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

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
Meeting the global challenge of unique identification of medicinal products

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
Meeting the global challenge of unique identification of medicinal products

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
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

[Diagram showing the relationships between Pharmaceutical Product (PhP), Medicinal Product (MP), Package (PC), and their identifiers (PhPID, MPID, PCID)]
Product is specified at any of the IDMP levels in an ePrescription.

Common level is usually pharmaceutical product, i.e. substitution or selection.

Product is further specified, thanks to standardised attributes.
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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
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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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