



Development Approach for Reference Sets

Australian Medicines Terminology

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1 Introduction

1.1 Purpose of this document

This document describes the development approach used in creating reference sets for use by the Australian Medicines Terminology (AMT) community of practice.

The reference sets have been developed by the National Clinical Terminology and Information Service (NCTIS) within the National E-Health Transition Authority Limited (NEHTA).

1.2 Intended audience

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

1.3 Scope of this document

The scope of this document is to provide information on reference sets that are available with the latest AMT Release.

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 Related documents

The documents tabulated below provide the context for development of the reference sets described in this document, and should be read in conjunction with this document to enhance understanding of our approach to terminology development. The location of each document within the NEHTA secure site¹ is provided as well.

Table 1: Related documents

Name	Location
<i>Reference set library – National Clinical Terminology and Information Service</i>	Downloads > SNOMED CT -AU > Information Specifications, Content and Requirements

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.

¹ <<https://nehta.org.au/aht/index.php>>

To provide feedback, or for further information regarding licensing, please contact us via:

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NEHTA,
Level 25, 56 Pitt Street
Sydney NSW 2000.

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.

Secondly, reference sets serve as a mechanism for creating subsets of content from the terminology. 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 has indicated 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

In distinguishing between the different types of reference sets and the different contexts in which they are applied we apply the following categorisations.

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 technical implementation of the AMT release files.

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. The AMT concept model is also considered in this alignment process.

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 reuse 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 Release Format 2

SNOMED CT^{®2} 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 [IHTS2010a] and [IHTS2010b].

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 so that our methods in 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.

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, which 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 IHTSDO[®] and SNOMED CT[®] are registered trademarks of the International Health Terminology Standards Development Organisation.

2.4.4 Source data exclusion method

This method uses reference sets as mechanisms for excluding content from another reference set. For example, the *Non-human reference set* within SNOMED CT³-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 *Non-human reference set* is not a veterinary reference set; some veterinary concepts are shared with humans such as the brain and the eye.

2.4.5 Attribute method

This method comprises 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 which 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 which 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 SNOMED CT[®] is a registered trademark of the International Health Terminology Standards Development Organisation.

3 Reference sets bound to information specifications

3.1 Containered trade product pack reference set

3.1.1.1 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 to be recorded in a health record.

3.1.1.2 Binding details

This reference set is applicable across the specifications listed in Table 2 below.

Table 2: Reference set bindings

Detailed Clinical Model or Specification	Details	Considerations
Medication DCM	<p>Medicine data element</p> <p>DE-10194</p> <p>OID: 1.2.36.1.2001.1001.101.103.10194</p> <p>Definition: The medicine, vaccine or other therapeutic good which was the focus of the action.</p>	
Adverse Reaction DCM	<p>Substance/Agent data element</p> <p>DE-15521</p> <p>OID: 1.2.36.1.2001.1001.101.103.15521</p> <p>Definition: Identification of a substance, agent, or a class of substance that is considered to be responsible for the adverse reaction.</p>	
	<p>Specific substance/Agent data element</p> <p>DE-16349</p> <p>1.2.36.1.2001.1001.101.103.16349</p> <p>Definition: Specific identification of the substance/agent considered to be responsible for the adverse reaction event.</p>	

3.1.1.3 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 a combination of the 'simple inclusion' and 'concept enumeration' methods. 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 3: Containered trade product pack reference set constraints

Constraint Type	Details
Inclusions	<ul style="list-style-type: none"> The content must contain only child concepts with 'current' or 'pending move' active status from the Containered trade product pack hierarchy.
Exclusions	<ul style="list-style-type: none"> The content must not contain any concepts that are: <ul style="list-style-type: none"> Children of Medicinal <i>product</i>. Children of Medicinal <i>product unit of use</i>. Children of Medicinal <i>product pack</i>. Children of <i>Trade product</i>. Children of <i>Trade product unit of use</i>. Children of <i>Trade product pack</i>.

3.1.1.4 Permissible values

Here are some examples of permissible values:

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

3.2 Medicinal product reference set

3.2.1.1 Reference set definition and usage

The *Medicinal product reference set* provides terminology to describe in the health record 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.

3.2.1.2 Binding details

This reference set is applicable across the specifications listed in Table 4 below.

Table 4: Reference set bindings

Detailed Clinical Model or Specification	Details	Considerations
Medication DCM	<p>Medicine data element</p> <p>DE-10194</p> <p>OID: 1.2.36.1.2001.1001.101.103.10194</p> <p>Definition: The medicine, vaccine or other therapeutic good which was the focus of the action.</p>	
Adverse Reaction DCM	<p>Substance/Agent data element</p> <p>DE-15521</p> <p>OID: 1.2.36.1.2001.1001.101.103.15521</p> <p>Definition: Identification of a substance, agent, or a class of substance that is considered to be responsible for the adverse reaction.</p> <p>Specific substance/Agent data element</p> <p>DE-16349</p> <p>1.2.36.1.2001.1001.101.103.16349</p> <p>Definition: Specific identification of the substance/agent considered to be responsible for the adverse reaction event.</p>	

3.2.1.3 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 a combination of the 'simple inclusion', 'concept enumeration' and 'source data exclusion' methods. 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 5: Medicinal product reference set constraints

Constraint Type	Details
Inclusions	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> The content must not contain any concepts that are: <ul style="list-style-type: none"> Children of <i>Medicinal product unit of use</i>. Children of <i>Medicinal product pack</i>. Children of <i>Trade product</i>. Children of <i>Trade product unit of use</i>. Children of <i>Trade product pack</i>. Children of <i>Containerized trade product pack</i>.

3.2.1.4 Permissible values

Here are some examples of permissible values:

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

3.3 Medicinal product pack reference set

3.3.1.1 Reference set definition and usage

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

3.3.1.2 Binding details

This reference set is applicable across the specifications listed in Table 6 below.

Table 6: Reference set bindings

Detailed Clinical Model or Specification	Details	Considerations
Medication DCM	<p>Medicine data element</p> <p>DE-10194</p> <p>OID: 1.2.36.1.2001.1001.101.103.10194</p> <p>Definition: The medicine, vaccine or other therapeutic good which was the focus of the action.</p>	
Adverse Reaction DCM	<p>Substance/Agent data element</p> <p>DE-15521</p> <p>OID: 1.2.36.1.2001.1001.101.103.15521</p> <p>Definition: Identification of a substance, agent, or a class of substance that is considered to be responsible for the adverse reaction.</p> <p>Specific substance/Agent data element</p> <p>DE-16349</p> <p>1.2.36.1.2001.1001.101.103.16349</p> <p>Definition: Specific identification of the substance/agent considered to be responsible for the adverse reaction event.</p>	

3.3.1.3 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 a combination of the 'simple inclusion', 'concept enumeration' and 'source data exclusion' methods. 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 7: Medicinal product pack reference set constraints

Constraint Type	Details
Inclusions	<ul style="list-style-type: none"> The content must contain only child concepts with 'current' or 'pending move' active status from the Medicinal product pack hierarchy.
Exclusions	<ul style="list-style-type: none"> The content must not contain any concepts that are: <ul style="list-style-type: none"> Children of <i>Medicinal product</i>. Children of <i>Medicinal product unit of use</i>. Children of <i>Trade product</i>. Children of <i>Trade product unit of use</i>. Children of <i>Trade product pack</i>. Children of <i>Containerised trade product pack</i>.

3.3.1.4 Permissible values

Here are some examples of permissible values:

- |46470011000036101 *aciclovir 5% (50 mg/g) cream, 10 g*|
- |63748011000036109 *pseudoephedrine hydrochloride 120 mg tablet, 10*|

3.4 Medicinal product unit of use reference set

3.4.1.1 Reference set definition and usage

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

3.4.1.2 Binding details

This reference set is applicable across the specifications listed in Table 8 below.

Table 8: Reference set bindings

Detailed Clinical Model or Specification	Details	Considerations
Medication DCM	<p>Medicine data element</p> <p>DE-10194</p> <p>OID: 1.2.36.1.2001.1001.101.103.10194</p> <p>Definition: The medicine, vaccine or other therapeutic good which was the focus of the action.</p>	
Adverse Reaction DCM	<p>Substance/Agent data element</p> <p>DE-15521</p> <p>OID: 1.2.36.1.2001.1001.101.103.15521</p> <p>Definition: Identification of a substance, agent, or a class of substance that is considered to be responsible for the adverse reaction.</p> <p>Specific substance/Agent data element</p> <p>DE-16349</p> <p>1.2.36.1.2001.1001.101.103.16349</p> <p>Definition: Specific identification of the substance/agent considered to be responsible for the adverse reaction event.</p>	

3.4.1.3 Method for defining reference set content

The *Medicinal 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 a combination of the 'simple inclusion', 'concept enumeration' and 'source data exclusion' methods. 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 9: Medicinal product unit of use reference set constraints

Constraint Type	Details
Inclusions	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> The content must not contain any concepts that are: <ul style="list-style-type: none"> Children of <i>Medicinal product</i>. Children of <i>Medicinal product pack</i>. Children of <i>Trade product</i>. Children of <i>Trade product unit of use</i>. Children of <i>Trade product pack</i>. Children of <i>Containerised trade product pack</i>.

3.4.1.4 Permissible values

Here are some examples of permissible values:

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

3.5 Trade product reference set

3.5.1.1 Reference set definition and usage

The *Trade product reference set* provides terminology to describe in a health record the product (medication) brand name or the grouping of products into a 'family', for either single component products or components of multi-component products.

3.5.1.2 Binding details

This reference set is applicable across the specifications listed in Table 10 below.

Table 10: Reference set bindings

Detailed Clinical Model or Specification	Details	Considerations
Medication DCM	<p>Medicine data element</p> <p>DE-10194</p> <p>OID: 1.2.36.1.2001.1001.101.103.10194</p> <p>Definition: The medicine, vaccine or other therapeutic good which was the focus of the action.</p>	
Adverse Reaction DCM	<p>Substance/Agent data element</p> <p>DE-15521</p> <p>OID: 1.2.36.1.2001.1001.101.103.15521</p> <p>Definition: Identification of a substance, agent, or a class of substance that is considered to be responsible for the adverse reaction.</p> <p>Specific substance/Agent data element</p> <p>DE-16349</p> <p>1.2.36.1.2001.1001.101.103.16349</p> <p>Definition: Specific identification of the substance/agent considered to be responsible for the adverse reaction event.</p>	

3.5.1.3 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 a combination of the 'simple inclusion', 'concept enumeration' and 'source data exclusion' methods. 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 11: Trade product reference set constraints

Constraint Type	Details
Inclusions	<ul style="list-style-type: none"> The content must contain only child concepts with 'current' or 'pending move' active status from the Trade product hierarchy.
Exclusions	<ul style="list-style-type: none"> The content must not contain any concepts that are: <ul style="list-style-type: none"> Children of <i>Medicinal product</i>. Children of <i>Medicinal product unit of use</i>. Children of <i>Medicinal product pack</i>. Children of <i>Trade product unit of use</i>. Children of <i>Trade product pack</i>. Children of <i>Containerized trade product pack</i>.

3.5.1.4 Permissible values

Here are some examples of permissible values:

- |65136011000036105 *Brolene Eye Drops*|
- |3422011000036106 *Pepzan*|

3.6 Trade product pack reference set

3.6.1.1 Reference set definition and usage

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

3.6.1.2 Binding details

This reference set is applicable across the specifications listed in Table 12 below.

Table 12: Reference set bindings

Detailed Clinical Model or Specification	Details	Considerations
Medication DCM	<p>Medicine data element</p> <p>DE-10194</p> <p>OID: 1.2.36.1.2001.1001.101.103.10194</p> <p>Definition: The medicine, vaccine or other therapeutic good which was the focus of the action.</p>	
Adverse Reaction DCM	<p>Substance/Agent data element</p> <p>DE-15521</p> <p>OID: 1.2.36.1.2001.1001.101.103.15521</p> <p>Definition: Identification of a substance, agent, or a class of substance that is considered to be responsible for the adverse reaction.</p> <p>Specific substance/Agent data element</p> <p>DE-16349</p> <p>1.2.36.1.2001.1001.101.103.16349</p> <p>Definition: Specific identification of the substance/agent considered to be responsible for the adverse reaction event.</p>	

3.6.1.3 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 a combination of the 'simple inclusion', 'concept enumeration' and 'source data exclusion' methods. 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 13: Trade product pack reference set constraints

Constraint Type	Details
Inclusions	<ul style="list-style-type: none"> The content must contain only child concepts with 'current' or 'pending move' active status from the Trade product pack hierarchy.
Exclusions	<ul style="list-style-type: none"> The content must not contain any concepts that are: <ul style="list-style-type: none"> Children of <i>Medicinal product</i>. Children of <i>Medicinal product unit of use</i>. Children of <i>Medicinal product pack</i>. Children of <i>Trade product</i>. Children of <i>Trade product unit of use</i>. Children of <i>Containerised trade product pack</i>.

3.6.1.4 Permissible values

Here are some examples of permissible values:

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

3.7 Trade product unit of use reference set

3.7.1.1 Reference set definition and usage

The *Trade product unit of use reference set* provides terminology to describe in a health record 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.

3.7.1.2 Binding details

This reference set is applicable across the specifications listed in Table 14 below.

Table 14: Reference set bindings

Detailed Clinical Model or Specification	Details	Considerations
Medication DCM	<p>Medicine data element</p> <p>DE-10194</p> <p>OID: 1.2.36.1.2001.1001.101.103.10194</p> <p>Definition: The medicine, vaccine or other therapeutic good which was the focus of the action.</p>	
Adverse Reaction DCM	<p>Substance/Agent data element</p> <p>DE-15521</p> <p>OID: 1.2.36.1.2001.1001.101.103.15521</p> <p>Definition: Identification of a substance, agent, or a class of substance that is considered to be responsible for the adverse reaction.</p> <p>Specific substance/Agent data element</p> <p>DE-16349</p> <p>1.2.36.1.2001.1001.101.103.16349</p> <p>Definition: Specific identification of the substance/agent considered to be responsible for the adverse reaction event.</p>	

3.7.1.3 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 a combination of the 'simple inclusion', 'concept enumeration' and 'source data exclusion' methods. 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 15: Trade product unit of use reference set constraints

Constraint Type	Details
Inclusions	<ul style="list-style-type: none"> The content must contain only child concepts with 'current' or 'pending move' active status from the Trade product unit of use hierarchy.
Exclusions	<ul style="list-style-type: none"> The content must not contain any concepts that are: <ul style="list-style-type: none"> Children of <i>Medicinal product</i>. Children of <i>Medicinal product unit of use</i>. Children of <i>Medicinal product pack</i>. Children of <i>Trade product</i>. Children of <i>Trade product pack</i>. Children of <i>Containerised trade product pack</i>.

3.7.1.4 Permissible values

Here are some examples of permissible values:

- |6355011000036103 *Alprim (trimethoprim 300 mg) tablet: uncoated, 1 tablet*|
- |65669011000036108 *Nurofen (ibuprofen 5% (50 mg/g)) gel*|

4 References

- [IHTS2010a] International Health Terminology Standards Development Organisation 2010, *SNOMED CT Release Format 2.0 reference set specifications*, v1.0, IHTSDO, Copenhagen.
- [IHTS2010b] International Health Terminology Standards Development Organisation 2010, *SNOMED CT Release Format 2.0 update guide*, v1.0, IHTSDO, Copenhagen.