Change request
Pharmaceutical Dose Form

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Project	-	Contact person	-
Dataset release	2023.1	Consulted expert	-

1   Change request input / rationale

The European Directorate for the Quality of Medicines & HealthCare (EDQM) is using the Pharmaceutical Dose Form (PDF) as a new standard coding system[1].
HCI Solutions has introduced the PDF defined by EDQM with new drugs making it available as part of its catalogue. A mapping between EDQM and SNOMED CT is currently under development[2].

In SNOMED CT, the pharmaceutical dose form and its descendants can be defined by up to five attributes (basic dose form, dose form intended site, dose form release characteristics, dose form transformation, dose form administration method). In return that means that for the highest granularity five data elements are necesssary to unambiguously model the PDF.

At multiple SPHN sites (CHUV, USB) data are modelled as galenic form and route of application separately making it difficult to map the PDF unambiguosly. Hence, it could make sense to model the concept on attribute level to account for highest resolution of available data and unambiguosness.

The document contains two proposals that have been discussed. Proposal A has been selected due to its advantages outweighing the ones of Proposal B (see Discussion), and was integrated into the SPHN Dataset release 2023.1. Suggested revision of Drug Administration Event and Drug Prescription concepts has been done and resulted in deletion of the composedOf administrable dose form in both concepts.
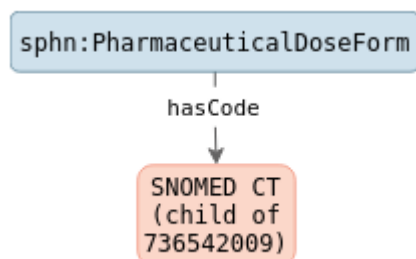
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[1]
https://www.edqm.eu/documents/52006/389906/standard_terms_internal_vocabularies_for_pharmaceutical_dose_forms.pdf/dd395dc1-4d44-9c2e-ce7f-0d788d57b328?t=1651562025434

[2]
https://confluence.ihtsdotools.org/display/USRG/Mapping+Guidance+for+EDQM+to+SNOMED+CT+Pharmaceutical+Dose+Form+Mapping

2 Change content

2.1 Currently released concept (Release 2022.1)

Concept name	Description	Type	Standard	Value set	Meaning binding SNOMED CT	Meaning binding LOINC
Pharmaceutical Dose Form	physical manifestation of a product that contains the active ingredient(s) and/or inactive ingredient(s) that are intended to be delivered to the patient				736542009 |Pharmaceutical dose form (dose form)|	
code	code, coding system and version used to define the pharmaceutical dose form	Code	SNOMED CT	child of : 736542009 |Pharmaceutical dose form (dose form)|		

2.2 Proposed new concept

Because of the complexety of the topic (see discussion for further details), there are two possible proposals for the Pharmaceutical Dose Form.
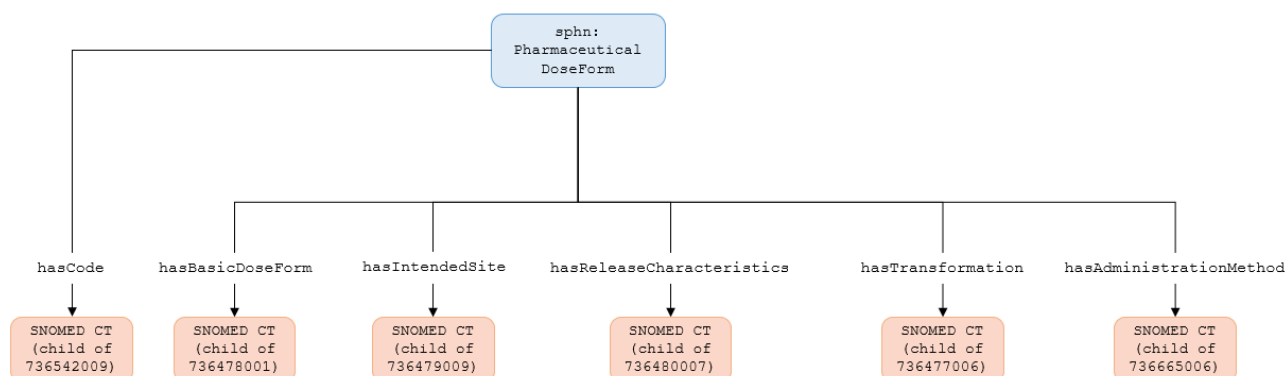
2.2.1 Proposal A: Keep concept as is and extend value set

The suggested approach would be to keep the current concept as it is and add EDQM as a standard.

Concept name	Description	Type	Standard	Value set	Meaning binding SNOMED CT	Meaning binding LOINC
Pharmaceutical Dose Form	physical manifestation of a product that contains the active ingredient(s) and/or inactive ingredient(s) that are intended to be delivered to the patient				736542009 |Pharmaceutical dose form (dose form)|	
code	code, coding system and version used to define the pharmaceutical dose form	Code	SNOMED CT, EDQM	for SNOMED CT : descendant of: 736542009 |Pharmaceutical dose form (dose form)|; for EDQM : descendant of: EDQMPDF		

2.2.2 Proposal B: Expand concept for attributes

The following concept set up could be used according to the SNOMED and EDQM semantics in case projects need detailed information or parts of it.

Concept name	Description	Type	Standard	Value set	Meaning binding SNOMED CT	Meaning binding LOINC
Pharmaceutical Dose Form	physical manifestation of a product that contains the active ingredient(s) and/or inactive ingredient(s) that are intended to be delivered to the patient				736542009 |Pharmaceutical dose form (dose form)|	
code	code, coding system and version used to define the pharmaceutical dose form	Code	SNOMED CT, EDQM	SNOMED CT: descendant of: 736542009 |Pharmaceutical dose form (dose form)|		
basic dose form	code, coding system and version used to define the basic dose form	Code	SNOMED CT	descendant of: 736478001 |Basic dose form (basic dose form)|		
intended site	code, coding system and version used to define the dose form intended site	Code	SNOMED CT	descendant of: 736479009 |Dose form intended site (intended site)|		
release characteristics	code, coding system and version used to define the dose form release characteristics	Code	SNOMED CT	descendant of: 736480007 |Dose form release characteristic (release characteristic)|		
transformation	code, coding system and version used to define the dose form transformation	Code	SNOMED CT	descendant of: 736477006 |Dose form transformation (transformation)|		

administration method	code, coding system and version used to define the dose form administration method	Code	SNOMED CT	descendant of: 736665006 |Dose form administration method (administration method)|

3 Pros and cons

3.1 Advantages

3.1.1 Advantage of Proposal A
- Relevant steps are depending on external parties (HCI Solutions/Compendium, EDQM, SNOMED), hence it makes sense to wait for progress on their side.
- Limit excessive work for the CDWH-Teams on the respective sites.
- Use information that is already available within the Compendium catalogue (should the PDF be available, all other attributes can be derived, allowing seamless analysis across all available data).

3.1.2 Advantage of Proposal B

- Gather as much information as possible about the properties of the PDF in case the code for the PDF itself is missing (depending on the context or the source, different attributes might be separately available to still provide some level of information).

3.2 Disadvantages

3.2.1 Disadvantage of Proposal A
- No use of historic drug data possible (drugs that are no longer published in the Compendium and hence don't have an EDQM code for the PDF).
- Dependency on external parties for releases of catalogues and mappings.

3.2.2 Disadvantage of Proposal B
- If executed on a hospital level, mappings might have differences in quality and high heterogeneity in content, exchange of data and overall analysis might be difficult because of that.
- Overloaded concept as a result with unnecessary elements that could be derived if the code for the PDF is available.
- Not all PDFs can unambiguously be reconstructed out of the attributes, even if all five of them are available.

4   Impact and effort

4.1   Impact on SPHN Dataset
In any case (Proposal A or B), the SPHN concepts for Drug Administration Event and Drug Prescription should be revised.

4.2   Impact on SPHN RDF Schema
The RDF schemes would probably have to be adapted, however, to which extent has to be separately discussed within the RDF-group following the three pillar approach. This concept proposal contains the maximal dataset. Realization within the RDF-scheme doesn't have to contain the maximal dataset but can be controlled by cardinalities.

5   Discussion

A few things need to be considered when deciding about the semantics of the Pharmaceutical Dose Form.

1.   **Terminology**: First of all, it needs to be discussed whether SNOMED CT is for now the right terminology for coding the PDF. The drug catalogue from HCI Solutions comes as of today with an EDQM code for the PDF, hence is already implemented in the hospitals and deliverable for all active drugs. Additional mapping from EDQM to SNOMED will be possible as soon as the SNOMED CT extension will be released (see link above). Therefore, either temporarily allowing EDQM codes or waiting with the mapping until the extension has been released seems sensible in the current situation.

2.   **Intended use**: The PDF is part of the properties of a drug. This is shown in form of the attribute "intended site" both in the SNOMED CT and the EDQM ontology, meaning that the PDF indicates the intended use of a drug as the actual use might differ. Currently, the sphn:PDF concept is connected to sphn:Drug as well as sphn:DrugAdministrationEvent and sphn:DrugPrescription. This on one hand is redundant, because both the sphn:DrugAdministrationEvent and sphn:DrugPrescription are already connected to sphn:Drug; on the other hand the usage of the PDF concept in the context of drug application is most likely not intended. As a consequence, we propose a change of the AdministrableDoseform within the sphn:DrugAdministrationEvent and sphn:DrugPrescription concepts, i.e. the removal of the PDF from the concept; additionally, it is to be discussed if another attribute to describe the application process besides the route of application (which is already included in the concepts) is necessary, e.g. "administered form". Additionally, respecting the intended use, the PDF should not be mapped to data of already administered drugs in the CDWHs.

3.   **Feasibility**: The PDF being the property of a drug means that mapping of the PDF should happen on drug catalogue level (in fact it is part of the HCI Compendium). Hence it needs to be discussed, whether a mapping for older drugs with a missing PDF is reasonable and feasible. Individual mapping on hospital-level will most likely lead to high heterogeneity in quality and content between hospitals and should only be carried out by a person with in-depth understanding of pharmacology.

Taking the above into account it needs to be decided whether there should be additional mapping besides the one provided by the Compendium, additional mapping meaning the mapping of historic drugs within the individual CDWHs that are no longer part of the active Compendium catalogue.

In this case, we recommend to execute this additional mapping as part of a project extension within the next project that requires the PDF concept. Also, the mapping should be governed centrally and not on an individual hospital level. We suggest to use Proposal B as a possible approach to the mapping process in order to allow more consistent mapping with higher granularity.