OPENMEDICINE

Meeting the global challenge of unique identification of medicinal products

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

Contact: William Goossen (NEN; wgoossen@results4care.nl)

www.open-medicine.eu

OPENMEDICINE is a project funded by the European Commission in the context of HORIZON 2020

# Goal

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

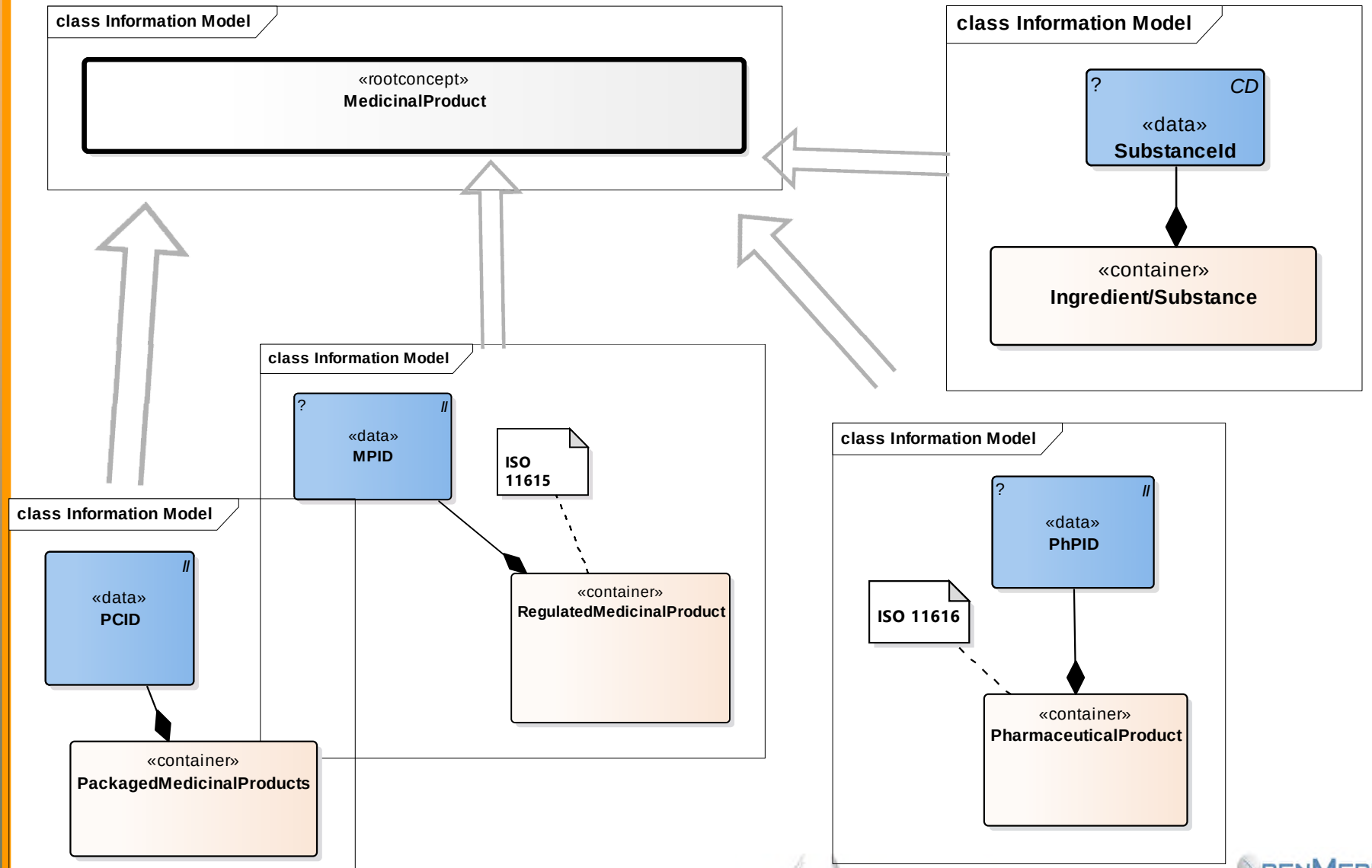
# Use Cases

- ePrescription
- eDispense
- Their documentation

# Identify the identifiers

| Table 1. Core identifying data elements from IDMP for all use cases for all domains. | | | | | |
|---|---|---|---|---|---|
| Source | **Data element** | **EMA article 57 database** | **Use case Xborder ePrescription / Dispense / Record keeping** | **Include/ exclude in DCM** | **Motivation** |
| ISO 11238 | Substance ID | Include | Include | include | Every substance will be identified by this mandatory ID. |
| ISO 11616 | Pharmaceutical Product Identifier PhPID | Include | Include | include | Every pharmaceutical product will be identified by this mandatory ID. |
| ISO 11615 | Medicinal Product Identifier MPID | Include | Include | include | Every (regulated) medicinal product will be identified by this mandatory ID. |
| ISO 11615 | Packaged Medicinal Product Identifier (PCID) | Include | Include | include | Every packaged product will be identified by this mandatory ID. |

# Medicinal product Detailed Clinical Model





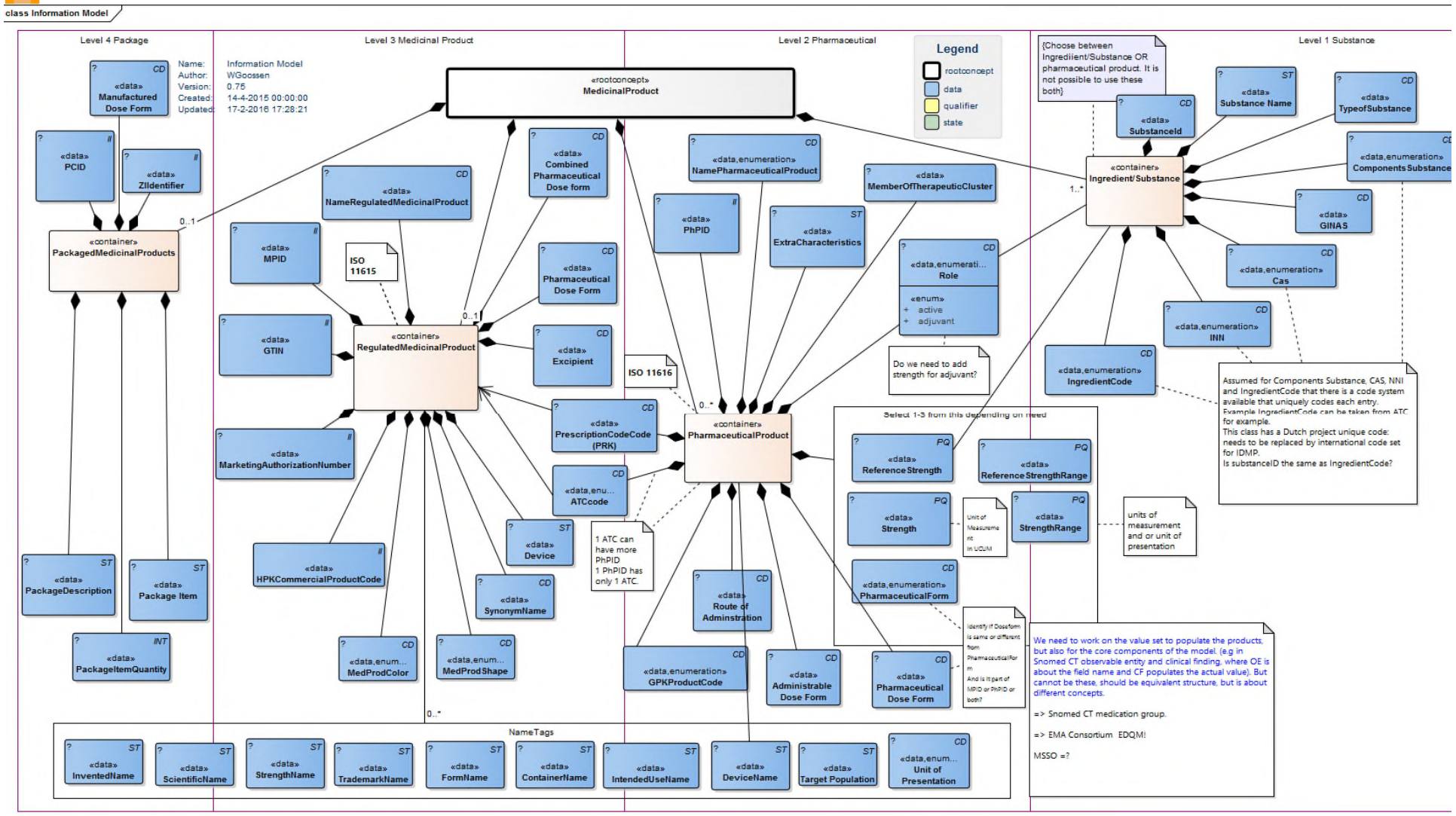
OPENMEDICINE is a project funded by the European Commission in the context of HORIZON 2020

# And all other IDMP items….

Table 2 Data elements from the substance standard EN ISO 11238 and implementation guide ISO TS 19844 (FRAGMENT ONLY)

| Source ISO IDMP | IDMP data elements | IDMP: Mandatory Should Conditional | EMA article 57 database | Xborder use case | DCM include/ exclude | Motivation |
|---|---|---|---|---|---|---|
| ISO TS 19844 | Ingredient | M | | include | include | 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. |
| ISO TS 19844 | 4.1. Specified_Substance | M | | include | include optional | This one is normally not used in clinical practice, and hence not yet included in the DCM. However, included optional based on expert input. |
| ISO TS 19844 | 4.1. Specified_SubstanceGroup | M | | include | exclude | Valueset 4 categories. Normally not used in clinical practice, could be considered for an extension later? |
| ISO TS 19844 | 4.2. Substance_ID | M | | include | include | 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. |

# Medicinal product DCM





PENMEDICINE is a project funded by the European Commission in the context of PENMEDICINE 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.