Meeting the global challenge of unique identification of medicinal products

Meeting the semantic challenge of the globally unique identification of medicinal products - the openMedicine approach

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Goals

- Enhance the safety and continuity of cross-border (and national level) healthcare through interoperable ePrescriptions

- Propose concrete solutions to the delivery problem: “The challenge in ePrescription is how medicines can be communicated in the cross border setting”:
  - Univocal identification of a medicinal product dispensed in another country
  - If and where substitution is permitted or required, dispensation of an equivalent or similar product in line with national regulations
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
Conceptual approach - Unique identification and description of medicinal products (MPs)

The overall concept to overcome the challenges identified 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 epSOS\(^1\) and existing ISO ID-MP standards

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

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\(^1\) epSOS - Smart Open Services for European Patients - Open eHealth initiative for a European large scale pilot of patient summary and electronic prescription

www.epsos.eu
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)

Application domains:
European, national, regional health systems; healthcare provider organisations; ...
Identification levels: from substance to cluster

- Cluster: no identifier <= possible?
- Pharmaceutical 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 e.g.

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

- NOT to
  - regulate on how to prescribe a brand medicinal product
  - standardise dispensing and administrating medicines
  - define how to document medication related information in the Electronic Health Record
  - define the content and structure of a comprehensive drug database

- NOR how to
  - handle investigational medicinal products
  - conduct clinical trials
  - manage pharmacovigilance information
  - do pharmacological research, pharamaco-economic research

- But to address the identification of the product in each of these applications and for each kind of product
Related standards (1)

- No standard is addressing only the identification issue

**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
Related standards (2)

- Competing “standards” to IDMP
  - IHE profile on exchange of prescriptions
  - HL7v- v3 medication domain
  - epSOS specifications

- What about article 57 EMA?

- What is needed?
  - Documentation of pros and cons
  - Decision on where we want to travel
  - Motivated decisions
  - Agreement on steps for implementation (roadmap)
Defining substitution

Therapeutic substitution

“Substitution with a chemically different drug. The substituted drug belongs to the same pharmacologic class and/or to the same therapeutic class.”
(WMA Statement on Drug Substitution, Chile 2005)

Substitution with a MP different from the one prescribed for therapeutic reasons (e.g. no availability of prescribed drug, but necessity of intervention)

Generic/economic substitution

“In a generic substitution, a generic drug is substituted for a brand name drug. Both drugs have the same active chemical ingredient, same dosage strength and same dosage form”
(WMA Statement on Drug Substitution, Chile 2005)

Due to financial reasons a cheaper generic drug, which is not necessarily bioequivalent, or a different treatment/therapeutic approach is prescribed to lower costs
(compare: http://www.sciencedaily.com/releases/2013/08/130821152114.htm)
Meeting the substitution challenge

epSOS Member States agreed to adopt a relatively simple substitution approach with the lowest risk of a negative impact for patient safety: Only two kinds of substitution were permitted:

- a) Substitution of the medicine itself is not allowed; only the package size can be changed
- b) Substitution of the medicine is allowed as long as the active ingredient and the strength are the same, i.e. the brand name can be changed

These rules enforce strong substitution limitations on the dispensation process, and in concrete instances patients may not be able to receive the medication needed.

Once a better global capability of describing / identifying medicinal products univocally is available, the probability that a given ePrescription can indeed be filled in another country increases considerably.

To realise this, a concise framework and rule set will be developed and recommended for the handling and adaptation of different concepts and practices of therapeutic and generic/economic substitution across Europe.
Different levels of substitution

- **Package** level: Different size of package (e.g. 56 tablets instead of 50 tablets)
- **Name** level: same product with a different name
- **Dosage** level: same product with a different dosage
- **Strength** level: same product with a different strength
- **Substance** level: Same active ingredient, different substance (different salt)
- **Active Ingredient** level: e.g. Ibuprofen instead of paracetamol (but still the same therapeutic class)
- **Complete** substitution: different therapeutic class (e.g. bisoprolol: betablocker instead of sartane)
Study process

• Concentrate on and give priority to the concepts and data elements related to Medicinal Product Identification for ePrescribing and eDispensing, and additional use cases (Pharmacovigilance, …)

• Address the process to validate medicinal descriptions

• Address process and architectural impacts of adopted solution on eHealth cross-border interoperability infrastructure (National contact points for eHealth – NCPeH - and national infrastructures)

• The datasets related to administration (posology, instructions for preparation, instruction for the patients) will only be considered as far as they are used for identification of the medicinal/ pharmaceutical product
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
### Timeline (subject to change)

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<thead>
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Coordination and partners

<table>
<thead>
<tr>
<th>Project coordination &amp; management</th>
<th>External co-operation, expert council</th>
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<tbody>
<tr>
<td>Prof. Dr. Karl A. Stroetmann</td>
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<td><a href="mailto:jos.devlies@custodix.com">jos.devlies@custodix.com</a></td>
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<tr>
<th>Participant organisations</th>
<th>Country</th>
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<tr>
<td>empirica Gesellschaft für Kommunikations- und Technologieforschung mbH, Bonn</td>
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<td>Custodix NV, Ghent</td>
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<td>Health Ministry of Regional Government Lombardia, Milano</td>
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<td>Health Level Seven International (Europe)</td>
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<td>Instytut Logistyki i Magazynowania, Poznań</td>
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<tr>
<td>Nederlands Normalisatie Instituut (for European Committee for Standardization (CEN)), Amsterdam</td>
<td>NL</td>
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<tr>
<td>Agencia Española de Medicamentos y Productos Sanitarios Parque Empresarial, Madrid</td>
<td>ES</td>
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<th>Co-opted international regulatory agencies</th>
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<tr>
<td>European Medicines Agency (EMA), London, UK</td>
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<td>World Health Organisation (WHO), Geneva, &amp; WHO</td>
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<tr>
<td>Uppsala Monitoring Centre (UMC)</td>
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Participating stakeholder groups/experts

Their duty: review and validate outcomes

- **Structural expert organisations**
  - International organisations focusing on medicinal products
  - Considered as consortium partners: fully involved
  - European Medicines Agency (EMA), WHO Uppsala, WHO Geneva, IHTSDO, FDA

- **Nominated experts with different background and roles:**
  - Organisations or individuals with specific expertise
    - Healthcare professionals (Physicians, pharmacists)
    - EHR / prescribing & pharmacy software system providers
    - Medicinal product databases editors
    - Pharma industry
  - National drug agencies
  - Role: Members of the expert council
    - Advisers to the consortium
    - 3 meetings during life time of the project
  - and/or quality reviewers of outcomes
Outcomes

- Common datamodel
- Common vocabulary
- Report on substitution
- A set of recommendations
- Roadmap for implementation
Outcomes

Practical solutions to identify, validate, and feed into practical deployment

- A common data model - based and expanding upon the standards used/extended by epSOS and by existing standards (e.g. the ISO/IDMP standards) - for the prescribed medicinal products
  - Draft data model to be available in Dec. 2015
- A common vocabulary for unambiguous definition, description, and identification of medicinal/pharmaceutical products throughout Europe
- Solution options for the handling of different concepts and practices of therapeutic and economic substitution across Europe
  - Recommended procedures and draft roadmap by April 2016
- A roadmap for post-project actions and implementations
  - Roadmap agreed and validated by Dec. 2016
- Coordination of practical solutions developed as well as policy recommendations and roadmap with the EU-USA road mapping process in the context of the eHealth MoU (USA/DHHS and EU/EC)
  - Planned: 2 coordination and exchange workshops in Oct. 2015 and June 2016 with at least 15 participants of the host country and 5 from “overseas” in Washington, D.C., respectively Brussels or another European capital
Benefits

- Safe dispensation to patients of a medicine at least equivalent to the one prescript in another country
- Clinicians understand fully the medicinal therapy information contained in foreign patient’s summary
- Pharmacists identify what is the most appropriate medicinal product that fulfils the therapeutic requirements of the product prescribed abroad, in accordance with local laws and substitution rules
- Further actors [regulators (e.g. EMA, AIFA); 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 by any actor in any country for obtaining the product’s “properties”
- Simplification and speeding up of the registration of new MPs
- Improved, easier pharmacovigilance
Acknowledgements

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