Implementing IDMP to improve patient safety and facilitate better healthcare for all

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WP1 – IDMP related standards and terminologies

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

Agenda for today

- Problems to be solved
- UNICOM at a glance
- UNICOM aim and objectives
- IDMP Standards and related terminologies

- Landscape of standards use
- Role of SNOMED CT in all of this
- Information about resources available to engage with the project and the outcomes of implementation tests

Some key terms and abbreviations:

- IDMP – IDentification of Medicinal Products
  - A set of five interrelated ISO International Standards with four dedicated implementation guides
- ICSR – Individual Case Safety Report
  - An HL7 based reporting standard, including references to IDMP and other terminologies
- ePrescription / eDispensation
  - Current scenarios in the Cross Border eHealth Digital Service Infrastructure (eHDSI) based on IHE profiles and HL7 standards
  - Making use of a Master Value Sets Catalogue to enable safe and automatic translation of clinical terms across borders

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Problem to be solved: A simple use case on drug-drug interactions

IF 

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THEN 

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A case of reported side-effects

IF

IS REPORTED TO CAUSE DEPRESSION

WOULD THE SAME PRECAUTION HOLD FOR

?

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Or the well-known case of drug substitution

IF 

IS NOT AVAILABLE AT THIS TIME

COULD THIS BE SUBSITUTED BY 

OR 

?

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UNICOM at a glance – an 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
  - 8 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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UNICOM aims:

- to break down barriers hindering
- the free flow of
  - detailed
  - semantically coded
  - interoperable
- drug 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, Patient Summary)
- Exploration and implementation of IDMP in clinical practice:
  - pharmacovigilance reporting
  - medicinal product dictionaries
  - digital health services

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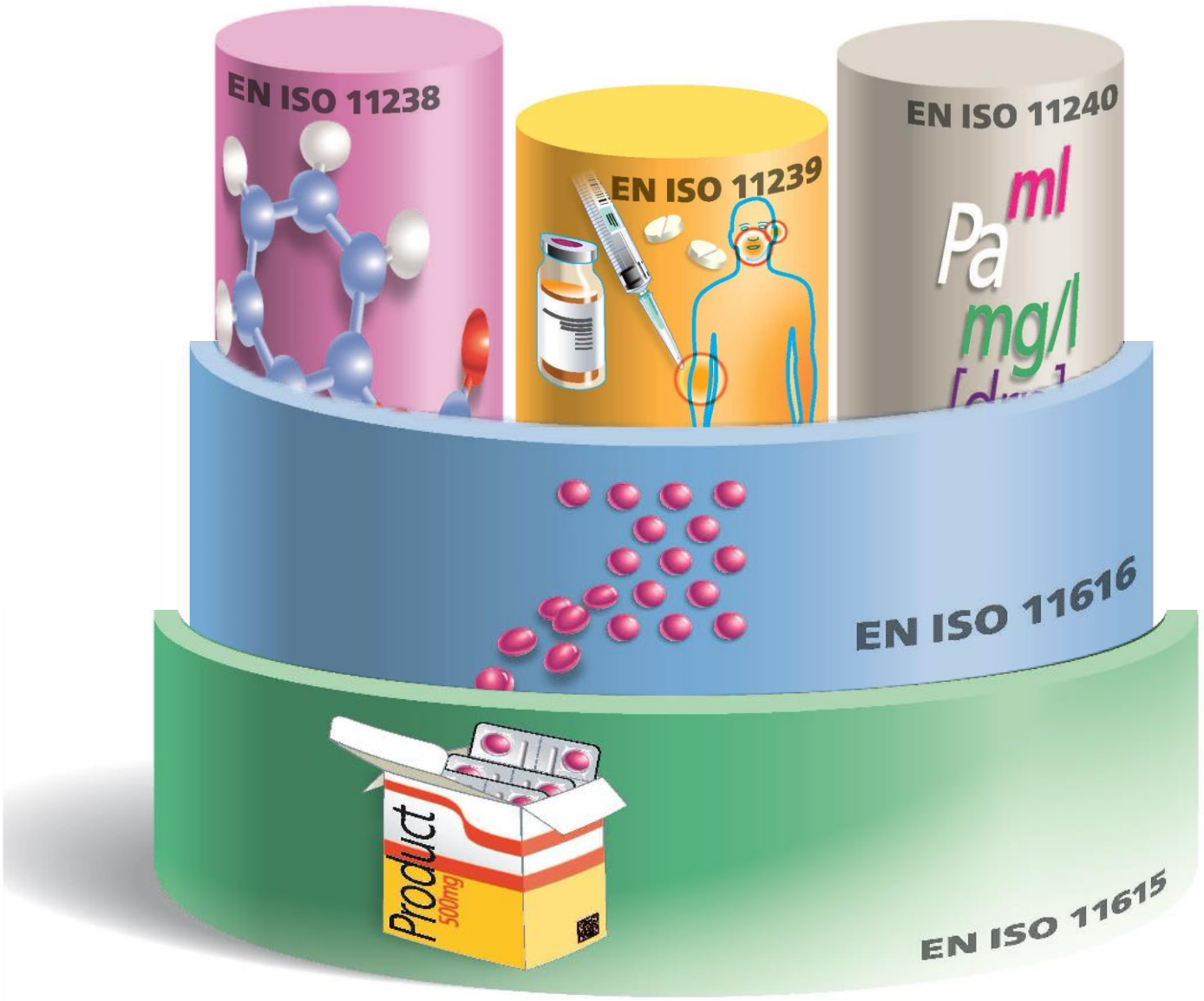
The IDMP standards are at the core of the standards and terminologies needed to achieve the objectives



EN ISO 11238:
identification and exchange of regulated information on **substances**

EN ISO 11239:
pharmaceutical **dose forms**, units of presentation, routes of administration and packaging

EN ISO 11240:
identification and exchange of **units of measurement**

EN ISO 11616
regulated **pharmaceutical product** information

EN ISO 11615
regulated **medicinal product** information

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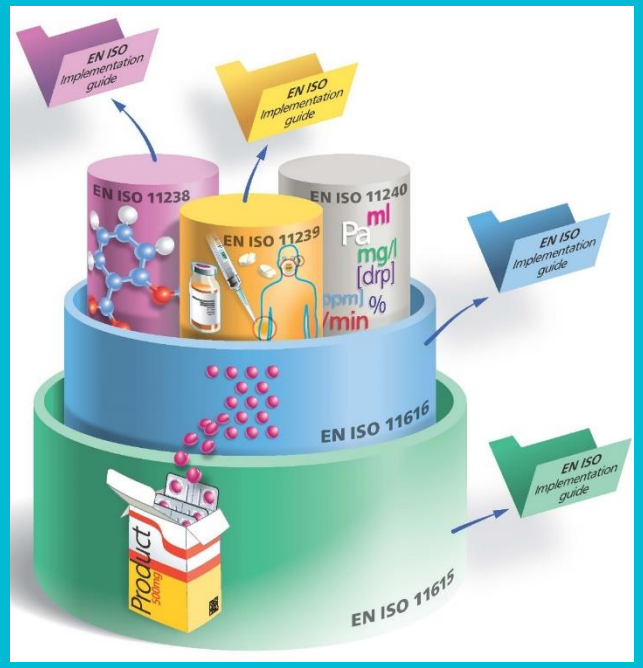

The relationship between IDMP and SNOMED CT

Jane Millar, SNOMED International

The use of standards varies across 3 Application fields and 5 Implementation domains

UNICOM

3 Application fields

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

5 Implementation domains

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

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Use cases requiring interoperability are found at the cross-roads of applications and implementations

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Combining the perspectives

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All Standards Developing Organizations will support the use of common identifiers for different purposes

UNICOM

CEN Health Informatics TC251

GS1

MedDRA

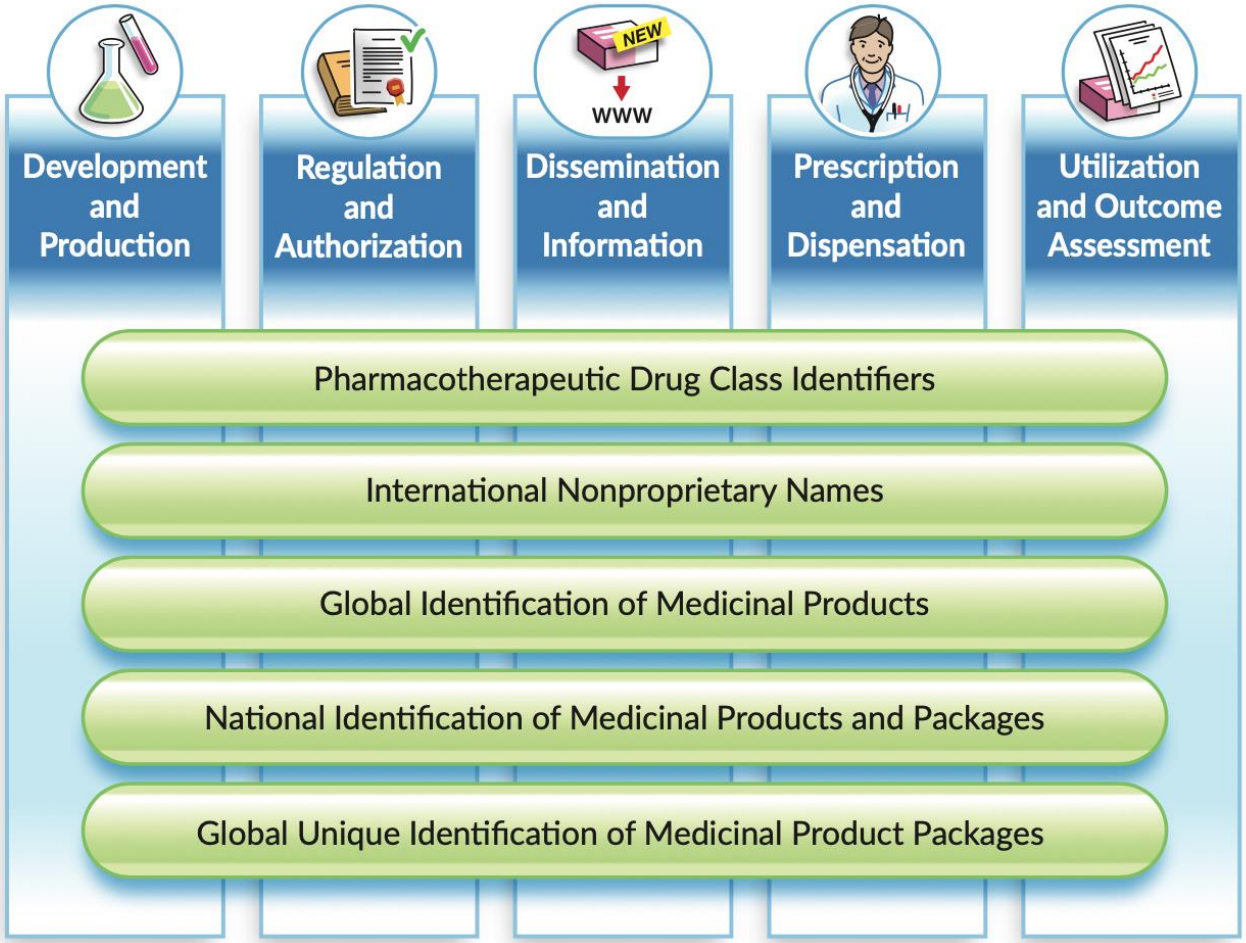
HL7 Europe

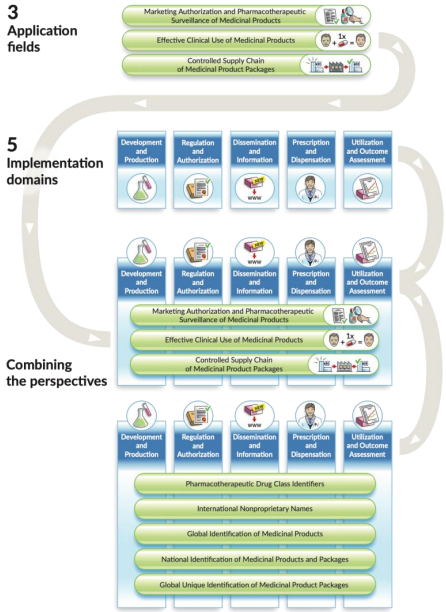
IHE EUROPE

ISO HEALTH INFORMATICS TC215

SNOMED International

WHO





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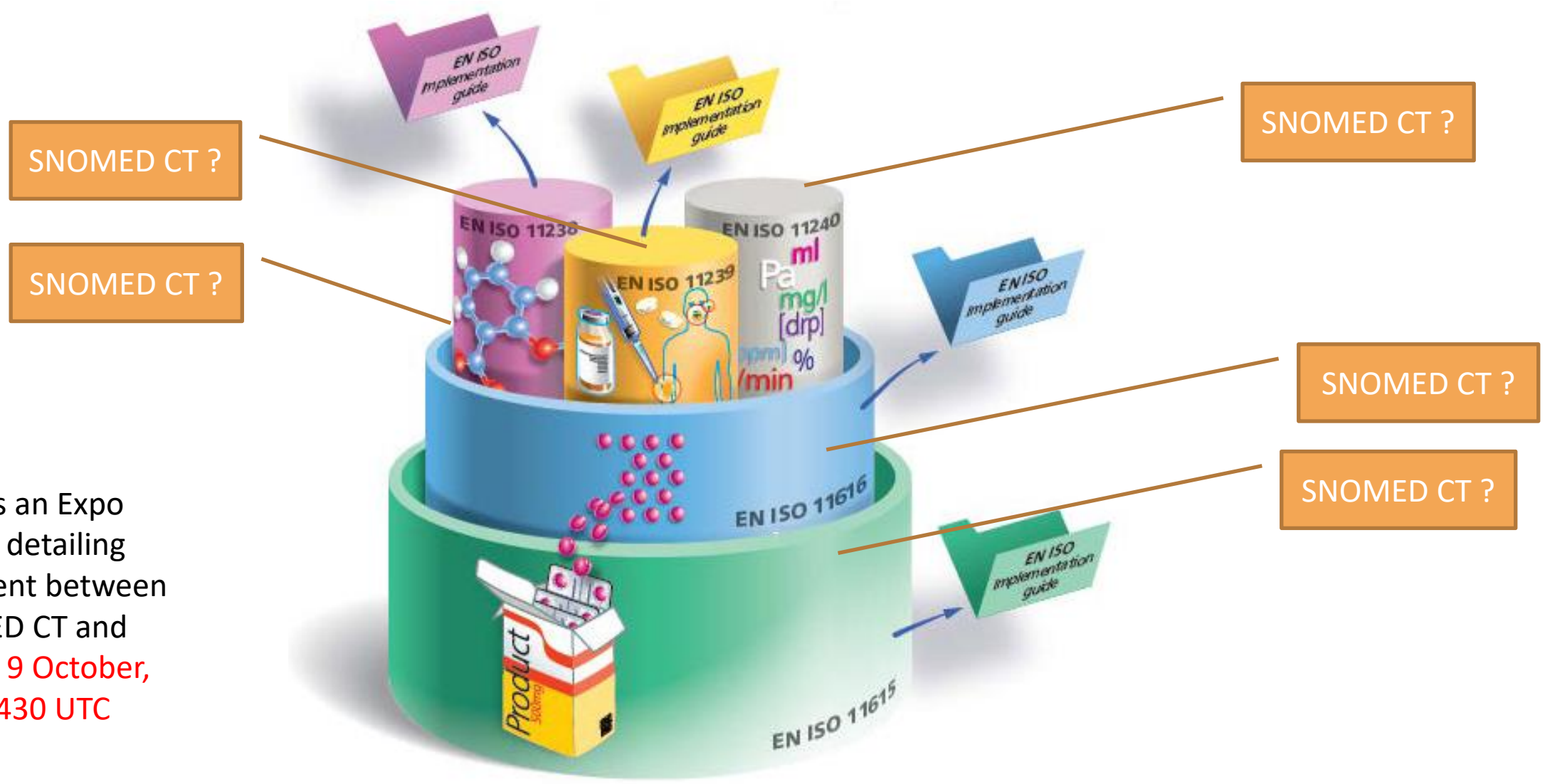
SNOMED CT can help implement the various IDMP standards with specific parts of the terminology



There is an Expo session detailing alignment between SNOMED CT and IDMP – 9 October, 1400-1430 UTC

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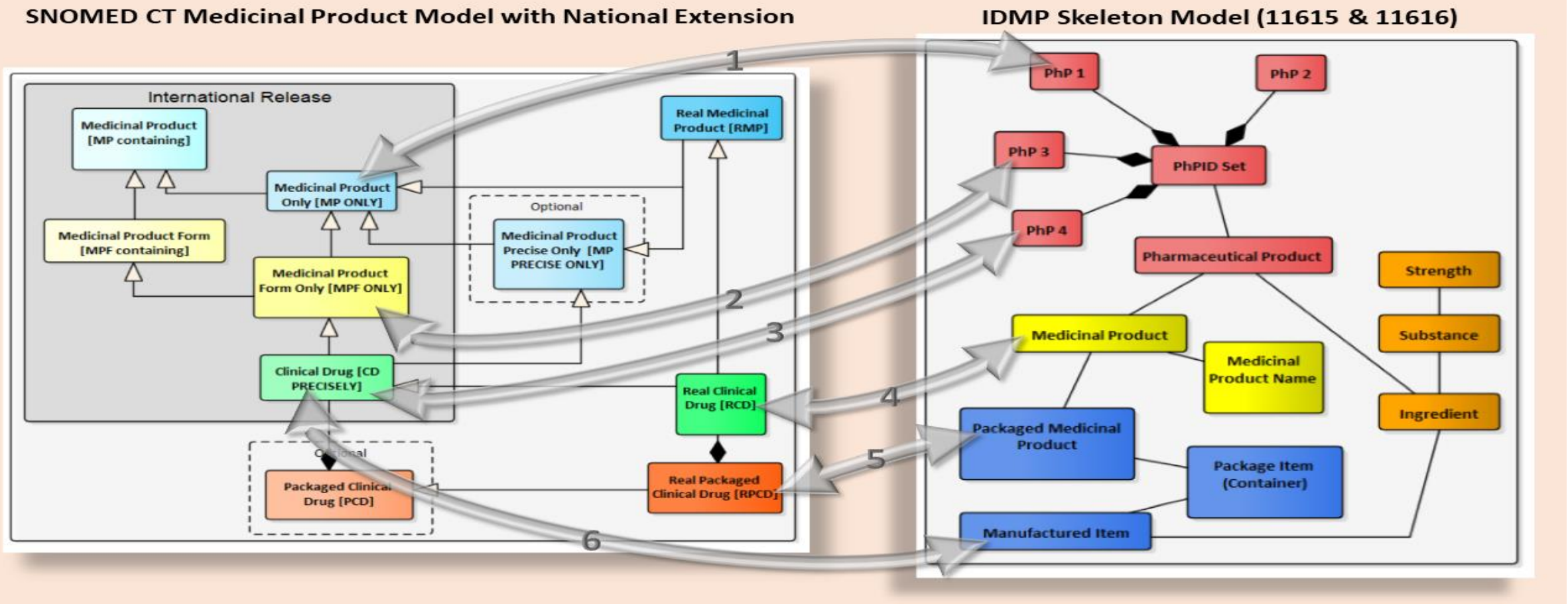
The SNOMED CT Drug Model is closely related with IDMP



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Overview of SNOMED CT and IDMP compatibility

SNOMED CT

- Real Clinical Drug (National extension model)
- Real packaged clinical drug (National extension)
- Clinical drug ‘containing precisely’
- Pharmaceutical Dose Form
- Medicinal Product ‘containing only’
- Medicinal Product Form ‘containing only’

IDMP compatibility

- Medicinal product – EN ISO 11615
- Packaged product – EN ISO 11615
- Manufactured item – EN ISO 11615

  Or PhP Level 4 – EN ISO 11616
- Model compatible with EN ISO 11239:2012
- PhP Level 1 – EN ISO 11616
- PhP Level 3 – EN ISO 11616

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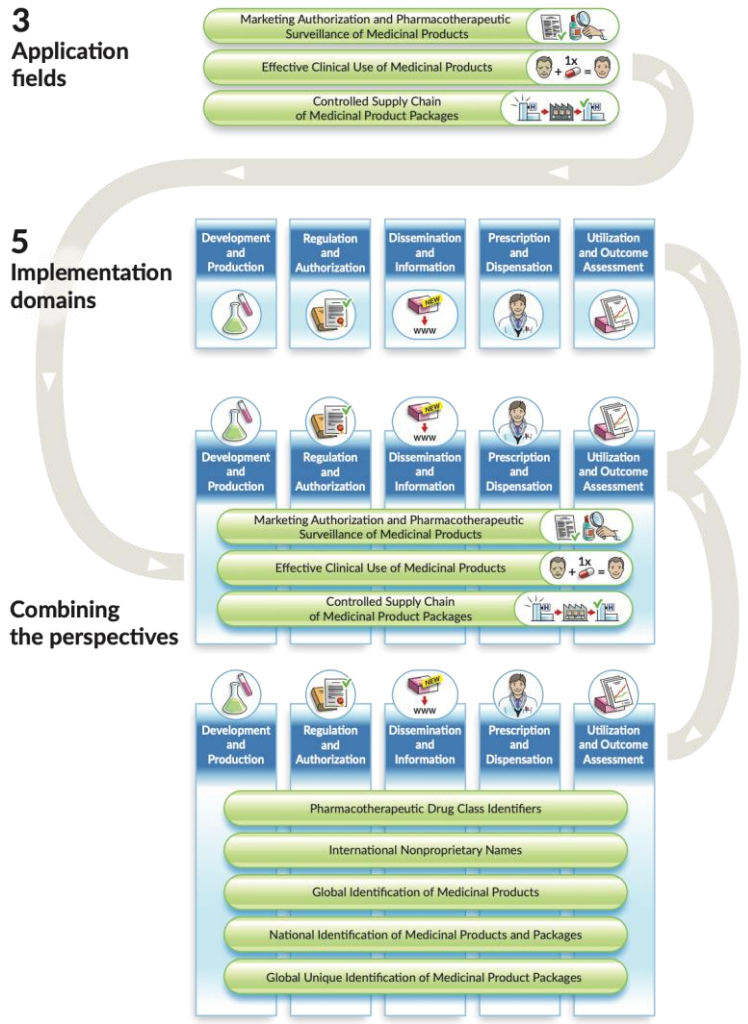
The involvement of SNOMED International with UNICOM

- WP 1 – focusing on use of IDMP, its implementation with other standards and identification of any work needed on any of the standards to facilitate implementation in the agreed use cases
- WP 8 – contribution to 'Clinical applications of IDMP' and 'IDMP and Pharmacovigilance'
- WP 9 – Medicinal Product Dictionaries and Clinical System Software. Potential areas of SNOMED CT content work and mapping, as the linkage between EHRs and regulation are explored
- Working with SNOMED International member countries who are participating in testing/piloting to facilitate linkage and also inform members globally who are considering implementation of IDMP
- Bringing to the project the maps SNOMED CT to MedDRA and MedDRA to SNOMED CT for reporting of adverse events created as part of the WEB-RADR 2 project.
- Exploring other areas where SNOMED International experience of maintaining, updating and distributing a terminology and its derivatives might facilitate the implementation of IDMP in its link to clinical and the different perspectives as they combine



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Resources available to engage with the project and the outcomes of implementation tests

- From a standards point of view an initial Gap Analysis has been published
  - Response from a series of workshops and initial appraisals by the users in the various work packages
  - Living document, identifying gaps and the way forward to address these through the SDO's, throughout the project
  - Engage with SNOMED International and/or your National Release Centre to get involved

- Website unicom-project.eu
- Introductory webinars and videos
- Educational offerings (in development)
- Community of Expertise on IDMP related standards and terminologies – meeting monthly
  - Specified topic with introductory speaker(s)
  - Open forum for all issues brought forward
  - Understanding of (parts of) the standards and terminologies involved is expected

- Many more to come …
  - Follow the UNICOM Project on LinkedIn and Twitter

- SNOMED International – info@snomed.org
- CEN/ISO WG 6 (for IDMP) – Shirin.Golyardi@nen.nl

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