nehta

Australian Medicines Terminology v3 Model Development Approach for Reference Sets v1.1

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Document information

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Product version history

Product version	Date	Release comments
Beta	04 Feb 2013	Beta release, for stakeholder review and comment. Not for clinical use.
Pre-Production	31 Mar 2014	Pre-Production release, for implementation testing. Not for clinical use.
Production	30 Jun 2014	Production release. (Equivalent to v1.0.)
v1.1	18 July 2014	Removed from release bundle and published separately.

Table of contents

1   Introduction

1.1   Purpose of this document

This document describes the development approach used by NEHTA's National Clinical Terminology and Information Service (NCTIS) in creating reference sets for use by the Australian Medicines Terminology (AMT) community of practice.

1.2   Intended audience

This document has been written for those in the AMT community of practice who have a solid understanding of the AMT and its associated concept model, its scope and underlying description logic. It is also helpful in understanding the content if the reader has some knowledge of clinical information models and data modelling principles.

1.3   Scope of this document

This document provides information on reference sets that are available with AMT v3 Model releases.

Progressive development on reference sets will be provided in this document when and if updates are made.

The definitions and statuses applied to reference sets are described in Section 2 of this document.

1.4   Supporting documentation

This document should be read in conjunction with the *NCTIS Reference Set Library* [1]. For general information about the AMT and details of each monthly release, see the release note published with each monthly AMT release.[1]

1.5   Questions and feedback

The development of products by the NCTIS relies on the input and cooperation of the Australian healthcare community. We value your feedback and encourage questions, comments or suggestions about NCTIS products. We also encourage your questions, comments or suggestions about the content of the reference sets.

To provide feedback, or for further information regarding licensing, please contact the Product Lead - AMT via the contact details on page 3.

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[1] The current AMT release is available at: http://www.nehta.gov.au/implementation-resources/ehealth-foundations/australian-medicines-terminology.

2 Reference sets

2.1 About reference sets

Reference sets have a range of diverse applications. At their simplest, they can be described by their two distinct purposes.

Firstly, reference sets serve as a mechanism for managing extensions, data structures and release formats for the technical implementation of AMT.

Secondly, reference sets serve as a mechanism for creating subsets of content from AMT. These reference sets can be used by the AMT community of practice to facilitate the recording, storing, retrieval and processing of information in an electronic health record at the point of care. Each of these reference sets is used to represent a set of AMT components for a specific purpose within a defined scope. Experience shows that while comprehensive terminologies are valuable, they can also pose a challenge for both users and implementers due to their size and breadth of scope. Constraining available concepts to relevant sets provides a means of managing this issue.

2.2 Categorising reference sets

The different types of reference sets and the different contexts in which they are applied are distinguished as follows.

2.2.1 Structural reference sets

Structural reference sets are those that serve as a mechanism for managing extensions, data structures and release formats. These are the reference sets that have the most relevance to implementers because they provide the foundation for and support the implementation of the AMT release files. These include metadata reference sets, cross maps and language reference sets.

2.2.2 Clinical content reference sets

Clinical content reference sets are those that serve as subsets of content from AMT. These are the reference sets that have the most relevance to clinicians and other users of AMT.

2.2.3 Bound and non-bound reference sets

Bound reference sets are those that align with a clinical information specification and take into account data element and data group definitions, as well as other surrounding data structures, which may or may not impact on the content of that reference set. NEHTA's clinical information components are referred to as Detailed Clinical Models (DCMs).[2] The AMT concept model is also considered in this alignment process.

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[2] More information about DCMs is available at: http://www.nehta.gov.au/implementation-resources/clinical-documents/detailed-clinical-model-library.

Non-bound reference sets are those that are agnostic of clinical information specifications and are instead developed against a statement of purpose, scope or general definition. Like bound reference sets, their development takes into account the AMT concept model. Unlike bound reference sets, however, they do not take into account any other definitions or data items that may co-exist where these reference sets might be implemented.

The re-use of bound or non-bound reference sets outside of the context within which they were developed should be approached with caution and a full analysis undertaken to ensure applicability.

Reference sets with specific bindings described in this document are categorised according to those bound to NEHTA clinical information specifications and those bound to other clinical information specifications.

2.3 Reference set patterns

2.3.1 Release Format 2

SNOMED CT[3] Release Format 2 (RF2) categorises AMT reference sets by their pattern, for example:

- Attribute value
- Simple map
- Complex map
- Language
- Query specification
- Annotation
- Association

For more information on the RF2 reference sets and patterns please refer to the *SNOMED CT Technical Implementation Guide* [2].

2.3.2 Concrete domain type reference sets

The AMT v3 model (hereafter "AMT v3") introduces the concrete domain type reference set pattern, which allows the association of a concrete value (numeric) with a component, in this case an AMT relationship. The concrete domain type reference set specification was developed to support the defining of numeric medication attributes – such as Basis of Strength Substance (BoSS). AMT v3 represents the first use of reference sets of this pattern. Further detail on these reference sets is provided in the *AMT v3 Technical Implementation Guide* [3].

This pattern is currently not part of the published SNOMED CT RF2 specifications, but is being considered for inclusion by the IHTSDO Technical Advisory Group.

If the concrete domain type reference set pattern is not included in a subsequent version of the SNOMED CT RF2 specifications, the pattern will continue to be supported as an Australian extension of the RF2 specifications.

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[3] This material includes SNOMED Clinical Terms® (SNOMED CT®) which is used by the permission of the International Health Terminology Standards Development Organisation (IHTSDO®). All rights reserved. SNOMED CT was originally created by The College of American Pathologists. IHTSDO®, SNOMED® and SNOMED CT® are registered trademarks of the IHTSDO.

2.4 Methods for developing reference sets

2.4.1 Overview

The NCTIS is defining and refining various manual and automated methods for developing reference sets. Our primary aim in making the development approach more automated and transparent is to ensure that our methods for identifying content are always understandable, reproducible and useful to the AMT community of practice. A secondary aim in a more automated process is to reduce the burden of maintenance.

This section briefly describes the methods developed to date. They are not mutually exclusive; methods can be combined to produce the desired output. These methods have been used to develop AMT and SNOMED CT-AU reference sets.

2.4.2 Source data mapping method

This method determines suitable AMT concepts on the basis of an existing value set, codeset or list of terms. The process involves mapping the source data to AMT concepts, determining the extent of content coverage, and then creating a reference set. New concepts may or may not be created, depending on the extent of coverage and other factors such as the quality of the underlying terms within the source data files.

The mapping process may be manual or semi-automated (using the appropriate IHTSDO workbench tools). However, the output is not a simple or complex mapping reference set, but an attribute value reference set. The aim is not to produce just a mapping of the source data, but to produce a reference set of AMT concepts that cover clinical or administrative content.

2.4.3 Source data inclusion method

This method uses reference sets as mechanisms for including content in another reference set.

2.4.4 Source data exclusion method

This method uses reference sets as mechanisms for excluding content from another reference set. For example, the Australian non-human reference set within SNOMED CT-AU can be used as a mechanism for identifying non-human concepts and then excluding them or filtering them from appearing in the reference set being created. Note that the Australian non-human reference set is not a veterinary reference set; some veterinary concepts are shared with humans such as "Brain" and "Eye".

2.4.5 Attribute method

This method is comprised of two identical processes, either of which can be used in isolation or jointly. The distinction between the processes is that one is automated and the other is not.

The first process examines the allowable attributes used to define the top-level hierarchies in the AMT concept model to identify the potential concepts for the reference set. The scope, statement of purpose or definition of the reference set is taken into account, and this scope may or may not be bound to a clinical information specification. If it is bound to a specification, then the related data elements within the data group are also considered, to avoid semantic overlap between the concept model and the specifications.

The second process is an automated version of the first. The modelled attribute relationships are identified and then used to create automated rules for the inclusion or exclusion of content.

2.4.6   Concept enumeration method

This method applies automated inclusion or exclusion rules that are built from the concept enumeration values appropriate to a certain field, or a combination of fields, in the AMT core files (tables) and/or structural reference sets.

An example of this method would be to use the active field in the concept file and the valueId field in an attribute value reference set, and then applying automated rules to certain concept enumeration values that equate to an inactive concept. This process enables the automated exclusion of inactive concepts within a reference set.

2.4.7   Simple inclusion method

This method is largely a manual method, even though an IHTSDO workbench tool is used to select concepts. The relevant top-level hierarchies are identified and then sub-hierarchies of concepts or individual concepts are selected for inclusion. The scope, statement of purpose or definition of the reference set is taken into account, and this scope may or may not be bound to a clinical information specification. If it is bound to a specification, then the related data elements within the data group are also considered to avoid semantic overlap between the concept model and the specifications.

As selections are made, rules or guidelines are produced that reflect the logic of the decisions made to include or exclude a concept. Of real importance are the justifications for the level of granularity, and the justification for how the decisions relate back to scope. While the primary aim of the guidelines is to enable reproducibility, they also form the basis of a quality check.

3 Reference sets bound to information specifications

3.1 Containered trade product pack reference set

3.1.1 Reference set definition and usage

The *Containered trade product pack reference set* provides terminology to describe the packaged product (medication) that is supplied for direct patient use including details of the container type.

3.1.2 Binding details

This reference set is applicable across the specifications listed in the following table.

Table 1: Reference set bindings

Detailed Clinical Model or Specification	Details	Considerations
Medication DCM	*Therapeutic Good Identification* data element DE-10194 OID: 1.2.36.1.2001.1001.101.103.10194 Definition: The medicine, vaccine or other therapeutic good that was the focus of the action.	None identified.
Adverse Reaction DCM	*Substance/Agent* data element DE-15521 OID: 1.2.36.1.2001.1001.101.103.15521 Definition: Identification of a substance, agent, or a class of substance considered to be responsible for the adverse reaction. *Specific Substance/Agent* data element DE-16349 OID: 1.2.36.1.2001.1001.101.103.16349 Definition: Specific identification of the substance/agent considered to be responsible for the adverse reaction event.	None identified.

3.1.3 Method for defining reference set content

The *Containered trade product pack reference set* provides terminology to support the recording of a medicine in health records within Australia.

The reference set was developed using the "simple inclusion" method. The *Containered trade product pack* hierarchy was identified as the source for applicable concepts and a further requirement of only "current" active concepts identified for inclusion.

The constraints that were applied to develop this reference set are tabulated below.

Table 2: Containered trade product pack reference set constraints

Constraint Type	Details
Inclusions	The content must contain only child concepts with "current" or "pending move" active status from the *Containered trade product pack* hierarchy.
Exclusions	The content must not contain any concepts that are: • Children of *Medicinal product*. • Children of *Medicinal product unit of use*. • Children of *Medicinal product pack*. • Children of *Trade product*. • Children of *Trade product unit of use*. • Children of *Trade product pack*.

3.1.4   Examples of permissible values

- |18830011000036103 *Alphamox 250 mg capsule: hard, 20, blister pack*|
- |20675011000036100 *Diaformin-1000 1 g tablet: film-coated, 90, bottle*|

3.2   Medicinal product reference set

3.2.1   Reference set definition and usage

The *Medicinal product reference set* provides terminology to describe the abstract representation of the active ingredient(s) or substance(s) (devoid of strength and form).

The *Medicinal product reference set* supports "generic prescribing" in a healthcare setting.

3.2.2   Binding details

This reference set is applicable across the specifications listed in the following table.

Table 3: Reference set bindings

Detailed Clinical Model or Specification	Details	Considerations
Medication DCM	*Therapeutic Good Identification* data element DE-10194 OID: 1.2.36.1.2001.1001.101.103.10194 Definition: The medicine, vaccine or other therapeutic good that was the focus of the action.	None identified.

Detailed Clinical Model or Specification	Details	Considerations
Adverse Reaction DCM	*Substance/Agent* data element DE-15521 OID: 1.2.36.1.2001.1001.101.103.15521 Definition: Identification of a substance, agent, or a class of substance that is considered to be responsible for the adverse reaction. *Specific Substance/Agent* data element DE-16349 OID: 1.2.36.1.2001.1001.101.103.16349 Definition: Specific identification of the substance/agent considered to be responsible for the adverse reaction event.	None identified.

3.2.3 Method for defining reference set content

The *Medicinal product reference set* provides terminology to support the recording of a medicine in health records within Australia.

The reference set was developed using the "simple inclusion" method. The *Medicinal product* hierarchy was identified as the source for applicable concepts.

The constraints that were applied to develop this reference set are tabulated below.

Table 4: Medicinal product reference set constraints

Constraint Type	Details
Inclusions	Contains only child concepts with "current" or "pending move" active status from the *Medicinal product* hierarchy that have a direct relationship with *Medicinal product unit of use* concepts.
Exclusions	The content must not contain any concepts that are: • Children of *Medicinal product unit of use*. • Children of *Medicinal product pack*. • Children of *Trade product*. • Children of *Trade product unit of use*. • Children of *Trade product pack*. • Children of *Containered trade product pack*.

3.2.4 Examples of permissible values

- |21823011000036103 *adrenaline*|
- |44940011000036106 *meropenem*|

3.3 Medicinal product pack reference set

3.3.1 Reference set definition and usage

The *Medicinal product pack reference set* provides terminology to describe an abstract concept representing the properties of one or more quantitatively and clinically equivalent Trade Product Packs (TPPs).

3.3.2 Binding details

This reference set is applicable across the specifications listed in the following table.

Table 5: Reference set bindings

Detailed Clinical Model or Specification	Details	Considerations
Medication DCM	*Therapeutic Good Identification* data element DE-10194 OID: 1.2.36.1.2001.1001.101.103.10194 Definition: The medicine, vaccine or other therapeutic good that was the focus of the action.	None identified.
Adverse Reaction DCM	*Substance/Agent* data element DE-15521 OID: 1.2.36.1.2001.1001.101.103.15521 Definition: Identification of a substance, agent, or a class of substance that is considered to be responsible for the adverse reaction. *Specific Substance/Agent* data element DE-16349 OID: 1.2.36.1.2001.1001.101.103.16349 Definition: Specific identification of the substance/agent considered to be responsible for the adverse reaction event.	None identified.

3.3.3 Method for defining reference set content

The *Medicinal product pack reference set* provides terminology to support the recording of a medicine in health records within Australia.

The reference set was developed using the "simple inclusion" method. The *Medicinal product pack* hierarchy was identified as the source for applicable concepts.

The constraints that were applied to develop this reference set are tabulated below.

Table 6: Medicinal product pack reference set constraints

Constraint Type	Details
Inclusions	The content must contain only child concepts with "current" or "pending move" active status from the *Medicinal product pack* hierarchy.
Exclusions	The content must not contain any concepts that are: • Children of *Medicinal product*. • Children of *Medicinal product unit of use*. • Children of *Trade product*. • Children of *Trade product unit of use*. • Children of *Trade product pack*. • Children of *Containered trade product pack*.

3.3.4 Examples of permissible values

- |46470011000036101 *aciclovir 5% cream, 10 g*|

- |63748011000036109 *pseudoephedrine hydrochloride 120 mg tablet, 10*|

3.4 Medicinal product unit of use reference set

3.4.1 Reference set definition and usage

The *Medicinal product unit of use reference set* provides terminology to describe an abstract concept representing the properties of one or more equivalent Trade Product Units of Use (TPUU).

3.4.2 Binding details

This reference set is applicable across the specifications listed in the following table.

Table 7: Reference set bindings

Detailed Clinical Model or Specification	Details	Considerations
Medication DCM	*Therapeutic Good Identification* data element DE-10194 OID: 1.2.36.1.2001.1001.101.103.10194 Definition: The medicine, vaccine or other therapeutic good that was the focus of the action.	None identified.

Detailed Clinical Model or Specification	Details	Considerations
Adverse Reaction DCM	*Substance/Agent* data element DE-15521 OID: 1.2.36.1.2001.1001.101.103.15521 Definition: Identification of a substance, agent, or a class of substance that is considered to be responsible for the adverse reaction. *Specific Substance/Agent* data element DE-16349 OID: 1.2.36.1.2001.1001.101.103.16349 Definition: Specific identification of the substance/agent considered to be responsible for the adverse reaction event.	None identified.

3.4.3   Method for defining reference set content

The *Medicinal product unit of use reference set* provides terminology to support the recording of medicines in health records within Australia.

The reference set was developed using the "simple inclusion" method. The *Medicinal product unit of use* hierarchy was identified as the source for applicable concepts.

The constraints that were applied to develop this reference set are tabulated below.

Table 8: Medicinal product unit of use reference set constraints

Constraint Type	Details
Inclusions	The content must contain only child concepts with "current" or "pending move" active status from the *Medicinal product unit of use* hierarchy that have a direct relationship with *Trade product unit of use* concepts.
Exclusions	The content must not contain any concepts that are: • Children of *Medicinal product*. • Children of *Medicinal product pack*. • Children of *Trade product*. • Children of *Trade product unit of use*. • Children of *Trade product pack*. • Children of *Containered trade product pack*.

3.4.4   Examples of permissible values

- |23550011000036101 *amoxycillin 250 mg capsule*|
- |23529011000036106 *iloprost 20 microgram/2 mL inhalation: solution, ampoule*|

3.5 Trade product reference set

3.5.1 Reference set definition and usage

The *Trade product reference set* provides terminology to describe the product (medication) brand name for either single component products or components of multi-component products regardless of ingredients.

3.5.2 Binding details

This reference set is applicable across the specifications listed in the following table.

Table 9: Reference set bindings

Detailed Clinical Model or Specification	Details	Considerations
Medication DCM	*Therapeutic Good Identification* data element DE-10194 OID: 1.2.36.1.2001.1001.101.103.10194 Definition: The medicine, vaccine or other therapeutic good that was the focus of the action.	None identified.
Adverse Reaction DCM	*Substance/Agent* data element DE-15521 OID: 1.2.36.1.2001.1001.101.103.15521 Definition: Identification of a substance, agent, or a class of substance that is considered to be responsible for the adverse reaction. *Specific Substance/Agent* data element DE-16349 OID: 1.2.36.1.2001.1001.101.103.16349 Definition: Specific identification of the substance/agent considered to be responsible for the adverse reaction.	None identified.

3.5.3 Method for defining reference set content

The *Trade product reference set* provides terminology to support the recording of a medicine in health records within Australia.

The reference set was developed using the "simple inclusion" method. The *Trade product* hierarchy was identified as the source for applicable concepts.

The constraints that were applied to develop this reference set are tabulated below.

Table 10: Trade product reference set constraints

Constraint Type	Details
Inclusions	The content must contain only child concepts with "current" or "pending move" active status from the *Trade product* hierarchy.
Exclusions	The content must not contain any concepts that are: • Children of *Medicinal product*. • Children of *Medicinal product unit of use*. • Children of *Medicinal product pack*. • Children of *Trade product unit of use*. • Children of *Trade product pack*. • Children of *Containered trade product pack*.

3.5.4 Examples of permissible values

- |34821000168106 *Panadeine Forte*|

- |53236011000036103 *Paraderm Plus*|

3.6 Trade product pack reference set

3.6.1 Reference set definition and usage

The *Trade product pack reference set* provides terminology to describe the packaged product (medication) that is supplied for direct patient use.

3.6.2 Binding details

This reference set is applicable across the specifications listed in the following table.

Table 11: Reference set bindings

Detailed Clinical Model or Specification	Details	Considerations
Medication DCM	*Therapeutic Good Identification* data element DE-10194 OID: 1.2.36.1.2001.1001.101.103.10194 Definition: The medicine, vaccine or other therapeutic good that was the focus of the action.	None identified.

Detailed Clinical Model or Specification	Details	Considerations
Adverse Reaction DCM	*Substance/Agent* data element DE-15521 OID: 1.2.36.1.2001.1001.101.103.15521 Definition: Identification of a substance, agent, or a class of substance that is considered to be responsible for the adverse reaction. *Specific Substance/Agent* data element DE-16349 OID: 1.2.36.1.2001.1001.101.103.16349 Definition: Specific identification of the substance/agent considered to be responsible for the adverse reaction event.	None identified.

3.6.3   Method for defining reference set content

The *Trade product pack reference set* provides terminology to support the recording of a medicine in health records within Australia.

The reference set was developed using the "simple inclusion" method. The *Trade product pack* hierarchy was identified as the source for applicable concepts.

The constraints that were applied to develop this reference set are tabulated below.

Table 12: Trade product pack reference set constraints

Constraint Type	Details
Inclusions	The content must contain only child concepts with "current" or "pending move" active status from the *Trade product pack* hierarchy.
Exclusions	The content must not contain any concepts that are: • Children of *Medicinal product*. • Children of *Medicinal product unit of use*. • Children of *Medicinal product pack*. • Children of *Trade product*. • Children of *Trade product unit of use*. • Children of *Containered trade product pack*.

3.6.4   Examples of permissible values

- |12167011000036107 *Adalat 20 mg tablet: film-coated, 60*|
- |11482011000036107 *Diazepam (DBL) 10 mg/2 mL injection: solution, 5 x 2 mL ampoules*|

3.7 Trade product unit of use reference set

3.7.1 Reference set definition and usage

The *Trade product unit of use reference set* provides terminology to describe a single dose unit of a finished dose form that contains a specified amount of an active ingredient substance and is grouped within a particular Trade Product.

3.7.2 Binding details

This reference set is applicable across the specifications listed in the following table.

Table 13: Reference set bindings

Detailed Clinical Model or Specification	Details	Considerations
Medication DCM	*Therapeutic Good Identification* data element DE-10194 OID: 1.2.36.1.2001.1001.101.103.10194 Definition: The medicine, vaccine or other therapeutic good that was the focus of the action.	None identified.
Adverse Reaction DCM	*Substance/Agent* data element DE-15521 OID: 1.2.36.1.2001.1001.101.103.15521 Definition: Identification of a substance, agent, or a class of substance that is considered to be responsible for the adverse reaction. *Specific Substance/Agent* data element DE-16349 OID: 1.2.36.1.2001.1001.101.103.16349 Definition: Specific identification of the substance/agent considered to be responsible for the adverse reaction event.	None identified.

3.7.3 Method for defining reference set content

The *Trade product unit of use reference set* provides terminology to support the recording of a medicine in health records within Australia.

The reference set was developed using the "simple inclusion" method. The *Trade product unit of use* hierarchy was identified as the source for applicable concepts and a further requirement of only "current" active concepts identified for inclusion.

The constraints that were applied to develop this reference set are tabulated below.

Table 14: Trade product unit of use reference set constraints

Constraint Type	Details
Inclusions	The content must contain only child concepts with "current" or "pending move" active status from the *Trade product unit of use* hierarchy.
Exclusions	The content must not contain any concepts that are: • Children of *Medicinal product*. • Children of *Medicinal product unit of use*. • Children of *Medicinal product pack*. • Children of *Trade product*. • Children of *Trade product pack*. • Children of *Containered trade product pack*.

3.7.4 Examples of permissible values

- |6355011000036103 *Alprim 300 mg tablet: uncoated*|

- |65669011000036108 *Nurofen 5% gel*|

3.8 Substance to SNOMED CT-AU mapping reference set

3.8.1 Reference set definition and usage

The *Substance to SNOMED CT-AU mapping reference set* is developed for the implementers of AMT, SNOMED CT-AU and NEHTA DCMs to enable rule development within decision support systems.

AMT and SNOMED CT-AU are currently separate terminologies, and therefore the relationships between AMT products (and their ingredients) and SNOMED CT-AU substances are not stated. The *Substance to SNOMED CT-AU mapping reference set* will contain all AMT substances that are used in a modelled AMT product with a corresponding equivalent or supertype[4] map to a substance in SNOMED CT-AU.

Decision support systems can utilise the relationship or the map for identification of potential allergies, drug-drug and drug-disease interactions:

- Adverse drug reaction and allergy

  The NCTIS has developed a Clinical Information Component for Adverse Reactions. The element capturing the agent or substance within the clinical information component can utilise the *Substance to SNOMED CT-AU mapping reference set* to link the recorded product that caused the reaction to the substance(s) (as described in SNOMED CT-AU) that the patient might have had a reaction to. This map can then be used for the purpose of adverse drug reaction reporting (e.g. TGA ADRS) and decision support alerts.

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[4] That is, the nearest relevant parent concept.

- Drug-drug and drug-disease interaction

  Decision support alerts embedded in medication dispensing software or electronic clinical reference materials are able to utilise the *Substance to SNOMED CT-AU mapping reference set* for identification of potential interactions between drugs and diseases.

A mapping file containing both the equivalent and supertype maps will be released as part of the AMT release, including:

- Equivalent (bi-directional) mapping of non-orphaned AMT substances to SNOMED CT-AU substances. (See "Equivalent Map" in Section 3.8.2.1 below.)

- Supertype (uni-directional) mapping of non-orphaned AMT substances that have no equivalent SNOMED CT-AU substances, are mapped to the nearest parent concept (i.e. supertype concept) in the SNOMED CT-AU *Substance* hierarchy. This is a directional map and must only be used from AMT to SNOMED CT-AU.

3.8.2 Method for defining reference set content and permissible values

3.8.2.1 Inclusions

All AMT substances that are used in a modelled AMT product are possible candidates for inclusion, unless otherwise stated in Section 3.8.2.2.

Equivalent map

Every AMT substance that has an exact concept match in SNOMED CT-AU is mapped as equivalent. Note, the definition of "exact concept match" is not only restricted to a simple description match but also includes semantic equivalence. See "Spelling difference" and "Same meaning different expression" types in the following table. This table lists different types of equivalent mapping, categorised in three groups.

Table 15: Inclusions – equivalent map types

Map Type	Explanation and permissible values	AMT (example)	SNOMED CT-AU (example)
Exact match	Substance descriptions in AMT and SNOMED CT-AU are exact (word for word) matches. • Example: nicotine	2393011000036109 |*nicotine*|	68540007 |*Nicotine*|
Spelling difference	Substance descriptions in SNOMED CT-AU FSN, PT or Synonym have the exact same meanings but have accepted spelling variations compared to the AMT description, e.g. Australian spelling. • Example: amoxicillin	1799011000036105 |*amoxycillin*|	372687004 |*Amoxicillin*|

Map Type	Explanation and permissible values	AMT (example)	SNOMED CT-AU (example)
Same meaning different expression	A substance description in SNOMED CT-AU FSN, PT or Synonym uses a different expression to represent an equivalent AMT substance. • Example: Vitamin K	31759011000036100 |phytomenadione|	65183007 |Vitamin K|

Supertype map

Where a substance in AMT has no equivalent concept in SNOMED CT-AU, it will be mapped to the nearest supertype substance, and an equivalent concept will be modelled in a future release. Table 16 lists different types of supertype mapping, categorised in six groups.

Table 16: Inclusions – supertype map

Substance Type	Explanation and permissible values	AMT (example)	SNOMED CT-AU (example)
Vaccine Substances	An AMT substance concept representing a vaccine component is more granular than a comparable SNOMED CT-AU substance concept. • Example: Pertussis vaccine	73654011000036109 |Bordetella pertussis, acellular pertactin vaccine|	396433007 |Pertussis vaccine|
Substance hydration	An AMT substance has a specific hydration but does not exist in SNOMED CT-AU. **Note:** SNOMED CT-AU substances that do not specify a hydration are considered to be "anhydrous". • Example: ipratropium bromide monohydrate	2231011000036105 |ipratropium bromide monohydrate|	386881005|Ipratropium bromide|
Antivenin/ Antivenom	An AMT antivenin substance concept is more specific than a comparable SNOMED CT-AU substance concept. • Example: king brown snake (Pseudechis australis) antivenom	73617011000036106|king brown snake (Pseudechis australis) antivenom|	398809003|antivenin|
Nutritional/ Dietary Supplements	AMT contains substances that represent a combination of substances contained in a nutritional/dietary supplement. In the mapping file, a map to the nearest supertype substance will be provided. • Example: multi-ingredient supplement	78583011000036109 |high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate|	427298002 |Enteral dietary supplement|

3.8.2.2   Exclusions

Any AMT substance concept that has been identified as erroneous will be excluded. The following table lists different types of AMT substance concepts that are excluded from the *Substance to SNOMED CT-AU mapping reference set*.

Table 17: Exclusion types

Substance Type	Explanation and examples	AMT (example)	SNOMED CT-AU (example)
Dressings	No map will be provided for AMT substances representing dressing products. Where the dressing in AMT contains a substance, e.g. Povidone or silver, an issue will be logged to remodel the AMT product to include a relationship to the contained substance. • Example: silver nitrate wound dressing	48159011000036101 *|dressing with silver|*	N/A

3.9   Australian Register of Therapeutic Goods Identifier (ARTGID) reference set

3.9.1   Reference set definition and usage

The ARTG ID is the primary identifier used to identify therapeutic goods as included in the Australian Register of Therapeutic Goods (ARTG). It is used for review process internally. It may also be used externally for mapping purposes and identification of products.

3.9.2   Method for defining reference set content

The *ARTG ID reference set* provides numerical values associated with the CTPP to support review processes and product identification internally. It can also be used externally for mapping purposes.

The *ARTG ID reference set* is an annotation type reference set. This annotation reference set pattern allows ARTG IDs to be associated with CTPP for the purposes of review and mapping.

Table 18: ARTG ID reference set constraints

Constraint Type	Details
Inclusions	The content must contain only values associated with the CTPP.
Exclusions	The content must not contain any concepts that are: • Children of *Medicinal product*. • Children of *Medicinal product unit of use*. • Children of *Medicinal product pack*. • Children of *Trade product*. • Children of *Trade product unit of use*. • Children of *Trade product pack*.

3.9.3 Examples

- ARTG ID 90925 |*Abilify 5 mg tablet: uncoated, 7 tablets, blister pack*|
- ARTG ID 115547 |*Ablavar 4.88 g/20 mL injection: solution, 10 x 20 mL vials*|

4 Concrete domain reference set

4.1 Strength reference set

4.1.1 Reference set definition and usage

- The *Strength reference set* is a concrete domain reference set type; it provides a machine computable strength representation of the Medicinal Product Unit of Use (MPUU) AS STATED relationship and HAS AUSTRALIAN BoSS relationship to *Substance.*

- It also provides strength representation of Trade Product Unit of Use (TPUU) as an inferred relationship.

4.1.2 Method for defining reference set content

The *Strength reference set* provides a machine-computable strength representation. It was developed using the concrete domain reference set type.[5] The constraints that were applied to develop this reference set are tabulated below.

Table 19: Strength reference set constraints

Constraint Type	Details
References	The AMT components being referenced must be Medicinal Product Unit of Use (MPUU) as stated relationship HAS AUSTRALIAN BoSS relationships to *Substance* with an active status.
	The AMT components being referenced must be Trade Product Unit of Use (TPUU) as inferred relationship HAS AUSTRALIAN BoSS relationships to *Substance* with an active status.
	The value and units included represent the active ingredient strength (specifically the BoSS) of these MPUU concepts.
Permissible values	• "operatorId" should always be "Equal to". • "value" is the concrete value to be associated with the referenced concept, which are to be rational numbers that are > 0. • "unitId" should always be the concept ID of a Unit of Measure (UOM) concept.
Example	• acamprosate 300 mg tablet HAS AUSTRALIAN BoSS acamprosate (referencedComponentId) • Equal to (operatorId) • 300 (value) • mg/each (unitId) • Campral (acamprosate calcium 333 mg) tablet: enteric HAS AUSTRALIAN BoSS acamprosate (referencedComponentId) • Equal to (operatorId) • 300 (value) • mg/each (unitId)

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[5] Refer to the *AMT v3 Technical Implementation Guide* [3] for further information on the *Concrete Domain reference set* pattern (an extension to the SNOMED CT RF2 specifications).

4.2   Unit of use size reference set

4.2.1   Reference set definition and usage

- The *Unit of use size reference set* is a concrete domain type reference set. It denotes the size of each unit of use of the Medicinal Product Unit of Use (MPUU) as a stated relationship and HAS UNIT OF USE relationship to *Unit of Use.*

- It also denotes the size of each unit of use of the Trade Product Unit of Use (TPUU) as an inferred relationship.

4.2.2   Method for defining reference set content

The *Unit of use size reference set* represents the size of an MPUU's unit of use. It was developed using the concrete domain reference set type. The constraints that were applied to develop this reference set are tabulated below.

Table 20: Unit of use size reference set constraints

Constraint Type	Details
References	The AMT components being referenced must be MPUU as stated relationship HAS UNIT OF USE relationships with an active status.
	The AMT components being referenced must be TPUU as inferred relationship HAS UNIT OF USE relationships with an active status.
	The value and units included represent the unit of use size value/units of these MPUU concepts.
Permissible values	• "operatorId" should always be "Equal to". • "value" is the concrete value to be associated with the referenced concept, which are rational numbers that are > 0. • "unitId" should always be the concept ID of a UOM concept.
Example	• aspirin 500 mg + codeine phosphate hemihydrate 9.5 mg tablet "has unit of use" tablet (referencedComponentId) • Equal to (operatorId) • 1 (value) • tablet (unitId) • Disprin Forte (aspirin 500 mg + codeine phosphate hemihydrate 9.5 mg) tablet: dispersible "has unit of use" tablet (referencedComponentId) • Equal to (operatorId) • 1 (value) • tablet (unitId)

4.3   Unit of use quantity reference set

4.3.1   Reference set definition and usage

The *Unit of use quantity reference set* is a concrete domain type reference set; it defines the quantity or number of Medicinal Product Units of Use (MPUUs) within a Medicinal Product Pack (MPP) as described by the MPP HAS MPUU relationship to MPUU.

4.3.2 Method for defining reference set content

The *Unit of use quantity reference set* determines the quantity or number of unit(s) of use of an MPP and TPP.

The reference set was developed using the concrete domain reference set type.

The constraints that were applied to develop this reference set are tabulated below.

Table 21: Unit of use quantity reference set constraints

Constraint Type	Details
References	The AMT components being referenced must be MPP HAS MPUU relationships to MPUU with an active status.
	The AMT components being referenced must be TPP HAS TPUU relationships to TPUU with an active status.
	The value and units included represent the unit of use quantity value/units of these MPP concepts.
Permissible values	• "operatorId" should always be "Equal to"
	• "value" is the concrete value to be associated with the referenced concept, which are rational numbers that are > 0
	• "unitId" should always be the concept ID of a UOM concept
Examples	• amoxycillin 250 mg capsule, 20 "has MPUU" amoxycillin 250mg capsule (referencedComponentId)
	• Equal to (operatorId)
	• 20 (value)
	• capsule (unitId)
	• Amoxil (amoxycillin (as trihydrate) 250 mg) capsule: hard, 20 capsules HAS TPUU Amoxil (amoxycillin (as trihydrate) 250 mg) capsule: hard
	• Equal to (operatorId)
	• 20 (value)
	• capsule (unitId)

4.4 Subpack quantity reference set

4.4.1 Reference set definition and usage

The *Subpack quantity reference set* is a concrete domain type reference set; it defines the quantity or number of subpacks contained within a sequential multi-component item at the product pack level. It typically relates to hormone replacement therapy and oral contraceptive products.

4.4.2 Method for defining reference set content

The *Subpack quantity reference set* represents the quantity or number of subpacks contained within a sequential multi-component item to facilitate decision support within Australia. It was developed using the concrete domain reference set type. The constraints that were applied to develop this reference set are tabulated below.

Table 22: Subpack quantity reference set constraints

Constraint Type	Details
References	The AMT components being referenced must be Medicinal Product Pack (MPP) concepts representing oral contraceptives, hormone replacement therapy products, and any other multi packs that are presented in multiple subpacks.
	The AMT components being referenced must be Trade Product Pack (TPP) AND Containered Trade Product Pack (CTPP) concepts representing oral contraceptives and hormone replacement therapy products that are presented in multiple subpacks.
	The value included represents the subpack quantity value of these MPP concepts.
Exclusions	Cold and flu products and other products not represented in subpacks.
Permissible values	• "operatorId" should always be "Equal to".
	• "value" is the concrete value to be associated with the referenced concept, which are rational numbers that are > 0.
	• "unitId" should always be the concept ID of "Each".
Example	• norethisterone 500 microgram + ethinyloestradiol 35 microgram tablet [84 tablets] (&) inert substance tablet [28 tablets], 112 [4 x 28 tablets] "has subpack" norethisterone 500 microgram + ethinyloestradiol 35 microgram tablet [21 tablets] (&) inert substance tablet [7 tablets], 28 (referencedComponentId)
	• Equal to (operatorId)
	• 4 (value)
	• each (unitId)
	• Microgynon 30 ED (ethinyloestradiol 30 microgram + levonorgestrel 150 microgram) tablet: sugar-coated [84 tablets] (&) (inert substance) tablet: sugar-coated [28 tablets], 112 tablets [4 x 28 tablets] HAS TPUU Microgynon 30 ED (ethinyloestradiol 30 microgram + levonorgestrel 150 microgram) tablet: sugar-coated
	• Equal to (operatorId)
	• 4 (value)
	• each (unitId)

Acronyms

Acronym	Term
AMT	Australian Medicines Terminology
BoSS	Basis of Strength Substance
CTPP	Containered Trade Product Pack
DCM	Detailed Clinical Model
IHTSDO	International Health Terminology Standards Development Organisation
MP	Medicinal Product
MPP	Medicinal Product Pack
MPUU	Medicinal Product Unit of Use
NCTIS	National Clinical Terminology and Information Service
RF2	Release Format 2
SNOMED CT-AU	SNOMED CT, Australian Release
SNOMED CT	Systematized Nomenclature of Medicine, Clinical Terms
TP	Trade Product
TPP	Trade Product Pack
TPUU	Trade Product Unit of Use
UUID	Universally Unique Identifier

Glossary

Term	Notes
Release Format 2	A SNOMED CT release format
SNOMED CT, Australian Release	Australian extension to SNOMED CT

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2.	IHTSDO. *SNOMED CT Technical Implementation Guide*. Copenhagen: IHTSDO; 2014. January 2014 release. Available from: http://www.snomed.org/doc.

3.	NEHTA. *Technical Implementation Guide: Australian Medicines Terminology (Version 3 Model)*. Sydney: NEHTA; 2013. v1.0. Available from: http://www.nehta.gov.au/implementation-resources/ehealth-foundations/EP-1719-2014/NEHTA-1237-2013.