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Meeting the global challenge of unique identification of medicinal products

openMedicine – The value added for medication management across Europe

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OpenMedicine Workshop:
Implementing ISO standards for the univocal identification of medicinal products (IDMP) in Europe -

The impact on the Nordic Countries
at Swedish eHealth Agency

eHälsomyndigheten

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Meeting the global challenge of unique identification of medicinal products

Project objectives

- **Univocal identification of a medicinal product for human use across Europe in**
  - ✓ ePrescriptions
  - ✓ eDispensation reports
  - ✓ Electronic Patient Summaries
- **Evidence on substitution**
- **In xBorder context**

Challenge in cross-border prescribing

- **Univocal identification of a**
  - ✓ **prescribed medicinal product**
  - ✓ **for human use in**
  - ✓ **cross-border healthcare by a**
  - ✓ **dispensing community pharmacist**
  - ✓ **in another Member State than that in which the prescription was issued**

The identification problem

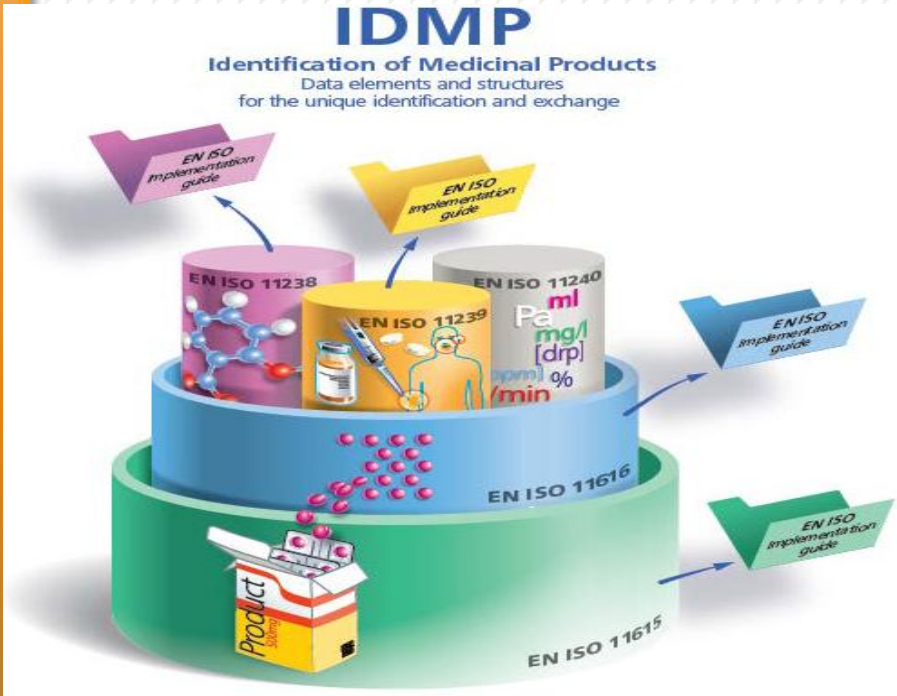
- **One active ingredient (INN – 5 languages)**
- **Many generic names**
  - **Metoprolol (beta blocker): 17**
  - **Simeticone (antiflatulent): 12**
- **Up to hundreds of brand names:**
  - **Metoprolol: > 400**
  - **Simeticone: > 300**

http://www.drugs.com/international/metoprolol.html
http://www.drugs.com/international/simeticone.html

Identification & patient safety challenges

- **Due to different marketing authorisation procedures**
  - ✓ *Not* every medicinal product is *available in each member state*
  - ✓ The same product may have *different names* across MSs
  - ✓ *The same name* may identify a different product in another MS
- **Regularly substitution is necessary to dispense a foreign ePrescription**
- **Analysis of identification problems in**
  - ✓ *Regulatory* context (pharmacovigilance; marketing authorisation)
  - ✓ *Clinical* records and documents

The Solution: ISO IDMP 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:
  - Regulated ***Medicinal*** **products** information (**MPID/PCID**) - ISO 11615
  - Regulated ***Pharmaceutical*** **products** information (**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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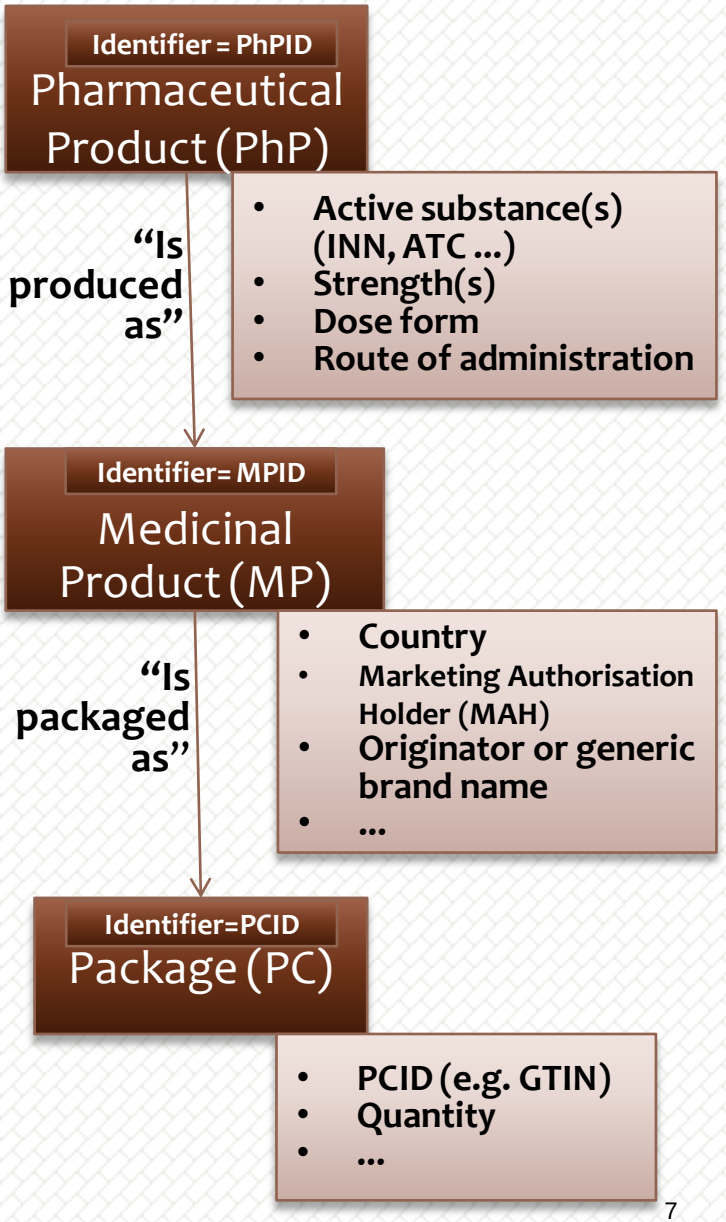
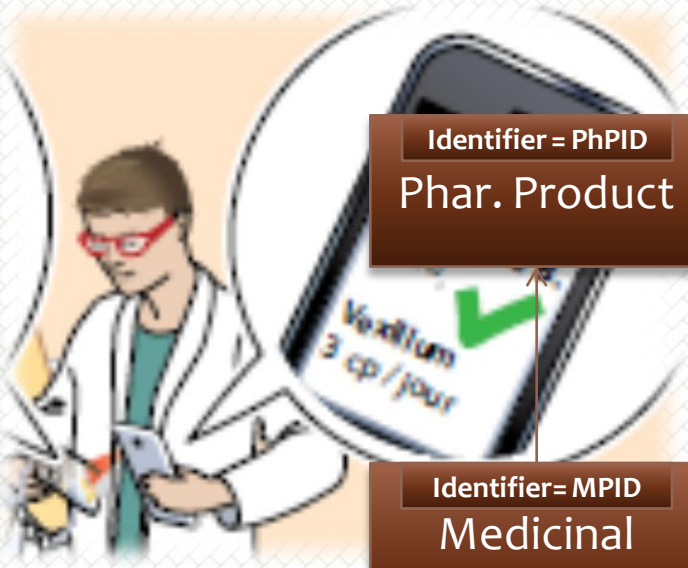
Standardised attributes for medicinal and pharmaceutical products

- The **ISO IDMP** (ID of medicinal products) suite of standards defines a set of attributes and their relations to identify different levels of medicines
- It harmonizes the concepts and the data elements (attributes)
- EMA & FDA will adopt it and maintain codes
- Pharmaceutical manufacturers will implement it (summary of product characteristics [SmPC]; pharmacovigilance)
- ePrescriptions may identify a package, a medicinal product, or an active substance plus further attributes as needed



xBorder ePrescription & dispensation



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

Identifier = PhPID
Phar. Product

Identifier = PhPID
PhP

Product is further specified, thanks to standardised attributes

Same medicinal product (if available)

Identifier= MPID
Medicinal Product

Identifier= MPID
MP

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

Identifier=PCID
Package

Identifier=PCID
Package

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Business case – Value propositions/benefits

- ✓ Patients
- ✓ Pharmacovigilance/ADE reporting
- ✓ Clinicians
- ✓ Pharmacists
- ✓ Pharma industry - registration of new medicinal products
- ✓ Further actors [national & international regulators (e.g. EMA, FDA); national/ regional/local information systems; clinical trials]

Clinical Relevance

- Active medication summary of electronic patient summary (ePS)
- Prescription history
- eDispensation report (up to 40% not dispensed)
- Reconciliation of medicines/contraindications
- Compliance (in DE 28% of dispensed MPs not taken)
- Global pharmacovigilance
- Patient information & empowerment
- Clinical research & studies
- Public health

Creating value – and costs

- ✓Who will bear the costs?
- ✓Who will assure sustainability?
- ✓Who will organise coordination across NCAs, SDOs…
- ✓Governance
- ✓Change management
- ✓Awareness and diffusion
- ✓…

Longer-term Challenge

Implementation & diffusion of solutions

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