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Up-scaling the global univocal identification of medicines

Goals, Activities, IDMP Implementation Challenges

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European Innovation Action – Goals, Context, Challenges

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Vision & Mission

Vision

- Improving patient safety
- Facilitating better healthcare for all

Mission

- Enabling the univocal identification of medicinal products by supporting and accelerating the
  - further development,
  - implementation, and
  - diffusion of ISO IDMP standards (IDentification of Medicinal and pharmaceutical Products)
- across European health systems, to
- facilitate the free flow of semantically coded interoperable drug information

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Key Challenges across Europe

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- Across health systems, the *same* medicinal product (MP) may have *different names*
- Dosage strengths or package sizes may also *vary* or *not be available*
- Across countries, the *same* name may identify a *different* product (with a different *active* substance)
- Across countries, the number and kind of MPs authorised for national marketing differ very considerably (due to marketing strategies of producers, plus three different marketing authorisation procedures at EU and national levels)
- The interoperable flow of MP data in regulatory processes is hampered and inefficient
- In cross-border ePrescription (eP) services this necessitates *substitution* in many, if not the majority of instances - if a *specific MP* is specified in a prescription
- CEF eHDSI (xBorder services) specifications require MPs in an eP or PS (patient summary) to be described in a structured & coded format, but these are not (yet) available in national MP Dictionaries for a significant number of MPs
- Similar challenges apply to the electronic recording of MPs in *other healthcare contexts*
- The missing univocal identification of medicines hampers timely global *pharmacovigilance* reporting and warnings

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Application Domains and Objectives

By accelerating the diffusion of ISO IDMP standards UNICOM supports

- **regulatory processes** of National Medicines Authorities (NMAs) & the European Medicines Agency (EMA)
- **cross-border digital health services** (ePrescription, Patient Summary**)**
- **global pharmacovigilance**
- **better healthcare, public health, medical research** (e.g. Big Data Analytics, Artificial Intelligence applications)

Core objectives focus on:

- Adaptation and **implementation of IDMP at NMA/EU levels**
- Adaptation of Member States **cross-border digital health services** (ePrescription; Patient Summary…) to IDMP
- Exploration and implementation of IDMP for **pharmacovigilance** reporting, Medicinal Product Dictionaries (MPDs), **digital health** support services, patient empowerment

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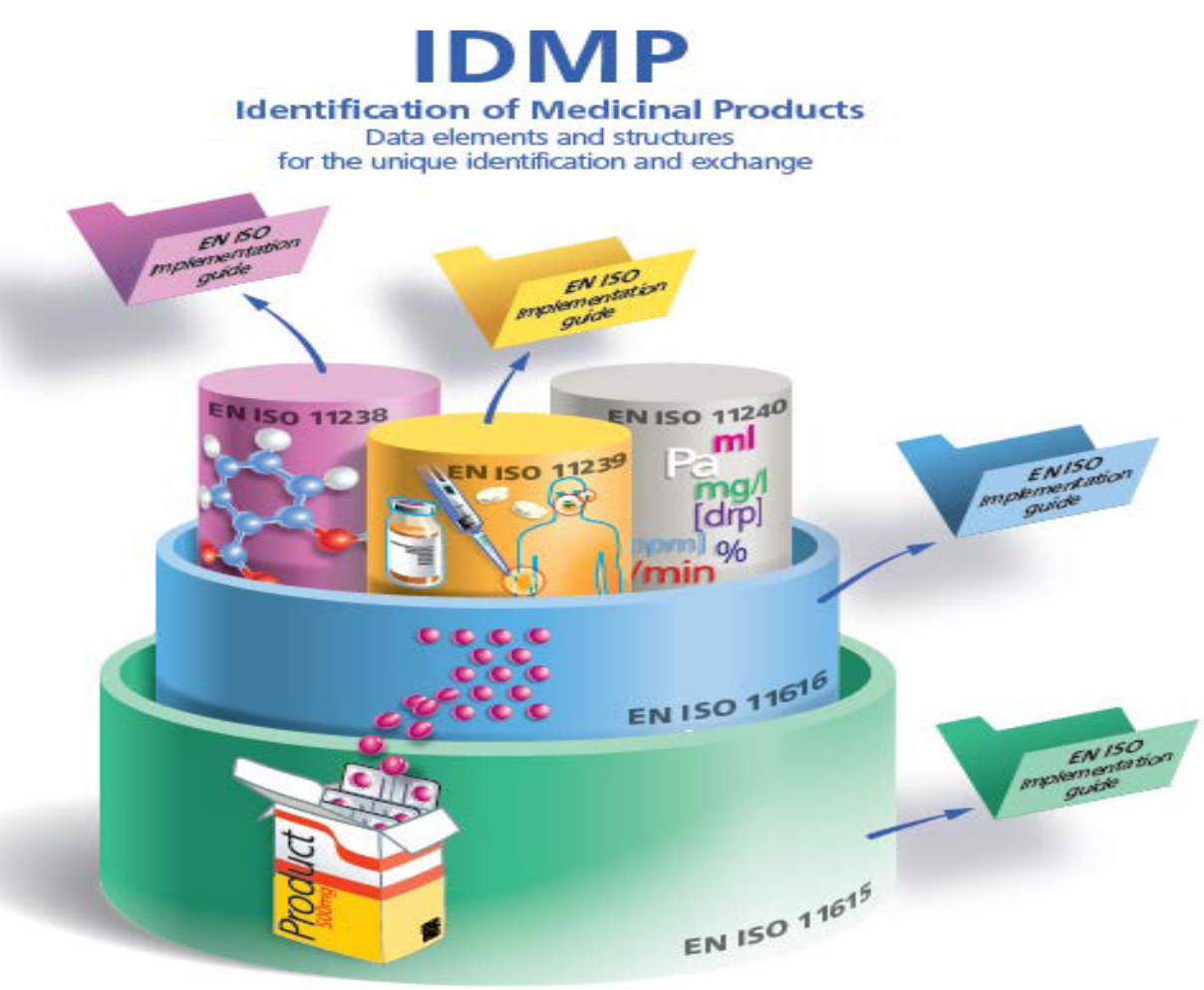
ISO IDMP Suite of Standards



The ISO IDMP standards establish definitions and concepts and describe data elements and their structural relationships that are required for the unique identification of:

- ***Medicinal* products** (MPID) and **packages** (PCID) - ISO 11615
- ***Pharmaceutical* products** (PhPID) - ISO 11616
- **Substances** (Substance ID) - ISO 11238
- **Pharmaceutical** dose forms, units of presentation, routes of administration and packaging - ISO 11239
- **Units of measurement** (UCUM) - ISO 11240

ISO IDMP standards apply to both authorised and developmental medicinal products for *human* use

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Response to Regulatory Requirements

Implementing Regulation (EU) No 520/2012 on "the performance of pharmacovigilance activities"

- **states that "*terminology* set out in the ISO IDMP suite of standards" is binding for "Member States, marketing authorisation holders and the [European Medicines] Agency."**
- **specifies this as "internationally agreed terminology" applied "for … electronic exchange and communication of pharmacovigilance and *medicinal product information*."**

- **notes that with respect to the use of *formats and standards*, the application of ISO IDMP is *not mandatory*,**
  - ➔ **but it suggests that "national competent authorities, marketing authorisation holders and the Agency may also apply" the IDMP suite of standards for these aspects.**

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Enabling a Seamless IDMP Data Value Chain

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UNICOM will help to break down barriers hindering the free flow of detailed, semantically coded interoperable drug information across the globe, thereby

- facilitating data sharing amongst health professionals and patients everywhere
- Providing semantically interoperable information for all actors dealing with data and issues around medicinal products

This will deliver individual, social, societal, and economic benefits to

- ✓ Pharmaceutical companies applying for marketing authorisation of medicinal products
- ✓ National medicinal products authorities
- ✓ Providers of medicinal product dictionaries
- ✓ Clinical software producers
- ✓ Healthcare professionals (incl. pharmacists)
- ✓ Patients
- ✓ Start-ups developing intelligent apps for patient empowerment
- ✓ xBorder Digital health services (patient summaries, ePrescriptions, and beyond)
- ✓ Medical research
- ✓ Public Health

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UNICOM Action Lines

To achieve the objectives envisaged and reach the outcomes foreseen, UNICOM is organised along three closely interrelated vertical action lines:

I. **Implementation of IDMP at national and EU level (WPs 2 – 4)**

II. **Adaptation of cross-border digital health services (WPs 5 – 7)**

III. **Exploration for pharmacovigilance services, Medicinal Product Dictionaries [MPDs], healthcare services, patient empowerment, Big Data etc. (WPs 8 – 9)**

These three action lines are supported by two horizontal activity clusters:

a) **Further development of IDMP standards and implementation support (WP 1)**

b) **Socio-economic impact assessment and sustainability strategies, scientific coordination, project management, awareness raising/dissemination, ethics (WPs 10 – 13)**

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IDMP (WP 1): Virtual Workshops presentations:

No.	Subject	Presenters
1	**ISO, CEN, and IDMP standards**	Christian Hay, GSI/ISO/NICTIZ
2	**IDMP Origins, Relationships and Use Cases**	Vada A. Perkins, Call to Action-Delivering Health Literacy (CTADHL), US ANSI Technical Advisory Group WG 6 IDMP Lead
3	**IDMP in HL7 FHIR**	Hugh Glover, Chris Kravogel
4	**GS1 and UNICOM**	Christian Hay, GS1; Laure Pontis, Assistant Manager Public Policy Healthcare, GS1 Global Office
5	**EN ISO 11238 IDMP Substances; 19844 Substance Implementation Guide**	Herman Diederik, CBG-MEB (NL), Operational Management Department, Scientific lead EU-Substance Registration System
6	**EN ISO 11239: Pharmaceutical dose forms, Routes of administration, Packaging, Units of presentation**	Chris Jarvis; Robert Stegwee
7	**IDMP & Falsified Medicines Directive**	Jean-Gonzague Fontaine; Laure Pontis
8	**Identifiers - Medicinal Product, Marketing Authorization, Pharmaceutical Product and Package Medicinal Product**	Jean-Gonzague Fontaine, ISO TC 215 WG 6 « Pharmacy and Medicines Business » Expert
9	**Medicinal Product identification - IDMP/ SNOMED/others**	Jane Millar; Monica Harry; Lise Stevens
10	**IDMP & Individual Case Safety Report (ICSR)**	Anja van Haren; Lise Stevens
11	**IDMP & ePrescription, dispensing**	Robert Vander Stichele; Giorgio Cangioli, HL7 Foundation-Europe
12	**HL7 Standards activities related to UNICOM**	Catherine CHRONAKI, Giorgio Cangioli, HL7 Foundation-Europe
13	**Pharmaceutical Product - sources for ID generation (algorithm)**	Leonora Grandia; Shirin Golyardi
14	**Introduction to Integrating the Healthcare Enterprise (IHE)**	Karima Bourquard, IHE-Europe
15	**Swiss Projectathons**	Juerg P. Bleuer, Deputy Head of „eHealth Suisse“

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Core activities by National Medicines Authorities (NMAs)

Action Line I: Implementation of IDMP at national and EU level

EU Substance Registration System (EU-SRS)

- **EU-SRS**
  - EU regulatory-network-wide accessible, structured database
  - unambiguous identification of substances in medicinal products based on their scientific properties
  - in accordance with ISO IDMP standard 11238 (Substance IDs) and ISO standard 19844 (Implementation guidelines for ISO 11238 for data elements and structures)
- **HMA endorsed implementation plan (first phase ready by 2021/22)**
- **Linked with EMA SPOR (substances, products, organisations, referentials) IDMP-compatible databank system, particularly SMS [Substance Management System])**

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Common EU Submission Platform (CESP)

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- Applying for authorisation of medicinal products & managing their life cycles
- Electronic forms compliant with IDMP
- IDMP compliant electronic tools supporting
  - Initial application
  - Variation
  - Renewal activities
- Replace the legacy PDF-technology based application forms with the web-based CESP Dataset Module
- Integration with EMA's SPOR services
- Ensure well-structured IDMP compliant interoperable drug information for all further processes and actors

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IDMP Implementation at National Medicines Authorities

- **11 national implementation projects**
- **Austria, Belgium, Croatia, Estonia, Finland, Germany, Ireland, Norway, Portugal, Spain, Sweden (plus The Netherlands)**
- **Development of guidelines, training and knowledge about IDMP**
- **Adaptation of the European Communication and Tracking System (CTS)**
  - Used for tracking and co-ordinating pre- and post-licensing regulatory processes
  - for human and veterinary medicinal products
  - authorised via mutual recognition and decentralised procedures

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IDMP and European crossBorder digital health services (ePrescription; Patient Summary)

Action Line II: Adaptation of cross-border digital health services

Use Case: xBorder ePrescription & dispensation process

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Country A

Pharmaceutical Product

Medicinal Product

Package

Common level is usually pharma-ceutical product, i.e. substitution or selection required

Same medicinal product (if available)

Product is specified at any of the IDMP levels in an ePrescription

Country B

PhP

MP

PC

Product is further specified, thanks to standardised attributes

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Changes foreseen on EU eHealth Digital Services Infrastructure (eHDSI)

- **Functional specifications revised** to include the adoption of ISO IDMP
  - **Revision** of the CEF eHDSI **Master ValueSet Catalogue (MVC)** for the ValueSets affected by the adoption of ISO IDMP coding
- **Guidelines and recommendations for implementation** of eP / eD and PS processes
- **The Implementation Guides of eP/eD and PS** are used by Member States to **implement the HL7 CDA documents and by the CEF eHDSI Solution Provider**
- Relevant CEF eHDSI **Change Proposals will be drafted** and submitted to the CEF eHDSI
  - These Change Proposals will **address technical specifications and the OpenNCP components** and functionalities

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Further Information on UNICOM

Facts

Duration:	**Dec. 2019 – Nov. 2023 (4 years)**
Budget:	**€ 21 m; European Commission funding is € 19 m**
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Open Issues, Discussion Points

Who are the most important SDOs and actors involved in or related to IDMP?

- **ISO/CEN**
- **HL7 – FHIR**
- **SNOMED**
- **MedDRA**
- **CDISC**
- **EDQM**
- **UCUM**
- **IHE**
- **WHO** (INN, ATC/DDD, ICD, …)
- **WHO CC:** UMC (Uppsala Monitoring Centre for Pharmacovigilance); Oslo Drug Statistics Methodology Centre
- **ICH (1E2B(R3) ICSR)**
- **GS1**
- **Joint Initiative Council**
- **… (others?)**

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Organisational structures and processes

- Beyond the Joint Initiative Council – how is IDMP development and implementation guidance coordinated globally?
- Does there exist a global governance for harmonisation?
- Should the involved SDOs establish a common knowledge and experience exchange/lessons learned repository?
- What processes have been/should be established for involvement of core actors like National Medicines Authorities, EMA, pharma industry, medicinal products dictionary providers, clinicians, …
- Where and how can new requirements or gaps identified by core actors be recorded?
- How can the consistent, compatible implementation of IDMP ensured?
- How can UNICOM become involved? What needs to be done?

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Concrete issues:

- **Who decides on how/on which basis globally unique PhPIDs (MPIDs…) will be calculated?**
- **Who takes definite decisions on the terminology to be used?**
- **Who ensures that the ‚relevant' languages are covered? („ SNOMED CT is currently available in US English, UK English, Spanish, Danish and Swedish" [only] – their website)**
- **Can we harmonise, or do we need mapping, and with how much resources? ("With regard to the IMI-WEB-RADR project, a bi-directional mapping of a *subset of terms* focusing on most frequently reported ADRs was created")**
- ***UNICOM National Medicines Authorities will create their own implementation guidance where no rules have been established – an implementation island may result***
- ***…***

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Thank you!