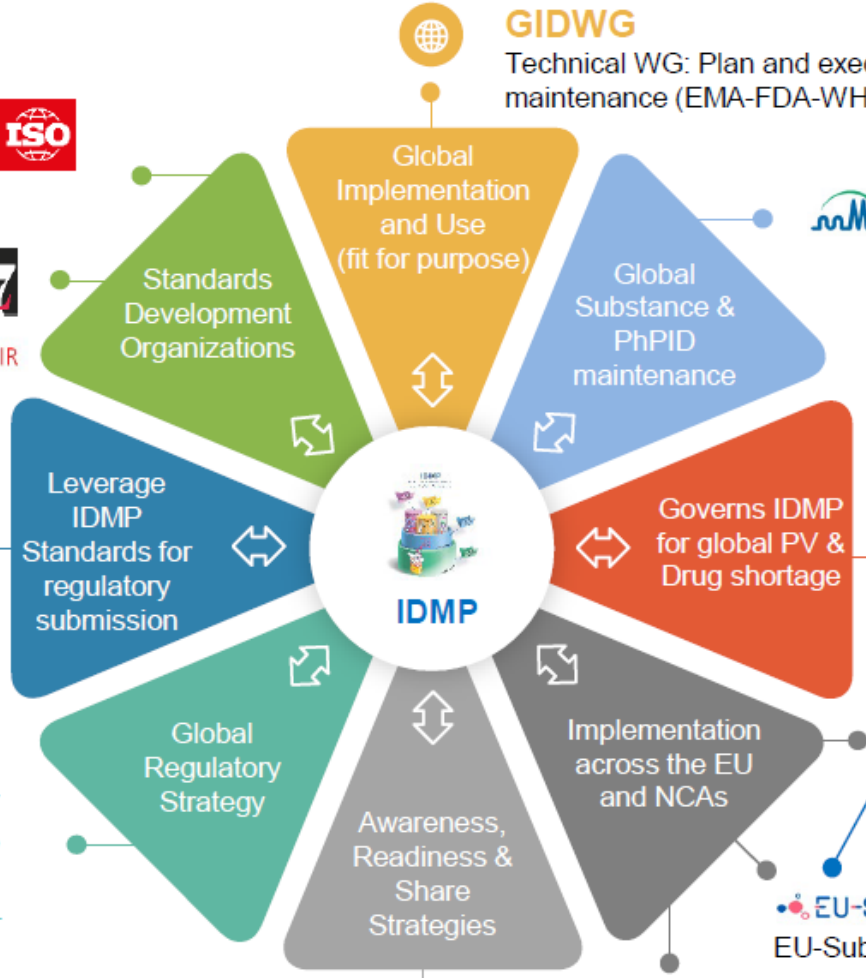

GIDWG

Technical WG: Plan and execute projects focused on global implementation and maintenance (EMA-FDA-WHO/UMC + Regulators + Observers +SMEs)

ISO

Develop and maintenance of the IDMP standards, technical specifications and reports

HL7

Develop and maintenance of the IDMP messaging standards

FHIR

WHO-UMC

Proposed Global IDMP Maintenance Organization

WHO EWG

Use & support of global IDMP for LMICs.

- 12 experts appointed by WHO HQ (representing 6 WHO regions) + Observers + SMEs
- Regulators can be observers

ICH

- M4Q Quality Data Standards
- E2B ICSR

ICMRA

A Regulatory Pharmaceutical Quality Knowledge Management System (PQ KMS) to enhance the availability of quality medicines.

ICMRA-ICH-PIC/S-IPRP Joint Reflection Paper

EMA/EU

IDMP/ SPOR master data management services

FDA GSRS

EMA-FDA international CF on IDMP

EU-SRS

EU-Substance Registration System

- IDMP Frequently asked Questions
- IDMP Readiness Checklist

IPRP International Pharmaceutical Regulators Programme

UNICOM

EU-funded project for IDMP implementation at NCA level

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EudraVigilance: from XEVMPD to PMS

Progress towards use of ISO IDMP in EudraVigilance

EudraVigilance Medicinal Product Dictionary (XEVMPD) – Art 57 database and development products

- Product database used for the submission of authorised medicinal product information under Article 57(2) of Regulation (EC) 726/2004
  - All authorised EU products, including nationally authorised, MRP/DCP and centrally authorised products – starting July 2012
  - Submission within required timelines after marketing authorisation (15 days) and maintenance following variations (30 days)
- Supporting submission of development/ investigational medicinal product information

Safety reports: making use of product names (XEVMPD)

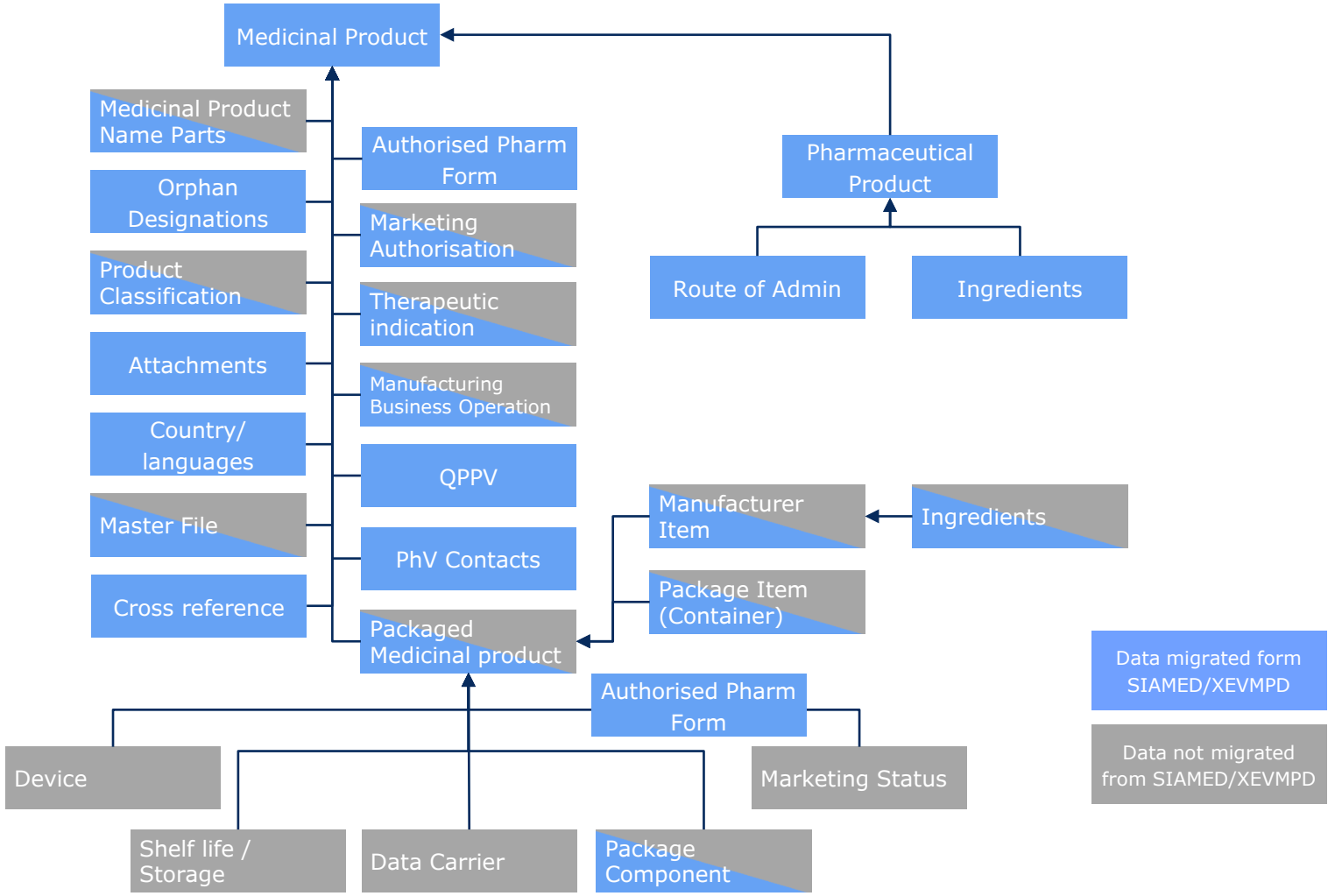
Num	EV Code	Full Presentation Name	Product Short Name
☑ 0001	PRD616412	Nurofen 400 mg überzogene Tabletten	Nurofen
☑ 0002	PRD2899373	NUROFEN 200 mg, comprimé orodispersible	NUROFEN
☑ 0003	PRD3337627	NUROFEN GEL, gel 5%	NUROFEN
☑ 0004	PRD620594	NUROFEN 200 mg drajeuri	NUROFEN
☑ 0005	PRD636255	Nurofen, 200 mg, tabletki powlekane	Nurofen
☑ 0006	PRD701281	Nurofen 40 mg/ml Suspension zum Einnehmen	Nurofen
☑ 0007	PRD642987	Nurofen for Children Sachets 100mg/5ml Oral Suspension	Nurofen for Children
☑ 0008	PRD640453	Nurofen for Children Orange 200 mg/5 ml suspensija iekškigai lietošanai	Nurofen for Children Orange
☑ 0009	PRD640872	Nurofen for Children Strawberry 200 mg/5 ml suspensija iekškigai lietošanai	Nurofen for Children Strawberry
☑ 0010	PRD640816	Nurofen for Children Six Plus Strawberry 200mg/5ml Oral Suspension	Nurofen for Children Six Plus Strawberry
☑ 0011	PRD639050	Nurofen für Kinder Zuckerfrei 4% Suspension zum Einnehmen	Nurofen für Kinder Zuckerfrei
☑ 0012	PRD616416	Nurofen für Kinder suppo 125 mg, Zäpfchen	Nurofen für Kinder
☑ 0013	PRD616417	NUROFEN VOOR KINDEREN 200 mg omhulde tabletten	NUROFEN VOOR KINDEREN
☑ 0014	PRD627875	Nurofen voor Kinderen suikervrije suspensie	Nurofen voor Kinderen suikervrije

- Reporting Names - Presentations (6)
  - Active - Nurofen
  - Active - NUROFEN 200MG
  - Active - Nurofen 200MG TABLETKI POWLEKANE
  - Active - Nurofen TABLETKI POWLEKANE
  - Hidden - Nurofen TABLETKI POWLEKANE 200MG
  - Active - Nurofen, 200 mg, tabletki powlekane

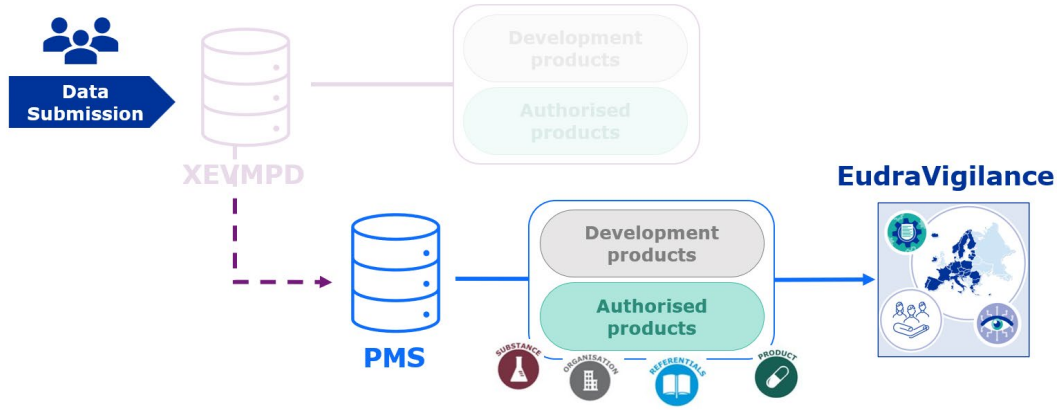
- Reporting Names - Scientific (4)
  - Active - IBUPROFEN, CODEINE PHOSPHATE HEMIHYDRATE
  - Active - IBUPROFEN, CODEINE PHOSPHATE HEMIHYDRATE - FILM-COATED TABLET
  - Active - IBUPROFEN 200mg Tablet, CODEINE PHOSPHATE HEMIHYDRATE 12.8mg Tablet
  - Active - IBUPROFEN 200mg Tablet, CODEINE PHOSPHATE HEMIHYDRATE 12.8mg Tablet - FILM-COATED TABLET

Data migration from XEVMPD to PMS

- ~180 PMS repeatable fields vs ~ 50 XEVMPD fields.
- Authorised products data is migrated from existing source systems: XEVMPD (and SIAMED for centrally authorised products).
- Fields are populated using structured logic to transform EV codes referring to substance, organisation, and referential data into SOR master data aligned with ISO standards.
- Free text fields (e.g., Package description) are migrated on a 1:1 match basis with PMS free text fields.
- Where possible, free text data (ie. Paediatric use indicator) is transformed into structured and standardised IDMP product data within PMS.

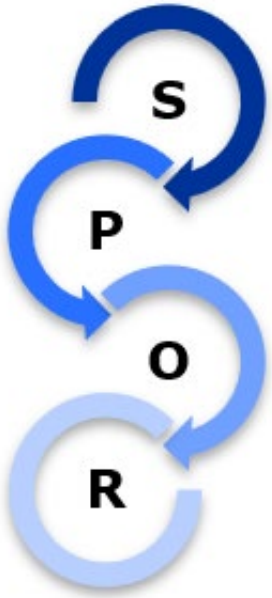


Towards integration of XEVMPD with SPOR data



SPOR integration – supporting data interoperability today

- Substance: data in XEVMPD is mapped to SMS and maintained by SMS service.
- Product: PMS consumes XEVMPD data and supports its enrichment
- Organisations: data is mapped against OMS and used during submission of data
- Referentials: mappings have been created and maintained for pharmaceutical forms, routes of administrations, ATC codes, MedDRA codes



SPOR integration – looking towards the future

- Substance: Supporting a better granularity and hierarchy, including the building of PhPIDs
- Product: data to be submitted directly in PMS and XEVMPD to be replaced
- Organisations: organisation data used in products; QPPV submission to be supported
- Referentials: directly used as part of product information

Moving forward with PMS

What it takes

- Enable data submission & management in PMS
- Address legacy data and systems
- Integrate with regulatory processes

Who needs to be involved

- Multiple teams across different regulatory use cases
- NCAs, MAHs and sponsors

When it will be done

- Many network and portfolio priorities
- NDSG & ROG recommendation
- No formal prioritisation has taken place yet

How it will be done

- With consideration of resource & system dependencies
- Close collaboration
- Open stakeholder communication

*PMS implementation (particularly XEVMPD replacement) is a **multi-year effort.***

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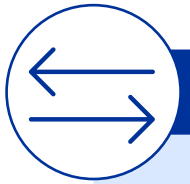
Key benefits of replacing XEVMPD with PMS

Improvements to eRMR generation

Improved eRMR (reaction monitoring report) and data analysis:

- additional product information will allow a better granularity, supporting the aggregation of data
- Improvements in the technology used will allow integration with technology advancements (e.g. use of AI, data analytics platform)



Enhanced interoperability

Benefits from the ISO IDMP (Identification of Medicinal Products) data standard, facilitating data exchange and data analysis. Integration with SPOR terminologies

Advanced reporting and analytics

Allows stakeholders (e.g. regulatory authorities, sponsors, MAHs, manufacturers) to track updates on a medicinal product more efficiently *(including regulatory status, safety monitoring and adverse event reporting, clinical trial results, …)*

Key takeaways

1. XEVMPD is **currently** the receiving system for authorised and development data and supporting pharmacovigilance use cases. PMS consumes XEVMPD data and enriches it, supporting several regulatory use cases.

2. **Transition** towards a target state has progressed over the past years, with substance, organisation and referential data mapped between XEVMPD and SPOR.

3. Target state: **unique and shared repository** of trusted product master data in ISO IDMP format for all human medicinal products in the EU throughout their life cycle (development and authorised) – integrating regulatory use cases, including pharmacovigilance

4. Exploiting the benefits of **ISO IDMP identifiers** in ICSRs requires well planned implementation with pharmacovigilance stakeholders to agree on a harmonized approach and guidance.

Thank you

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