SNOMED International Position Statement

SNOMED CT Pharmaceutical Product Concept Model and Content, relative to International Third Party Standards

Version	Changes and Additions
Version 1.1 2017-06-27	1. Section 7 - Value Statement(s) added 2. Section 4.2 - Use cases for dugs added 3. Section 4.7 - Correction to Editorial Guide section

1. Introduction

SNOMED CT® is a clinical terminology, created for use in clinical records, for recording relevant clinical information to support patient care and sharing and analysis of information. SNOMED CT® provides Pharmaceutical/biologic product information in a dedicated hierarchy. A key emerging theme globally is the requirement to link clinical medications data and the data required for pharmacovigilance, regulation and supply chain.

Following requests from Members and other stakeholders, SNOMED CT® provides this statement describing the relationship between the proposed SNOMED CT Pharmaceutical/biologic product concept model and other international standards, and includes plans for the coming years.

2. Audience

This *Position Statement* is for policy makers, or equivalent agencies, SNOMED International stakeholder groups, Standards Development Organizations (SDOs), SNOMED CT® implementers and software vendors, pharmaceutical regulators and the pharmaceutical industry.

3. Approach

SNOMED International is proceeding with a two-phase strategy. As described below, Initial efforts will focus on immediate progress for both the July 2017 and Jan 2018 International Releases. An established project with an associated stakeholder-working group has progressed with establishing the scope, editorial guidance and identification of potential impacts to member countries. The detail of long-term efforts has been outlined and will be finalized once constraints from the first phase are removed.

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4. Short Term (July 2017, Jan 2018 International Release)

The short term goals of the SNOMED Drug project will include an agile, risk adverse approach in the area of drug products specifically to;

4.1. Provide coarse level content internationally, supporting granularity at national level.
4.2. Focus on international requirements and regulations, such as initial IDMP alignment to support interoperability defined by the use cases and remove some barriers of adoption.
4.3. Focus specifically on manufactured dose form, not the administrable form.
4.4. The "depth" of the SNOMED CT International drug concept model, is limited to the level of Clinical Drug
4.5. Products that represent foods, additives, and complementary medicines are out of scope for this phase of the project.
4.6. Progressive positive change in the following areas of concentration;
    4.6.1. **Medicinal Product (MP) -**The Medicinal Product (MP) concept is an abstract representation of the intended active ingredient for a drug product. It implies that the drug product non-exclusively contains the intended active ingredient specified in the FSN but may contain other intended active ingredients as well.
    4.6.2. **Medicinal Product Form (MPF**)- The general Medicinal Product Form (MPF) concept is an abstract representation of active ingredient and site-based dose form for a drug product. It implies that the drug product non-exclusively contains the active ingredient in the specific dose form specified in the FSN but may contain other active ingredients as well.
    4.6.3. **Clinical Drug (CD)** -The Clinical Drug (CD) is an abstract representation of the intended active ingredient, basis of strength substance (BoSS), strength, and manufactured dose form of a drug product. It implies that the drug product contains the BoSS(s) in the strength(s) specified in the fully specified name (FSN) but does not necessarily mean that is the only BoSS and strength(s) in the drug product.
4.7. **Editorial Guidelines** -There are ongoing discussions and testing around the modeling and editorial guidelines for product strength, including requirements for strength comparison, normalized versus actual strength, reusability of strength, and harmonization with IDMP. The Editorial Guidelines are expected to continue to evolve as decisions are reached and validated by testing.
4.8. National Extension RFP to progress National level modeling.

5. Long Term (2018 and beyond)

Potential approach of SNOMED international to medical products specifically to;

5.1. SNOMED CT® drug content includes grouper terms to support browsing and analytics.
5.2. The SNOMED CT International Release provides a level of content specification which allows National drug models to link to this high level model to enable the development of

national drug dictionaries that leverage SNOMED CT® to support use cases including data aggregation, decision support, and interoperability and equivalence testing between national extensions. This approach enables a level of consistency globally whilst still allowing flexibility at a national level; e.g. common characteristics, dose forms.

5.3. Development of products to support implementation, provision of value sets to support consistent representation across global standards.

5.4. Mapping of SNOMED CT® Concepts to IDMP Medicinal Products (MPs).

6. Anticipated Outcomes

6.1. Robust concept model for Drugs content

6.2. Consistent and explicit naming

6.3. Initial representation of clinical drugs (those that can be prescribed)

6.4. Phase 1 - Changes, MP (app 1,300), MPF (app 1,300), CD (app 3000)

6.5. Phase 2 - To be confirmed

7. Value Statement(s)

7.1. The redesign of the SNOMED DRUGs hierarchy will provide a more consistent and usable set of international medications concepts for member nations to build their national extensions from.

7.2. For member nations that do not currently maintain a drugs extension a redesigned international drugs hierarchy will provide a consistent basis from which to design their extension.

7.3. It will enable them to learn from the experiences of other nations who have developed extensions.

7.4. It will enable the leveraging of existing national extension data to start population of their extension thereby considerably reducing start-up costs.

7.5. Smaller healthcare markets will benefit because system vendors creating systems based on a model that is used across a number of nations is a more attractive option.

7.6. For member nations that currently maintain a drugs extension a redesigned international drugs hierarchy will facilitate mapping of their extensions to that data providing.

7.7. A consistent basis against which to add national extension content.

7.8. Interoperability of data between systems and nations.

7.9. Will ultimately support the classification of both national and international drugs concepts.

8. Collaboration

SNOMED International welcomes all opportunities to discuss partnerships in order to advance our drug content and quality for our members and stakeholders.