WP2: D 2.3 Final data elements for identification and descriptive attributes

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Goal

- Determine final identifiers for medicinal products
- Describe the identifying attributes
- Describe additional attributes
- Document source and use
Use Cases

- ePrescription
- eDispense
- Their documentation
## Identify the identifiers

<table>
<thead>
<tr>
<th>Source</th>
<th>Data element</th>
<th>EMA article 57 database</th>
<th>Use case ePrescription / Dispense / Record keeping</th>
<th>Include/ exclude in DCM</th>
<th>Motivation</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO 11238</td>
<td>Substance ID</td>
<td>Include</td>
<td>Include</td>
<td>include</td>
<td>Every substance will be identified by this mandatory ID.</td>
</tr>
<tr>
<td>ISO 11616</td>
<td>Pharmaceutical Product Identifier PhPID</td>
<td>Include</td>
<td>Include</td>
<td>include</td>
<td>Every pharmaceutical product will be identified by this mandatory ID.</td>
</tr>
<tr>
<td>ISO 11615</td>
<td>Medicinal Product Identifier MPID</td>
<td>Include</td>
<td>Include</td>
<td>include</td>
<td>Every (regulated) medicinal product will be identified by this mandatory ID.</td>
</tr>
<tr>
<td>ISO 11615</td>
<td>Packaged Medicinal Product Identifier (PCID)</td>
<td>Include</td>
<td>Include</td>
<td>include</td>
<td>Every packaged product will be identified by this mandatory ID.</td>
</tr>
</tbody>
</table>
Medicinal product Detailed Clinical Model

Class Information Model «rootconcept» MedicinalProduct

Class Information Model «container» Ingredient/Substance

Class Information Model «data» SubstanceId

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Class Information Model «container» PharmaceuticalProduct

Class Information Model «data» PhPID

ISO 11616

Class Information Model «container» PackagedMedicinalProducts

Class Information Model «data» PCID

ISO 11615

Class Information Model «container» RegulatedMedicinalProduct

Class Information Model «data» MPID

ISO 11615

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European Commission

openMedicine
And all other IDMP items....

<table>
<thead>
<tr>
<th>Source</th>
<th>ISO IDMP</th>
<th>IDMP data elements</th>
<th>IDMP: Mandatory</th>
<th>Should Conditional</th>
<th>EMA article 57 database</th>
<th>Xborder use case</th>
<th>DCM include/exclude</th>
<th>Motivation</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO TS 19844</td>
<td>Ingredient</td>
<td>M</td>
<td>include</td>
<td>include</td>
<td>Core concept for the ingredient level of data elements. A substance is any matter that has a discrete existence, irrespective of origin, which may be biological or chemical.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ISO TS 19844</td>
<td>4.1. Specified Substance</td>
<td>M</td>
<td>include</td>
<td>include/optional</td>
<td>This one is normally not used in clinical practice, and hence not yet included in the DCM. However, included optional based on expert input.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ISO TS 19844</td>
<td>4.1. Specified SubstanceGroup</td>
<td>M</td>
<td>include</td>
<td>exclude</td>
<td>Valueset 4 categories. Normally not used in clinical practice, could be considered for an extension later?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ISO TS 19844</td>
<td>4.2. Substance_ID</td>
<td>M</td>
<td>include</td>
<td>include</td>
<td>Every substance will be identified by an ID. Once a substance has been defined, a unique identifier that is permanently associated with that substance will be assigned.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Medicinal product DCM

is a project funded by the European Commission in the context of Horizon 2020.
Identifiers & controlled terminology and codes

- Each class in Model needs a unique code to identify it (unavailable)
- Some data elements (defining characteristics) use controlled concept oriented terminologies and codes
- The data go in a specific fields in databases, EHRs and specific tags in messages
- This field name or tag must be uniquely identified as to not mix it with other data elements
- OIDs are required for each controlled vocabulary and for each value set: EMA working on it.
Characteristics of medicinal products

- Reviewed by experts
- Checked against results of D 2.1 & D 2.2. & EMA art 57
- Determine one unique code for each class in the model (EMA?)
- Identify vocabularies per DCM class that has a concept descriptor data type (CD) to populate.
- Assign OIDs for DCM, classes, unique codes and value sets if not available
- Finally express the DCM as HL 7 v3 content, e.g. for use in CDA and v3 messages, FHIR and as 13606-3 Refererence archetype.