Meeting the global challenge of unique identification of medicinal products

Meeting the cross-border challenge of unique identification of medicinal products

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- **MBA** (Diplom-Kaufmann) Berlin, Free University – 1968
- **PhD** (International Finance, Business Administration, Economics) University of British Columbia, Vancouver, BC, Canada – 1974
- eHealth projects in Europe, trans-Atlantic and Africa
The business case

Have you ever visited a pharmacy in a foreign country presenting a prescription from your doctor at home and the pharmacist did not have a clue?

- What is needed:
  - Univocal identification of a medicinal product (MP) prescribed in another country
  - If the (identical) MP is not available, suitable regulation of substitution in the country of dispensation

- Why it is needed:
  - Assuring patient safety of cross-border ePrescription/Dispensation
  - Assuring continuity of care cross borders
European Union policy priorities

A Digital Single Market Strategy for Europe

- Digital interoperability & standardisation in the health domain as a means to boost competitiveness:

The Commission will launch an integrated standardisation plan to identify and define key priorities for standardisation with a focus on the technologies and domains that are deemed to be critical to the Digital Single Market, including essential sectoral interoperability and standards in areas such as health (telemedicine, m-health), transport (travel planning, e-freight), environment, and energy. The Commission will revise and extend the European Interoperability Framework.

Source: COM(2015) 192 final; Brussels, 6.5.2015, p. 16
The solution

The overall concept to solve the problem is to develop concrete solutions in a global context:

- A **common data model** (a set of coherent conceptual, logical and implementable data models) - expanding upon the ones developed by epSOS¹ and facilitating adoption of the ISO IDMP set of standards²

- A **common nomenclature** (a set of code and identification systems) for the unambiguous definition, description, and identification of medicinal products, pharmaceutical products, and ingredients

- **Global cooperation**: European Medicines Agency (EMA), FDA, national drug agencies and health authorities, industry, other stakeholders

This will be complemented by

- a report on **substitution**
- a set of **recommendations**, as well as
- a **roadmap for implementation**

¹ epSOS - Smart Open Services for European Patients - Open eHealth initiative for a European large scale pilot of patient summary and electronic prescription
² ISO IDMP suite (11615/16, 11238-40) - Identification of medicinal products
Identification

- Identification is more than assigning a code
- A code is one possible identifier
- Identification = defining the minimal set of descriptive attributes of a medicine
- Content of the set depends on the kind of medicine
- A core challenge is to define the different “sets of identifying attributes” required to identify a medicinal product or a pharmaceutical product in a given context / for a given application
Conceptual approach – Interoperability framework

Application domains:
European, national, regional health systems; healthcare provider organisations; ...

IOp Policy Domain:
Priorities, strategies, budget

IOp Governance & Legal Domain:
Gov. framework, laws, regulation

IOp Organisational Domain:
Structure, processes, resources

Data Access & Exchange Domain:
• Technical interoperability level (e.g. information transferred using IHE profiles)
• Structural interoperability level (CDA, data fields structured)
• Semantic interoperability level (data coded)
Identification levels: from substance to cluster

- Cluster: no identifier << possible?
- Pharmaceutical or therapeutic class

- Medicinal Product Package
  - Package identification NATIONAL
  - Extended identification: each instance of a medicinal product package

- Medicinal Product
  - Marketing authorisation holder
  - NO / not always an identifier

- Pharmaceutical product
  - Manufacturer => batch / Batchnumber
  - NO identifier. No name. Description of a composition

- Manufacturer => batch => batch number
  - Substance => Ingredient => active ingredient OR excipient
  - Ingredient Identifier <= ATC or INN

The ISO IDMP suite (11615/16, 11238-40) is only a starting point
Related standards

- No single standard is addressing the full identification issue
- ISO IDMP suite:
  - 11615... for the unique identification and exchange of regulated *medicinal* product information
  - 11616... for the unique identification and exchange of regulated *pharmaceutical* product information
  - 11238... for the unique identification and exchange of regulated information on *substances*
  - 11239... for the unique identification and exchange of regulated information on pharmaceutical *dose forms, units of presentation, routes of administration and packaging*
  - 11240... for the unique identification and exchange of *units of measurement*
Envisaged solution: EMA Art. 57 DB on Medicinal Products and pharmacovigilance will adopt ISO IDMP standards
The workflow

WP1
epSOS & Use Cases
Existing Standards

WP2
Prepacked branded mono products

WP3
Other prepacked products & biologics

WP4
Class or cluster and reverse identification

WP5
Substitution

WP6
Recommendations, Roadmap, Validation

WP7
Communication, Liaison

WP8
Management
The benefits

- Safe dispensation to *patients* of a medicine at least equivalent to the one prescript in another country
- **Clinicians** understand better the medicinal therapy information contained in foreign patient summaries
- **Pharmacists** identify what is the most appropriate medicinal product that fulfils the requirements of the product prescribed abroad, in accordance with national substitution rules
- **Further actors** [national & international regulators (e.g. EMA, FDA); national/ regional/local information systems; pharmaceutical companies; sponsors of clinical trials] can meaningfully exchange MP data across countries and share the same source of information
- Identifiers can be used in any country for *obtaining the product’s “properties”*
- Simplification and speeding up of the *registration of new MPs*
- Improved, easier *pharmacovigilance*
Coordination and partners

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<thead>
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<th>Project coordination &amp; management</th>
<th>External co-operation, expert council</th>
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<tr>
<th>Participant organisations</th>
<th>Country</th>
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<td>World Health Organisation (WHO), Geneva, &amp; WHO Uppsala Monitoring Centre (UMC)</td>
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