

The UNICOM Project :
**How will medicinal products will be represented
in the European Health Data Space ?**

Robert Vander Stichele; Dipak Kalra, UNICOM, Work Package Lead WP8

UNICOM

November 29, 2022, ETHEL Symposium

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.



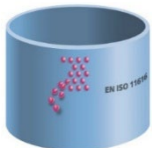
Substances (Substance ID/Specified Substance ID) - ISO 11238



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



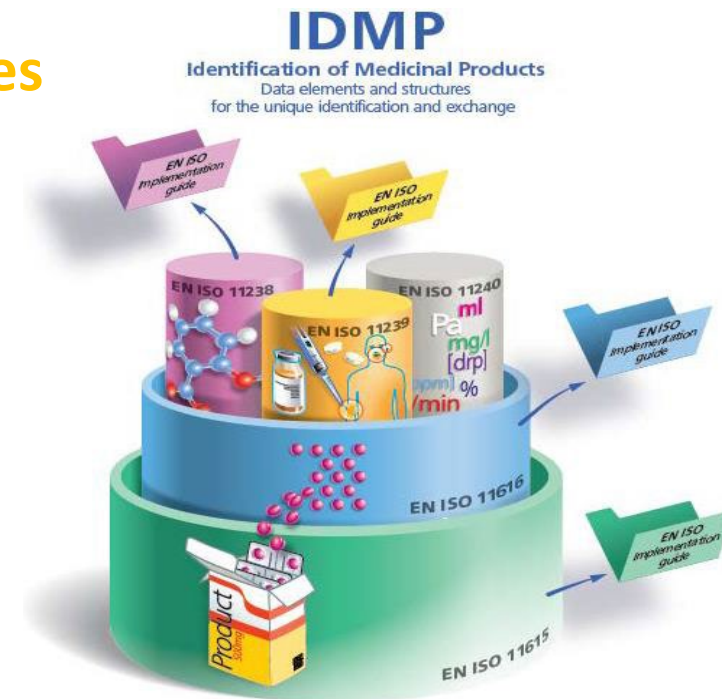
Units of measurement - ISO 11240



Pharmaceutical product (PhPID) - ISO 11616

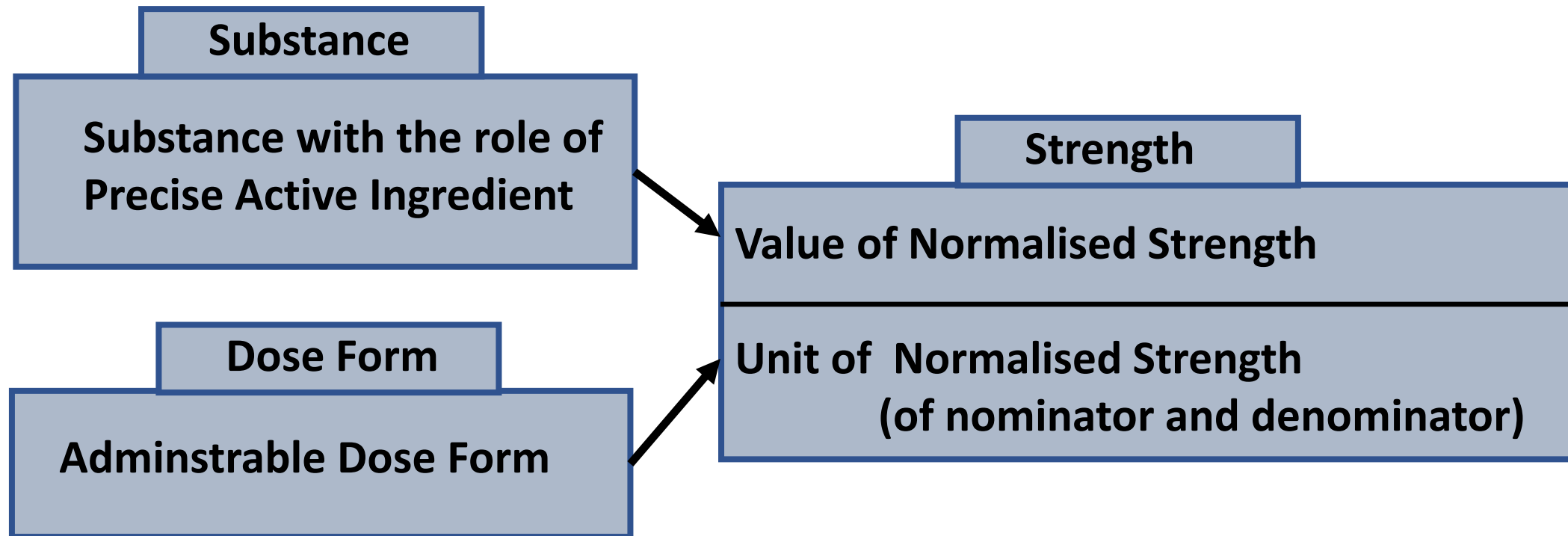


Medicinal product (MPID/PCID) - ISO 11615



Standards needed to correctly identify 3 key elements of medicinal products

Substance, together with dose form, determines the normalisation of strength expression of medicinal products



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

How to ensure interoperability in the way medicinal products are represented internationally ?

For 3 core identifying concepts of medicinal products :

- Substance
- Dose form
- Strength,

We will need standardized terminologies, and business rules to govern also the relationships between these concepts

**To be implemented by the national Agencies for Marketing Authorisation
In US, in Europe, and globally**

To flow seamlessly into the medicinal product dictionaries, used in clinical systems all over the world



▶ Legacy conversion of 500.000 Medicinal Products

▷ In 27 member states

each having 8.000 to 12.000 Medicinal Products authorized on their market

each having up to 5 medicinal product dictionaries besides the regulatory databases

Regulatory information systems

eHealth information system

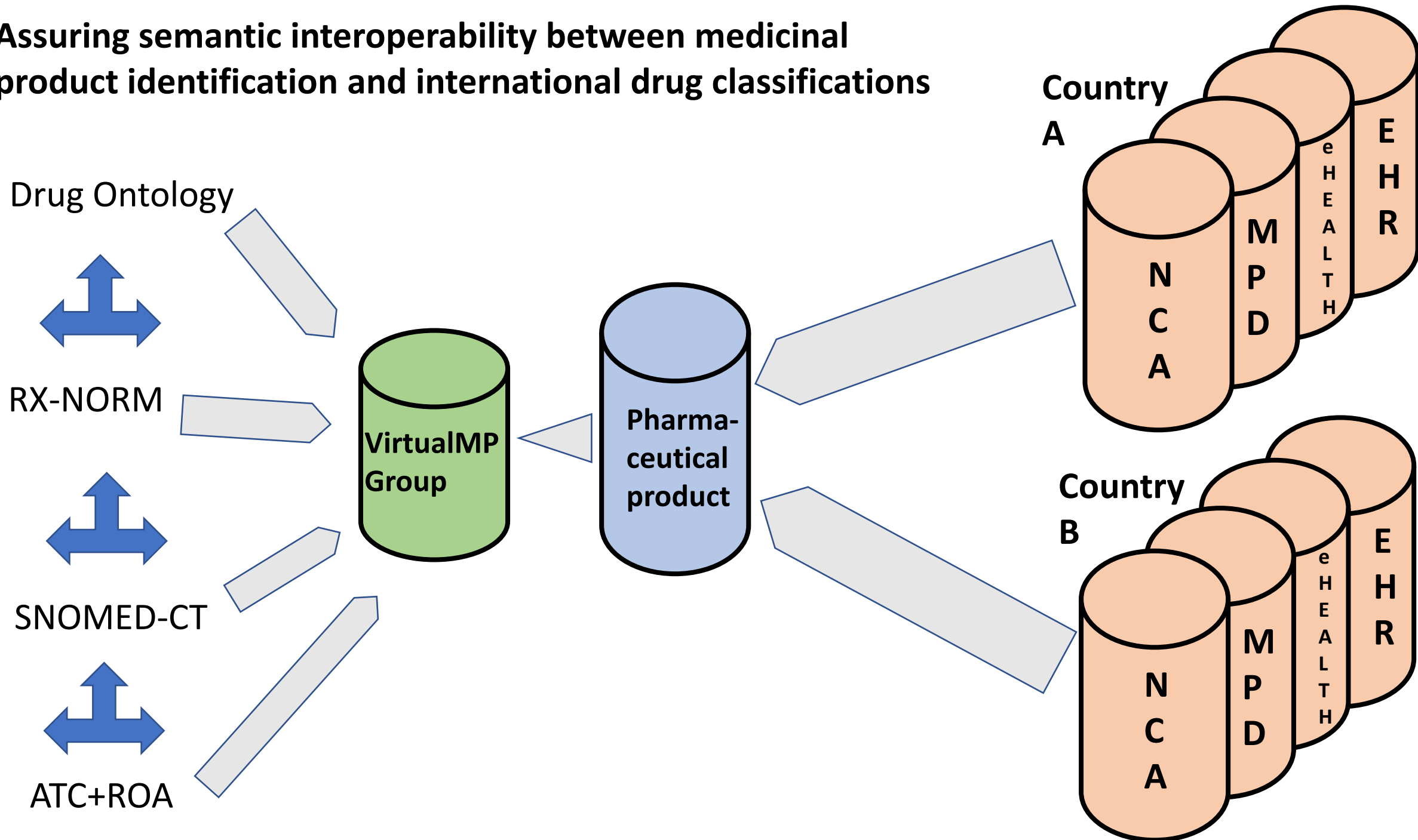
Reimbursement information System

Drug Information Centre

Vendors of pharmacy and medical information systems



Assuring semantic interoperability between medicinal product identification and international drug classifications



- 3 consecutive European Projects of 4 years each:
epSOS / Open Medicine / UNICOM (2021 to 2024)
- ICH (International Council of Harmonisation)
- Global IDMP Working Group (GIDWIG)
bringing together
FDA, EMA, WHO_Uppsala Monitoring Centre for Pharmacovigilance
- UNICOM
A large EU Horizon Action Program, 20 MEURO Budget,
44 participating organizations, among which 11 National Competent
Agency for marketing authorization of Medicinal Products.

Website : <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 European Health Data Space ?

- Assisting traveling patients
 - Citizens needing health care during travel
 - Patients traveling for health care
- Assuring interoperability for medicinal products in big data collections
 - More precise representation of medicinal products in the common data models
 - Fostering powerful pharmaco-epidemiological research
- Facilitating global deployment of trustworthy drug information
 - In patient labeling (ePI electronic Product Information)
 - In Evidence-based Guidelines
 - In independent Drug Information Centres
 - In Decision Support System
 - Multidisciplinary Medication management
 - Support for deprescribing
 - Electronic teaching platforms for pharmacotherapy

