UNICOM: IDMP in Europe

What does it mean for you?
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UNICOM Work Package Lead on IDMP-related standards and terminologies
UNICOM aims:

to break down barriers hindering the free flow of detailed semantically coded interoperable medicinal product information across the globe

UNICOM objectives:

Implementation of IDMP for Marketing Authorization in EU countries and at EU level

Adaptation of Member States’ cross-border digital health services to include IDMP ePrescribing and eDispensing Patient Summary

Exploration and implementation of IDMP in clinical practice:
pharmacovigilance reporting medicinal product dictionaries digital health services
What Digital Health Services to expect?

Elena's Journey
From Athens to Brussels

Elena's Journey
Intestinal pain

Elena's Journey
OTC medicine options in Belgium

Elena's Journey
Overcome language barrier

Elena's Journey
Decision support

Elena's Journey
Update Health Record

Full video on YouTube
EC supported Innovation Action on the implementation of IDMP standards

A broad consortium of partners
- 14 National Competent Authorities for Medicinal Products – including support from the European Medicines Agency
- 7 National eHealth Competence Centers / National eHealth Contact Points
- 5 Industry Partners (Health IT)
- 5 Research Organisations
- 2 Medicinal Database Providers
- 11 Standards Developing Organizations

4 year program: 2020-2023

13 work packages

21 M€ total budget

National implementations in: Austria, Belgium, Croatia, Estonia, Finland, Germany, Ireland, Norway, Portugal, Spain, Sweden, The Netherlands

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The UNICOM project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 875299
Work Package 1 is grouping Standard Development Organisations (SDO) and related organisations, which have a transversal impact on UNICOM.

Our main task: to facilitate the implementation of IDMP Data Exchange

- Nearly 100 different standards define, use or should use IDMP in data exchange
- Liaising with all other WP, to gather their needs and provide inputs about standards
What is your role in the life-cycle of a medicinal product?
Which of the high-level processes are you engaged in?

- Development and Production
- Regulation and Authorization
- Dissemination and Information
- Prescription and Dispensation
- Utilization and Outcome Assessment

- Marketing Authorization and Pharmacotherapeutic Surveillance of Medicinal Products
- Effective Clinical Use of Medicinal Products
- Controlled Supply Chain of Medicinal Product Packages
Examples from our UNICOM Community of Expertise

SNOMED International presentation on the representation of clinical information

1. Medicinal Product Dictionaries making available the Formulary and Decision Rules
2. Clinical Decision Support based on Formulary and Decision Rules
3. Ambulatory prescribing
4. Ambulatory dispensing
5. Adverse event reporting for (global) pharmacovigilance

Full recording available on YouTube including real experience from MHRA
Medicinal Product Dictionaries

Application fields

Combining the perspectives

Implementation domains

Regulation and Authorization

Dissemination and Information

Prescription and Dispensation

Utilization and Outcome Assessment

Development and Production

Marketing Authorization and Pharmacotherapeutic Surveillance of Medicinal Products

Effective Clinical Use of Medicinal Products

Controlled Supply Chain of Medicinal Product Packages

Pharmacotherapeutic Drug Class Identifiers

International Nonproprietary Names

Global Identification of Medicinal Products

National Identification of Medicinal Products and Packages

Global Unique Identification of Medicinal Product Packages
Medicinal Product Dictionaries

IDMP Identifiers

SNOMED Drug Model

SNOMED National Drug Extension

IDMP and Local Medication Identifiers

National Drug Database

MedDRA codes for Indication, Adverse Effects, etc.

EDQM for Route of Administration and Dose Forms

ISO TS 19256 Requirements for MPD Systems

EDQM and MedDRA maps to SNOMED CT

ISO TS 22756 Requirements for a CDS knowledge base

SNOMED CT for disorders, allergies, dose forms in decision rules

Formulary

Decision Rules
Clinical decision support for prescribing

- Development and Production
- Regulation and Authorization
- Dissemination and Information
- Prescription and Dispensation
- Utilization and Outcome Assessment

- Marketing Authorization and Pharmacotherapeutic Surveillance of Medicinal Products
- Effective Clinical Use of Medicinal Products
- Controlled Supply Chain of Medicinal Product Packages
- Global Identification of Medicinal Products and Packages
- Global Unique Identification of Medicinal Product Packages

Pharmacotherapeutic Drug Class Identifiers
International Nonproprietary Names
Global Identification of Medicinal Products
National Identification of Medicinal Products and Packages
Clinical decision support for prescribing

- IDMP and Local Medication Identifiers
- SNOMED Drug Model and National Extension
- Local Medication Identifiers
- Formulary
- Decision Rules
- SNOMED CT for Conditions, Allergies, and Dose Forms in decision rules
- ISO TS 22756 Requirements for a CDS knowledge base
- SNOMED CT for Problems, Allergies, Current Medication in patient record
- EHR-S
- Prescription or Medication Order
Ambulatory prescribing and dispensing

Development and Production

Regulation and Authorization

Dissemination and Information

Prescription and Dispensation

Utilization and Outcome Assessment

Marketing Authorization and Pharmacotherapeutic Surveillance of Medicinal Products

Effective Clinical Use of Medicinal Products

Controlled Supply Chain of Medicinal Product Packages

Pharmacotherapeutic Drug Class Identifiers

International Nonproprietary Names

Global Identification of Medicinal Products

National Identification of Medicinal Products and Packages

Global Unique Identification of Medicinal Product Packages

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Ambulatory prescribing of medication

Local Medication Identifiers

EHR-S

SNOMED CT for Problems, Allergies, Current Medication in patient record

Prescription

ISO 17523 Requirements for Electronic Prescriptions

HL7 FHIR or CDA

Local Medication Identifiers

SNOMED CT codes for Problems, Indication and Allergies

IHE Community Prescription (PRE)
Ambulatory dispensing of medication

- HL7 FHIR or CDA
- Local Medication Identifiers
- GS1 item number and batch number
- SNOMED CT code for Indication and Allergies
- ISO TS 19293 Requirements for Record of Dispense

Pharmacy

Dispense record

IHE Community Dispense (DIS)
Adverse event reporting

Development and Production

Regulation and Authorization

Dissemination and Information

Prescription and Dispensation

Utilization and Outcome Assessment
Adverse event reporting

- EHR-S
- Local Medication Identifiers
- EHR-S → Local maps to IDMP Medication Identifiers
- Individual Case Safety Report
- Prepopulate
- SNOMED CT enabled codes for Route of Administration, Dose Forms, History, Indication and Reactions
- SNOMED CT maps to EDQM and MedDRA
- HL7 CDA Document
- IDMP Medication Identifiers
- EDQM for Route of Administration and Dose Forms
- MedDRA codes for History, Indication and Reactions
- EMA EU ICSR Implementation Guide
IDMP is being implemented in Europe right now

It involves an intricate interplay between a large number of standards and terminologies

It provides opportunities for all players in the medicinal product life-cycle
- Sometimes the impact is very limited
  - E.g. mapping of local codes to IDMP-compliant codes
- Sometimes it is quite extensive
  - E.g. redesigning the interface with the national drug database

You have the chance to get or stay involved:
- The UNICOM Community of Expertise discusses key issues
IDMP – an opportunity to streamline the use of medication data across the globe

Stay tuned through https://unicom-project.eu/ or contact robert@trace-health.nl directly!