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EDQM to SNOMED CT Dose Forms Map User Guide

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Table of Contents

1. Introduction 2
Background 2
Document Purpose 2
Document Scope 2
Audience 2
2. Use Cases 3
3. Mapping Policy 6
Aim and Objectives 6
Scope 6
Association/Correlation and Cardinality 8
4. Mapping Principles 9
Semantic match, even if characteristics/attributes are not an exact match 9
Matching the granularity of PDF description 9
Patterns for administration method 10
The device/physical object boundary 10
4.1 The Semantics of the Source and Target Dose Forms 12
5. Implementation Guidance 20
Appendix A - Map View and Download Options 21

EDQM is a directorate of the Council of Europe, created in 1964 to provide common standards to control the quality of medicines and substances used in the manufacture of medicines. EDQM's Standard Terms Database contains terms and definitions to describe pharmaceutical dose forms, routes of administration, methods of administration, containers, closures, administration devices and units of presentation. These standard terms are designed to support a range of use cases in Europe (and beyond), including use in marketing authorisation applications (MAAs), summaries of product characteristics (SmPCs), labelling, electronic communications, adverse event reporting (pharmacovigilance) and clinical trials.

SNOMED International, in collaboration with EDQM, has published a map from EDQM's pharmaceutical dose forms to SNOMED CT's pharmaceutical dose forms, to help support a range of medication use cases, including authoring a SNOMED CT drug extension (based on authorised product information), linking to patient care processes (which reference drugs that use EDQM dose forms), mapping national/local medication product dictionaries to SNOMED CT for international interoperability, clinical decision support, and mapping an IDMP-compliant regulatory database to SNOMED CT drug concepts.

This user guide describes the main use cases for the map, how to obtain the latest version of the map, the mapping principles that were used to develop the map, and guidance for implementing the map.

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SNOMED CT Document Library: http://snomed.org/doc

1. Introduction

Background

EDQM (the European Directorate for Quality of Medicines - a directorate of the Council of Europe) is a leading organisation that protects public health by enabling the development, supporting the implementation and monitoring the application of quality standards for safe medicines and their safe use. These quality standards are recognised as a scientific benchmark and applied worldwide.

One of these quality standards is the "Standard Terms", a set of concepts used in the definition and description of medicinal products; these include the Pharmaceutical dose form (i.e. the dosage form), Route or method of administration, and certain important Packaging items such as the Container, Closure and Administration device. These Terms were initially produced by the European Pharmacopoeia (Ph. Eur.) Commission following a request from the EU Commission prior to being overseen by EDQM. Now, Standard Terms are managed by EDQM in compliance with the ISO 11239 standard for the description of pharmaceutical dose forms, which is itself part of the IDMP (**ID**entification of **M**edicinal **P**roducts) suite of standards, and as such, gives them global applicability as opposed previously a European focus. Regulatory agencies beyond Europe may submit requests to EDQM for new Terms; supporting evidence for all requests for new Terms must be provided.

The Terms are designed to be used in marketing authorisation applications, medicinal product labelling (including the summary of product characteristics (SmPC), and in electronic communications about medicines. Additionally, in the last 5 years, the Standard Terms have been used for related purposes such as adverse event reporting (pharmacovigilance) and clinical trials. But, whilst the primary use is in the regulatory domain, the Standard Terms bring information to the patient/user/prescriber through their use in SmPC, and it is this that underpins the requirement to map the EDQM Pharmaceutical Dose Forms to the Pharmaceutical Dose forms in SNOMED CT, where dose form is one of the definitional attributes of the Clinical Drug and Real Clinical Drug concepts.

For further information on EDQM and Standard Terms, please see https://standardterms.edqm.eu/

Document Purpose

The purpose of this document is to describe the principles and guidelines that have been used when producing the EDQM to SNOMED CT pharmaceutical dose form map so as to provide support and information for the users of the map such that the map can be used to its best effect.

Document Scope

This user guide covers the following topics:

- The **Use Cases** for the map
- The **Policies** that govern the map in its entirety
- The **Principles** that guide the specific decisions on individual maps
- The **Implementation Guidance** that should be followed when using the map in one or more of its use cases so as to obtain best value from it

Audience

The EDQM to SNOMED CT dose form map and user guide are provided by SNOMED International, in collaboration with EDQM, to support the mapping use cases of SNOMED International Members and Affiliates that:

- Are using EDQM dose forms in the description of medicinal products in their regulatory, national, local or system medicinal product dictionary; and
- Need to use SNOMED CT dose forms to support one or more use cases, e.g. authoring a national SNOMED CT drug extension, international interoperability, or clinical decision support.

For a more complete list of use cases, please refer to Section 2 Use Cases.

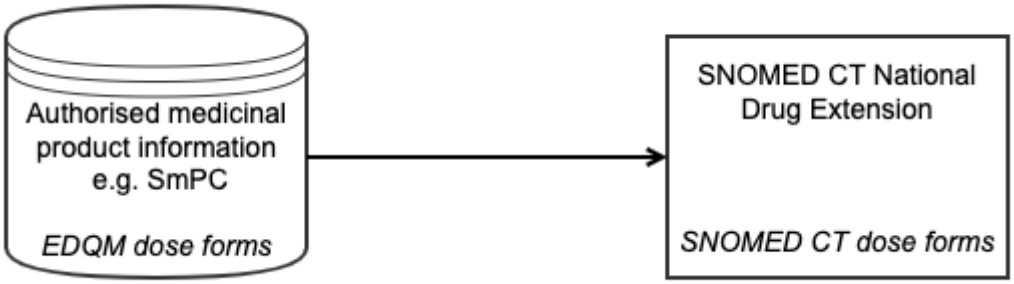
2. Use Cases

The EDQM to SNOMED CT dose form map was developed to support a range of use cases, including:

1. Authoring a SNOMED CT drug extension based on authorised medicinal product information (e.g. SmPC) that uses EDQM dose forms.
2. Mapping a national Medicinal Product Dictionary (MPD) to international SNOMED CT medicine concepts for patient care.
3. Facilitating international interoperability of medication information.
4. Maintaining decision support.
5. Mapping an IDMP-compliant regulatory database to SNOMED CT.

This section describes each of these use cases in more detail.

Authoring a SNOMED CT National Drug Extension



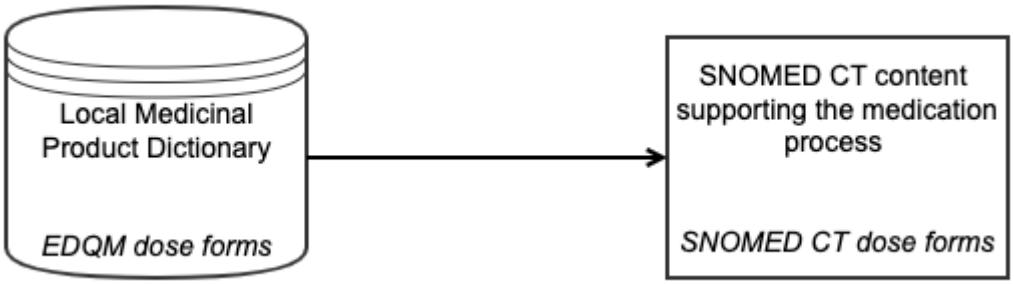
- The national extension wants to represent authorised (real/branded) medicinal products in a SNOMED CT drug extension as Real Clinical Drugs (RCDs), based on the authorised product information, and this authorised product information uses EDQM dose forms.

Therefore: a map from EDQM dose forms to SNOMED CT dose forms significantly helps the authoring of the RCDs, because “pharmaceutical dose form” is a definitional attribute of an RCD.

- The national extension may want to have a more granular abstract representation of some authorised (real/branded) medicinal products than is provided by the SNOMED CT international Clinical Drugs (CDs). These more granular CDs use the more granular pharmaceutical dose form concepts than the ones that are used for describing international CDs.

Therefore: a map from EDQM dose forms to SNOMED CT dose forms significantly helps authoring these additional CDs, as it contains the more granular pharmaceutical dose form concepts used for real products.

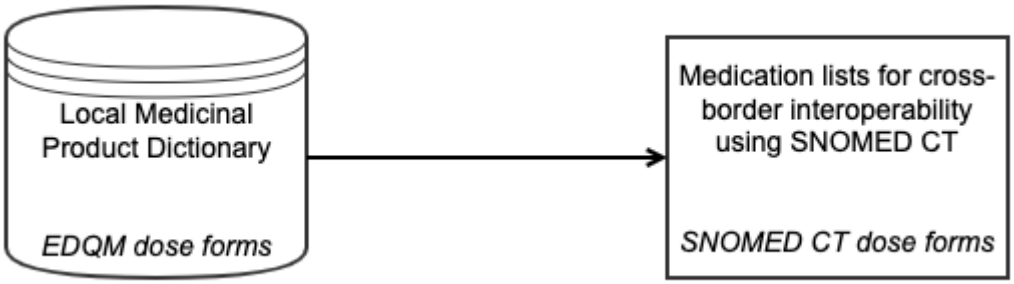
National use of international medicine concepts in patient care



- An organisation wants to map concepts from a national or local Medicinal Product Dictionary (MPD) to international SNOMED CT clinical drugs to support the patient medication process - prescribing/dispensing/administration/recording
  "Prescription" uses abstract concepts (from the international edition), but these must be matched to a local authorised product for dispensing/administration.
- Many or all of the concepts in the MPD use EDQM dose forms as their pharmaceutical dose form.

Therefore: a map from EDQM dose forms to SNOMED CT dose forms significantly helps the mapping because "pharmaceutical dose form" is a definitional attribute of a SNOMED CT clinical drug and is usually a stated attribute of the concept in the national/local MPD. By mapping at the attribute level, much of the medicinal product concept level mapping can be "automated" (at least initially).

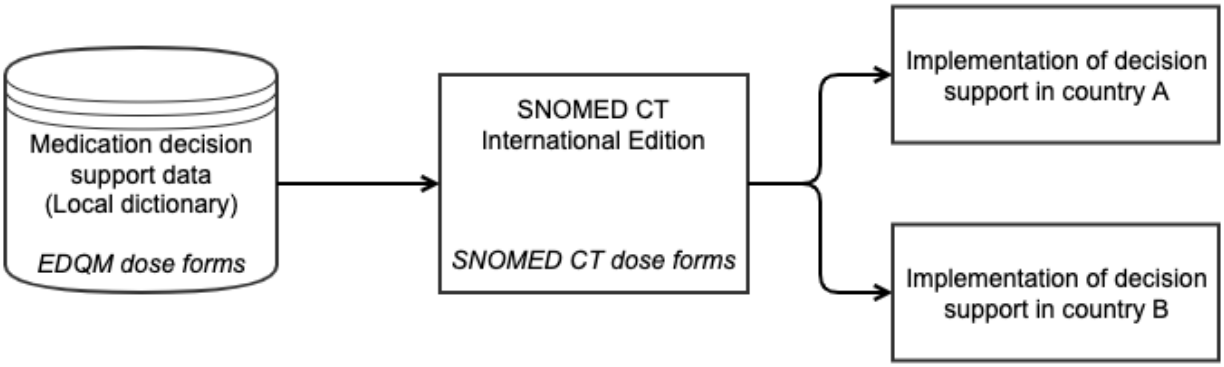
International interoperability of medication information



- An organisation wants to map concepts from a national or local medicinal product dictionary (MPD) to international SNOMED CT clinical drugs for interoperability purposes, such as sharing patient medication lists for cross-border patient-care, pharmacovigilance, and clinical research.
- Many or all of the concepts in the MPD use EDQM dose forms as their dose form.

Therefore: a map from EDQM dose forms to SNOMED CT dose forms significantly helps the mapping because "pharmaceutical dose form" is a definitional attribute of a SNOMED CT clinical drug and is usually a stated attribute of the concept in the national/local MPD. By mapping at the attribute level, much of the concept level mapping can be "automated" (at least initially).

Decision support



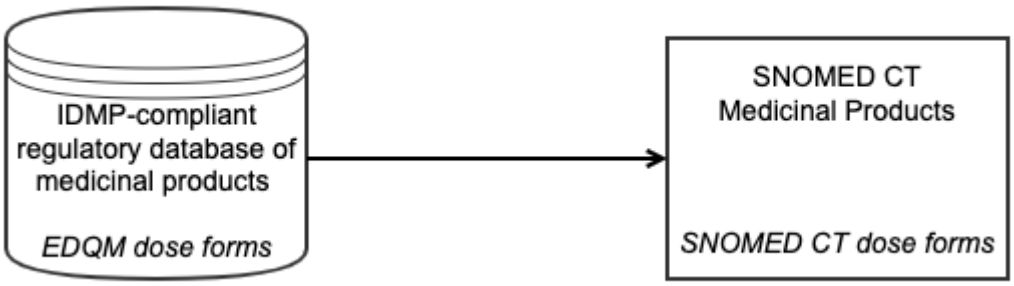
- An organisation wants to manage its knowledge base of medication decision support data by using "international" medication concepts, so uses SNOMED CT and its structures, either directly or indirectly.
- It then needs to map from the local MPD to SNOMED CT for implementation (if the local MPD is not already mapped to SNOMED CT).

- It may also want to "stream in" IDMP data for processing in its decision support system (as described in the next use case).

Therefore: a map from EDQM dose forms to SNOMED CT dose forms significantly helps the mapping because "pharmaceutical dose form" is a definitional attribute of a SNOMED CT clinical drug and is usually a stated attribute of the concept in the national/local MPD. By mapping at the attribute level, much of the concept level mapping can be "automated" (at least initially).

Note: in many ways, this UC is another view on all of the previous use cases since it involves mapping from local/ national MPD to SNOMED CT, using authorised product data etc.

Using IDMP / UNICOM



IDMP (**ID**enditification of **M**edicinal **P**roducts) is a suite of five international standards for representing medicinal products in the regulatory domain and includes, in ISO 11239, a standard for representing pharmaceutical dose forms. UNICOM (https://unicom-project.eu/) is an EU project helping to ensure that any medicine can be accurately identified globally, to improve patient safety (especially in cross-border healthcare), and, through pharmacovigilance and clinical research, enable better healthcare for all.

- An organisation wants to map data from an IDMP-compliant regulatory database of medicinal products to SNOMED CT concepts.
- An IDMP-compliant regulatory database should use EDQM dose forms as their dose form.

Therefore: a map from EDQM dose forms to SNOMED CT dose forms significantly helps the mapping because "pharmaceutical dose form" is a core part of SNOMED CT medicinal product information.

Note: in many ways, this UC is another view on all four of the previous use cases, but we document it separately because of the importance of UNICOM, especially to our European members.

3. Mapping Policy

The **Mapping Policy** describes the guidelines that govern the map as a whole.

Aim and Objectives

The aim of the EDQM to SNOMED CT map is to produce as close as possible to an **exact semantic match mapping** between the EDQM Pharmaceutical Dose Forms in EDQM Standard Terms as the source and the SNOMED CT descendants of 736542009 | Pharmaceutical dose form (dose form) | as targets, to support the use cases described.

The map aims as much as possible for a 1..1 exact semantic match of the pharmaceutical dose forms. In order to achieve that aim, the semantics of each source concept and possible target concepts have been examined in detail, using all available information and ascertaining what within that information was definitional and what was to be considered either descriptional (only) or "implementation guidance" (the latter applying especially for the EDQM Standard Terms).

If, having undertaken that examination, an exact match was not possible, where appropriate within existing guidance, additional concepts were authored within SNOMED CT to support an exact match. For some individual concepts and groups of concepts (for example, those with more than one intended site), this is an ongoing process and may involve further changes within the SNOMED CT dose form content.

Although the process for change within EDQM Standard Terms is more complex for various reasons, some recommendations for change to EDQM Standard Terms have also been made, especially when these are in accordance with recommendations from other groups working with the EDQM Dose Forms.

When studying fully specified names for SNOMED CT dose form concepts and particularly when requesting new concepts, the implications of different languages and the translation process have been considered in order to facilitate as much as possible clarity in the **semantics** of the domain in different languages. However, not all the challenges are directly resolvable, especially when a particular language does not have words to distinguish between concepts with different pharmaceutical meanings (for example, some languages do not have a different word for a transdermal patch, only a word for a plaster).

Scope

Map source: EDQM Pharmaceutical Dose Forms (PDFs)

- Active PDFs at 2021-07-31 that are **not** 'Veterinary only'
- A "snapshot" full download of EDQM PDF data was taken via the EDQM API

The following EDQM PDFs are considered "out of scope" since they either support types of products that are currently out of scope for the SNOMED CT medicinal product hierarchy (e.g., herbal products, blood products), or they are not PDFs within the SNOMED CT definition (e.g., the solvent terms, the living organisms).

EDQM ID	EDQM Term		EDQM ID	EDQM Term
10122000	Herbal tea		11216000	Solvent for parenteral use
10202000	Instant herbal tea		13035000	Solvent for...
13106000	Oral herbal material		10608000	Eye drops, solvent for reconstitution
12105000	Radiopharmaceutical precursor		10611000	Eye lotion, solvent for reconstitution
12106000	Radionuclide generator		50076000	Solvent for solution for infusion
12107000	Kit for radiopharmaceutical preparation		50074000	Solvent for solution for intraocular irrigation
50056500	Radiopharmaceutical precursor, solution		12118000	Living tissue equivalent

EDQM ID	EDQM Term		EDQM ID	EDQM Term
12102000	Anticoagulant and preservative solution for blood		13115000	Medicinal leech
12103000	Solution for blood fraction modification		13124000	Medicinal larvae
12112000	Solution for organ preservation		13118000	Tablet with sensor
10121500	Dispersible tablets for dose dispenser			

Map target: SNOMED CT 20220731 international edition

- Active concepts that are < 736542009 | Pharmaceutical dose form (dose form) |

See also the "No Map" section below for further information about Scope and concepts that are marked as "No map".

⚠ **Definition of a pharmaceutical dose form: "the physical manifestation of a Medicinal Product that contains the active ingredient(s) and/or inactive ingredient(s) that are intended to be delivered to the patient"**
Based on the use cases, PDFs that have been inactivated in EDQM may still be used in product SmPCs; these will require a historical association to an active PDF. This should be considered once the initial scope has been completed.
Patient Friendly Terms (PFT) are currently excluded; these may be used in product labelling but are not used as a definitional attribute for a medicinal product.
Authorised dose forms (those that may be used in section 3 of an SmPC in Europe) include Combined Pharmaceutical Dose Forms, Combined Terms and Combination Pack concepts as well as PDFs. In order to fulfill use case 1, these concepts may require the addition to SNOMED CT, but currently they are out of scope.
A map between the EDQM and SNOMED CT dose form characteristic/attribute values has not been undertaken since in EDQM the characteristics are not definitional. But as discussed in the Principles section following, consistent patterns for the characteristic/attribute values for the various groups of dose forms have been considered wherever possible.

"No map" codes

When an EDQM Standard Terms code is in the scope of the map but no semantically matching concept is present in SNOMED CT this is considered a "No map". A significant number of new PDF concepts have been authored in SNOMED CT to resolve this "No map" situation *when it has been possible to confirm that the PDF is used to describe one or more medicinal concepts authorised in member countries.* As noted in the section describing the EDQM PDFs, EDQM will categorise a dose form as for "human and veterinary use" even if it is requested for initial use with a veterinary medicinal product unless the PDF is specifically for veterinary application (e.g. "Continuous-release intraruminal device"). Therefore there are EDQM PDFs that are within the scope stated above but which have never been used to describe a medicinal product for human use. Whilst it would be possible to author PDF concepts in SNOMED CT that are an exact match for many of these EDQM PDFs, having concepts in SNOMED CT that are not directly required to support patient care is not sensible. However, as each of these EDQM PDFs have been evaluated, they have been assigned an additional category:

- PDF concepts that **SHOULD be added** to SNOMED CT if requested by a member to support authoring of medicinal products. These are PDFs whose semantics can be fully defined using the SNOMED CT PDF concept model and would be clinically useful PDFs for the use cases.
    - For all of these, a fully specified name and logical definition have been suggested.
- PDF concepts that **COULD be added** to SNOMED CT if requested by a member to support authoring of medicinal products. The Dose Form should have an international value for the SNOMED community. These are PDFs whose semantics are not as easy to fully define in SNOMED CT and/or for which there are some reservations as to their clinical usefulness.
    - For these, a fully specified name and logical definition have been tentatively suggested.

- PDF concepts that **SHOULD NOT be added** to SNOMED CT. These are concepts with ambiguous semantics or significant reservations about their clinical usefulness. There are very few of these, and they mostly occur from early, less rigorous requests to EDQM or to describe products that would now not be considered medicinal products. (for example, the EDQM term "implantation tablet"; any new products would be encouraged to use the term "implant").

The assignment of intended maps to these categories will be used to inform future updates of this map.

Association/Correlation and Cardinality

The aim is for the source and target to be "**equivalent**" (i.e. an exact semantic match).

However, some maps will not be exact. In these situations, the map will have a different association type:

A **narrower (than) map**: This association is used when the meaning of the SNOMED CT concept is *narrower than* the meaning of the EDQM concept.

- Another way of saying this is that this is a "broad-to-narrow" map (from the EDQM source concept to the SNOMED CT target concept); this is a 'narrower' mapping because the map is ***to*** a concept with a narrower meaning than the source concept
    - For example, a mapping between "Medicated sponge" in EDQM to "Conventional release cutaneous sponge (dose form)" in SNOMED CT is "narrower" - as the EDQM concept is very generic in terms of not specifying an intended site of administration, whereas the SNOMED CT concept does explicitly have an intended site of administration (cutaneous).
- Note that when 'Narrower than target' maps are made, these may give a 1..* cardinality between an EDQM concept and SNOMED CT concepts, especially when the mapping is considered in its entirety.

A **broader (than) map**: This association is used when the meaning of the SNOMED CT concept is *broader than* the meaning of the EDQM concept, and it is not possible or considered reasonable to author new, more granular SNOMED CT concepts

- Another way of saying this is that this is a "narrow-to-broad" map (from the EDQM source concept to the SNOMED CT target concept); this is a 'broader' mapping because the map is ***to*** a concept with a broader meaning than the source concept
    - For example, a mapping between "Inhalation powder, hard capsule" in EDQM to "Conventional release powder for inhalation (dose form)" in SNOMED_CT is "broader" - as the EDQM concept is precise, particularly in regard to the encapsulation of the dose form whereas the SNOMED CT concept is less explicit, with no description of encapsulation of the inhalation powder.
- Note that when "'Broader than target' maps may be made; these may give a *..1 cardinality when the mapping is considered in its entirety.

In all cases where the mapping is 'Broader than' or 'Narrower than', implementation guidance is provided.

4. Mapping Principles

The **Principles** that guide the specific decisions on individual maps or particular groups of concepts are described below.

The following mapping principles were used to develop the map.

Semantic match, even if characteristics/attributes are not an exact match

The map was developed based on the principle that the source and target codes of 'equivalent' maps must be an exact semantic match. However, the characteristics of a given PDF in Standard Terms may not exactly match the logical definition of a SNOMED CT concept, as long as the "mismatch" does not cause a semantic conflict. Indeed in some cases, the mismatch may enhance the match. Here are some examples:

- The SNOMED CT FSN is apparently narrower than the EDQM Term based on the intended site characteristic but is an exact match based on the definition; this usually occurs when the EDQM Term uses a grouper concept for the characteristic, whereas the SNOMED CT uses the specific concept for the attribute.
    - EDQM intended site "cutaneous/transdermal" whereas SNOMED CT has explicitly either cutaneous or transdermal as appropriate.
    - EDQM intended site "oromucosal" whereas SNOMED CT has explicitly either buccal, sublingual, etc., as appropriate.
- The SNOMED CT PDF uses a different administration method than the EDQM Term, but the difference is not considered clinically significant.
    - EDQM administration method for "rectal foam" is the very generic "administration," whereas SNOMED CT has the administration method "apply".

A characteristic/attribute mismatch must respect the semantics of the Term: for example, the EDQM PDF "oral gel" is used for medicinal products that will be swallowed, whereas the SNOMED CT "conventional release oral gel" has an administration method of "apply" is not appropriate since application implies use on a body surface. (Note, this SNOMED CT concept is currently subject to a change request to resolve this and allow a semantic match)

For more information on the semantic representation of codes in the source and target terminologies, please refer to 4.1 The Semantics of the Source and Target Dose Forms.

Matching the granularity of PDF description

Several groups of EDQM PDFs have greater granularity than the similar dose forms used in the definition of clinical drugs in the SNOMED CT International edition. In order to provide a good semantic match, especially for the description of RCDs, SNOMED CT has the more granular dose form concepts modeled such that the more granular PDF concepts can be grouped under a less granular parent concept.

Basic dose form

In order to achieve the full definition of PDFs with this greater granularity, some additional basic dose forms have been created in SNOMED CT. This occurs particularly (but not exclusively) with oral dose forms:

- Hard and soft capsules:
    - Whilst the prescription process is rarely interested in the difference between hard capsules (two halves of a firm shell, one of which "slips over" the other to seal) and soft capsules (filled and sealed in a single process), it is of importance to the dispensing/administration process because there is a difference in divisibility and administration (open the capsule and sprinkle), and therefore this granularity is needed to describe RCDs in national extensions.
- Coated and film-coated concepts; molded and compressed lozenges:
    - Although when describing abstract concepts such as clinical drugs, this level of granularity is not considered, it is frequently used in the description of RCDs since there are pharmacopoeial differences in the dose forms. By having the greater granularity in the basic dose form attribute, RCDs

can be fully described using the exactly matching PDF, and more abstract concepts can be grouped using the parent grouper basic dose form.

Powders and granules

For oral PDFs, powders and granules are differentiated, whereas, for parenteral products for human use, they are not; although EDQM does have the term: "Granules for suspension for injection" it appears not to be used to describe any medicinal products.

Administrable / Transform dose forms

As a general principle. if there is a pharmaceutical dose form that undergoes a transformation to another pharmaceutical dose form, the transformed PDF concept should be available in SNOMED CT International content even if there are no CDs that directly require it. This is because even though the RCD would use the manufactured dose form, some extensions may also model "administrable clinical drugs" or equivalent concepts and require the administrable dose form.

For example, "Powder for intravesical solution" will transform to "Intravesical solution"; both must exist as PDF concepts.

Patterns for administration method

Wherever possible, patterns for administration method have been used for all PDF concepts, and these contribute to ensuring concepts have an exact semantic match.

Drops and sprays

Both drops and spray liquid dose forms are present in EDQM and in SNOMED CT. In EDQM, some terms use "drops" or "spray" as the basic dose form, and terms that use the more usual "solution/suspension/emulsion/dispersion" basic dose forms. The former terms are original and are not recommended for use in new medicinal product authorisations.

In SNOMED CT, there are also unspecified "drops" or "spray" concepts, where the basic dose form is not given (nor is a transformation, since there cannot be the certainty that a transform will not occur), and the definition is supported by the administration method (instill for drops and spray for sprays); these concepts are used to describe international clinical drugs. SNOMED CT also has more granular concepts with the basic dose form and transformation specified to support a direct match to the EDQM concepts; however, these concepts do not relate to each other directly in the hierarchy because of the lack of basic dose form.

The administration method of "instill" is also used for liquid installations, liquids administered to body cavities (bladder instillation, etc.).

"Rinse or wash" and bath

Several EDQM PDFs are described as "washes" (for example, "ear wash") where the semantic is of the liquid (containing one or more medicinal substances) flowing over or through the site, flushing and cleansing it but not remaining in or at the site for a prolonged period. To obtain semantically matching concepts, SNOMED CT has PDFs that have the administration method of "rinse/wash". Irrigation solutions also use the administration method of "rinse/wash".

Other EDQM PDFs are described as for bathing, where the intended site is in contact with the liquid (containing one or more medicinal substance(s)) - often by immersion - for a prolonged period.

The device/physical object boundary

Finding the boundary between some dose forms and the products and medical devices, which are physical objects in SNOMED CT, can be challenging. Medicinal products contain one or more substances that are intended "for treating or preventing disease, with the view to making a medical diagnosis or to restore, correct or modify

physiological functions"[1], so in any situation where there is a requirement to "contain" those substances for administration, a pharmaceutical dose form should exist. This means that, for example, PDFs for dialysis solutions are required since these "contain" the substances that pull the toxins from the patient's blood into the dialysate.

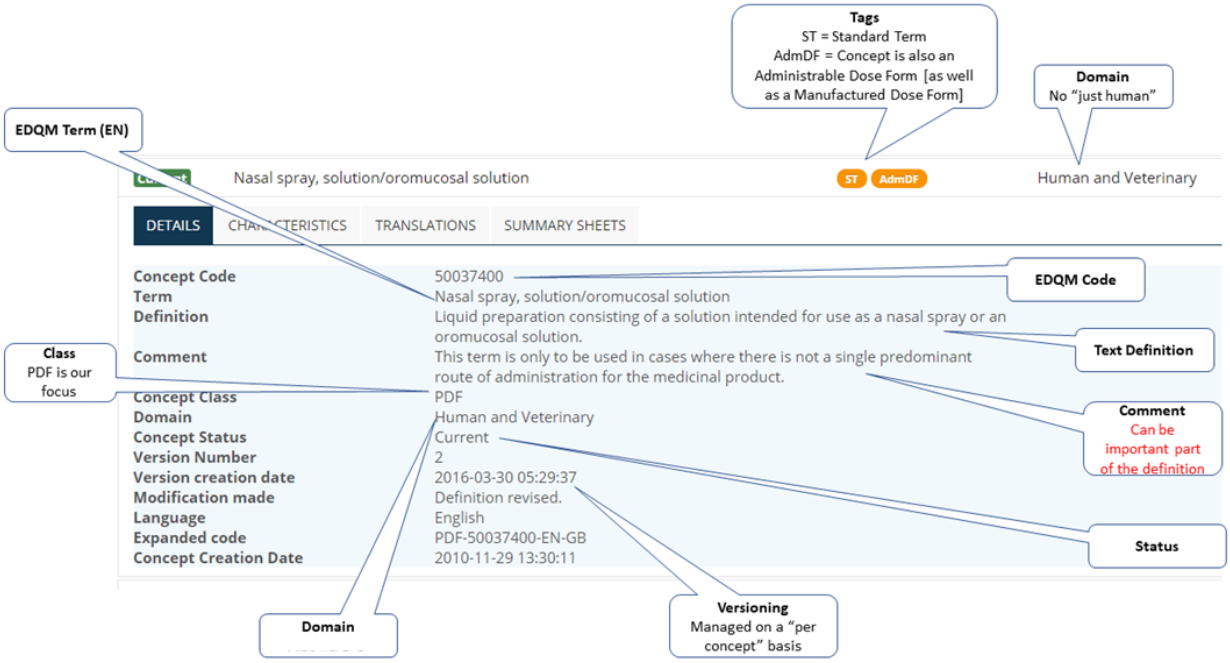
[1] ISO 11615: Identification of Medicinal Products

4.1 The Semantics of the Source and Target Dose Forms

In this section, we compare the different approaches used by EDQM and SNOMED CT to represent the meaning of pharmaceutical dose forms. This understanding was used to develop the principles for defining semantic matches between EDQM and SNOMED CT dose forms.

Source Terminology: EDQM Pharmaceutical Dose Forms (PDFs)

An example of the source EDQM pharmaceutical dose form terminology is shown below, taken from the Standard Terms browser:



EDQM Term, Definition, and Comment

The EDQM PDF concept has a name (term) and a (text) definition; these are the most important pieces of data to understand the concept's meaning; this is given in English. In the "Translations" tab, the name of the dose form is given in the other European languages.

Exclusion statements

Exclusion statements may be found either in the main Definition (as in the first example) or in the Comment section (as in the second example below). These are provided not as explicit exclusion from a higher level concept but as implementation guidance" for marketing authorisation applicants to support them when selecting a PDF to describe their product. This means that, despite these exclusion statements, an EDQM higher-level PDF concept is semantically equivalent to a SNOMED CT higher-level (grouper) concept PDF.

DETAILS | CHARACTERISTICS | TRANSLATIONS | LINKED TERMS | SUMMARY SHEETS

Concept Code	10308200
Term	Oromucosal spray, solution
Definition	Liquid, usually multidose preparation consisting of a solution intended for oromucosal use. It is administered by spraying into the oral cavity or onto a specific part of the oral cavity or the throat. It is presented in a container with a spray pump or in a pressurised container with or without a metering valve. Sublingual sprays are excluded.
Concept Class	PDF

This exclusion statement guides a marketing authorisation applicant with a product that is intended for use sublingually to select the specific PDF "Sublingual spray, solution" rather than this less explicit "Oromucosal spray, solution" PDF.

Term	Laryngopharyngeal spray, solution
Definition	Liquid preparation consisting of a solution intended for spraying onto the laryngopharynx for a local effect.
Comment	'Laryngopharyngeal solution' is excluded.

This exclusion statement in the Comment section guides a marketing authorisation applicant with a product that is intended to apply directly as laryngopharyngeal solution to not use this PDF since this PDF is explicitly for use as a spray.

Intention of use

Within the EDQM definition, there may be statements that are more "descriptional" than definitional that have to be evaluated for the mapping.

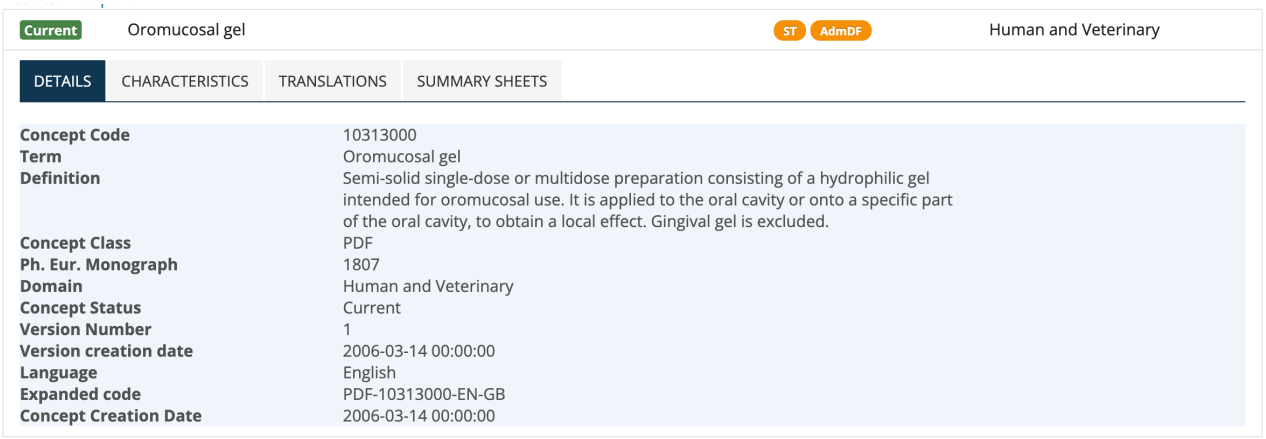
For example, for the "Granules" term, the text says this dose form is a "Solid single-dose or multidose preparation consisting of solid, dry aggregates of powder particles that are sufficiently resistant to withstand handling. Granules are intended for oral use to release active substance(s) in the gastrointestinal fluids at a rate depending essentially on the intrinsic properties of the active substance(s) (conventional release). They may be swallowed as such and/or chewed before swallowing, and some may also be dissolved or dispersed in water or another suitable liquid before oral administration. 'Granules for oral solution' and 'Granules for oral suspension' are excluded". The principle is that if the *intention* is that the dose form *will be* dissolved or dispersed, then the more explicit dose forms should be used ('Granules for oral solution' and 'Granules for oral suspension') whereas if the context is that the granules *may* be dissolved or dispersed but this is not required, then "no transform" is the transform characteristic.

Similarly, the *intention* is that the granules will be swallowed; they may be chewed prior to swallowing or swallowed directly. Although EDQM has both "chewing" and "swallowing" as Administration Method characteristics, "chewing" is not the primary intention and should not be considered definitional. Note that this is in contrast to SNOMED CT, where the attributes, including Administration Method, are definitional (and indeed should be reflected in the Fully Specified Name - within the parameters of the Editorial Guide for Pharmaceutical Dose Forms).

Local or systemic effect

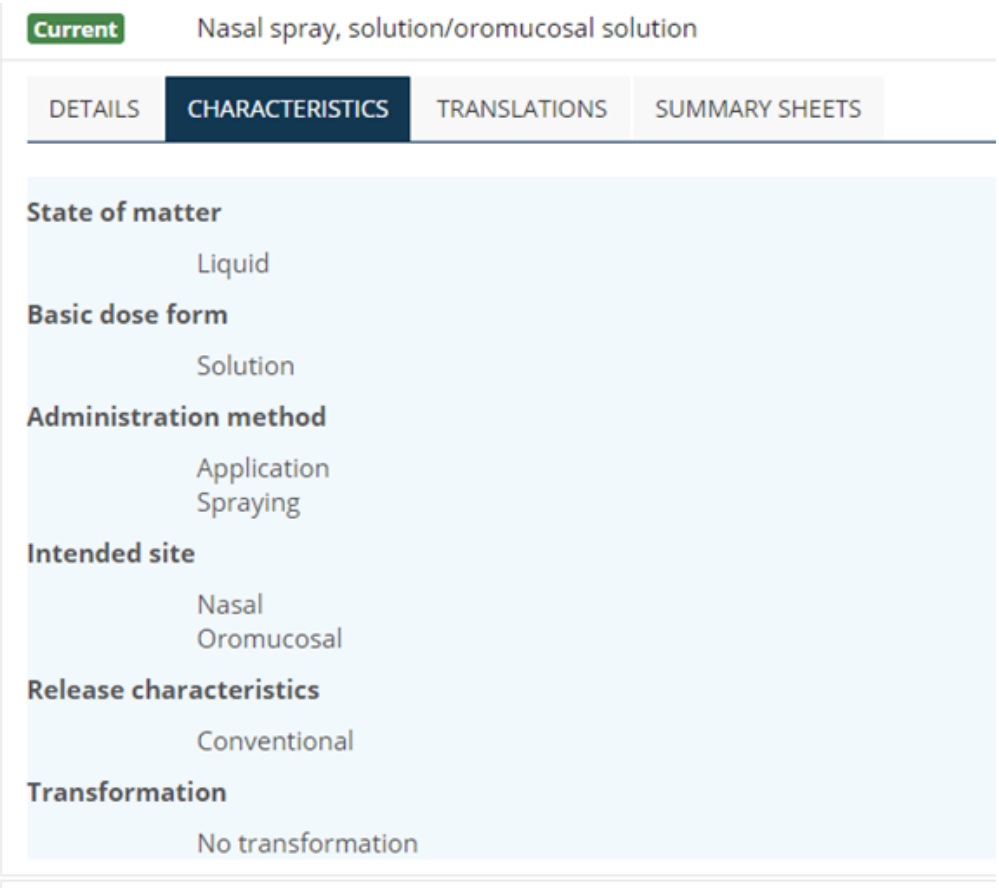
In the concept below "to obtain a local effect" is stated in the definition. The definition of a PDF is concerned with it being the thing that "formulates or encapsulates or contains the active and inactive ingredient substances either at the point of supply (the manufactured dose form) or at the point of administration (the administrable dose form)"; therefore there should be no consideration of what happens to the active substance(s) once the administration has been made and no consideration of what or where their effect will occur. It is not possible to state accurately for any one PDF whether its effect (either therapeutically desired or undesired) will be "local" or "systemic"; for example, there are oral tablets that have no systemic effect (e.g. nystatin). Therefore, even if "for local effect" (or

"for systemic effect") is part of either the definition or the comment for an EDQM PDF concept, it will not be deemed part of the semantic of the concept for mapping.



Characteristics

The characteristic values for a PDF should also be examined whilst remembering that currently, the attributes of a PDF concept in EDQM are **NOT** definitional for the concept. Therefore, there is no requirement for a complete match between the characteristic values of an EDQM PDF and the logical definition of a SNOMED CT PDF.



Definitions for the various values that can be used in the characteristics can be found at:

https://www.edqm.eu/sites/default/files/standard_terms_internal_vocabularies_for_pharmaceutical_dose_forms.pdf

Definitions

State of matter		
ID	**Name**	**Definition**
SOM-0100	Gas	A state of matter consisting of molecules in an elastic aeriform fluid, separated from one another and with freedom of movement, no independent shape or volume and the ability to expand indefinitely.
SOM-0099	Liquid	A state of matter consisting of molecules in a non-rigid structure that retains its volume but conforms to the shape of any container applying pressure to it, and is subject to flow.
SOM-0098	Semi-solid	A state of matter consisting of molecules in a non-rigid structure that can retain its

Multiple Value Characteristics

Term	Nasal spray, solution/oromucosal solution
Definition	Liquid preparation consisting of a solution intended for use as a nasal spray or an oromucosal solution.
Comment	This term is only to be used in cases where there is not a single predominant route of administration for the medicinal product.

A number of EDQM PDF concepts have multiple values for a characteristic; most of these have the comment emphasising that the multiple values have equal emphasis in use; in the above example for the dose form will function equally as a nasal spray or in oromucosal application. This corresponds well to a SNOMED CT PDF concept where the logical definition will not support any "weighting" between attributes.

Multi-site dose forms

As described in the Introduction, the EDQM Standard Terms have their roots deep in the European Pharmacopoeia and this continues to guide their development. This is most clear when describing terms with multiple possible intended sites of administration. For safety reasons, terms with different intended sites (where no site predominates in the usage) will only be accepted if the sites share the same microbiologic (and sometimes other, e.g. pH) requirements. For example, the term "powder for solution for injection, infusion or inhalation", although it has been used to describe some medicinal products (for example, colistimethate products) it is rejected as a Standard Term because of the different specifications for solutions to be inhaled compared to parenterally administered solutions.

Prolonged release

The definition of "prolonged release" is clear that this is "achieved by a special formulation design and/or manufacturing method" - and therefore, by implication, not by the substance. Therefore products containing substances like "haloperidol decanoate", "insulin isophane", or "insulin zinc suspension" should not have prolonged release dose forms as it is the modification of the substance that makes its release longer than the unmodified or simply modified substance, not the dose form.

Category - Human/Veterinary

If EDQM accepts a request for a new pharmaceutical dose form for use with a veterinary product, this will be marked as for "**human and** veterinary use" unless the dose form is specifically formulated for a "veterinary only" intended site - such as a beak or a rumen. For example, "beak dip" is marked as veterinary only. This means that there are some PDFs in the EDQM Standard Terms that have never been used to describe medicinal products for human use.

Target Terminology: SNOMED CT Pharmaceutical Dose Forms (PDFs)

SNOMED CT Fully Specified Name

In SNOMED CT, the fully specified name (FSN) '**unambiguously**' represents the meaning of the concept. In addition:

- For "defined" concepts: the set of defining relationships (the "concept model" - see below) sufficiently represents the logical meaning of the FSN
- For "primitive" concepts: the set of relationships represents part of the logical meaning of the FSN (the totality of the meaning is captured in the FSN)

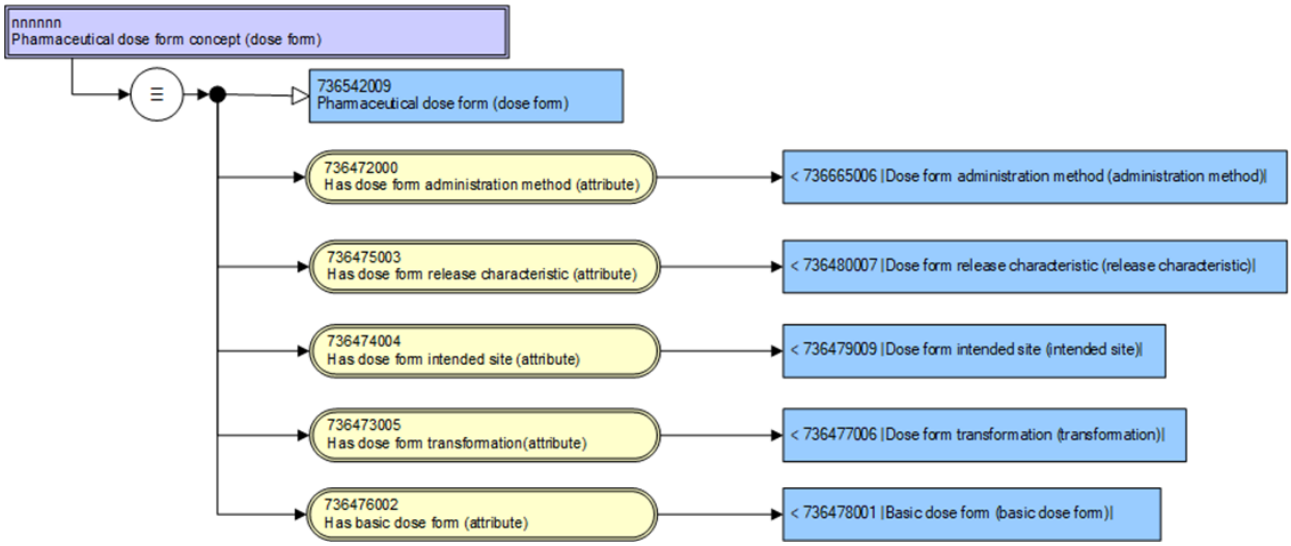
Some text definitions exist, especially for primitive concepts used as attributes in the concept model. For example, the "method of administration" attribute value concepts have a textual definition.

SNOMED CT PDFs are "qualifier values" because they are used as attributes in the medicinal product concept model, but they are still full concepts in their own right.

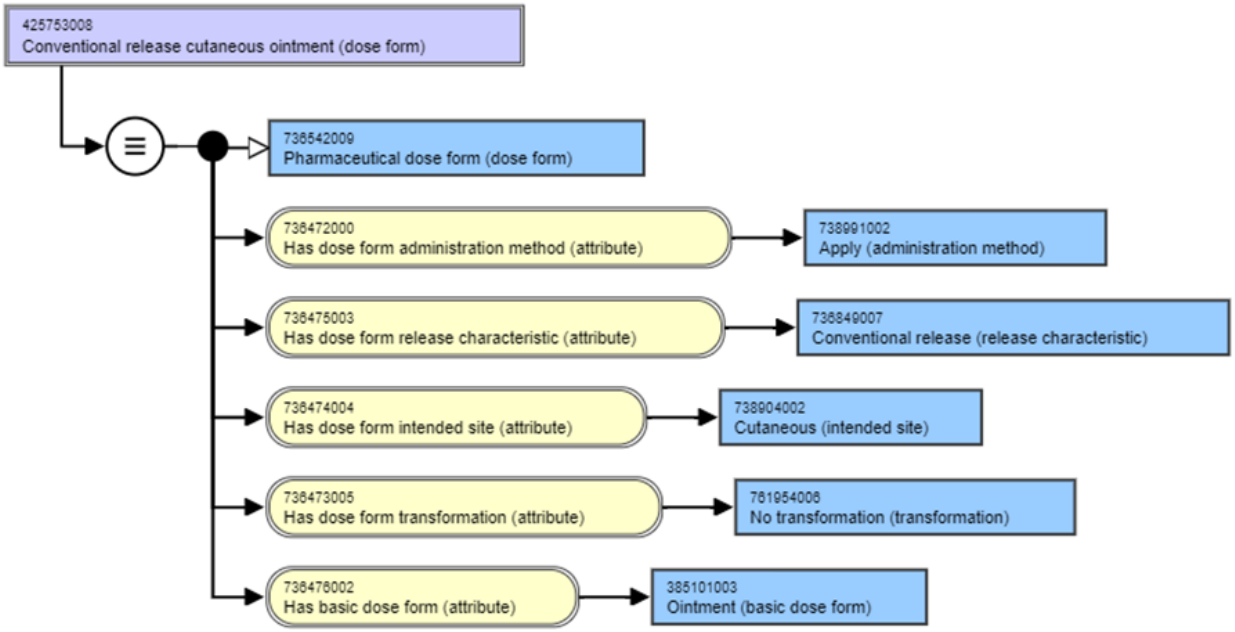
In SNOMED CT, the "stated view" shows the concept as it is directly authored; the "inferred view" adds in relationships to other (grouper) concepts based on the SNOMED CT logic rules.

Pharmaceutical Dose Form Concept Model

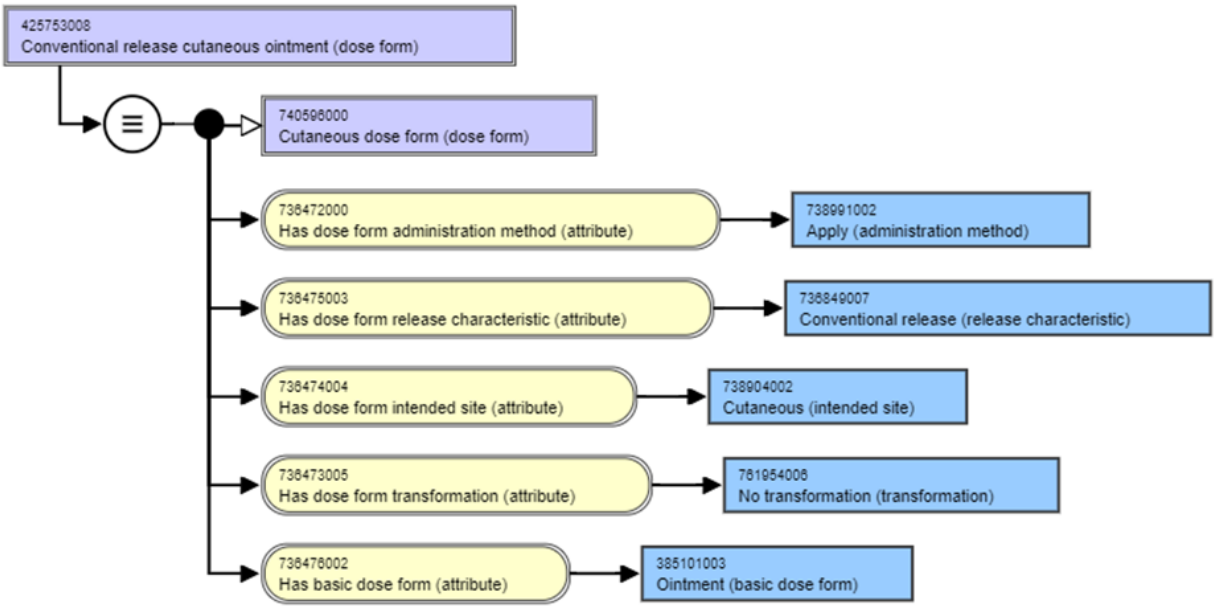
The parent (grouping) concept 736542009 | Pharmaceutical dose form (dose form) | has no attributes (and is therefore marked as "primitive"), but the child concepts - the PDF concepts themselves, have a concept model:



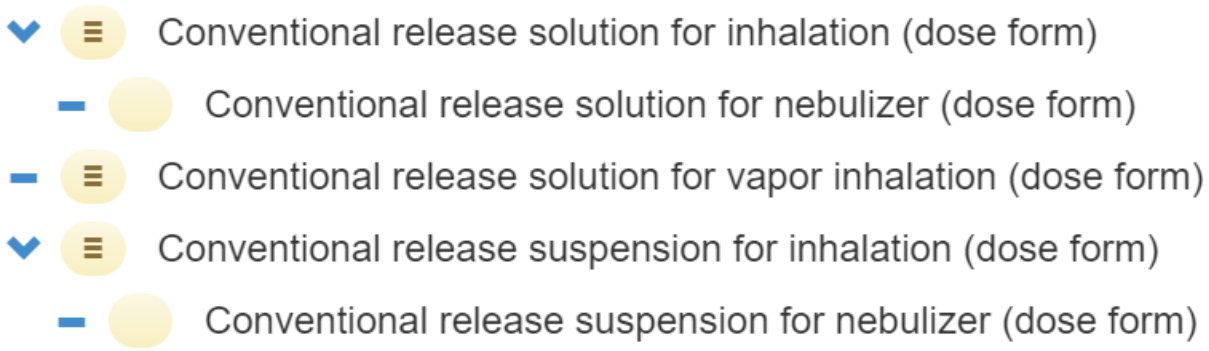
In the diagram above, we can see an example (stated view) showing the single primary (primitive) parent concept that the PDFs are authored under (as an "is_a").



The diagram above shows the stated view of a cutaneous dose form concept and how the primitive concept is selected as a parent. Below, we can see in the same concept how the inferred view is showing the "Cutaneous dose form" grouper concept added in as the inferred parent concept after classification.

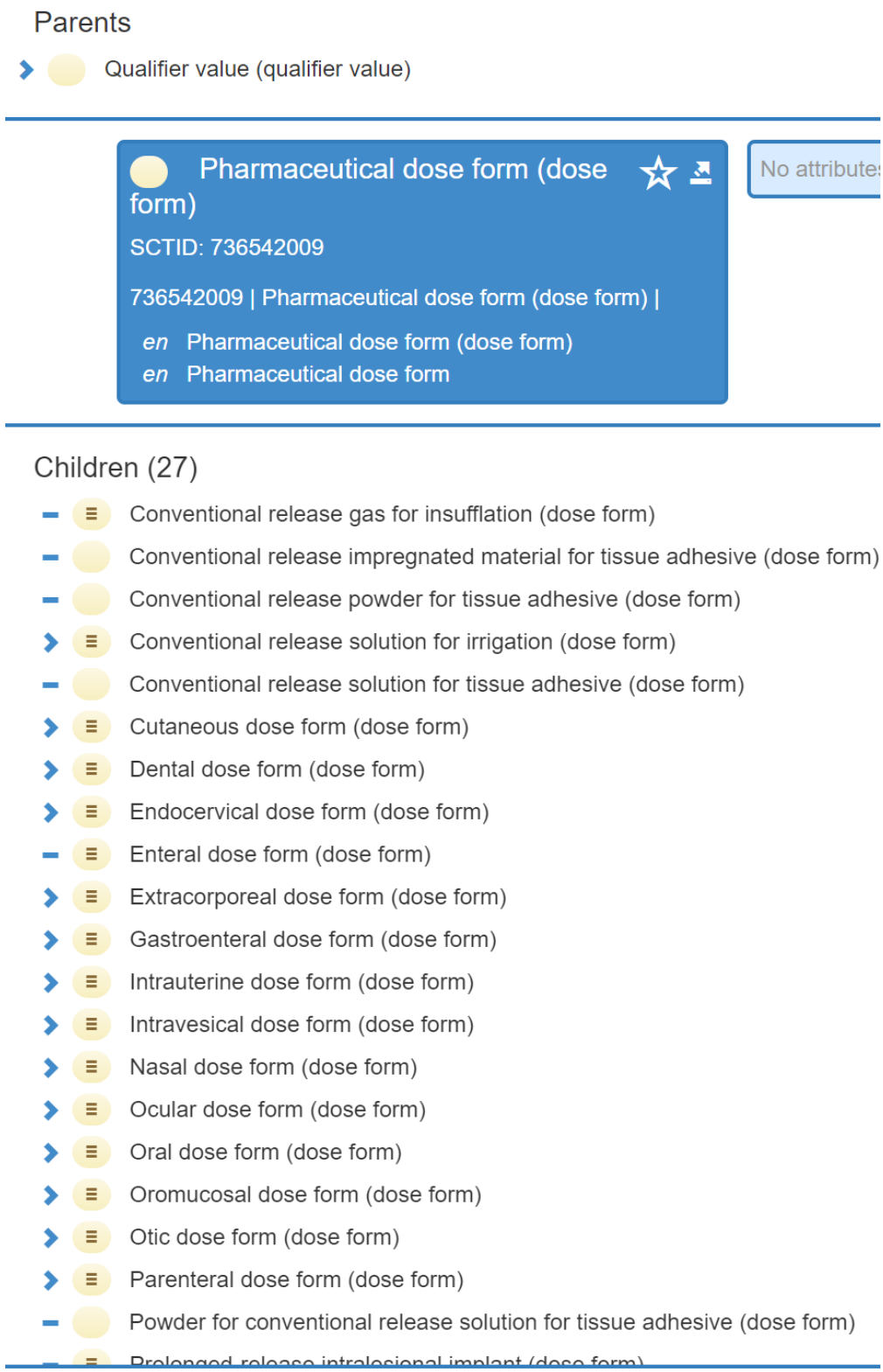


For various reasons, not all PDFs in SNOMED CT can be fully defined. For example, two SNOMED CT concepts cannot share the same logical definition, and both be fully (logically) defined. The diagram below shows some inhalational PDFs that are primitive; the extra meaning (that the PDF is to be used for nebuliser inhalation) is present only in the FSN and cannot be sufficiently described using the attributes in the model.



Hierarchy

Although polyhierarchical, the SNOMED CT browser will display PDF concepts in the inferred view in a hierarchy based on the value of the intended site of the dose form, with a grouper concept acting as the parent:



5. Implementation Guidance

The map is released as a standard RF2 component. A derivative product that can be used in an implementation along with the corresponding version of the International edition and any relevant national extensions.

Loading the map and its dependencies in a terminology server will support the conversion between EDQM and SNOMED codes using a REST API, supporting integration in health information systems and simple adaptation to new versions of the maps. In simpler use cases, the human readable version released as a spreadsheet in the package Release Notes may be sufficient for single-time conversions.

Appendix A - Map View and Download Options

The **draft** EDQM to SNOMED CT pharmaceutical dose form map can be viewed and downloaded in a range of different formats, including:

- The map can be viewed and downloaded (as a CSV, TSV or Excel file) via the Snap2Snomed mapping tool at https://snap.snomedtools.org.
    - Note: For access to the map via Snap2Snomed, please send a request to info@snomed.org with the subject "Access to EDQM dose form map in Snap2SNomed (Implementation Support)", including your Confluence user name.
- The Excel file below contains the 31 Jul 2022 version of the map. To access a more recent version of the map, please refer to one of the previous sources.

File	Modified
EDQM to SNOMED CT Pharmaceutical Dose Form Map (20220731)_20220731.xlsx	2022-Nov-22 by Alejandro Lopez Osornio

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