Will the implementation of ISO/CEN Standards for global Identification of Medicinal Products (IDMP) make any difference for general practice ?

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1 European Institute for Innovation through Health Data; 2 Unicom

2 Annual Meeting Classification International des Soins Primaires (CISP-Club)

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What if ?

We would be able to identify any medicinal product from anywhere in the world anywhere in the world ?

That is the ambition of 5 ISO/CEN Standards !

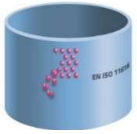
ISO standards for IDentification of Medicinal Products: IDMP

Set of 5 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

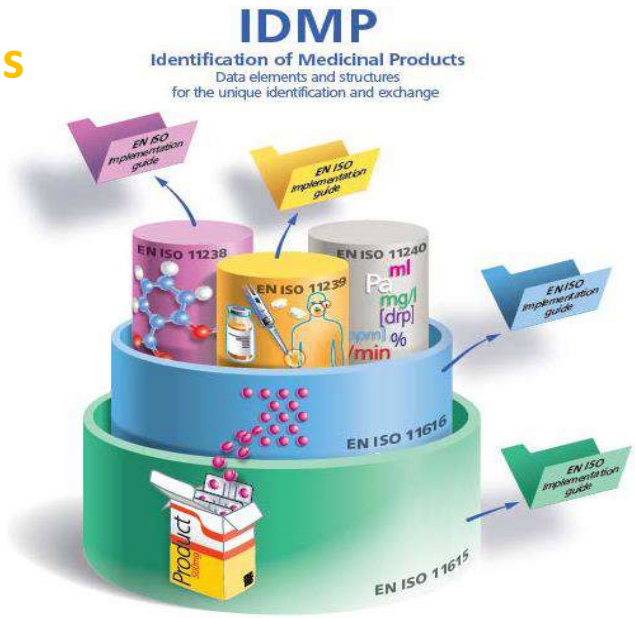
Pharmaceutical dose forms, units of presentation, routes of administration and packaging - ISO 11239

Units of measurement - ISO 11240



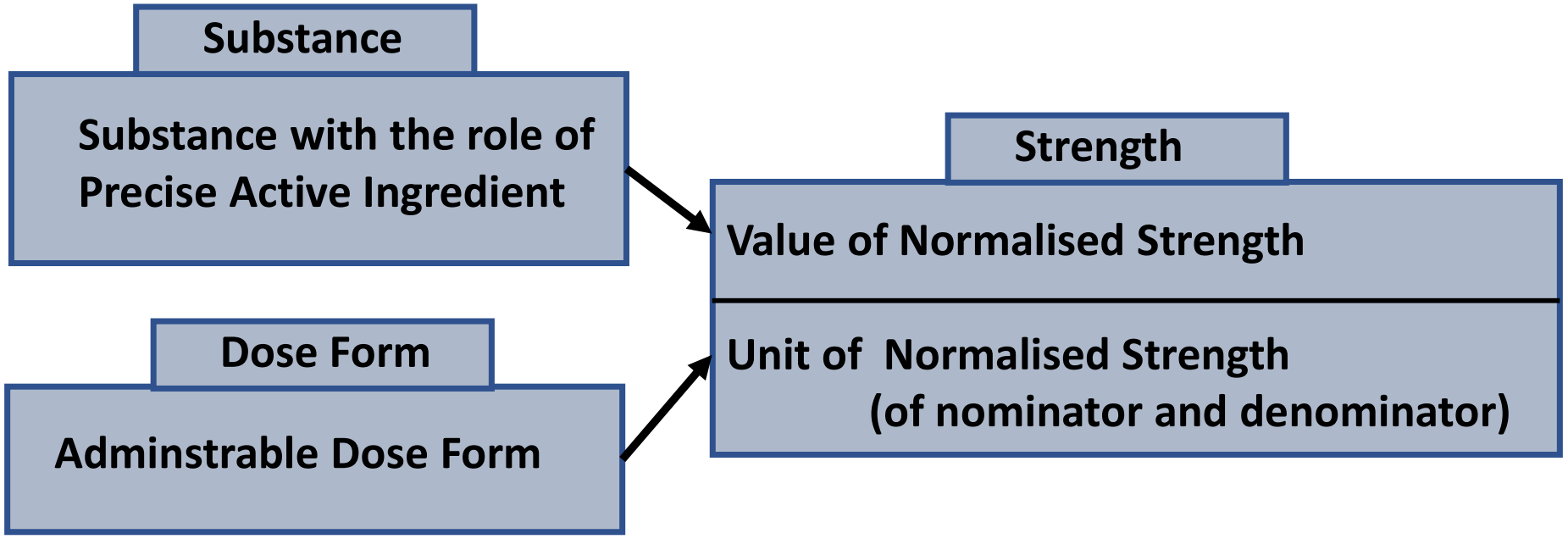
Pharmaceutical product (PhPID) - ISO 11616

Medicinal product (MPID/PCID) - ISO 11615



Three key elements to identify medicinal products

Substance is a key element that determines, together with dose form, the normalisation of strength expression of medicinal products



Note: Substance with dose form and strength determine the effect of the medication

Using standardized terminologies and
creating established rules to represent
3 core identifying concepts of medicinal products :

- **Substance**
- **Dose form**
- **Strength,**

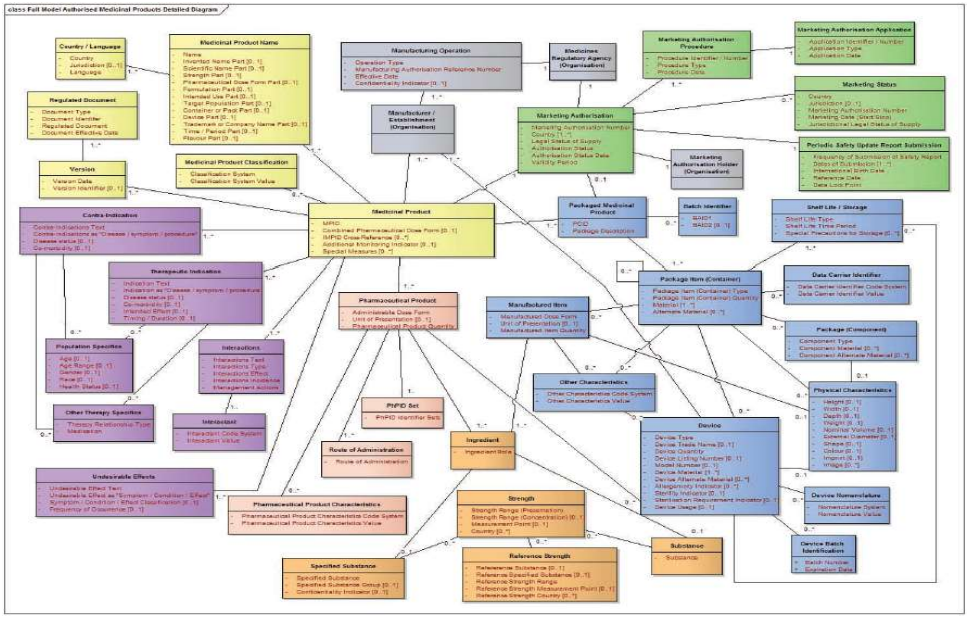
While also governing also
the relationships between these concepts

To be implemented by the national Agencies for Marketing Authorisation for new but also old medicines

To flow to medicinal product dictionaries in all the coutries

IDMP: from data models and terminologies to identifiers

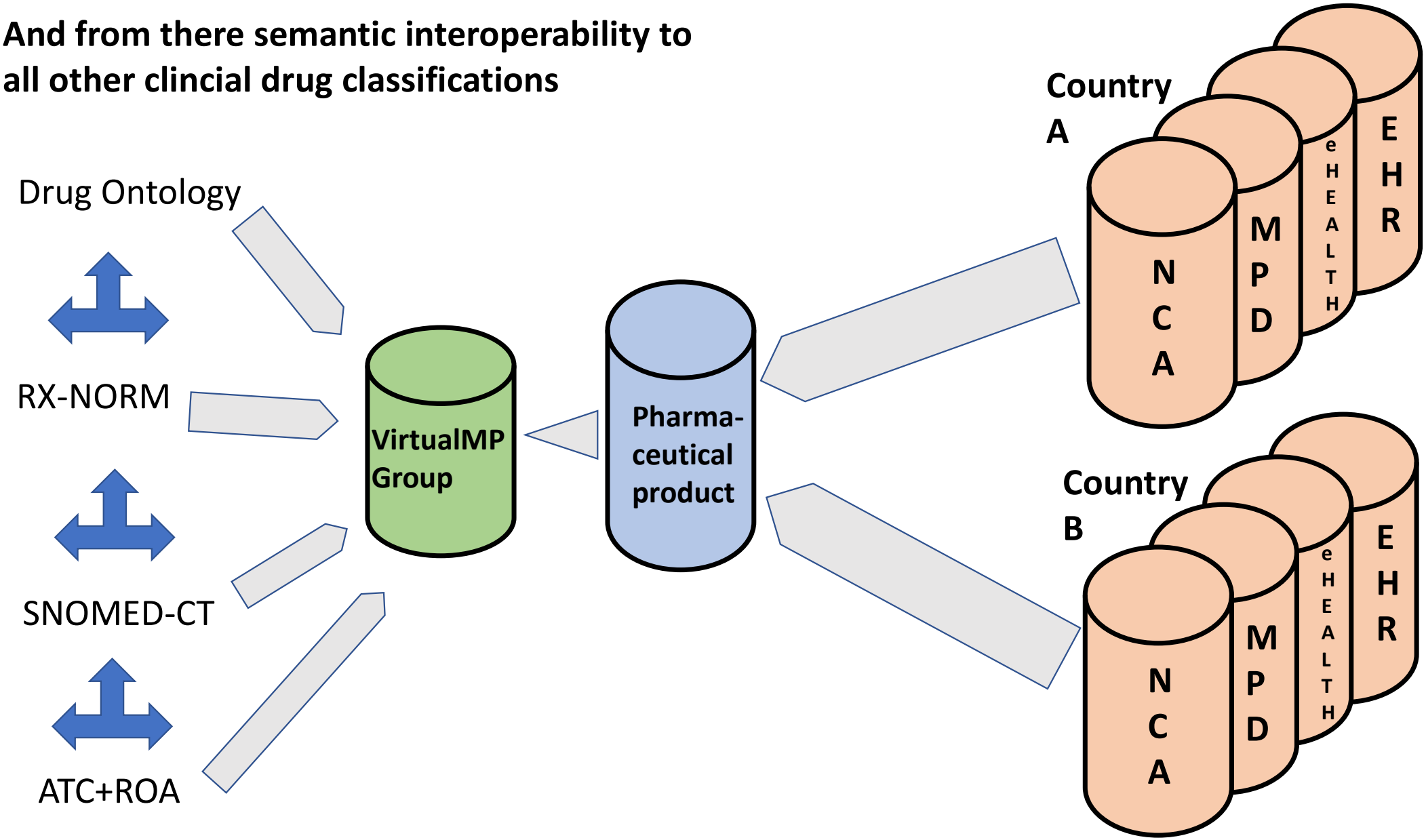
5 ISO Standards
containing ~250 data attributes



Unique Product Identifiers

- **PHPID** — Pharmaceutical Product ID
- **MPID** — Medicinal Product ID
- **SID** — Substance ID
- **PCID** — Medicinal Product Package ID
- **BAIDs** — Medicinal Product Batch IDs

And from there semantic interoperability to all other clincial drug classifications



Supported by

- 3 consecutive European Projects of 4 years each:
  epSOS / Open Medicine / UNICOM (2021 to 2024)
- ICH (International Council of Harmonisation)
  and a global Working Group (bringing together FDA, EMA, WHO_Uppsala Monitoring Centre for Pharmacovigilance)
- UNICOM, a large action program, from the EU Horizon programme, with a 20 MEURO Budget, and 44 participating organizations, among which 11 National Competent Agency for marketing authorization of Medicinal Products.
  https://unicom-project.eu

What if

a Greek patient shows up on in a Belgian Pharmacy and requests a prescription for

αμλοδιπίνη

By identifying the IDMP data on the box, the pharmacist realizes that this about

amlodipine,

and more specifically

amlodipine oral 10 mg,

and even more specifically :

amlodipine besilate capsule, hard 10mg

In Belgium available as : Amlor 10 mg (Upjohn), and in generics by a number of companies but as tablets

What is in for General Practice ?

- Facilitating global deployment of
  - Evidence-based Guideline, Drug Information
  - Decision Support System
    - Multidisciplinary Medication management
    - Support for deprescribing
- Assisting Travelers-patients and our patients traveling
- Supporting Teaching Pharmacotherapy to medical students

in INN Prescribing (Prescription DCI)