EDQM Dose Forms to SNOMED CT Map package ALPHA Release Notes - December 2022

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1. Introduction

The SNOMED CT terminology provides a common language that enables a consistent way of indexing, storing, retrieving, and aggregating clinical data across specialties and sites of care. The International Health Terminology Standards Development Organisation (IHTSDO[®]) maintains the SNOMED CT technical design, the content architecture, the SNOMED CT content, and related technical documentation.

EDQM (the European Directorate for the Quality of Medicines & HealthCare - 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.

This document is intended as release notes for the EDQM Dose Forms map to SNOMED CT map release. *This document is a complement to the more general EDQM Dose Form Map User Guide, which describes the map use cases, principles and implementation guidance in detail.*

2. Audience for this document

This document should be read by all those (National Release Centers, vendors of electronic health records, terminology developers and regulators) with an interest in the usage of the EDQM Dose Forms map to SNOMED CT.

3. Background

The EDQM "Standard Terms" is 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/

4. Scope and Purpose of the collaborative work

4.1. Use cases

The scope of the EDQM Dose Forms to SNOMED CT map project was the delivery of a linkage table that would support the following use cases:

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.

A more detailed description of the use cases is available in the User Guide.

The map is distributed as a Simple map with correlation to SNOMED CT type reference set.

The directionality of the map is from EDQM Dose Forms to SNOMED CT. There are currently no plans to produce a map in the other direction (from SNOMED CT to EDQM Dose Forms) - if you have a strong business case for requiring a map in this direction, however, please let us know by sending an email to support@snomed.org.

The User Guide describes the policies and principles used as guidance to produce the mappings.

4.2. Scope: Map Source and Target

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

Some 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). For a complete list of the excluded PDFs you can refer to the map user guide.

Map target: SNOMED CT 20220731 international edition

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

5. Release content

5.1. Overview

The EDQM Dose Forms map derivative content is released under a project-specific module (1237620007 |European Directorate for the Quality of Medicines & Healthcare module (core metadata concept)|) with component identifiers that are within the main IHTSDO (International Release) namespace. The content links into the main International Release dose forms hierarchy, and therefore all the fully specified names in target concepts have a ("physical object") semantic tag.

5.2. Content detail

This release includes 286 map rows, with correlations between the EDQM map source and the SNOMED CT map target defined as either "Equivalent", "Narrower than", or "Broader than".

When an EDQM code was in the scope of the map but no semantically matching concept is present in SNOMED CT this is considered a "No map". In the cases when it has been possible to confirm that the Dose forms were used in pharmaceutical products authorised in member countries this was resolved by creating new content in SNOMED CT during the mapping process. The remaining cases are not part of the release map, these source terms were logged as "No maps" and categorised based on possible mapping approaches in future versions of this product.

5.2.1. Versions of the dependent content

The content in the December 2022 EDQM Dose Forms to SNOMED CT Map package has been updated in line with updates received from EDQM in July 2022, and so the version of EDQM that this ALPHA Release map is based upon is July 2022.

EDQM has been mapped to the July 2022 International Edition of SNOMED CT.

However, the metadata for the EDQM product was published in the December 2022 International Edition, and so the EDQM map content was upgraded in line with the December 2022 International content. The maps themselves were not updated, and are still based on July 2022 content, but the release itself is dependent on the December 2022 International Edition. Therefore, all component states in the December 2022 EDQM Dose Forms to SNOMED CT Map package have been assigned an effectiveTime of 20221231.

The package will be published in January 2023, and so the version of the Package itself is "ALPHA_20230104" - this is to distinguish the Published date (20230104) from the effectiveTime of the underlying dependent content (20221231).

6. Technical Notes

6.1. RF2 package format

The RF2 package convention dictates that it contains all relevant files, regardless of whether or not there is content to be included in each particular release. Therefore, the package contains a mixture of files which contain both header rows and content data, and also files that are intentionally left blank (including only a header record). The reason that these files are not removed from the package is to draw a clear distinction between:

1. ...files that have been deprecated (and therefore removed from the package completely), due to the content no longer being relevant to RF2 in this or future releases, and
2. ...files that just happen to contain no data in this particular release (and are therefore included in the package but left blank, with only a header record), but are still relevant to RF2, and could therefore potentially contain data in future releases.

This allows users to easily distinguish between files that have purposefully been removed or not, as otherwise if files in option 2 above were left out of the package it could be interpreted as an error, rather than an intentional lack of content in that release.

6.2. ALPHA Release Feedback

Feedback should be sent as soon as possible, but no later than the 17th February 2022.

When providing feedback, please include as much detail as possible, incorporating references to, or samples of, specific instances of the issue being reported. The absence of sufficient information to allow SNOMED International to confirm the reported issue may result in no action being taken prior to the Production release. Feedback on content related issues will be assessed and prioritized by SNOMED International, and a decision will be made as to whether to address any reported content issues for the Production release or as part of a future release.

If you have any questions about the EDQM Alpha release, or have difficulties downloading this file, please contact SNOMED International at support@snomed.org with "SNOMED CT EDQM Simple Map package Alpha release question" in the subject line.

Approvals

Final Version	Date	Approver	Comments
1.0	20 Dec 2022	Jane Millar	Approved
1.0	20 Dec 2022	Christopher Jarvis	Approved

Draft Amendment History

Version	Date	Editor	Comments
0.1	11 Nov 2022	Andrew Atkinson	Initial draft
0.2	16 Dec 2022	Andrew Atkinson	Updates in line with new Publication date in Jan 2023
1.0	16 Dec 2022	Alejandro Lopez Osornio	Final updates

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